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Innovation in Digital Health

Guide

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D5.3 Innovation in Digital Health. Guide

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Abstract	*The rapid evolution of digital technologies is transforming the landscape of European healthcare, ushering in an era of unprecedent opportunities for innovation in Digital Health. This guide serves as a comprehensive resource for stakeholders seeking to navigate the complexities of developing, implementing, and scaling innovative Digital Health solutions within the European Union. By addressing the multifaceted dimensions of Digital Health, including technological advancements, regulatory frameworks, EU market and intellectual Property issues, this guide aims to provide a structured approach that enable innovations in Digital Health.*

Keywords *Innovations, Digital Health, Targets, Resources, Regulation, Intellectual Property, Mobilisation for Innovations, EU Market*

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Yet we are aware that the book has gaps in subject matter and in its global coverage. We urge readers to call attention to the gaps and to help us fill them in an eventual second edition. We are eager for feedback from researchers, students, professors, managers and employees from companies related to Digital Health.

Chapter 1. Introduction

The rapid evolution of digital technologies is transforming the landscape of European healthcare, ushering in an era of unprecedented opportunities for innovation in Digital Health. This book serves as a comprehensive resource for stakeholders seeking to navigate the complexities of developing, implementing, and scaling innovative Digital Health solutions within the European Union. By addressing the multifaceted dimensions of Digital Health, including technological advancements, regulatory frameworks, EU market, and Intellectual Property issues, this guide aims to provide a structured approach that enable continuous innovation in the sector.

Digital Health is "*the field of knowledge and practice associated with the development and use of digital technologies to improve health*" (WHO, 2021). It encompasses a broad spectrum of technologies and approaches, from mobile health (mHealth) applications and telehealth services to advanced data analytics and robotics in healthcare. It refers to the use of digital tools to address broader determinants of health, including applications in the areas of insurance, education and training, income inequality, and the impact on health of physical environment and climate change. These technologies span a wide range of uses, from applications in general wellness to technologies intended for use as a medical product or as an adjunct to other medical products (devices, drugs, and biologics) or for development or assessment of medical products (US Food and Drug Administration, 2020). Considering that often the term digital health is presented in literature as being interchangeable with eHealth technologies, such as in digital health definition by European Commission (European Union. Digital health and care) the term Digital Health (as is written) refers in this book to the definition given by World Health Organization and US Food and Drug Administration that have a broader meaning including digital consumers, with a wider range of smart and connected devices.

Digital Health plays a prominent role in digital transformation of health. Innovations in this domain help drive the necessary transformation towards more sustainable and resilient healthcare systems as well as prosperous society and sustainable economy. The products and services related to Digital Health can have an impact on all stages of healthcare, from prevention, diagnosis and monitoring to treatment. European Commission in the *Communication on enabling the digital transformation of health and care in the digital single market, empowering citizens and building a healthier society* (COM(2018) 0233) (European Commission, 2018) considered as three pillars for digital transformation of health and care:

- "*Providing citizens with secure access to their health data and sharing health data;*

- *better data to promote research, disease prevention and personalised health and care.*
- *digital tools for citizen empowerment and for person-centred care*."

Digital Health is already redefining how healthcare is delivered, emphasizing person-centred care, enhancing accessibility, and promoting preventive health strategies. Even though the development of integrated Digital Health ecosystem holds promising potential, there are practical challenges that hinder efficiency and sustainability. Among them are issues of collaboration for coordinated or integrated operations of stakeholders from Digital Health ecosystem and funding and sharing of material and human resources.

The book highlights the critical role of Digital Health in addressing contemporary challenges, such as aging populations, rising healthcare costs, and the increasing prevalence of non-communicable diseases, and also the potential for digital transformation of health and healthcare, economic growth and societal benefits through human-centred innovations.

Innovations in Digital Health may support reaching the Goal 3 of the 2030 Agenda for Sustainable Development, the targets of European Pillar of Social Rights and Europe's Digital Decade.

European Union set up the Action Plan to turn **European Pillar of Social Rights** into reality until 2030. European Pillar of Social Rights encompasses 20 principles related to: health and safety; healthcare (i.e., everyone has the right to affordable, good-quality healthcare); people with disabilities; long-term care; work-life and home-life; education, training and life-long learning; equal treatment between women and men; equal opportunities; help to get a job; work that is flexible and lasts for a long time; fair pay; clear information about job; listening to workers; childcare and support to children; protection from being very poor; unemployment benefits; help from the government for people who don't have enough money; old age pensions; housing; basic services (access to water, electricity, banking and internet) (European Union. European Pillar of Social Rights).

2030 Agenda for Sustainable Development, adopted in 2015 by United Nations General Assembly - resolution 70/1, a global framework consisting of 17 Sustainable Development Goals (SDGs) aiming at ending poverty, protecting the planet, and ensuring prosperity for all by 2030, emphasizes in Goal 3 the expectation that countries would "***Ensure healthy lives and promote well-being for all at all ages***" (United Nations). The pace of reaching this goal was accelerated by the Global Initiative on Digital Health (GIDH), launched in October 2023 and managed by the World Health Organization (WHO) is aiming to "*foster improved alignment in the digital health sector, providing governments and partners tools, building blocks, and platforms needed for sustainable health system*" (WHO. Global Initiative on Digital Health).

The **Europe's Digital Decade** policy programme, with concrete targets and objectives for 2030, guides Europe's digital transformation (European Union. Europe's Digital Decade). This governance framework is based on an annual cooperation mechanism involving the Commission and Member States. The European Commission (2023) has developed EU-level trajectories. Baseline trajectories outline how the EU will progress according to current trends, and projected trajectories outline the path that yearly progress should follow to achieve the targets by 2030. The difference between the estimated trends and the ideal path will allow the Commission to monitor the gap in the effort needed. The targets and objectives that were established in Europe's Digital Decade policy programme are categorized in government (digitalization of public service), infrastructures (secure and sustainable digital infrastructure), skills and business (digital transformation of business) (see Figure 1).

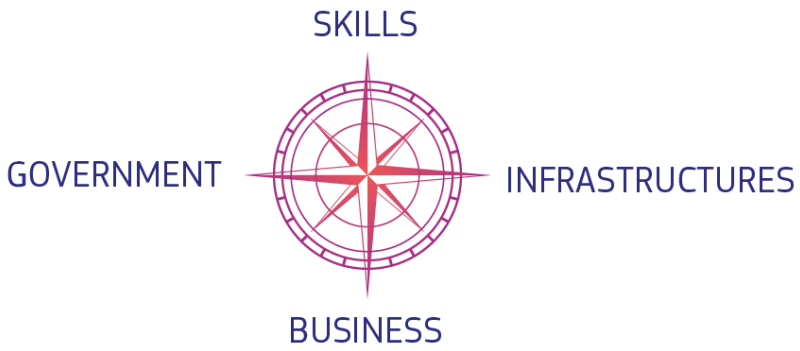

Figure 1. **The Digital Decade policy programme's concrete targets and objectives for 2030.**
Source: European Union. Europe's Digital Decade

The book *Innovations for Digital Health* is structured to provide actionable insights for a diverse audience, including healthcare providers, technology developers, policymakers, and researchers. Sections delve into the targets and resources for innovations, the regulatory landscape, and the EU market environment, with a focus on practical strategies for product development and market entry. Special attention is given to the importance of collaboration across ecosystems, the mobilisation of resources for continuous innovation, and the protection of intellectual properties such as patents, copyrights, and trademarks. The book provides some guiding tools that shall be considered when developing health related products and services as well when proactively fostering an environment that supports the innovations in Digital Health. The information from the book may contribute to mobilisation for innovations in Digital Health that may enable solutions to scientific and societal challenges. Scientific definitions of the relevant terms related to innovations and patents in Digital Health that may help understanding the complexity of the domain are presented in annexes. Therefore, the book is contributing to reaching

targets of Europe's Digital Decade related to **skills** and **business**. The targets of Europe's Digital Decade are summarized in Table I.

Chapter 2 introduces the concepts of health, Digital Health and innovation and provides a glossary of definitions associated to the concepts, as a result of systematic research of scientific literature related to health, healthcare, digital technologies, eHealth, mHealth, innovation and invention, digital innovation in health and healthcare, digital transformation of health.

Tabel 1. **Targets of Europe's Digital Decade.** Source: European Union. Europe's Digital Decade

Skills	Business	Infrastructure	Government
ICT Specialists: 20 million+ gender convergence	**Tech up take**: 75% of EU companies using Cloud, AI, or Big Data	**Connectivity:** Gigabit for everyone	**Key Public Services:** 100% online
Basic Digital Skills: min 80% of population	**Innovators**: grow scale-ups & finance to double EU Unicorns	**Cutting edge Semiconductors:** double EU share in global production	**e-Health:** 100% of citizens have access to medical records online
	Late adopters: more than 90% of SMEs reach at least a basic level of digital intensity	**Data - Edge & Cloud:** 10,000 climate-neutral highly secure edge nodes	**Digital Identity**: 100% of citizens have access to digital ID
		Computing: first computer with quantum acceleration	

Chapter 3 addresses European healthcare systems challenges (i.e., such as aging populations, the increasing prevalence of non-communicable diseases, the rising healthcare costs and workforce deficit) and presents potential innovation targets in health information change, medical devices, data analytics, database for health and healthcare, e-Learning for health technologies, pharmaceutical technologies and bioengineering and biotechnologies sectors.

Innovations infrastructure and potential financial resources for innovations in Digital Health are addressed in Chapter 4. Examples of different European health clusters, living labs, innovation hubs and technology parks are presented. Differentiation of companies

related to Digital Health is also presented. Specific details in reimbursement framework for digital solutions for healthcare and medical devices from several European countries are summarized and presented in Annex I and II.

Chapter 5 addresses the regulatory entities and instruments (e.g., regulation regarding medical device regulation; digital single market; general data protection regulation; web accessibility directive; e-IDAS regulation; European Health Data Space; EU artificial intelligence Act; Data Act; Cyber resilience Act, European innovation Act), source of information on regulation related to Digital Health, key national regulatory differences in EU digital healthcare. Examples of country legal instrument for regulation of medical devices or Digital Health solutions and an example of regulatory readiness checklist are presented in Annex II and III.

Description of the domains of Intellectual property and their rules, and information that may help the inventors to apply for a patent at the right time and in efficient manner, and the companies to plan the strategy for knowledge transfer and patents protection is presented in Chapter 6. To better understanding of different aspects of patenting process a case study – electrocardiograph invention is also discussed in the chapter.

Chapter 7 addresses the human factors and organizational environment for innovation at workplace, incentive and rewards for innovation, Digital Health ecosystem, knowledge transfer, and provide information on how to put an innovative Digital Health solution or medical device on the market.

By synthesising evidence-based research, market analyses, and case studies from across the EU, this book aims to empower stakeholders to create impactful Digital Health solutions that align with the EU's vision for a sustainable, equitable, and digitally transformed healthcare future. Through a collaborative effort involving contributors of ManagiDiTH partners dealing with Digital Health innovations from different perspectives, this book seeks to bridge the gap between innovation and implementation, ensuring that digital health advancements contribute to improved health outcomes and enhanced quality of life for all.

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Chapter 2. Concept of Innovation in Digital Health

Perspectives on Health

Innovations versus Invention

Digital Health

Conceptual clarity can help understand the complexity of the factors associated with innovations in Digital Health. Although basic meaning of health, digital and innovation terms are well understood, there are nuances that may have great importance in the processes of the integration of innovative digital technologies in healthcare systems and in people's daily lives.

What is Health

According to the Constitution of the World Health Organization (the United Nations agency having as goal health promotion) **health** is defined as "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*'

(WHO, 1948). The Constitution of the World Health Organization (WHO) was adopted by the International Health Conference held in New York in 1946, signed by the representatives of 61 states, and entered into force in 1948. There are different approaches to health and diseases in public healthcare systems, businesses and corporations, charitable or community groups, family and informal networks. **Several concepts were derived from the interpretation** of the WHO defined dimensions of health, in different sectors of society, the differences between concepts being associated with **the importance that is given for each term in the WHO definition, the ways by which principles derived from this definition are implemented, the perceptions of practices for preserving individual and populations health in relation with policy and the functioning of healthcare system of each country.** Despite criticism of the WHO definition (Leonardi, 2018), this definition has great relevance from holistic perspectives where health is a state of "*exhaustive well-being, including all relevant dimensions of its constitutive elements*" (Schramme, 2023). Following is presented a few concepts derived from interpretation of WHO health definition:

Biomedical model of health. In the biomedical model (that is being used in Western medical systems) health is defined mainly as absence of illness and disease. A "*magic bullet*" (Antonovsky, 1979) (mainly a medication but also a surgery) is often searched to fight a disease and restore the health. It gave great importance to biological determinants of illness (i.e., infections, genetics, or physical injuries) and "*assumes disease to be fully accounted for by deviations from the norm of measurable biological (somatic) variable*" (Engel, 1977).

Biopsychosocial model of health - proposed by George Engel in 1977 recognizes the interplay between biological, psychological, and social factors on individual health (Bolton, 2023). It is the model that is mostly used nowadays in healthcare systems.

Healthism – A holistic health and self-care new consciousness and movements to address problems related to health. Health is often perceived as individual responsibility and moral value (Crawford, 1980).

Wellbeing (or well-being) – Currently the wellbeing is not clearly defined. It can be understood as *"how people feel and how they function both on personal and social level,*

and how they evaluate their lives as a whole" (Michaelson et al., 2012), or a state of satisfaction with life, "*a sense of tranquillity resulting from inner peace and harmonious interactions with the external environment*" that may arise "*from a system for adaptive motivation*" (Jarden & Roache, 2023) or a "*state of positive feelings and meeting full potential in the world"* (Simons & Baldwin, 2021).

Wellness - "*the active pursuit of activities, choices and lifestyle that lead to a state of holistic health*" (Global Wellness Institute, 2020).

Salutogenic model of health – The term salutogenesis was introduced by Aaron Antonovsky in his 1979 book *Health Stress and Coping* as a combination of Latin terms "*salutem*" for health and "*genesis*" or coming into being of something. Salutogenic model of health described by Aaron Antonovsky and discussed by numerous authors of various scientific domains (e.g., healthcare, promotion of health, psychology, work conditions, restorative environment, architecture, residential care and community settings) include complex concepts of "*generalized resistance resources*" (GRRs), "*potential endogenic and exogenic stressor*", "*state of tension*", "*state of stress*", "*sense of coherence*" (SOC), "*salutary factors*" "*health ease/dis - ease continuum*" "*other ease/dis - ease continuum*" (Mittelmark et al., 2017). In this model emphasis is given on dynamic relationship between resources (i.e., major psychosocial GRRs – material, knowledge, intelligence, ego identity, coping strategy, social support, commitment, cultural stability, magic, religion, philosophy, art, preventive health orientation; and genetic and constitution GRRs) and stressors (i.e., psychosocial stressors – accidents and survivors, others' experiences, horrors of history, intrapsychic conflicts, fear of aggression, immediate world change, phase-specific crises, other normative crises, conflicts in social relations, goals-means gap; physical and biochemical stressor). Antonovsky criticized the biomedical of health and the dichotomic perspective on health (sick/health) and proposed a perspective where health is seen as "*a continuum between ease and dis-ease*". "S*ense of coherence*" and "*salutary factors*" ("*factors which are negentropic, actively promote health, rather than just being low on risk factors*") help people to move to the healthy end of the health ease - dis/ease continuum (Vinje et al., 2017). He introduced the concept of sense of coherence as "*a global orientation that expresses the extent to which one has a pervasive, enduring*

though dynamic feeling of confidence that 1) the stimuli deriving from one's internal and external environment in the course of living are structured, predictable, and explicable; 2) the resources are available to one to meet the demands posed by these stimuli; 3) these demands are challenges, worthy of investment and engagement" (Antonovsky, 1987). Different than the construct of coping strategy, SOC is flexible - the higher SOC turn people able to mobilize more of their resources, and the more GRRs people are conscious of and are able to mobilize and make use of, the higher SOC (Vinje et al., 2017).

Functioning – "*Functioning is an umbrella term for body functions, body structures, activities and participation. It denotes the positive aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors).*" (WHO, 2013). The term is mainly used to describe the associated functioning dimensions of a health problem or diseases, in multiple perspectives at body, person and social level, using ICF (International Classification of Functioning, disability and health) model. "*ICF put every person in a context*": the functioning of an individual in a specific domain reflects an interaction between the health condition and the environmental and personal factors (WHO, 2013).

Spiritual health. It was suggested that spiritual health should be included as 4th dimension of health (i.e., consideration of physical, mental, social and spiritual well-being). Spiritual health is being characterized as "*a state of being where an individual is able to deal with day-to-day life issues in a manner that leads to the realization of one's full potential, meaning and purpose of life and fulfilment from within. Such a state of being is attainable through self-evolution, self- actualisation and transcendence….where there is a continuous effort for developing universality of love, compassion and equanimity to replace anger, jealousy, ego and hatred, resulting in utilization of one's abilities to the fullest and even transcending beyond that.*" (Dhar et al., 2013).

Lifestyle medicine concept disseminated by American College of Lifestyle Medicine (https://lifestylemedicine.org/) considers six key interconnected pillars for health – optimal nutrition; physical activity; stress management; restorative sleep; connectedness (i.e., foster supportive relationships and build connections that bring meaning and purpose to life); risky substance avoidance.

Lifestyle medicine (LM) in Middle Eastern region (particularly in Saudi Arabia) employs a comprehensive concept for health and healthcare. Lifestyle medicine Middle Eastern region is based on "*AlAfiah"* characterized as *"the sum of physical, mental, psychological, emotional, social, spiritual, environmental, economic health, universal living security, and well-being. It is influenced by genetics, epigenetics, education, faith, economic status, life and living security, nutrition, and environment. Moreover, it utilizes the shared resources of individuals, families, groups, societies, cultures, faiths, governments, and private and public entities. It is supported by an advanced and integrated AI, machine learning, and digital AlAfiah system (DAS®)."* (Alrajhi et al., 2025). DAS is an electronic medical records (EMRs) system with integrated multi-stakeholder capabilities that use artificial intelligence (AI). The LM pillars to the Middle Eastern population are considered: *food as medicine; generational management (pre-conception to older adults); physical activity and exercise as medicine; sleep health and sleep disorders; life, living, and stress management - social connectedness (Alselah and Alber), mindset, the power of (Aleman and Fikr), mindfulness (Alehsan), work burnout, community and social determinants of health (cultural ethics and moral norms); addiction and substance abuse management; driving disturbance; smart technology disturbance; spirituality; mental and emotional health; sexuality health. …LM utilizes preventive, pro-active, and pre-emptive strategies supporting timely access to healthcare services, cost effectiveness, healthy disease-free living, chronic disease reversal, and improving quality of life by employing the resources of public and private entities, communities, and individuals*." (Alrajhi et al., 2025).

Health capital is defined as "*a set of health-related assets of individuals that enable them to pursue their interests and to collaborate with others and gain competitive advantages*". The "*capital*" term in this theoretical model of health was used with the meaning "*actually usable resources and powers".* It allows to distinguish the instruments that can be used to produce health from the "*health stock*" perceived as "*specific malleable health-related constitution of a person*" (i.e., "*organismic constitutions*" and circumstantial determinants of health). In that theory is suggested that social justice should enable "*people to achieve enough health capital to meet threats to health*" (Davies & Schramm, 2025).

Global health - "*Global health deals with only medical and health issues with global impact, the main task of global health is to seek for global solutions to the issues with global health impact; and the ultimate goal is to use the power of academic research and science to promote health for all, and to improve health equity and reduce health disparities. Therefore, global health targets populations in all countries and involves all sectors beyond medical and health systems, although global health research and practice can be conducted locally*". (Chen et al., 2020).

A dynamic concept of health shall be addressed during innovation process in research, healthcare, welfare or insurance institutions. Multidimensional aspects of health, such as the absence of disease, people's disposition to prevent disease, alimentation, sleep, meaningful work opportunities, education, health literacy, environmental changes, etc. may be considered in design and development of an innovative product or process for individual or populational health assessment and care. Analysis of the health spectrum allows comparison and ranking of individuals health statuses and extraction of information on social, economic, environmental impact on health and on biological markers of diseases.

What about Innovation

Innovation refers generally to "*the creation of a new way of doing something, whether the enterprise is concrete (e.g., the development of a new product) or abstract (e.g., the development of a new philosophy or theoretical approach to a problem).*" (Britannica https://www.britannica.com). Innovators create alternatives to conventional ways of doing things, improve a process, service or method, a product or device. "*An innovator is someone who introduces new ideas, methods, or products, often with added value or improvement over what already exists, focusing on practical implementation and market adoption*" (Innovations 4 EU https://innovations4.eu).

Although in many published works the terms innovation and invention are used interchangeably, several nuances that allow differentiation of terms utilization can be highlighted.

Invention is" something *that* ***has never been made before****, or the process of creating something that has never been made before*" (Cambridge Dictionary https://dictionary.cambridge.org/dictionary/). **Innovation** refers mainly to the **improvement** of a products, process, services, technologies or a business that already exist or to the new ways to apply existing ideas. Also, innovation may refer to using the right data to improve what already works. Innovation may be an improvement of a product or a service, an adaptation of a process, or application of an invention. An invention can be used for future innovations. An innovator seeks to enhance functionality, efficiency, or user experience. He can use an invention or existing knowledge to create a successful solution. An inventor is often driven by necessity to solve a problem or curiosity. Both innovation and invention can refer to physical or non-physical things, tangible objects or non-tangible things. However, in inventive process, something new and original, new knowledge (i.e., expanding the boundaries of understanding things and phenomena) is produced.

Innovations can be categorized in:

- **Product innovation** – "*a new or improved good or service that achieves benefits for a company, which may include improving customer experience or opening a new market*" (Stanford ONLINE) (e.g., teleconsultation);
- **Process innovation** – improvement in a process (e.g., remote monitoring of a pacient; remote working);
- **Technology innovation** – "*the creation and application of new or improved technologies, tools, systems, and processes that bring about significant advancements or breakthroughs in various fields. It involves harnessing knowledge, expertise, and resources to develop innovative solutions that solve problems, improve efficiency, drive progress, and deliver value."* (IDEASCALE. by Jain, 2023) (e.g., digital diagnostic imaging);
- **Transformational (transformative) innovation** – "*major changes to products and services that redefine what customers expect by delivering significantly improved performance, providing new kinds of value, resolving long-standing trade-offs, and/or radically reducing manufacturing costs.*" (Harvard Business School. by Koen et al., 2024) (e.g., Electronic Health Records for hospitals)
- **Incremental innovation** – small changes that produce improvement to existing product/service/process (e.g., updating smartphone features);
- **Radical innovation** – groundbreaking changes that create new market or redefine existing ones (e.g., telemedicine);

- **Disruptive innovation** – radical innovation, disruptive innovation may transform an industry, create new market or new solution to societal challenges but may have a higher impact, influencing various aspects of society (e.g., portable computer had impact on economy, health, education, culture);
- **Sustaining innovation** – that enhance features of the existing product/service/process aiming to reinforce competitive positioning or to maintain market (e.g., faster processor in high-resolution camera);
- **Business model innovation** – reconfiguring the way a business is functioning (e.g., Amazon online books seller to AWS cloud computing service);
- **Organization innovation** – changes of structure or practices to improve performance (e.g., EMRs - electronic medical records improve hospital management of data and patient care);
- **Open innovation** – innovation practices by which valuable ideas for innovation are obtained both from internal and external sources, mainly through collaboration with external partners (i.e., a business collaboration with customers, suppliers, and competitors, to get ideas for product/service improvement or for co-creation of new product/service);
- **Social innovation** – "*involves the creation and implementation of novel ideas – spanning products, services and processes – while promoting new forms of social interactions and partnerships*" (OECD. Local Economic and Employment Development, 2025) (e.g., GitHub database on open-source software; crowdfunding);
- **Commercial innovation –** an innovative product/service commercially viable (e.g., new Apple smartphone).

There are several innovation theories/models and methodologies. Understanding these frameworks helps organization/business to recognize potential threats and opportunities arising from market, take decision related to new idea implementation, establish strategies to create an environment for innovation and to increase adoption of an innovative product/service.

- **Open innovation model** - emphasizes the importance of collaboration and/or co-creation for producing innovative product/service.
- **Triple Helix model** – highlight the importance of collaboration and knowledge exchange between academia, industry, and government to drive technological advancement and societal progress.
- **Blue Ocean strategy** – encourage businesses to establish new, uncontested market sectors that are named "blue ocean" in order to avoid the struggle on

putting a new product/service in a highly competitive market that is named "red ocean".

- **Stage-Gate process/governance** is a "*project management technique that divides the innovation process into distinct stages – each separated by decision points known as gates. Project progress is evaluated at each gate and determined whether to move on, make changes, or end the project. This model offers an organized framework for resource and risk management throughout the innovation lifecycle.*" (StartUs Insights)
- **Agile methodology** – employs principle of working in short cycle, delivering incremental values, and adapting as needed by analyzing the feedback from product/service users. Scrum is an Agile team collaboration framework commonly used in software development. Scrum prescribes for teams to break work into goals to be completed in sprints (period no longer than one months) iteration.
- **Design Thinking methodology** is characterized by its structured framework of five key steps (empathizing with customers, defining problems, ideating solutions, prototyping, testing).
- **Lean Startup methodology** – emphasize rapid experimentation and iterative learning. Encourage development in first stage of a minimum viable product to test hypothesis (for validation of new product/service) and to obtain customer feedback.
- **Innovation Intelligence methodology** refers to the use of data and technology to anticipate trends, identify opportunities, and optimize innovation processes. For instance, the use of ITONICS platform (https://www.itonics-innovation.com/) to optimize innovation, collect manage and evaluate ideas. ITONICS use artificial intelligence to scout, track, and evaluate trends, technologies, risks, and startups.
- **Diffusion of innovations theory** - highlight the significance of social systems, time and channels of communication in diffusion of an innovation first at early adopter, then to early majority, then late majority and potentially laggards.
- **Disruptive innovation theory** - consider that disruptive innovation begin in niche market (underserved market) and is adopted in large scale by providing more affordability or convenience.

Patent and Intellectual Property Analysis tools, Innovation Management platforms, Trend Analysis and Market Intelligence tools, Data-Driven Innovation platforms, Artificial Intelligence and Machine Learning tools are the main tools for Innovation Intelligence. These tools are used for achieving following objectives (StartUs Insights):

- **Innovation Scouting**: Identifying new ideas and technologies that align with business goals.

- **Startup Scouting**: Identifying startups for partnerships, investment or access to fresh ideas and capabilities.
- **Technology Scouting**: Identifying and evaluation of emerging technologies for integration.
- **Trend Intelligence**: Monitoring shifts in technology adoption, consumer behavior, industry trends, and market dynamics (e.g., Gartner Hype-Cycle for emerging technologies) (Gartner);
- **Open Innovation**: Collaboration with external partners to co-create value.
- **Business Intelligence**: Analysis of existing data to optimize business operations and strategies.
- **Market Intelligence**: Market conditions and opportunities assessment.
- **Customer Intelligence**: Customer needs and preferences assessment.
- **Competitor Intelligence**: Getting information into competitor strategies and weaknesses and potential strategies for competitive new product/service.

Innovation and invention have the potential to disrupt industries, create new markets or new solutions to societal challenges and may have impact on various aspects of society (e.g., economy, health, education, environment, security, culture).
Innovation management is the process used in an organization or business to create environment or culture of innovation and to implement new ideas that meet customer needs or create new market opportunities. It should be a systematic process of developing and implementing new ideas for innovative commercially viable product/service. It may encompass:

- Prioritization of the ideas that may be implemented after analysis of the opportunities and business impact;
- Testing best feasibility;
- Managing risks by identification of uncertainties, assessing impacts, and applying strategies;
- Integrate the validated solution into offering for commercialization;
- Measure KPIs (key performance indicators), balance short-term results with long-term growth;
- Planning for scaling product.

Innovations have different roles in various sectors of society:

- Enhance operational efficiency (e.g., simplify processes for patient admission or discharging from a hospital or clinics);
- Differentiate business through new product/service (e.g., physiotherapy centre that provide physiotherapy at his centre and telerehabilitation in comparison with traditional centres);

- Increase trust and loyalty through customer-centric solutions (e.g., E-Prescribing);
- Support sustainability and resilience of a business (e.g., innovations from Medtronics).

Digital Health

Digital Health refers to "*the field of knowledge and practice associated with the development and use of digital technologies to improve health*" (WHO, 2021). The term encompasses all eHealth technologies but also other technologies such as Internet of Things or Internet of Medical Things, Artificial Intelligence, Big Data, robotics, genomics, phenomics, technologies that explore how the consumer interacts with technologies and media in their everyday lives, among others. European Commission definition did not make difference between Digital Health and e-Health "*Digital health is a set of tools and services that use information and communication technologies (ICTs) to support and improve all stages of healthcare, from prevention and diagnosis to treatment, monitoring, and management of health conditions*" (see European Union. Digital health and care) but WHO team clearly state that digital health encompasses eHealth and "*digital consumers, with a wider range of smart and connected devices*". (WHO, 2021; see definitions from Annex I). Various digital technologies are being used to "*address broader determinants of health, including applications in the areas of income inequality, insurance, education, and the physical environment.*" (Kickbusch et al., 2021)

"*Digital health technologies use computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products.*" (US Food and Drug Administration, 2020). By using different technologies physicians may provide personalised care, the individuals and communities may manage their own health and wellbeing, and the authorities can use vast amounts of data for public health purposes.

Innovation in Digital Health

Digital innovation is defined as "*new combinations of digital and physical components to produce novel products or services or to the embedding of digital computer and communication technology into a traditionally non-digital product or service*" (Svensson, 2012). From business perspective digital innovation is defined as "*the creation of (and consequent change in) market offerings (product and services), business processes, and business models that result from the use of digital technology*" (Nambisan, 2017).

Innovation in Digital Health may be related to health information exchange, medical devices, data analytics, data storage, e-learning, pharmacological technologies, bioengineering or biotechnology sectors.

Digital innovation may be categorized as being incremental or continuous or sustaining; radical or disruptive; commercial; social; business; industrial; transformative; architectural; modular. Nowadays great importance is giving to disruptive digital

innovation (DDIs) that refer to the innovations that "*involve using digital technologies in innovative and novel ways, and their value comes from their inherent architecture. DDIs refer to innovations such as AI, blockchain, virtual/augmented reality, 3D printing, and the Internet of things (IoT), which are quite drastic in their impact and bring about highly visible changes in the way things are done at work as well as play. DDIs enable major business improvements and transformations across various commercial functions and industries. DDIs include a higher degree of customer involvement, enhanced firm performance through rapid innovation and operational efficiency, entrepreneurship transformation, digital boosts/transformations and value creation, user-wellbeing*" (Bamel et al., 2023).

Innovations and inventions related to Digital Health may be the result of:

- critical analysis of the existing products, processes, services or business models;
- discovery of a problem(s) or a necessity for new way of doing existing things;
- exploration (e.g., ideation sessions, design thinking, hackathons, prototyping) or search for solution to problem(s) (i.e., research, experimentation, creative thinking, iterative prototyping) and/or spotting emerging trends and technologies;

- creativity and talent to pick up the opportunities (e.g., investment, infrastructure, know-how) for developing or improvement of a new product, service or a process;
- good management of intellectual property and knowledge transfer.

Considering the analysis of evidence on enablers that support diffusion of disruptive digital innovations in healthcare provided by Bamel et al. team (Bamel et al., 2023) the role of institutions, actors (users, providers, other stakeholders), infrastructure/resources, products and services, and partnerships/collaborations may be studied for creation of an adequate and stimulating environment for innovation in Digital Health. The knowledge on barriers for digital innovations related to health systems or health care monitoring and interventions (i.e., categorized in data-related, user-related, organizational-related, ecosystem-related, policy and regulation-related, strategic orientation related, and resource/infrastructure constraints-related) (Bamel et al., 2023) may also be important for the implementation of strategies for efficient and faster selection of the technologies and consumer insights that would boost innovation in Digital Health.

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Annex I - Glossary for Innovation and Digital Health

Ambient Assisted Living (AAL) technologies refer to the use of information and communication technology to empower individuals to maintain an active and independent lifestyle for as long as possible. (Gupta et al., 2025) May refer to the use of information and communication technology-based products, services and systems to provide older and vulnerable people with a safe environment, improving their quality of life and reducing the costs of health and social care.

Appropriate Use of Digital Technologies – Information and communications technology that takes into account safety, ethical use, cost-effectiveness and affordability and is people-centred, evidence-based, effective, efficient, sustainable, inclusive, equitable and contextualized. (WHO, 2021)

Artificial Intelligence (AI) - Technology that enables computers and machines to simulate human learning, comprehension, problem solving, decision making, creativity and autonomy. (Stryker, 2024) Artificial intelligence may refer to the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings. The term is frequently applied to the project of developing systems endowed with the intellectual processes characteristic of humans, such as the ability to reason, discover meaning, generalize, or learn from past experience. (Britannica)

Big Data - The emerging use of rapidly collected, complex data in such unprecedented quantities that terabytes (1012 bytes), petabytes (1015 bytes) or even zettabytes (1021 bytes) of storage may be required. The unique properties of big data are defined by four dimensions: volume, velocity, variety and veracity. As more information is accruing at an accelerating pace, both volume and velocity are increasing. (Wyber et al., 2015)

Blockchain: A blockchain protocol is a set of predefined rules or procedures that govern how the nodes interact with the network, view, verify, and add data to the ledger. (Fatoum et al., 2021)

Change Management. Change management is defined as the methods and manners in which a company describes and implements change within both its internal and external processes. This includes preparing and supporting employees, establishing the necessary steps for change, and monitoring pre- and post-change activities to ensure successful implementation. When an organization's goals, processes, or technologies transform or transition, this significant change can be challenging and requires cooperation of different independent entities within an organization. Developing a structured approach to change is critical to help ensure a beneficial transition while mitigating disruption. Used properly, quality-based change management practices can help any sized organization overcome resistance to change, update outdated processes to advance, and recognize the need for clear communications and alignment across all levels of the workforce. Used improperly, organizations will likely continue to struggle with overcoming barriers and low productivity or may even experience frequent staff turnover. (ASQ. American Society for Quality)

Cloud computing can be described as a model for enabling convenient, ubiquitous on-demand network access to a shared pool of computing resources. (Mell & Grance, 2011)

Data breach occurs when unauthorized parties infiltrate computer systems, networks or databases to gain access to confidential information. Breached data can include personal information, financial records, intellectual property or any other protected information that falls into the wrong hands. The consequences of a data breach can be severe such as financial losses, reputational damage, legal implications and potential harm to victims. This can include anyone from individual consumers to smaller businesses and even large multinational enterprises. Data breach and cyber-attack are terms used interchangeably—but they mean different things. In a data breach, the primary focus is unauthorized access to the data. For example, a hacker gains access to users' names, Social Security numbers and passwords. On the other hand, a cyber-attack refers to a broader range of malicious activities that cybercriminals use, such as malware infections and phishing schemes targeting computer systems. (Forbes, 2023)

Data cooperatives - allow data subjects to voluntary pool their data together, retaining control over how such data are managed for mutual benefits and how these benefits are shared. (Kickbusch et al., 2021)

Data trusts are legal structures that provide independent stewardship of data, aggregating data from multiple sources and deciding who has access, under what conditions, and to whose benefit. (Kickbusch et al., 2021)

Data-driven decision-making (DDDM) is an approach that emphasizes using data and analysis instead of intuition to inform business decisions. It involves leveraging data

sources such as customer feedback, market trends and financial data to guide the decision-making process. By collecting, analysing and interpreting data, organizations can make better decisions that more closely align with business goals and objectives. (IBM, by Mucci, 2024)

Digital Health – the field of knowledge and practice associated with the development and use of digital technologies to improve health… Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart and connected devices. It also encompasses other uses of digital technologies for health such as the Internet of Things (IoT), advanced computing, big data analytics, artificial intelligence including machine learning, and robotics. (WHO, 2021) Digital health has been coined to represent the broadest term covering the application of digital technologies in the context of health, and while being rooted in electronic health, this term also encompasses other adjacent areas such as "big data" applications, genomics, and artificial intelligence. (Yeung et al., 2023) The broad scope of digital health includes categories such as mobile health (mHealth), health information technology, wearable devices, telehealth and telemedicine, and personalized medicine. …Digital health technologies use computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products. (US Food and Drug Administration, 2020) Digital Health offers opportunities for physicians to offer more personalised care, for individuals and communities to track, manage, and improve their own health and wellbeing, and for authorities to make use of vast amounts of data for public health purposes. Digital tools are being used to address broader determinants of health, including applications in the areas of income inequality, insurance, education, and the physical environment. (Kickbusch et al., 2021)

Digital Health Interventions refer to the use of digital technology and connected devices to improve health outcomes and healthcare delivery. (Kasoju et al., 2023)

Digital Health Readiness should only be seen as having been achieved when all people and their communities, the health ecosystems they interact with, and the countries they live in are prepared, equipped, and empowered to use digital technology and data to meet personal health and wellbeing needs and to improve the health and wellbeing of the whole population. This interpretation of readiness necessitates analysis of the intersecting forms of discrimination and inequalities that undermine the agency of people as holders of rights in relation to digital health. (Kickbusch et al., 2021)

Digital Innovation can be defined as the creation of (and consequent change in) market offerings (product and services), business processes, and business models that result from the use of digital technology. (Nambisan, 2017)

Digital Public Goods - They can be defined as open-source software, open data, open artificial intelligence models, open standards and open content that adhere to privacy and other applicable international and domestic laws, standards and best practices and do no harm. (United Nations General Assembly, 2020)

Digital Transformation - The multiple processes of integration of digital technology and data into all areas of everyday life, including health, and the resulting changes that they bring about. (Kickbusch et al., 2021) Digital transformation is a process that aims to improve an entity by triggering significant changes to its properties through combinations of information, computing, communication, and connectivity technologies. (Vial, 2019) It involves a series of distinct digitalization initiatives with an overarching aim to facilitate far-reaching, person-centred organizational change. Organizations and agencies are adjusting their key performance indicators by integration of different digital technologies into a well-coordinated health system. (Iyamu et al., 2021)

Digital Transformation of Health - refers to the multiple processes of integration of digital technologies and data into all areas that affect individual and collective health and well-being. (Forslund et al., 2024)

Digitalization - a sociotechnical process that involves the integration of digital technologies into existing operations and tasks with the goal of improving efficiency and adding value to users. (Iyamu et al., 2021)

Digitization – a technical process involving the conversion of analogue information into digital formats (signals). (Iyamu et al., 2021)

Disruptive Digital Innovations (DDIs) are innovations that involve utilization of digital technologies in innovative and novel ways, and their value comes from their inherent architecture. DDIs refer to innovations such as AI, blockchain, virtual/augmented reality, 3D printing, and the Internet of things (IoT), which are quite drastic in their impact and bring about highly visible changes in the way things are done at work as well as play. DDIs enable major business improvements and transformations across various commercial functions and industries. DDIs include a higher degree of customer involvement, enhanced firm performance through rapid innovation and operational efficiency, entrepreneurship transformation, digital boosts/transformations and value creation, user-wellbeing. (Bamel et al., 2023)

e-Health The cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health care services, health surveillance, health literature, and health education, knowledge and research. (WHO, 2021) It refers to the use of digital technologies and telecommunications, such as computers, the Internet, and mobile devices, to facilitate health improvement and health care services. (Britannica https://www.britannica.com/science/e-health). The Telehealth, Electronic Health Records, Electronic Medical Records, Telemedicine,

Telerehabilitation, m-Health, Ambient Assisted Living Technology, E-Prescribing, e-Patient, Personal Health Community are e-Health technologies.

e-Learning (distance learning, electronic learning or online learning) - is delivery of training and education via networked interactivity and a range of other knowledge collection and distribution technologies. (Fry, 2000)

Electronic Health Records (EHRs). Electronic Health Records are digital versions of patients' medical histories, maintained over time and across different healthcare providers. They typically include key clinical data such as demographics, progress notes, medications, past medical history, immunisations, laboratory results, discharge and radiology reports. (OECD/European Commission, 2024) EHRs are not focusing on patient diseases and go beyond standard clinical data collected in the provider's office by including a broader view on a patient's care. EHRs are designed to reach out beyond the health organization that originally collects and compiles the information. They are built to share information with other health care providers, such as laboratories and specialists, so they contain information from all the clinicians involved in the patient's care. The National Alliance for Health Information Technology stated that EHR data "can be created, managed, and consulted by authorized clinicians and staff across more than one healthcare organization." (U.S. Department of Health & Human Services Web site, HealthITBuzz)

Electronic Medical Records (EMRs) are a digital version of the paper charts in the clinician's office. An EMRs contains the medical and treatment history of the patients in one practice. EMRs have advantages over paper records. For example, EMRs allow clinicians to track data on patient over time; monitor and improve overall quality of care within the practice. EMRs is mainly implemented in hospital. (U.S. Department of Health & Human Services Web site, HealthITBuzz)

e-Patient (e-Patients, e-Patient movement) - is a health consumer who fully participates in his own medical care and consider himself an equal partner with his doctor(s). The phrase e-patient was first coined by Tom Ferguson, the founder of the Society for Participatory Medicine. An e-patient is equipped, enabled, empowered, and engaged and encouraged to use electronic (and Internet) resources. (Croskerry et al., 2017) May refer to those patients gathering information about medical conditions that impact them and their families, using the Internet and other digital tools. The term encompasses those who seek guidance in social networks for their own ailments, and the friends and family members who research on their behalf.

e-Prescribing (electronic prescription, e-prescription) - enables a prescriber to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care. It is an important element in improving the quality and safety of patient care. (CMS.gov Centers for Medicare & Medicaid Services) E-prescribing

refers to processes to generate a prescription, to sign a prescription, and to transmit it to a pharmacy. Only true computer-to-computer electronic data interchange using a nationally accepted data standard is defined as genuine electronic prescribing. Various methods that employ a computer to print a prescription, or that employ facsimile, are not classified as e-prescribing. (U.S. Pharmacist. The Pharmacist's Resource for Clinical Excellence)

Health Information System - A system that integrates data collection, processing, reporting, and use of the information necessary for improving health service effectiveness and efficiency through better management at all levels of health services. (WHO, 2021)

Health Literacy refers to the degree to which individuals can obtain, process, understand, and communicate about health-related information needed to make informed health decisions (Berkman et al., 2010). Patients with adequate health literacy can read, understand, and act on health care information. More recent evolutions of the concept include a variety of competencies and skills, including knowledge, motivation, and competencies related to accessing, understanding, appraising, and applying health-related information in health care, disease prevention, and health promotion settings. (Sorensen et al., 2012)

Infodemic refers to acute outpouring of information, including potentially misleading or inaccurate information that, in a digital, hyper-connected society such as the present one, is likely bound to accompany every epidemic or acute health crisis. (WHO, 2020)

Innovation management is the systematic process of developing, directing, and implementing new ideas, methodologies, products, or services to drive growth and maintain a competitive edge. This field covers the entire innovation lifecycle – from ideation and development to execution and evaluation. This way, innovation management ensures that new ideas align with the organization's strategic objectives and deliver tangible value. Consequently, companies adapt to evolving market dynamics, meet emerging customer needs, and capitalize on new opportunities. (StartUs Insights. by Tamanna, 2024)

Internet of Things A system of interrelated computing devices, mechanical and digital machines, objects, animals or people that are provided with unique identifiers and the ability to transfer data over a network without requiring human-to-human or human-to computer interaction. (WHO, 2021)

Interoperability - The ability of different applications to access, exchange, integrate and cooperatively use data in a coordinated manner through the use of shared application interfaces and standards, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize health outcomes. (WHO, 2021)

Learning Health System - one in which science, informatics, incentives, and culture are aligned for continuous improvement, innovation, and equity—with best practices and discovery seamlessly embedded in the delivery process, individuals and families' active participants in all elements, and new knowledge generated as an integral by-product of the delivery experience. (National Academy of Medicine)

Management Information System (MIS) - A management information system refers to an element of business that gathers relevant company data, fosters communication between people in a company, and helps to guide the decisions of company leaders. (EBSCO Management Information System)

mHealth (m-Health or mobile health) defined by WHO as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (WHO, 2011). The term mHealth is most used to refer to the use of mobile communication devices such as a mobile phone or tablet computer. The mHealth field encompasses the use of mHealth apps to gather healthcare information on both sides, patients trying to access health care information online and health care providers gathering clinical information from patients for the use of clinical decision making. (Twilt 2023)

National Interoperable Digital Health Ecosystem - All kinds of digital information technology infrastructure established on the national level of a country that is interoperable and primarily used by the health care community, in particular by the health care providers, health service providers and patients but also by the public health authorities, universities and research institutions. It enables the seamless exchange (Health Information Exchange -- IHE) and processing of health data – which is predominantly generated by the health care providers – between them and the health care community. (WHO, 2021)

Personal Health Community (PHC) can be defined as the patient's own 'online hospital'. Online, he or she can gather all different health-care professionals from different health care organizations, who are relevant for his or her health. With the patient in the lead, all members of the community can share information about the patient's health and communicate with each other about this information through several functionalities in the PHC, including blogs and forums. The PHC puts the individual patient in the heart of the health system, acknowledging the multiple and personal contexts of individuals' lives. Second, the PHC makes the complex patient's network transparent for both the patient and his or her health care providers. Third, to have access to the PHC, health-care professionals need consent from their patient. Combining medical data with the possibility to communicate with others seems required to meet self-management goals and is possible within PHCs. (Aarts et al., 2014)

Precision Medicine - An approach to disease treatment and prevention that seeks to maximise effectiveness by taking into account individual variability in genes, environment, and lifestyle for each person. In this report, the rapid advances in the area of genomics are considered (and referred to) as part of the broader dynamics of digital transformations, owing to the facts that the evolution of genomic sequencing techniques is strictly related to the drastic expansion of possibilities offered by digital technologies (i.e., decreasing computing costs, growing capacity for big data and data analytics), and that precision medicine depends on the combination of genomics and machine learning techniques. (Kickbusch et al., 2021)

Precision Public Health - An approach to improving population health through the use of digital and genomic technologies, which enable health organisations, policy makers, and wider health systems to guide public health practice by generating more individually tailored or community-tailored interventions and policies. (Kickbusch et al., 2021)

Technology Innovation is defined as the creation and application of new or improved technologies, tools, systems, and processes that bring about significant advancements or breakthroughs in various fields. It involves harnessing knowledge, expertise, and resources to develop innovative solutions that solve problems, improve efficiency, drive progress, and deliver value. (IDEASCALE. By Jain, 2023)

Transformational Innovation refers to major changes to products and services that redefine what customers expect by delivering significantly improved performance, providing new kinds of value, resolving long-standing trade-offs, and/or radically reducing manufacturing costs. (Harvard Business School. by Koen et al., 2024)

Telehealth is defined as the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, health administration, and public health. (Health Resources&Services Administration)

Telemedicine - The delivery of health care services, where distance is a critical factor, by all health-care professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and the continuing education of health care workers, with the aim of advancing the health of individuals and communities. (WHO, 2010)

Telerehabilitation (or e-rehabilitation) Telerehabilitation is defined as the use of telecommunication technologies to provide distance therapeutic rehabilitation. It comprises interventions like exercises, education, and pain control in the absence of a healthcare specialist. (Agnihotri et al., 2024)

Chapter 3. Targets for Digital Health Innovation

The need for innovative new products and services in healthcare in EU

The European population was estimated at 449.3 million people on 1 January 2024. Elderly population (people aged 65 years and over) had a 21.6% share in the total population, with Italy (24.3%), Portugal (24.1%), Bulgaria (23.8%), Finland (23.4%), Greece (23.3%) and Croatia (23.0%) registering the highest shares in Europe region. (European Union. Population structure and ageing, 2025). According to preliminary 2024 data life expectancy at birth in the EU was 81.7 years, up 0.3 years compared with 2023, Spain and Sweden registering the highest value (i.e., 84.0 years in Spain and 84.1 years in Sweden). The lowest values were registered in Bulgaria and Romania (i.e., 75.9 years and 76.6 years, respectively) (European Union. Life expectancy estimated at 81.7 years in 2024, 2025). The number of healthy life years at birth in 2023 was 63.3 years for women and 62.8 years for men (European Union. Healthy life years statistics) meaning that a great percentage of elderly population is living with lower level of health. Population ageing is expected to increase public healthcare expenditure necessary to ensure care for geriatric ailments (e.g. arthritis, dementia, heart disease, diabetes, osteoporosis, depression, incontinence, chronic pain, vision and hearing loss, falls and mobility issues) in the next decades. The public healthcare expenditure had increased in the last decades not related to the ageing population but due to a broad range of factors (e.g., rising costs in medicine, healthcare procedures and medical equipment) (Amiri et al., 2021). Among the EU countries, the largest expansions (in percentage terms) in current healthcare expenditure per inhabitant between 2014 and 2022 were recorded in Latvia, Romania, Lithuania, Malta, Cyprus and Czechia, where expenditure more than doubled. Germany (12.6%), France

(11.9%) and Austria (11.2%) had the highest current healthcare expenditure relative to GDP in 2022 (European Union. Healthcare expenditure). Although there is evidence that preventive measures may reduce the incidence and prevalence of a large number of diseases preventive health care expenditure in the European Union was equivalent to only 0.57% of GDP in 2022. EU countries spent €90.4 billion on preventive health care in 2022 (European Union. Preventive health care expenditure). Cardiovascular diseases and cancers the leading cause of death in Europe (European Union. Causes of death) are among those diseases that can be prevented. An analysis of 116 221 participants over a 30-year follow-up period found a reduction in the risk of mortality by 26-31% for adults who perform two to four times the currently recommended amount of moderate physical activity per week (Lee et al. 2022). Digital technologies like smartphone apps, wearable devices for fitness may increase awareness on healthy lifestyle and engagement on self-health management that may considerably decrease the burden on healthcare system operations and expenditure.

European countries are currently facing complex challenges ensuring universal access to high quality care. The main issues that European countries are considering in planning strategies for strengthening the capacity of their healthcare systems to provide quality, affordable and equitable care (see OECD/European Commission, 2024) are:

- workforce deficit;
- budgetary pressure of continuous increases in public healthcare systems expenditure;
- inefficiency in day-to-day operations of healthcare systems;
- the higher proportion of the elderly population (i.e., from 16% in 2000 average proportion of EU citizens aged 65 and above increased to over 21% in 2023, and forecasts show a further rise in elderly population) that are placing growing demands on healthcare systems;
- declining birth rates;
- a rise in proportion of people having chronic conditions and comorbidities (e.g., rising rate of obesity and diabetes);
- higher impact of lifestyle risk factors (i.e., such as harmful alcohol consumption, lack of physical activity, poor nutrition, the use of tobacco or electronic cigarettes) on the total burden of morbidity;
- deterioration in the physical and mental health of adolescents (i.e., caused by problematic computer, smartphone or social media use, increased exposure to cyberbullying);
- unequal access to services;
- growing human health implications of exposure to environmental hazards (e.g., impact on population health of air pollution, heat wave);
- health systems that still respond rather than prevent

To address such issues, professionals generally speak about the 4Ps of current healthcare: predictive, preventive, personalized, and participatory (Miltiadis et al., 2025). These principles offer a framework for systems that are able to predict risks, react ahead of time, adapt according to each individual, and include citizens in actively taking care of their well-being.

An increase in market of health, healthcare and wellness products and services is produced in Europe region both due to increasing awareness of the importance of healthy lifestyle but also, not less important due to augmented percentage of elderly population. Digital tools are empowering patients with self-monitoring capabilities and access to medical advice without visiting hospitals or clinics.
To facilitate understanding of multiplicity and complexities of the targets for innovation in Digital Health the technologies that may "*promote healthy lives and wellbeing for everyone, everywhere, at all ages*" (WHO, 2021) are categorized as following:

- Health Information Exchange;
- Medical Devices;
- Database for Health Care;
- Data Analytics for Health Care;
- Pharmaceutical Technologies;
- Bioengineering and Biotechnology sector;
- e-Learning for health.

A glossary of terms related to innovation and Digital Health is presented in the **Annex I** of Chapter 2. Concept of Digital Health.

Health Information Exchange

Health Information System (HIE) "*integrates data collection, processing, reporting, and use of the information necessary for improving health service effectiveness and efficiency through better management at all levels of health services*." (WHO, 2021). It encompasses telemedicine, teleconsultation, electronic medical records (EMRs), electronic health records (EHRs), teletherapy/teletreatment, e-Prescribing, telerehabilitation, hospital emergency technologies, point of care diagnostic, personal health records (PHRs), Personal health community (PHC), ambient assisted living (AAL), wellness technologies (see the definition of terms in Annex I).

Differences in different HIE systems are related not only to their role for improving health care services but also to components of these systems that may be medical devices, smart wearable, different communication technologies, distributed ledger

technology/blockchain, blockchain smart contract, Web3, Internet of Medical Things, different technologies for data storage and data analytics and different interfaces.

There is evidence on HIE contribution for efficient and effective delivery of healthcare services and to improving patient outcomes by:

- reducing manually introduced errors in the healthcare workflow;
- facilitating accurate diagnosis;
- evaluating of acuity risk in hospital emergency department;
- increasing the availability and transparency of data;
- providing remote consultations;
- monitoring chronic health conditions;
- enabling informed clinical decisions;
- providing effective and personalized treatment/therapy;
- improving rehabilitation services;
- improving patient engagement and compliance;
- reducing waste in the delivery system (optimizing workflows and efficiency);
- reducing costs in healthcare services;
- improving accountability across health system.

In spite of registered benefits of HIE technologies in different settings, there is evidence on **reduced access to these technologies mainly for the population that needs most**, such as population in geographically isolated areas, rural population underserved by public health system, population with low access to Internet, elderly population having low health and digital literacy (Kickbusch et al., 2021; Mwanza et al., 2023; Grosman-Rimon & Wegier, 2024; European Commission, 2024). At the end of 2023, all European countries provided some form of national or regional health information exchange technologies (European Commission, 2024). However, there are still gaps in the population coverage. "*Only seven Member States (26%) report that at least 60% of healthcare providers across all applicable categories of facilities (e.g. primary care facilities, secondary care facilities, geriatric nursing homes, etc.) are supplying (at least some) relevant data to the access service*." (European Commission, 2024). **Only 14 European States reported that their citizen can access their electronic health records through online portal and mobile application**(s). **Less accessible data via national electronic health data portals and apps are the medical images (26%), hospital discharge reports (69%) and procedures/operations (70%)** (European Commission, 2024).

The internet has become an integral part of most people's lives, changing the way people study, work, communicate and enjoy their free time. In 2024, 93 % of people (aged 16 to 74 years) in the EU declared they had used the internet during the 3 months prior to being

surveyed (Europe-Data, 2024). Among the EU countries, the highest share of people using the internet to make telephone or video calls in 2023 was 87.0% in Cyprus, followed by 84.7% in the Netherlands. The lowest shares were 56.1% in Poland and 57.3% in Croatia and Slovenia (Eurostat, 2024). Netherlands, Iceland and Ireland have the population that is more active online, an important role on having the Fast Broadband coverage, with the Netherlands reporting 99% coverage, which makes it easier for their populations to get online and access different platforms compared to lower ranking countries on the list (EchoLive.ie, 2024).

Concerns are rising with increased cyberattacks on hospital systems. The attacks on health information exchange structure can be used for different criminal activities such as identity frauds, phishing, ransomware, or may be used to impede health care delivery or to compromise people' trust in medical providers. **Therefore, innovations in the security of the HIE systems have high importance.**

The main issues related to implementation and adoption of HIE technologies is interoperability, inadequate infrastructure (e.g., connectivity), design of interfaces. World Health Organization provides several guidelines and tools that may support countries in implementing interoperable digital health ecosystem that may ensure seamless and secure exchange of health data by and between users, health care providers, health systems managers, and health data services. (WHO, 2021; WHO, Smart Guidelines; Saban et al., 2024; WHO. Global Initiative on Digital Health). The SMART (Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable) Guideline is designed to standardize national health guidelines on digital technologies for health in a way that facilitates their implementation across different health systems.

Innovations in ambient assisted living, point of care diagnostic, personal health records and wellness technologies would support care continuity by supporting self-management of health, tracking physical activity and vital signals (e.g., heart rate, respiratory rate, blood pressure), and facilitating social support network. Low connectivity, interfaces that are not user-friendly, with inappropriate delivery of information (e.g., a lot of information that prevents obtaining actionable insights and raise user anxiety) (Grosman-Rimon & Wegier, 2024) privacy and security of data, low digital literacy are barriers for adoption of these technologies. Innovations in these domains may enhance their potential for quality, efficient and affordable care.

The importance of using technologies for HIE to integrate critical social services, welfare system services into care delivery has been underscored during COVID-19 pandemic by disproportionate impacts on economically disadvantaged communities and on population with low access to public services. (Abernethy et al., 2022)

Progress of technologies for HIE shall consider the principles of transparency, accessibility, scalability, replicability, interoperability, privacy, security and confidentiality (WHO, 2021).

Medical Devices

"*Medical devices are products or equipment intended for a medical purpose. In the European Union (EU) they must undergo a conformity assessment to demonstrate they meet legal requirements to ensure they are safe and perform as intended. They are regulated at EU Member State level, but the European Medicines Agency (EMA) is involved in the regulatory process.*" (European Medicines Agency Science Medicines Health).
Imaging equipment for diagnosis, wearable devices, point of care equipment, internet of things/internet of medical things, biomedical materials are examples of medical devices.
Imaging equipment is mainly used for diagnosis (e.g., echography, echocardiography, angiography, computer tomography, magnetic resolution imaging) but also for some medical interventions (e.g., radiation therapy for cancer).

Wearable devices (e.g., Holters for electrocardiography monitoring; devices for pneumography monitoring; devices for plethysmography monitoring; insulin delivery device) may be used in different areas of health care as well as for fitness and wellness. Remote monitoring of patients' vital signs and/or other body parameters outside traditional hospital settings facilitate early changes in the severity of the diseases and timely interventions. Wearable devices are being used also for monitoring and therapeutic intervention of conditions related to behavioral disorders. A substantial proportion of human diseases are nowadays characterized by behavioral disorders (GBD 2019 Diseases and Injuries Collaborators, 2020).

Point of care diagnostic equipment (e.g., devices for: blood pressure and heart rhythm assessment; pneumography assessment; blood glucose measurement; blood lipid profile assessment; Sars-Cov-2 rapid detection; Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) DNA detection) has an important role in providing accessibility to health care system, mainly in underserved region of health system, and support programs for preventions of non-communicable disease as well as infectious diseases surveillance. Portable diagnostic machine stations enabling the conduction of 11 tests (e.g., blood pressure, electrocardiographs, blood analyses, routine urine are used in China in village health care facilities. The equipment upload test results and medical records to an online platform that enables data analytics (Ding et al., 2023).

The data provided by different medical devices can be compromised by different variables, such as lighting, electrical interferences, sound interferences, etc. Therefore, during design, development and use of the equipment the context of use shall be considered for adequate evaluation of reliability for diagnosis, monitoring or treatment.

Cloud based operation of wearable devices (e.g., internet of medical things, mobile applications for health monitoring) may support telemedicine, teleconsultation, telerehabilitation, ambient assisted living, or personal health records, etc. The domain is evolving by different innovations in businesses, services and processes that provide different functionalities for applications (apps) of wearable devices. **Great importance for developers has free software/open software. However, concerns are raised by developers who discover that for building and dissemination of an application they often need to pay for software tools or platform** (e.g., Apple App Store or Google Play Store often place software-related demands on developers).
Smart biomedical materials are used in construction of:

- biosensors (e.g., various biochemical materials may be used for detection and measurements of different biomarkers from body fluids through various biosensor technologies);
- prosthesis (e.g., dental, breast, upper-limb and lower limb, organ prosthesis);
- flexible wearable health monitoring devices;
- e-textile for health monitoring. Innovations in additive manufacturing (also known as rapid prototyping using 3D printers), may find application in the development of cost-effective prosthetics or other medical devices.

Innovations in additive manufacturing (also known as rapid prototyping using 3D printer), may find application in the development of cost-effective prosthetics or other medical devices. Inventions and innovation in the domain of nanotechnology have made a great contribution to accelerating the progress of smart biomedical materials.

Data Analytics

Data analytics for health care may:

- support identification of subpopulations for intense care management that prevent inappropriate emergency room use and provide early intervention for an acute worsening event;
- provide relevant information for diagnosis and monitoring (e.g., AI-driven ECG processing);
- enable informed clinical decisions;
- support data-based treatment decisions;

- prevent adverse drug events by identification of interactions between different drugs taken by a patient;
- support monitoring of the interactions between environmental changes and human health outcomes;
- support efficient resource allocation;
- contribute to the identification of behavioral risk factors associated with chronic diseases;
- support health behavior change by providing personalized feedback and messaging to the customer/patient;
- provide information for neurodegenerative diseases management (e.g., AI-driven predictive modeling of diseases progress);
- provide information for environmental impact on health (e.g., effects of climate change on different populations);
- improve and accelerate the process of epidemiological surveillance.

Data analytics is turning disparate data in meaningful content necessary for actionable insights and strategies for healthcare. Data from different technologies for health information exchange, data from mobile applications, data from wearable medical devices, data from insurance can be processed using different algorithms to obtain actionable information for increased efficiency in health systems services.

Artificial Intelligence (AI) based data analytics has transformational effects in society. Increase in number of patents related to Artificial Intelligence shows the importance for businesses. Analysis of patents granted by the United States Patent and Trademark Office between 2008 – 2018 had shown that IBM had the highest number of AI-related patents (~7100) followed by Microsoft (~5000) and Google (~4000). United States, Korea, Japan, Germany, Israel, and China were in the top ranked by number of AI patents (Habibollahi & Pecht, 2020). Nowadays, China leads the generative AI patents and machine learning. China submitted 38 210 generative AI patents between 2014-2023 (RAPACKE by Rapacke, 2025). In the last decade artificial intelligence (AI) plays an important role in advancing capacity of different technologies for diagnosis (e.g., AI for diagnostic imaging, AI for processing ECG), biomarkers detection (e.g., AI based biomarkers discovery in cancer diagnosis and prognosis), treatment planning (e.g., support for decision making, forecasting potential health complications), infectious-disease surveillance (e.g., for early-warning systems, hotspot detection, epidemiologic tracking and forecasting), for healthcare administration (e.g., for appointment, scheduling, billing). (Brownstein et al., 2023; Bhagat & Kanyal, 2024; Zuhair et al., 2024).

Data analytics using web scraping, a process that automatically extract information from websites may be implemented to gather systematic information from different websites related to guideline, standards, policies, healthcare specialists' published information

citizen opinions on health. For instance, web scrapping on LinkedIn and Monster databases may offer data on the skills sought by different industry sectors based on the information contained in their online job offers (OECD, 2019).
Following are a few examples of platform for data analytics.
SimulConsult uses an algorithm that combines a variety of patient data—including symptoms, family history and laboratory results—to generate a list of differential diagnoses. It was integrated with the Human Phenotype Ontology that augmented the precision and individualization of the diagnostic process.
SUOG (Smart Ultrasound in Obstetrics and Gynecology) is a EU-funded decision support system for early pregnancy and fetal disorders based on semantic reasoning and machine learning.
Face2Gene uses machine learning algorithms for facial analysis to help doctors diagnose genetic diseases. It uses Human Phenotype Ontology to assign facial phenotypes to possible genetic causes.
*Exomiser i*s a Java program, developed as a collaboration between members of the Monarch Initiative for finding potential disease-causing variants in whole-exome or whole-genome sequencing data
Moreover, data analytics may support characterization of social, behavioral, and environmental determinants of health for planning tailored preventive or therapeutic care (Abernethy et al., 2022).

Databases for Health Care

Databases for healthcare encompasses the technologies and techniques capable of managing the data lifecycle to support many different purposes. Managing data includes activities of storing, cleaning, integrating, and anonymizing data, just to name a few, and these can be done in near/real time or not.
In the Digital Health ecosystem data may be collected from different sources:

- platform for health information exchange and medical devices (e.g., electronic medical records, electronic health records, telemedicine, telerehabilitation, personal health records);
- real-life digital trials (e.g., data from patient hospitalizations, data from wearable devices, in-home medical devices);
- virtual digital trials (e.g., data from social media, data self-reported health-related attitudes and behaviours).

A few examples of institutions that coordinate large databases related to Digital Health are MIT Laboratory for Computational Physiology; National Heart, Lung and Blood Institute; International Genome Sample Resource (IGSR).

MIT Laboratory for Computational Physiology together with Margret and H.A. Rey Institute for Nonlinear Dynamics at Beth Israel Deaconess Medical Center is managing ***PhysioNet*** platform. PhysioNet "*includes collections of cardiopulmonary, neural, and other biomedical signals from healthy subjects and patients with a variety of conditions with major public health implications, including sudden cardiac death, congestive heart failure, epilepsy, gait disorders, sleep apnea, and aging. These collections include data from a wide range of studies, as developed and contributed by members of the research community.*" (PhysioNet https://physionet.org/about/)

National Heart, Lung and Blood Institute is managing the ***TOPMed*** platform (https://topmed.nhlbi.nih.gov/about). TOPMed integrates -omics data (i.e., data resulted from collective characterization of measurable changes in biological molecules, such as genes, metabolites, proteins, and RNA) with molecular, behavioral, imaging, environmental, and clinical data from diverse participants. It enables research for identification of the factors that increase or decrease the risk of disease, the subtypes of disease, and development of more targeted and personalized treatments for different subtypes of disease.

The International Genome Sample Resource (***IGSR*** https://www.internationalgenome.org/) maintains and shares the genetic variation from 1019 samples obtained from people who declared themselves to be healthy from 26 different population.

Database may incorporate structured data (e.g., demographic information, values of blood pressure, heart rate, weight, results of blood analysis, healthcare procedure coding system, reimbursement codes, genomics sequences, financial data) and unstructured data (e.g., physician notes related to preliminary case history of a patient, discharge summaries, medical images and their reports). **Most healthcare data is unstructured, and the amount of data produced by an average hospital is approximatively 50 petabytes per year** (HealthTech, 2023; World Economic Forum, 2024). In all European countries the market of data centres is increasing year-on-year. Data centres and their connectivity are of growing importance in Digital Health. Portugal is building in Sines the largest colocation site (leasing to different users) from Europe with a capacity of 1.2 GW, powered by renewable energy. It would support development of artificial intelligence tools for health data analytics and also would enforce the Portugal role in the connectivity of global network (i.e., Lisbon has a strategic position, close to major submarine cables from America and Africa) (Cushman Wakefield, by Sena, 2025).

Data is a resource that goes far beyond healthcare providers. It can be very useful for caregivers, but also for any stakeholder in the digital health ecosystem. There is evidence that **only a small proportion of vast amount of produced health data are used for public health management and for prevention and treatment of diseases** (World Economic

Forum, 2024). Three major obstacles to the effective use of health data were identified in a recent report of OECD (OECD by Girot et al, 2025):

- The fragmentation of health data governance frameworks across countries;
- Bureaucratic hurdles (i.e., researchers and people from public healthcare system administration face slow, complicated and unclear approval processes necessary for accessing the data);
- Trust in the use of health data for public interest purposes varies across countries (i.e., public interest is not found in all legal systems, few and unclear criteria for public interest are establish, concerns about potential risks related to data privacy and security).

User and data access facilitating and/or simplifying access to research institution facilities and to the data generated during research are frequently indicated as a major objective for research ecosystems. Research institutions often allow/facilitate the access for their member, but supporting access to new users requires dedicated resources (e.g., training) and specific mechanisms as those new users usually do not have the necessary expertise for leveraging the research centres facilities to their full capacity (OECD, 2025). Managers underline that data access can be more complex than anticipated as each researcher often has a background of policies and use different types of languages (related to digital technologies or even spoken language) that need to be harmonised (OECD, 2025). Furthermore, when collaboration is between different international institutions, and towards multi-disciplinary research, their members may be subjected to specific and conflicting national rules or requirements turning access to data more difficult. There is a general trend towards FAIR (findable, accessible, interoperable, reusable) data access. Many countries support this by overall data policies. Overarching harmonised data management approaches in European countries, that would be suitable to all member needs, is considered as a very important objective in European Health Data

Space initiative and is very challenging. This require efforts towards establishing coordinated approaches and standardisation for data access, often coupled to the production of metadata that can be accessible to larger communities of users, and the harmonisation of the different data standards. Technical issues, conflicting priorities between the objective of sharing data and that of preserving ownership of research or intellectual property are challenges that shall be address for data sharing.

While people are increasingly aware of potential cybersecurity issues, this is usually managed independently by individual members of digital ecosystems. However, with a growing number of intrusion attempts reported, there is an emerging trend towards sharing of good practices among different stakeholders (OECD, 2025).

Artificial Intelligence (AI) is currently used to exploit the vast amount of data produced by research centres or e-Health technologies. The EU AI Act (EU Artificial Intelligence Act, 2024) address the concerns related to the data accessible and ethical use of data.

Recommendations were published by OECD (OECD, 2025) and WHO (WHO, 2021; WHO Initiative) that may also contribute for sustainable and effective databases:

- A. Promote of global collaboration and advance the transfer of knowledge on digital health by development and use of common standards and terminology;
- B. Use a risk-based approach for the implementation of national digital health strategies, which would prioritise high-benefits application with low risks for breaching privacy and security of data;
- C. Build public trust through engagement.

A. Common standards and terminology

There are several international and European associations aiming to sets standards for digital health systems.

SNOMED International (https://www.snomed.org/) - determines global standards for health terms. SNOMED CT is one of a suite of designated standards for use in U.S. Federal Government systems for the electronic exchange of clinical health information and is also a required standard in interoperability specifications of the U.S. Healthcare Information Technology Standards Panel.

HL7 *(*https://www.hl7.org/) - Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

WHO- Classification of digital health interventions *v1.0* provides a shared language to describe the uses of digital technology for health, specifying discrete digital capabilities applicable to clients, health workers, health system managers, and data service (WHO, 2018a)

WHO - ***Global Initiative on Digital Health (GIDH)*** **(**GIDH, https://www.who.int/initiatives/gidh) includes standardized digital health tools for country-specific application (see WHO Digital Health Transformation Toolbox). One of the main activities of GIDH is to provide "*high-level visibility of digital transformation needs*". The GIDH Transformation Toolbox is a repository of: "*standardized digital health tools for country-specific application; tools tailored to discern and prioritize national digital health needs; assistance for countries to circumvent duplication of efforts; integration with*

existing or in-development Who-led digital platforms and tools; monitor and track the progress of national digital health maturity."

***EHDS* - European Health Data Space** includes common standards and rules for European health ecosystem (EHDS, https://european-health-data-space.com/).

Global Alliance for Genomics and Health (GA4GH) – set standards and frames policies to expand genomic data use within a human rights framework (GA4GH, https://www.ga4gh.org/our-products/#)

HPO - Human Phenotype Ontology – set standard for the computational encoding of human 'deep phenotype' data (HPO, https://hpo.jax.org/). HPO currently encompass over 18,000 terms and over 156,000 annotations to hereditary diseases.

The standards enable consistent data entry and interpretation by different healthcare providers and researchers, accurate representation of health content in digital health records, and support semantic interoperability between different systems for sharing information on disease, genetic and phenotypic information, diagnoses and treatments. **Innovations are necessary both for supporting interoperability between different databases and cost-effective storage of health data from different institutions and individuals.**

B. A risk-based approach that prioritise high-benefits application

By assessing the benefits, harms, acceptability, feasibility, resource use and equity consideration WHO team presented recommendations for specific digital interventions (e.g., for digital tracking of patients'/clients health status and services via mobile devices across all health conditions; for client-to-provider telemedicine across all health conditions; for targeted client communication via mobile devices; for provider-to-provider telemedicine across all health conditions) (WHO, 2018b). The use of Failure Modes and Effects Analysis was recently proposed by Waseem HM team (Waseem et al., 2025) for evaluation of risks across clinical, operational and patient reported categories and five major data modalities (i.e., text, image, tabular, audio, video). The team also provide recommendations for secure, interoperable digital healthcare systems.

Work published in the European Journal of Public Health shows that several Member States already have solid foundations, such as cross-border digital services and technical capacity, which can accelerate European Health Data Space (EHDS) adoption (Kessissoglou et al., 2024). The EHDS can help scale precision health across Europe, not only by moving data but by enabling proven governance and methodological frameworks to circulate between Member States (Horgan et al., 2022). An interoperability framework directly aligned with the EHDS enable to translate regulatory ambitions into concrete implementation patterns using standards such as Fast Healthcare Interoperability Resources (FHIR) and FHIR APIs, was presented recently, demonstrating how primary and secondary uses of data can coexist in practice (Hussein et al., 2025). The role of EHDS to emergency preparedness by harmonizing infrastructures that can shorten the time to

detect signals and improve coordinated crisis response across Europe was presented (Arroyo et al., 2025).

Federated EHRs was presented as a solution that respects privacy while enabling cross-border learning health systems, an approach that aligns with Europe's values and technical needs (Raab et al., 2023). Recent open-access studies on real-world evidence demonstrate how federated networks of European data sources can standardize hundreds of datasets, making them ready for large-scale clinical research and regulatory use (Blacketer, C. et al., 2025). In cancer research, the EUCAIM infrastructure was described as a federated, FAIR-aligned imaging resource that strengthens AI development and makes Europe globally competitive in digital oncology (Martí-Bonmatí et al., 2025).

Innovations are necessary for development and management of effective databases that support evaluation of vast amount of digital health applications, their value-added to individual health, and also identification and control of risks for individuals or different populations.

C. Build public trust through engagement

Advocate for people-centred health systems, awareness-raising campaigns on the societal benefits of digital technologies for health, public assemblies on the use of health data, meaningful involvement of citizens in decision making related to their health and functioning of health systems may all contribute to increase trust on digital health technologies. **Innovations for cost-effective databases in private or public health institutions may advance knowledge on biological, social or environmental determinants of health and diseases.**

European Health Data Space can restore trust in European health systems by ensuring citizen-controlled access, improving data quality, and creating confidence in secondary use when implemented consistently across Member States (de Frutos Lucas & Haugo, 2024).

A study that explored the risks, challenges, and gaps in the implementation of privacy-enhancing technologies (PETs) within EHDS has found five distinct categories of concerns, based on fourteen risks, and highlight seven governance and technological solutions. It emphasizes the importance of public engagement and awareness, in addressing multiple risks (van Drumpt et al., 2025). Secondary use of data supported by privacy-enhancing technologies may allow research and innovation without compromising patient trust.

Pharmaceutical Technologies

Digital Health is transforming not only the provision of healthcare, but also the pharmaceutical sector, from drug development to compliance. Digital health is revolutionizing pharmaceutical technologies along the entire value chain, right from discovery to patient use. Digital technologies are used for decentralized clinical trials, drug

development supported by artificial intelligence (AI), ingestible digital pills, additive manufacturing of pharmaceuticals, computer-aided drug design, predictive toxicology, big data analytics for trial management.

Digital health technologies are being increasingly incorporated into regulatory frameworks for clinical trials. FDA guidance on the use of digital health technology in drug development highlights the potential of ***sensors and connected devices to bring precision and diversity to clinical trials*** (FDA - US Food and Drug Administration, 2023). Decentralized and hybrid clinical trials are a cornerstone of innovation, expanding on this. More recently, there is evidence that trial decentralization increases breadth of recruitment, reduces participant burden, and enables continuing remote data capture without sacrificing scientific integrity (Izmailova et al., 2020; Coravos et al., 2020).

Artificial intelligence is revolutionizing pharma research and development. ***In silico clinical trials allow simulation and predictive modeling*** that optimize trial design, dose optimization, and prediction of adverse events, reducing cost and timelines (Viceconti et al., 2016). Artificial intelligence through machine learning algorithms is being applied more and more in drug discovery pipelines with successes being seen in new molecule discovery, formulation optimization, and simplifying safety profiling (Vamathevan et al., 2019). For instance, Halicin an antimicrobial agent for the treatment of infections caused by antibiotic-resistant bacteria, was developed by MIT lab through deep learning algorithm (Belghiti et al., 2025).

Digital pills—drugs that contain ingestible sensors within them—are also enabling real-time adherence monitoring. Clinical trials in psychiatry and chronic care demonstrate their viability, with improved adherence monitoring and pharmacological data generation, although concerns are about privacy and expense (Kane et al., 2018).

Additive manufacturing is increasingly used in pharmacology. The approval of Spritam®, the first 3D-printed drug approved by the FDA, opened the door for pharmaceutical 3D printing innovation (Alhnan et al., 2016). Research has since shown that techniques such as fused deposition modeling and semi-solid extrusion can offer patient-specific dosage forms, including multi-compartment tablets and controlled-release systems (Awad et al., 2020).

Computer-aided drug design (CADD) utilizes structure-based virtual screening, molecular docking, and pharmacophore modeling for high-throughput screening of large chemical libraries. CADD increases efficiency in early drug discovery and reduces attrition rates (Lionta et al., 2014).

Predictive toxicology, led by computational modeling and programs such as *ToxCast,* allows for early detection of hepatotoxicity and cardiotoxicity, reduces late-stage trial failures, and highlights regulatory momentum toward New Approach Methodologies (NAMs) (Richard et al., 2016).

Big data analytics is improving how clinical trials are managed. By linking electronic health records, genomic databases, and patient-reported outcomes, **Big Data** approaches

simplify trial design, predict recruitment bottlenecks, and monitor safety signals in real time. There is evidence that these methods improve trial transparency (Huser & Cimino, 2013).
Progress in digital technologies supports integration of pharma technologies into a unified Digital Health ecosystem. Advances in AI-driven discovery, 3D printing, technologies for decentralized trials, for predictive toxicology, for big data management may contribute for more predictive, preventive, personalized, and participatory medicine.

Bioengineering and Biotechnology Sector

The bioengineering and biotechnology sector has emerged as one of the most dynamic areas of science, marked by the convergence of biology, engineering, and data science. Over the last two decades, the development of omics technologies has transformed the way we understand health and disease. ***Genomics, proteomics, metabolomics, and transcriptomics*** enables researchers to examine biological systems on a previously unimaginable scale, providing worldwide snapshots of molecular processes involved in physiological and pathological processes across the globe. Progress in genomics allow identification of human genetic variations and more understanding of their role in disease susceptibility (Goodwin et al., 2016). Proteomics and metabolomics have provided functional insights into disease mechanism and therapeutic response (Aebersold & Mann, 2016), and transcriptomics, through innovations such as single-cell RNA sequencing enable more comprehensive description of cellular heterogeneity (Stuart & Satija, 2019). Multi-omics technologies are transforming biomedical research and precision medicine.
A revolutionary pillar of biotechnology is ***synthetic biology***. This enables to reprogram living systems to perform desired functions, with utilizations ranging from vaccine and bioplastics manufacturing to the development of novel therapeutics. The CRISPR-Cas9 genome editing discovery has provided a flexible and accurate tool for genome manipulation, revolutionizing fundamental research and applied biotechnology (Doudna & Charpentier, 2014). There are currently many applications of CRISPR-Cas9 technology (e.g., microbes engineered for bio-based production; genetic therapy for cancer treatment). The future of synthetic biology is ever more reliant on computational design and automation tools, which can potentially compress development cycles along with cost (Nielsen & Keasling, 2016).
Systems biology supports better description of interactions and behavior of the components of biological entities (e.g., between molecules or cells) based on network-level thinking. By integrating heterogeneous omics datasets and mathematical modeling, systems biology predicts emergent properties of complex biological systems. Systems biology is being applied in metabolic network modeling, immune response modeling, and drug–target interaction simulation at a systems level (Kitano, 2002).

Bioprinting for regenerative medicine refers to the creation of functional tissue components or of the whole organ by using 3D printing technologies. Regenerative medicine has begun to employ 3D bioprinting methods to create highly specialized tissue models. It includes the implantation of scaffolds alone, isolated cells and other bioactive molecules, or a combination of cells implanted within or on scaffolds to model the body's natural extracellular matrix (ECM) (Saini et al., 2021).

Each of these scientific advances depends heavily on the ability to handle enormous amounts of data. The biotechnology and bioengineering sector have become a forcefully data-intensive sector, with sequencing technologies, imaging systems, and high-throughput screening producing terabytes of data on a daily basis. Therefore, analysis and processing of the data for omics or systems biology require robust infrastructures that bring together big data analytics, cloud computing, and artificial intelligence. ***Big Data*** approaches have enabled biomarker discovery from omics data sets, predictive toxicology through in silico models, and the optimization of clinical trial design according to real-world evidence (Stephens et al., 2015).

The integration of biomedical data with electronic health records and biobanks is accelerating translational research and is creating direct bridges between laboratory findings and clinical practice. It contributes to advancement in ***precision/personalized medicine***. With the intersection of genomics, biomarkers, and clinical data, precision oncology enables clinicians to select targeted therapies based on the molecular profile of an individual's tumor (Collins & Varmus, 2015). Progress is being made to implement precision medicine in cardiology, neurology, and orphan diseases.

The emergence of ***companion diagnostics***, ***pharmacogenomics***, and ***AI-based patient stratification*** mirrors the ways in which bioengineering and biotechnology are transforming the practice of health care. The trend in bioengineering technology is towards even more integrative approaches. For instance, ***Digital Patient Twin*** is based on highly developed model that can simulate cell, tissue, organs or even entire individual, ideally containing all of the information on its real-world counterpart. Digital Patient Twins are dynamic, virtual model reflecting changing in real biological structure. Digital Patient Twin may be used to identify a medication's effects, including drug interactions and side effects, even before the person takes the pill (Reis, 2025).

Ethical and regulatory issues shall be carefully analyzed before and during bioengineering and biotechnology research. Moreover, concerns related to data privacy, genetic editing, and equitable access to innovation must be adequately addressed.
Bioengineering and biotechnology hold the promise of more efficient and personalized healthcare. Such promise will be fulfilled, however, only through careful integration of

scientific advances, strong digital infrastructures, and strong commitment to ethics and equity.

E-Learning for Health

E-learning platform can be used for capacity building and improvement in health literacy.
Staff training and engagement

Different stakeholders from the Digital Health ecosystem (e.g., universities, research centres, innovation hubs, companies) are using e-learning platform to transfer know-how and skills to the economy and society.
For digital transformation to be successfully adopted, healthcare professionals need to both understand and embrace the digital health technologies. Building trust, fostering positive attitudes, and offering targeted training are key factors in reducing resistance to change (Söling et al., 2023; Gustafsson & Dannapfel, 2025).
Trust, perceived usefulness, social influence, and facilitating conditions significantly drive the behavioral intention to adopt digital health tools. At the same time, inadequate training, infrastructure gaps, and poor usability remain major obstacles to adoption. To address these challenges, specialized digital health training is being integrated into educational programs. However, the training should be tailored to different competence levels in order to enhance readiness and encourage positive attitudes toward digital solutions (Alotaibi et al., 2025). Educational initiatives more broadly should be diverse and ongoing, ensuring that healthcare staff receive continuous learning opportunities throughout the process. Actively involving professionals from the early stages of transformation increases engagement and ownership (Back et al., 2022; Bhakta et al., 2022), while sustained organizational support is essential to help staff adapt to new workflows and ways of working (Martin et al., 2024; Petersson et al., 2024).

In Digital Health ecosystem e-Learning may be employed for:

- training health and healthcare professionals;
- care system' employees training (e.g., for nursing assistant, for employees from elderly care residential, for personal care aides or home care aides, for administrators);
- training employees of regulatory institutions related to Digital Health;
- training employees of social assistance;
- training diverse employees from companies having products or services related to health (e.g., pharma companies employees, digital technologies researchers, engineers, specialists in biology or biochemistry, computer scientists, business people);

- patients education (e.g., for efficient use of digital technology used in ambulatory care; for self-management of health);
- patient and/or community engagement in the process of care;
- coach for wellness.

The e-Learning environment may include technologies for:

- videotaped trainees' information-giving sessions storage;
- engagement measurement at regular intervals;
- checklists, guides, and videos that support day-to-day tasks;
- collecting feedback on the sessions from peers;
- communication between experts and patients;
- collecting feedback from patients;
- on-demand health information and education.

Currently, the mostly developed e-Learning platforms in Digital Health ecosystem are those for healthcare professionals training. As healthcare industry has strict compliance standards and regulations and new standards or technologies are frequently introduced in healthcare systems, the organizations provide employees with up-to-date compliance training and ensure those standards are met. Efficient e-Learning platforms support healthcare teams to master new tools, reinforce core skills (e.g., lifesaving protocols and procedures, infection control, patient safety, and medical ethics), and to comply with evolving standards.

E-Learning makes training accessible and stress-free. It offers online course access, multi-device compatibility (i.e., desktops, tablets, or smartphones can be used to access the training session), and supports self-paced learning. Learners can revisit training modules anytime to reinforce knowledge. E-learning platforms are cost-effective tools for training large groups (i.e., platforms can handle thousands of learners). Large-scale updates on e-Learning platforms (e.g., when new compliance rules or medical guidelines are introduced in the system), can reach all staff quickly, no matter how many there are or where they're located. E-learning platforms may also provide technologies for on-demand access to trusted information supporting efficient decision-making processes.

Digital Health Literacy

Nowadays, many people use e-Learning apps to actively engage in self-management of health. It is estimated that 350,000 digital health apps are accessed globally through different platforms (Hou et al., 2023). People are integrating different devices for health monitoring, coaching programs, self-education, and social networks to achieve a healthy life. Many countries are seeing a trend toward the consumerization of health care to accommodate patients' and families' personal preferences so that the care they receive is better tailored to their unique needs (Hou et al., 2023). Healthiest people often have the knowledge and capacity to make the best decisions regarding their health (Demos

Helsinki, 2016). There seems to be a positive correlation between health literacy and health-related behaviors (Kim et al, 2023). According to surveys in the European Region (Sorensen et al., 2015), approximately half of population (47%) had limited (insufficient or problematic) health literacy. Population that is characterized by financial deprivation, low social status, low education or old age, had low level of health literacy, and this can further reinforce existing inequalities. Health literacy is defined as the capacity "*to access, understand, appraise and use information and services in ways that promote and maintain good health and well-being. Health literacy means more than being able to access web sites, read pamphlets and follow prescribed health-seeking behaviors. It includes the ability to think critically about, as well as the ability to interact and express personal and societal needs for promoting health*." (WHO, 2024, Health Literacy)

Digital technologies are currently being used for health promotion. "*The ability to appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health-related problem*" define digital health literacy (Smith & Magnani, 2019). In addition to health literacy, digital health literacy requires the ability to use computers and related technology efficiently to accomplish tasks, media literacy to use search engines, and capacity to identify and understand misinformation and disinformation. Misinformation is "*false information spread inadvertently without the intent to harm*" and disinformation is "*false information that is designed to mislead others and is deliberately spread with the intent to manipulate truth and facts"* (Britannica, https://www.britannica.com). Misinformation concerning health can have severe consequences regarding people's quality of life and even their risk of mortality. Incentive for critical thinking during evaluation of different data from online sources, incentive for collaborative platform between patients and health professionals, standards for "trustworthy" health data may contribute to avoid harm produced by misinformation and disinformation. The source of information should always be checked. For example, reputable sources such as government health agencies, academic institutions, medical associations, and peer-reviewed journals are normally filled with reliable information (Swire-Thompson & Lazer, 2020).

Lack of access to internet or smartphone for people living in poverty, the digital content that in many cases require high-level general literacy, complex medical terminology and jargon, dense paragraphs of educational material, complexity of navigation in e-Learning platform, abundance of information without sufficient guidance and explanation that lead to confusion and stress, are a few among others issues that contribute to low digital health literacy (Smith & Magnani, 2019). While nearly 90% of people in the EU use the internet at least once a week, only 54% had basic or above basic digital skills in 2021 (World Economic Forum, 2023).

Health care organizations must ensure that information is communicated in a way that facilitates understanding (Smith & Magnani, 2019) engagement in education process and

increase in health literacy. Innovations in digital technologies for e-Learning may greatly contribute to health promotion.

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Chapter 4. Resources for Innovation

Innovation Infrastructure – Universities and Research centres; European Health and Digital Executive Agency (HaDEA); European Agency for Safety and Health at Work (EU-OSHA); Living Labs; Innovation Hubs and Technology Parks; Companies, Innovation Testbeds

Finance Resources - EU - Funding Programmes; National and Regional Funding Program

Annex I - Country specific details in Reimbursement of Digital Solutions for Healthcare

Annex II - Comparative summary of medical device reimbursement systems from several European countries

Annex III - Examples of digital technologies used in the COVID-19 pandemic response. Source:

WHO Regional Office for Europe, 2021.

Innovations Infrastructure

Universities and Research Centres

Innovation-driven growth is based mainly on science. Universities and Research Centres play a prominent role in advancing knowledge in all scientific domains. Through their research labs, biobanks, academic spin-offs, and collaborations on national, European, or international research projects, collaboration at Innovation Hubs, Universities serve as catalysts for the transmission of knowledge to the industry. Universities and Research Centres enable researchers to carry out projects and investigate problems using a diversity of high-performance and sometimes unique scientific equipment, data and digital services (OECD, University - Industry Collaboration, 2019). Research Centres may have complex structures, often multimodal, and distributed over different sites in the city, in a country or even trough different countries (e.g., Fraunhofer https://www.fraunhofer.de/en.html). Universities and Research Centres contribute to policy-makers as they address the different societal challenges. Universities and

Research Centres collaborate with businesses, healthcare providers and patients to develop innovative solutions through health Innovation Hubs and Living Labs (OECD. University – Industry Collaboration, 2019). Recent report of OECD on Research Infrastructure (RI) (OECD, 2025), based on analysis of the survey responses of over 40 RI ecosystems (i.e., exploring the rationales for the development of partnerships between RIs, the challenges and policies related to collaboration of RIs) presented several recommendations to advance the development of RI ecosystem:

"Strategic exercises and road-mapping by institutions and governments should incorporate an ecosystem view into their design objectives and therefore ***incentivise RI collaboration and synergies****, particularly at the international level where collaboration between RIs remains challenging.*

Governments and research agencies should ***explore various models of cooperation*** *that can respond to the needs of RI ecosystems, and in particular flexibility and dynamism. There is considerable opportunity for mutual learning across countries and scientific domains in this respect.*

Research funders and governments should ***implement sustainable funding models*** *for RIs to stimulate the creation of RI ecosystems and incentivise RIs to join existing ecosystems, with enhanced efforts to include the participation of RIs from emerging economies.*

RI ecosystems should, where appropriate, include in their objectives the task of ***developing shared digital platforms and data access mechanisms and policies as well as standardised data formats*** *to enhance the usefulness of the data produced by their members.*
RIs should be ***incentivised, including with funding, to leverage their capacities in training, staff development and mobility, and skills exchange*** *with different sectors through RI ecosystems.*
RI ecosystems should lead and actively ***facilitate activities to monitor and evaluate not just the impact of their member facilities, but also that of the ecosystems themselves.*** *They should develop common approaches to impact assessment and building evidence to support funding applications for individual facilities and for the ecosystem.*
RI ecosystems should develop common ***actions in security risk assessment and risk mitigation*** *through the* ***sharing of good practice, raising awareness*** *and* ***developing shared principles and protocols****."*

OECD team recommended introduction of a regulatory framework that may facilitate the participation of industry and civil society in the governing boards of universities and public research centres, and consultations of diverse stakeholders in decision-making process of the higher educations institutions and research centres. The collaboration with industry partners and civil society would ensure that the interests and demands of those organizations are taken into consideration, including those relating to research directions, teaching curricula, and the local engagement of institutions. This can make universities and research centres more responsive to business and societal needs (OECD. University – Industry Collaboration, 2019).

European Health and Digital Executive Agency (HaDEA)

HaDEA (https://hadea.ec.europa.eu/index_en) implement actions that strengthen Europe in the domains of health, food safety, digital technologies and networks, industrial capacities and space. Emerged in mid-2021 and is localized in Brussels (Belgium). The HaDEA is involved in funding and the implementation of two health-related programmes for the European Commission: most of the EU4Health programme, and Horizon Europe – Cluster 1 and 4.

European Agency for Safety and Health at Work (EU-OSHA)

EU-OSHA (https://osha.europa.eu/en/about-eu-osha) is the EU's information agency for occupational safety and health, located in Bilbao (Spain). The agency promotes a culture of safe working conditions for healthier and more productive workforce by risks identification and prevention.

EU-OSHA's foresight studies and overview projects aim to anticipate risks and identify priorities. It contributes to the development of OSH practice and policy in areas such as digitalisation and green jobs, and stress and psychosocial risks. EU-OSHA also provides easy-to-use resources to help workplaces put prevention into practice (i.e., guidance for keeping workers safe during the pandemic).

EUDAMED – Medical Devices

It is the IT system established by Regulation EU 2017/745 on medical devices and Regulation EU 2017/746 on in vitro diagnosis medical devices. EUDAMED encompasses six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance. The registered manufacturers in EUDAMED can protect their intellectual property, prevent counterfeits, and demonstrate their commitment to compliance.

Living Labs

"*Living Labs are* ***open innovation ecosystems*** *in real-life environments based on a systematic* ***user co-creation approach*** *that integrates research and innovation activities in communities and/or multi-stakeholder environments, placing citizens and/or end-users at the centre of the innovation process.*" (European Network of Living Labs. https://enoll.org/living-labs/). In Living Labs producers and users collaborate to develop new ideas. Digital health solutions may be tested and validated in real-world settings thanks to the many health-focused labs hosted by the European Network of Living Labs (ENoLL). By including patients, medical professionals, and researchers in the creation process, these labs promote user-centric innovation.

Health Cluster

Regional networks known as health clusters encourage cooperation between healthcare providers, academia, and industry. Following are some examples of health cluster and their main activities.

Health Cluster Portugal

(https://www.healthclusterportugal.pt/pt/apresentacao/quem-somos/) is a private non-profit association that currently brings together more than 220 members, including R&D institutions, universities, hospitals, organisations from civil society, and companies in the areas of pharmaceuticals, biotechnology, medical technologies, and services. The Health Cluster promotes the collaboration and knowledge transfer between research centres, health industry collaboration, facilitate the access to health data, support implementation of value-based healthcare and health ecosystem expansion.

Digital Health Portugal (https://www.digitalhealthportugal.eu/) is a health cluster that congregates founders, guest chief experience officers and top managers from a mix of Portuguese organizations comprising patient associations, health services and technology providers and the Ministries of Healthcare in mainland Portugal and the autonomous regions of Madeira and Azores. The cluster: organizes events supporting the exchange of knowledge and experiences regarding the application of artificial intelligence (AI) in healthcare and the discussions on policies and strategies for its effective implementation; disseminates success stories, challenges, and opportunities related to the integration of AI into the National Health Service; promote collaboration between academic institutions, technology companies, and healthcare organizations for development of pilot projects and initiatives that demonstrate the value of AI in promoting sustainable healthcare.

HealthTech cluster (https://healthtech.teknologiateollisuus.fi/en/association/member-services) is a Finnish association that provides regulatory support, growth and internationalization, information and tools, model contracts, and training for developing corporate responsibility and communication competence to companies having products or services related to technologies for health.

Health Capital Helsinki (https://healthcapitalhelsinki.fi/covid19-finnish-health-tech-companies/) is listing Finnish companies with innovative health tech solutions to COVID-19.

Hellenic Digital Health Cluster (https://www.hdhc.gr/en/partners-and-members) is a dynamic initiative of the Foundation for Research and Technology – Hellas (FORTH) that aims to include Greece among the leading countries in the field of digital health internationally. HDHC includes 30 innovative and dynamic companies of the digital health ecosystem in Greece and internationally, as well as FORTH.

Global Health Cluster is supported by World Health Organization through the team in the WHO Emergency Response Division, Health Emergencies Programme. Global Health Cluster encompasses over 900 partners at country level of which 66 partners having activities at global level. These partners include international organizations and UN agencies, nongovernmental organizations, national authorities, affected communities, specialized agencies, academic and training institutes and donor agencies. Global Health Cluster build capacity of Health Cluster Coordinators and other Health Cluster staff in countries, provide expertise, best practices and standards for health interventions, and promote and advocate for the importance of humanitarian health action (Health Cluster. https://healthcluster.who.int/).

Innovation Hubs and Technology Parks

Startups and SMEs in the digital health space can get infrastructure and support from technology parks and innovation hubs. Technology parks are also known as science parks, research parks, innovation centres, or technopoles. The International Association of Science Parks (IASP) defines a technology park as "*an organization managed by specialized professionals, whose main aim is to increase the wealth of its community by promoting the culture of innovation and the competitiveness of its associated business and knowledge-based institutions. To enable these goals to be met, a Science Park stimulates and manages the flow of knowledge and technology amongst universities, R&D institutions, companies and markets; it facilitates the creation and growth of innovation-based companies through incubation and spin-off processes; and provides other value-added services together with high-quality space and facilities*". (Interreg Europe, 2022). The technology parks contribute to industrialization of a region, catalyse the economic development and create synergy across innovation players.

A few examples of innovation hubs and technology parks are the following:

European Digital Innovation Hubs (EDIHs) are one-stop shops that help businesses and government agencies adapt to digital issues and boost their competitiveness (European Digital Innovation Hub https://digital-strategy.ec.europa.eu/en/policies/edihs). EDIHs focus on innovations on artificial intelligence, cybersecurity, high-performance computing, advanced digital skills (EUcalls, 2024). The main components of EDIH are:

- Services – tailored to the needs of SMEs and startups (i.e., technology testing and validation, consultancy on digital transformation, funding and investment advice, training programs);
- Network and Collaboration for knowledge sharing and dissemination of best practices;
- Funding and Support Mechanisms that are supported by European Commission and various national and regional governments.

EDIHs support SMEs and startups by providing access to technology and expertise, offering training and upskilling opportunities, facilitating market access and scaling (EUcalls, 2024).

EIT Regional Innovation Scheme (EIT RIS) – was created by European Institute of Innovation and Technology in 2015 (eitHealth, https://eithealth.eu/in-your-region/ris/). Innovators from countries with the modest and moderate innovation capacity receive aid for validation of their ideas, products development, and to build successful business. It links talent pools and creative organizations in RIS regions with healthcare innovators from

the EIT Health network. As part of this effort, the RIS Academy trains healthcare professionals, entrepreneurs, and innovators to give them the skills they need to succeed in the healthcare innovation ecosystem.

Digital Innovation Hub Artificial Intelligence & Data Science for Public Administration (AI4PA). ISCTE-IUL participated in 2020 to the creation of this Innovation Hub which consists of a collaborative network that includes specific digital competence centres organised to support the digital transition of Public Administration. The AI4PA's activities are guided by five axes of activity: experimentation (testing before investing); skills and training; strategies for digital transformation; facilitation, intermediation and networking; access to finance.

Sophia Antipolis Technopole Ecosystem
(https://www.sophia-antipolis.fr/en/ecosystem/) is a technological park that hosts 3IA Côte d'Azur an interdisciplinary institute for Artificial Intelligence and MIA (House of Artificial Intelligence) that foster innovations based on Artificial Intelligence.

TAGUSPARK Knowledge City (https://taguspark.com/about-us/) is the largest science and technology park in Portugal supporting development of business, innovation and teaching activities, collaboration between companies , R&D centres and Universities, and promote an environment of international competition and sustainable urban environment.

Companies

However, in Europe numerous companies have products related to Digital Health, reshaping the way in which healthcare is delivered, accessed, and managed. The Europe Digital Health market size was estimated at USD 66.75 billion in 2023 and is projected to be around USD 507.94 billion by 2033, growing at a CAGR of 22.5% during the forecast period 2024 to 2033. The mHealth and telemedicine had the highest revenue share in 2023. Cardiovascular applications dominated the Europe digital health market. Software held the largest share in the component segment, as it is used for Electronic Health Records, diagnostic platforms, mobile applications, AI-based platforms, for ensuring interoperability. Hospitals and clinics invest heavily in custom software platforms to enhance workflow efficiency, teleconsultation, and patient engagement (NOVA1ADVISOR, 2025). Services are emerging as the fastest-growing component, driven by demand for monitoring, integration, analytics, support for training, and digital system maintenance (NOVA1ADVISOR, 2025).

Companies Differentiation

The business related to Digital Health could be categorized by considering:

- product or service
- the size
- business readiness
- business model for innovation
- market focus

Product or service

The classification of the digital technologies used during Covid19 pandemic presented in the report of WHO Regional Office for Europe (WHO Regional Office for Europe, 2021) are an example of products and services diversities related to Digital Health (e.g., products for testing; robots for disinfection; telemedicine for intensive care; apps and websites for risk communication and dissemination of public health information) (see Annex II).

Size of Company

Startups are young, creative businesses that usually focus on disruptive technologies and scalable business structures. The core focus is on a model that allows for rapid and smooth growth (Investopedia by Grant et al., 2025)

Academic startups account for around 15% of overall start-up activity. The share of academic start-ups is particularly high in science-based technological fields – for instance, they account for 23% of all innovative start-ups in biotechnology. Start-ups founded by PhD students and academic researchers are significantly more likely to patent than non-academic start-ups (OECD. University – Industry Collaboration, 2019).
Patenting and academic start-ups, while very useful for science-based sectors, are concentrated in leading academic institutions, with the leading 100 universities worldwide producing 45% of all academic start-ups. Other institutions are also contributing at developing student start-ups (which are less science based) and support knowledge transfer through the mobility of students to industry. In the latter case, it is important that academic curricula are regularly revised to respond to emerging industry needs (e.g. strengthening digital skills, setting up more interdisciplinary programmes) (OECD. University – Industry Collaboration, 2019).

Startups and SMEs are agile and frequently bring cutting-edge solutions to the market. In the EU, businesses with fewer than 250 people and a yearly revenue of less than €50 million are referred to as SMEs (small and medium-sized enterprises). They account for 99% of all EU companies and are important forces behind innovation, especially in the life sciences and health sectors (European Commission. SME Definition, 2003/2018). SMEs play a key role in the diffusion of innovation, competitiveness and job development. Disruptive developments in the healthcare industry, such as wearable technology, telemedicine platforms and AI-based decision support, are frequently the result of startups and SMEs (OECD. Industry, Business and Entrepreneurship). Also, they support

regional innovation ecosystems by utilizing local strengths in ICT, biotech and health, aligning with Smart Specialization Strategies (RIS3) (OECD. University - Industry Collaboration, 2019).

Some examples of Startups and SMEs in healthcare across the three European countries are:

Portugal:

- ***Sword Health*** - Digital Physiotherapy Platform (since 2015, Sword Health – *Artificial Intelligence to heal our world*, https://swordhealth.com/)
- ***TonicApp*** – Clinical Decision Support (since 2016, TonicApp - *What's Up, Doc? Too many professional apps on your phone?,* https://tonicapp.io)

Greece:

- ***Vidavo*** - Remote patient monitoring solutions (since 2002, Vidavo – *Health for all, Any Time, Any Where*, https://www.vidavo.eu)
- ***LLM Care*** - Integrated ICT-based healthcare system startup (since 2012, LLM Care. *Long Lasting Memories. Mind and body fitness for life*, *Combines the most modern mental exercises with physical activity through a fun environment,* https://www.llmcare.gr/)

Finland:

- ***Elekta Kaiku*** - Digital Therapeutics (since 2020, Elekta Kaiku – *Pioneering the personalization of cancer care.* https://www.elekta.com/products/life-sciences/elekta-kaiku/)
- ***Buddy Healthcare*** - Automation of patient flow (since 2015, Buddy Healthcare - *Streamline care in every department*, https://www.buddyhealthcare.com/en/)

Philips Healthcare, Medtronic, Siemens Healthineers, Smith & Nephew, Roche Diagnostics are companies ranked in the top 10 in terms of marketed digital health products.

Philips Healthcare is at the forefront of developing patient-centric medical technologies. Their product portfolio includes advanced imaging modalities, patient monitoring systems, and health informatics solutions. Philips developed and commercialized different digital products based on artificial intelligence (AI), IntelliSpace AI, AI manager, ECG AI Marketplace.

Medtronic, a global leader with a strong presence in the EU, specializes in medical devices for various therapeutic areas, including cardiovascular, diabetes management, and neurology. Their innovations, such as the Micra pacemaker and the Guardian Connect

CGM system, are transforming patient care. Medtronic's focus on digital health and remote patient monitoring is expected to drive significant growth in the coming years.

Siemens Healthineers produces and sells advanced imaging systems, laboratory diagnostics, and healthcare IT solutions. Their innovative products, such as the ARTIS icono angiography system, are designed to enhance diagnostic accuracy and streamline clinical workflows. Siemens Healthineers is also developing products for diagnostic and precision medicine based on AI.

Smith & Nephew produces and sells advanced wound management, orthopaedics, and sports medicine products. For wound treatment the PICO Single Use Negative Pressure Wound Therapy System is a notable innovation.

Roche Diagnostics excels in in-vitro diagnostics and personalized healthcare/precision medicine. Their cutting-edge molecular diagnostics (e.g. Roche's cobas 8800 system) and integrated laboratory solutions are critical for disease management and treatment optimization.

Based on readiness

The TRL framework is a 1-to-9 scale used to evaluate technology maturity that was first created by NASA and is currently widely utilized by the European Commission (Horizon 2020, Horizon Europe). TRL 7–9 denote near-market readiness (operational demonstration, qualified system, market deployment), whereas TRL 1–3 denote early-stage research (basic concepts, proof of concept) (Enspire Science, 2014).

Based on business model innovation

Business model innovation in the healthcare industry entails significant adjustments to the way value is provided, such as the use of subscription-based services. Wearable technology, telemedicine platforms, and personalized medicine are examples of disruptive digital developments that are revolutionizing service delivery by increasing its efficiency and accessibility (Angadi P.V., 2023).

Based on the market focus

There are companies that fall into the category of niche innovators. They produce digital health solutions designed with a narrow focus: addressing specific conditions or functions with high specialization. Also, there are companies that combine data, telemedicine and AI. These companies offer comprehensive digital health ecosystems, integrating multiple functions and technologies under one roof.

Innovation testbeds

Innovation testbeds "*are programmes that provide access to physical or virtual environments in which companies or public sector stakeholders can test, develop, and introduce new products, services, processes, organizational solutions, and business models, typically in collaboration with multiple stakeholders. They provide an environment where an innovation can be trialled in real- or near-real-world conditions and demonstrate its market viability.*" (IDB. by Rosemberg et al., 2020). Feasibility testing of a new product/service, health technology assessment, regardless of whether the environment is fully controlled, simulated or within the real world, may be supported by these programmes. The innovation testbeds have great importance particularly when innovations attempt to enter complex and regulated markets, such when new medical device or software for healthcare should be tested (e.g., diagnostic imaging equipment, AI-based human body signals processing, digital therapeutics). The level of control in the environment can range from highly controlled laboratory environments to real-world environments. In Europe, innovation testbeds are often financed and coordinated in the framework of Horizon Europe programme and have a role of demonstrators for sectors or technologies.

Financial Resources for Innovations in Digital Health

Funding innovations is carried out through various instruments: research & development and innovation grants, tax incentives with a focus on collaboration, financial support to recruit PhDs or postdoctoral students.

In order to turn concepts into digital health solutions that are ready for the market, funding is necessary. Innovators in Europe have access to a multitude of funding sources at European, national and regional level. Important sources of funding include the following:

EU - Funding Programmes

European Health and Digital Executive Agency (HaDEA)

HaDEA is involved in funding and the implementation of two health-related programmes for the European Commission: most of the EU4Health programme, and Horizon Europe – Cluster 1 and 4 and various other programs that may contribute to the development and efficient functioning of Digital Health ecosystem (e.g., see Connecting Europe Facility, Digital Europe Programme).

There are several European platforms that provide information on publicly funded science-industry collaborative research projects. For example, the European Commission's Community Research and Development Information Service (CORDIS) gathers

information about all Horizon 2020 projects. There are several European programs that provide grants for research and innovation related to Digital Health.

Horizon Europe (https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/horizon-europe_en)is the EU's key funding programme for research and innovation, with a budget of €95.5 billion for 2021-2027. It supports research collaboration for tackling European and global challenges and for achieving UN's s Sustainable Development Goals.

Digital Europe Programme (https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/digital-europe-programme_en) - provide funding for projects accelerating digital transformation, such as artificial intelligence, cybersecurity, advanced digital skills, supercomputing projects. The programme supports the wide use of digital technologies across the economy and society.

European Innovation Council (EIC) (https://eic.ec.europa.eu/index_en) - for ground-breaking inventions. Provides Accelerator, Transition, and Pathfinder programs.

EIC Accelerator (https://eic.ec.europa.eu/eic-funding-opportunities/eic-accelerator_en) part of Horizon Europe, provides funding and support to start-ups and SMEs with innovative, game-changing products, services, or business models to develop and scaleup innovations. It aims to help them create new markets or disrupt existing ones globally. The EIC Accelerator targets high-risk, high-impact ventures, offering substantial financial support through grants up to €2.5 million and equity investments reaching €15 million.

Joint Research Centre (https://commission.europa.eu/about/departments-and-executive-agencies/joint-research-centre_en) employs scientists to carry out research in various fields to provide independent advice to EU policymakers.

European Innovation Council (EIC) (https://eic.ec.europa.eu/index_en) - for ground-breaking inventions. Provides Accelerator, Transition, and Pathfinder programs.

AAL Programme (https://www.aal-europe.eu/) is a programme funding innovation that support more independent live for as long as possible.

EU4Health (https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en). It is designed, among other objectives, to boost the EU's preparedness for major cross-border health threats by establishing reserves of medical supplies for crises; a reserve of healthcare staff and experts that can be mobilised

to respond to crises across the EU; increased surveillance of health threats. EU4Health has a budget of €5.8 billion for the period 2021–2027 and will support a longer-term vision of improving health outcomes via efficient and inclusive health systems across the EU Member States. The funding is provided for turning medical devices and crisis-relevant products available and affordable, for strengthening health data, digital tools and services, digital transformation of healthcare, for improving access to healthcare among other objectives.

InvestEU (https://investeu.europa.eu/index_en) encourages both public and private funding for medical facilities.

EIT Health (https://eithealth.eu/) - offers education programs, grants for innovative projects and accelerators of innovations.

National and Regional Funding Program

European nations use a wide range of tools at the national and regional levels to encourage innovation in Digital Health. The diverse financing channels support EU-level initiatives related to particular healthcare and economic concerns. Public funding, private funding, donor/non-public funding or public-private partnerships are being used to support the development, improvement in functionalities, or to scale a business related to Digital Health. Funds are usually distributed by national governments:

- Ministries of health and innovation that issue demands for clinical research, eHealth adoption and the digital transformation of healthcare systems.
- National innovation organizations that provide grants, vouchers and R&D tax benefits to help SMEs, startups and technology transfer.
- Organizations financing public health by making investments in digital infrastructures such as cybersecurity improvements, telemedicine networks or electronic health records platform.

Many European countries are in the first 20 positions of the World Index of Healthcare Innovation (FREOPP, 2024). Switzerland, Ireland, Germany, Netherlands has the best score on the measured dimension – Quality (disease prevention, pandemic preparedness, patient-centred care, infrastructure), Choice (affordability of health coverage, freedom to choose healthcare services, access to new treatment), Science and Technology (medical advances, scientific discoveries, health digitization), Fiscal Sustainability (national solvency, public healthcare spending, growth in public healthcare spending). Although at measured dimension of science and technology did not excel, Germany sits atop the Index in Choice and Fiscal Sustainability (FREOPP). The access to new treatments and the

affordability of health coverage are mainly favoured by the reimbursement system (see Annex I and II).

National innovation organizations have great importance on innovation environment. For instance, Bpifrance play an important role in the Digital Health ecosystem in France. Bpifrance support mainly micro-businesses and SMEs but also large company that are considered important to the interests of France in terms of national economy, the territories or employment. It supports a business' creation and growth by financing, guarantees or equity investment. Bpifrance has a network of collaborators around the world.

Smart Specialisation Strategies

The EU Science Hub provide information on funding innovation in the EU Enlargement and Neighborhood Region (https://joint-research-centre.ec.europa.eu/projects-and-activities/territorial-development/innovation-eu-enlargement-and-neighbourhood-region_en) and on the design and implementation of Smart Specialisation Strategies (RIS3) (https://ris3.gov.cz/en/about-ris3/ris3-basic-description-and-meaning). Smart Specialisation Strategies is a process aiming to create long-term competitive advantages in Europe by "smart", "intelligent" exploitation of European country or regional potential. European states select for financing the priority areas with a high potential for development based on strengths of a country or region and its specific economic, research and innovation resources. Financing and systematically developing local and regional opportunities for development of products or services leads to higher-value-added activities, shifts within value chains and the creation of specific market niches and segments that give a competitive advantage for companies in European and international markets.

Mission and challenge-oriented funding schemes

Mission and challenge-oriented funding schemes can help mitigate gaps in the research funding landscape, by helping to connect, structure, and boost existing working partnerships and networks of research centres (OECD, 2025).

Healthcare Reimbursements

Healthcare Reimbursement is often made by a government agency or insurer for the cost of providing a medical service (e.g., digital applications) or product (e.g., pharmaceutical, diagnostic or medical device). Reimbursement decisions are made at national or regional level. Each country has its own criteria, processes, and timelines for approving reimbursement.

Products or services related to Digital Health may gain reimbursement from public payers or private insurers. Patients or health-conscious citizens, healthcare providers, employers or industry partners may also pay for new digital solutions for healthcare management or for new medical devices. For instance, patients can choose to pay for a digital health solution to manage their medical condition, employers may choose to pay either to improve their employee value proposition or to reduce the level of sick leave, and industry may pay if the solution gives access to data or complements their own products or therapies (McKinsey&Company, 2020).

Reimbursement pathways in each European country differ depending on whether the company product or service is used in inpatient (hospital) or outpatient (ambulatory) care. Inpatient care often uses **Diagnosis-Related Groups (DRGs)** for reimbursement, while outpatient care may involve **Specific Product or Procedure Lists/Coding System** or **Fee-For-Service models** (see IGES MedTech; AiM&IGES MedTech Company; MedicClever. Reimbursement Consultat; MTRC Med Tech Reimbursement Consulting). Countries like Germany and France are developing specific reimbursement pathways for software as a medical device (SaMD) and digital health apps (DiGA), requiring CE marking and clinical evidence (IQVIA, 2023; Van Kessel et al., 2023). Germany, Belgium, United Kingdom, France has reimbursement frameworks for digital therapeutics (DTx). Reimbursement of a digital therapeutics app in Germany is regulated by Digital Healthcare Act – DVG. A DTx app in the country is known under digital health applications (DiGA). A reimbursement process in the country involves providing a CE marking and having privacy-GDPR compliance, as well as offering proof of requirements related to data protection, interoperability, and ease of use. Proof of scientific evidence evaluation is also required (Binariks, 2025; disrupting.healthcare by Wrzosinski, 2025).

The reimbursement process depends on Coding Systems, such as Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) analogs, which vary by country. Proper coding is essential to define payment mechanisms and tariffs. (AVANIA, 2021; MTRC Med Tech Reimbursement Consulting).

Payers generally ask for solid proof of the efficacy of the digital product or service, some form of health economic modeling that shows the value at stake, any potential cost savings, and the improvement in outcomes for patients or adherence to treatment (McKinsey&Company, 2020). Although many European countries require **Health Technologies Assessment (HTA)** in the process of payment approval (see Table I) only a few countries have clearly defined standards for HTA of digital health solutions (e.g., United Kingdom, Germany).

The new EU Health Technology Assessment Regulation (HTAR), effective from 2025, introduces **Joint Clinical Assessments (JCAs)** for certain high-risk devices to harmonize evaluations, though reimbursement decisions remain national (ProPharma, 2024; Tarricone et al., 2024). The EU HTAR aims to standardize clinical assessments, but reimbursement decisions will remain national. Cross-country collaboration (e.g., Nordic countries) is increasing (Tarricone et al., 2024).

Key components of reimbursement

To secure reimbursement, manufacturers typically need to address three interdependent components:

Coding. Devices and procedures must be assigned appropriate codes to facilitate billing. If no code exists, manufacturers may need to apply for a new one, which can take 6 months to 2 years (AVANIA, 2021)

Coverage. Payers determine whether a device or procedure is medically necessary or cost-effective. Coverage decisions vary by payer and country, and innovative devices may face scrutiny as "experimental" (AVANIA, 2021).

Payment. The reimbursement amount must cover the cost of device and associated fees. Payment mechanisms include DRGs, add-on payments, or inclusion in positive lists (e.g., France's LPRR) (AVANIA, 2021; Wood, 2018).

Several country specific details of reimbursement process are described in **Annex I** and **Annex II.**

Challenges in Reimbursement

Complexity and Variation. The lack of EU-wide harmonization means manufacturers must navigate different requirements in each country, increasing costs and timelines (IGES MedTech.; Fierce Healthcare, 2012).

Evidence Requirements. Payers demand robust clinical and economic data, often requiring costly clinical trials or health economic models (ECLEVAR MedTech, 2023; MediClever).

Table 2. **HTA body or structure and notes on HTA in several European Countries**

Country	HTA Body or Structure	Notes
France	HAS	Mandatory HTA for devices; linked to reimbursement
Germany	IQWiG / G-BA	HTA for devices; reimbursement decisions based on benefit
Sweden	TLV / SBU	HTA for devices; TLV handles reimbursement

Norway	NIPH (FHI)	HTA includes devices; used in funding decisions
Netherlands	ZINL	HTA includes devices; part of basic insurance package
Belgium	INAMI-RIZIV	HTA includes devices; reimbursement linked to HTA
Austria	AIHTA	HTA includes devices; reimbursement decisions influenced
Denmark	Medicinrådet / Treatment Council	HTA includes devices; national steering group for EU HTA
Czechia	SUKL	HTA includes devices; formal reimbursement process
Poland	AOTMiT	HTA includes devices; reimbursement linked to HTA
Slovakia	MZ SR	HTA includes devices; reimbursement decisions influenced
Slovenia	JAZMP	HTA includes devices; formal process
Estonia	EHIF	HTA includes devices; reimbursement decisions influenced
Hungary	NEAK	HTA includes devices; reimbursement linked to HTA
Lithuania	VASPVT	HTA includes devices; formal process
Portugal	INFARMED	HTA includes some devices; DRG-based funding
Italy	AIFA / Regional HTA bodies	HTA for devices varies regionally; reimbursement linked
Spain	AEMPS + Regional HTA bodies	HTA includes devices; decentralized system
UK (England)	NICE	HTA covers devices, diagnostics, procedures

Innovative Devices. High-risk or novel devices (e.g., AI-based or digital health solutions) face stricter scrutiny and longer reimbursement pathways (ProPharma Group, 2024; IQVIA, 2023).

Regional Differences. Even within countries, regional variations (e.g., Germany's decentralized insurance funds) can complicate reimbursement (AiM&IGES MedTech).

Time and Cost. Securing reimbursement can take over a year, with significant investment in evidence generation and stakeholder engagement (McKinsey&Company, 2020).

Strategies for Success

Early Planning. Develop a reimbursement strategy during the product design phase, aligning clinical trials with payer requirements (ProPharma, 2024; AVANIA, 2021).

Understand Local Systems. Research country-specific coding, payment mechanisms, and HTA processes. Engage with local payers and healthcare providers early (MediClever, n.d.; McKinsey & Company, 2020).

Leverage Existing Codes. Use existing procedure codes to expedite reimbursement. For novel devices, apply for new codes or add-on payments (AVANIA, 2021).

Value-Based Pricing. Demonstrate clinical efficacy and long-term cost-effectiveness to appeal to payers, especially in budget-constrained systems like the NHS (Skorka, 2024).

Collaborate with Stakeholders. Work with medical societies, hospitals, and insurers to pilot projects or apply for innovation funding (MediClever).

Monitor EU HTAR. Prepare for joint clinical assessments under the HTAR, which will impact high-risk devices and IVDs starting in 2025 (ProPharma Group, 2024).
Companies must invest time to learn about the relevant reimbursement pathways (i.e., considering the reimbursement pathways for digital product or service for in- or outpatient hospital care, for preventative care, or for care that qualifies for reimbursement set up to promote new forms of care, and the clinical guidelines and patient pathways for treatment set by each country) and which stakeholders (apart from patients) have the most to gain from adopting their product or service (e.g., digital applications or medical device) (McKinsey&Company, 2020)
Reimbursements policy is an important factor that may influence innovations. Designing strategy for obtaining reimbursement for innovative Digital Health products or services in European countries is difficult due to high complexity of process (i.e., stringent criteria for different procedures) but also because of rapid change in funding mechanisms and the regulations. The heterogeneity of reimbursement pathways in different European countries can make Digital Health products and services harder to scale than those in other industries (McKinsey&Company, 2020). Companies must understand the incentive for using their product or service before they can craft the value propositions of their innovative product or service. Specialists on reimbursement landscape in Europe may shorten the reimbursement process for digital solutions, medical devices or pharmaceuticals. They may help in developing reimbursement strategies, preparing value dossiers and other value communication tools, performing pricing and reimbursement assessments, creating tools for health economic modeling and developing market access

strategies (see AiM&IGES MedTech; ECLEVAR MedTech; IGES MedTech; MedicClever; MTRC Med Tech Reimbursement Consulting).

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Annex I - Country specific details in Reimbursement of Digital Solutions for Healthcare

Belgium

In Belgium National Institute for Health and Disability Insurance is a regulatory body that oversees the DTx reimbursement framework in Belgium. Evaluation of digital technologies is made by Federal Agency for Medicines and Health Products. To get reimbursed, the DTx products in the country should pass the following validation process:

- CE markings and compliance with GDPR;
- Evaluation for data security, confidentiality, and interoperability;
- Evaluation of clinical evidence and socio-economic added value.

Finland

Finland does not have a formal, centralized HTA and reimbursement system for medical devices. Although HTA activities are coordinated by FinCCHTA and some assessments are conducted (i.e., through the Digi-HTA initiative) the evaluations are not systematically linked to reimbursement decisions. Funding for medical devices is typically handled at the regional level by well-being services counties. While DRG-based models exist, they are not consistently used in conjunction with HTA outputs. Finland does participate in EU JCA efforts, but its HTA maturity level for devices remains in a developing phase. Medical devices are not formally included in reimbursement decisions (OYS; ESiOR, 2021; European Union. Implementation of the Regulation on health technology assessment).

France

PECAN (Prise en Charge Anticipée Numerique des Dispositifs) – Digital advance care is a framework for reimbursement of digital medical devices, therapeutic or telemedical

monitoring activities (see G.NIUS). France is the second-largest medical device market in Europe, with a mandatory social health insurance system (Assurance Maladie Obligatoire) supplemented by private insurance for 90% of the population (Wood, 2018)
Devices in ambulatory care or expensive inpatient devices are reimbursed via the Liste des Produits et Prestations Remboursables (LPRR). Generic lines allow reimbursement without evaluation if the device meets existing criteria; innovative devices require evaluation by the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) (Wood, 2018).
Manufacturers must obtain CE marking and, for innovative devices, submit clinical and economic data to demonstrate benefits (Wood, 2018).

Germany

Germany Reimbursement system is highly regulated and centralized, with over 100 statutory health insurance funds (e.g., Techniker Krankenkasse) and private insurers (BVMed, 2024; AiM&IGES MedTech Company).

Inpatient use

Uses DRGs for hospital reimbursement, introduced nationwide in 2004. New devices can be used unless excluded by the Federal Joint Committee (G-BA) (AiM&IGES MedTech Company).

Outpatient use

Devices must be listed in reimbursement catalogs or approved via specific processes. Innovative devices may receive add-on payments (NUBs) (MediClever).

Digital Health

Germany pioneered reimbursement for digital health apps through the BfArM DiGA system (2019), requiring clinical evidence and CE marking (IQVIA, 2023; Van Kessel et al., 2023).

Greece

Greece does not currently have a formal HTA and reimbursement system for medical devices. The existing HTA framework, established in 2018, applies only to medicines. While there are discussions and plans to expand the scope to include medical devices, this has not yet been implemented (OHE, 2023; Syenza News, 2023).

Portugal

In Portugal, the national HTA body INFARMED is responsible for evaluating medical technologies, including some medical devices. While the HTA system is more mature for pharmaceuticals, medical devices are also assessed, particularly those used in hospitals. These assessments can influence reimbursement decisions, especially when devices are tied to procedures funded through Portugal's DRG-based hospital payment system. Portugal participates in the EU Joint Clinical Assessment (JCA) initiative and has a moderately developed HTA framework that includes medical devices in its reimbursement

logic. (European Medicines Agency, 2025; European Union. Implementation of the Regulation on health technology assessment).

United Kingdom

United Kingdom system is centralized, publicly funded National Health Service (NHS) covers most healthcare costs. (BVMed, 2024; Skorka, 2024.)

The reimbursement pathway in the UK follows Digital Technology Assessment Criteria (DTAC). According to DTAC, applications must meet NHS standards for clinical safety, interoperability, and data protection. DTx reimbursement involves having a CE mark or UKCA mark, being compliant with GDPR, and following criteria to Digital Technology Assessment Criteria. As of 2023, there is no single digital therapeutics reimbursement network in the UK, and apps are supposed to follow the requirements of a local NHS organization (Binariks, 2025).

Reimbursement uses ICD-10 and procedure codes. No specific product codes are required, simplifying reimbursement for devices used in existing procedures (Pria Healthcare).

The National Institute for Health and Care Excellence (NICE) evaluates devices for cost-effectiveness and patient impact. Positive NICE assessments can enhance reimbursement prospects (Pria Healthcare).

Startups must emphasize long-term cost savings to secure NHS adoption (Skorka, 2024).

Annex II - Comparative summary of medical device reimbursement systems from several European countries

A comparative summary of medical device reimbursement systems in some European countries, highlighting their advantage (pros) and disadvantages (cons) as well as opportunities and challenges for manufacturers are the following:

Germany

System	Statutory health insurance (SHI); inpatient via DRG, outpatient via EBM.
Innovation Pathway	NUB (for inpatient) allows early access for novel devices.
Pros	Fast-track for innovative devices via NUB. Clear DRG structure for hospitals.
Cons	Outpatient reimbursement is restrictive—requires G-BA approval. High evidence burden for new methods.

Manufacturer Opportunity	Strong market size and structured innovation funding.
Challenges	Complex dual-path system and high regulatory scrutiny.

France

System	Mandatory health insurance; reimbursement via LPPR list.
Innovation Pathway	CNEDiMTS assessment for inclusion in LPPR.
Pros	Centralized system with clear HTA process. High population coverage.
Cons	Long timelines (up to 180 days). Requires strong clinical and economic evidence (SMR/ASMR).
Manufacturer Opportunity	Large market with structured evaluation
Challenge	Rigid criteria and limited flexibility for niche devices.

United Kingdom (England)

System	NHS-funded; reimbursement via HRG tariffs or local commissioning.
Innovation Pathway	NICE evaluation + MedTech Funding Mandate.
Pros	NICE endorsement accelerates adoption. Funding mandate for cost-saving, effective devices.
Cons	No national reimbursement mandate—local variability. Many devices bypass NICE, leading to fragmented access.
Manufacturer Opportunity	Early engagement with NICE can yield national traction.
Challenge	Navigating decentralized purchasing and proving cost-effectiveness.

Netherlands

System	Private insurers under mandatory scheme; DBC-based reimbursement.
Innovation Pathway	Negotiation with insurers; HTA by ZIN.
Pros	Transparent cost-effectiveness focus.

	Flexibility in insurer negotiations.
Cons	No centralized reimbursement list. High bar for economic justification.
Manufacturer Opportunity	Tailored agreements with insurers.
Challenge	Requires strong local partnerships and economic modeling.

Sweden

System	Tax-funded, decentralized; regional decision-making.
Innovation Pathway	Local HTA by county councils.
Pros	Regional pilots and innovation-friendly culture. Emphasis on patient outcomes.
Cons	No national reimbursement catalog. Fragmented access across regions.
Manufacturer Opportunity	Entry via regional champions and pilots.
Challenge	Scaling nationally is complex and slow.

Aspect	Advantage	Challenge
Centralized HTA (e.g., France, UK)	Structured process	Long timelines, rigid criteria
Decentralized systems (e.g., Sweden, UK)	Local flexibility	Fragmented access
Innovation funding (e.g., Germany NUB, UK Mandate)	Early access	Competitive and evidence-heavy

Annex III - Examples of digital technologies used in the COVID-19 pandemic response. Source: WHO Regional Office for Europe, 2021.

WHO Regional Office for Europe. (2021) Seventy-first Regional Committee for Europe: virtual session, Copenhagen, 13–15 September 2021: Health system transformation in the digital age during the COVID-19 pandemic. Available: https://apps.who.int/iris/handle/10665/343164

Awareness, prevention and tracking

• Apps and websites for risk communication and dissemination of public health information
• COVID-19 dashboards, mapping and forecasting utilities
• Social media-based chatbots and online community forums
• Case management software for contact tracing
• Digital contact tracing apps
• Infodemic management tools
• Voluntary reporting tools
• Self-management tools

Diagnosis, diagnostics and therapeutics

• Symptom assessment apps and online utilities
• AI-based remote vital signs monitoring using devices or smartphone cameras
• AI-powered computerized tomography imaging interpretation tools
• Temperature-based diagnostic screening for border control

Management of contacts with the health system

• Online chat triage services
• Online or app-based access to polymerase chain reaction test results
• Telehealth or telemedicine use in primary health care

Surge management and protection in hospital settings

• Intensive care unit surge simulation tools
• Inventory resource mapping and supply chain management tools
• Telemedicine use in intensive care settings
• E-learning platforms for health-care worker orientation
• Robots (for disinfection, isolation ward communication and companionship, and medical waste transfer)
• Volunteer databases

Testing and research

• Support to accelerated testing regimes
• AI support to adaptive clinical trials

Recovery and reestablishment

• Smart vaccination certificates
• Augmented reality-based temperature monitoring in public spaces

Chapter 5. Regulation – Regulatory Entities and Instruments

Regulatory Entities

Regulatory Instruments – Medical Device Regulation; Digital Single Market; General Data Protection Regulation; Web Accessibility Directive; e-IDAS Regulation; European Health Data Space; EU Artificial Intelligence Act; Data Act; Cyber Resilience Act.

Source of information on Regulation related to Digital Health

Regulatory sandboxes

Examples of Digital Health regulation approach in European countries

Annex I - Commitments from Ministerial Declaration on Transformative Science, Technology and Innovation Policies for a Sustainable and Inclusive Future (OECD Legal Instruments, 2024)

Annex II - Example of Regulatory Readiness checklist

Annex III - Examples of Country Legal Instrument for Regulation of Medical Devices or Digital Health Solutions

An important guidance for development and implementation of regulation related to Digital Health is represented by commitments of OECD states in 2024 Ministerial Declaration on Transformative Science, Technology and Innovation Policies for a Sustainable and Inclusive Future (see OECD Legal Instruments, 2024), as a base for development of the Agenda for Transformative Science, Technology and Innovation Policies (see Annex I).

Recommendations resulted from the scientific research of World Health Organizations (WHO) is playing an important role in regulation of Digital Health solution in European countries. WHO has a mandate, as outlined in the World Health Assembly resolution WHA60.29 to encourage Member States "*to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and, where appropriate, to participate in international harmonization*" (WHO. Regulating medical product). WHO Diagnostic Imaging and Medical Devices team assists member states through regulatory guidance, training, coordination and promotion of international best practices. The International Health Regulations coordinated by World Health Organization (WHO, 2024) provide an overarching legal framework that defines countries rights and obligations in handling public health events and emergencies that have the potential to cross borders.

Regulatory Entities

There are various entities that establish norms, standards, guidelines, code of ethics, and coordinates their implementation.

European Regulatory Entities

European Commission – is the primary executive branch of European Union. It operates as a cabinet government.
European Parliament – adopts European legislation, following a proposal by the European Commission.
European Council – defines the general political direction and priorities of the European Union.
European Health and Digital Executive Agency (HaDEA) – is involved in implementation of two health-related programmes for the European Commission: most of the EU4Health programme, and Horizon Europe
European Safety and Health at Work (EU-OSHA) - EU's information agency for occupational safety and health. EU-OSHA contributes to the development of OSH practice and policy in areas such as digitalisation and green jobs, and stress and psychosocial risks. EU-OSHA also provides easy-to-use resources to help workplaces put prevention into practice.
European Medicines Agency (EMA) – provide scientific opinion for medical device assessment.
European Patent Organization (EPOrg) – include Administrative Council that act as supervisory body and European Patent Office (EPO) that act as executive body.

National Regulatory Entities

Each European country has regulatory agencies related to Digital Health technologies. Infarmed for Drugs and Health Products from Portugal, BfArM (Bundesinstitut fur Arzneimittel und Medizinprodukte) for Medical Devices and Digital Health Application from Germany are examples of Regulatory agencies for medical devices.

Regulatory Instruments

Regulation related to Digital Health refers to:

- Regulations regarding MDR - Medical Devices (e.g., European Medical Device Regulation 2017/745);
- Regulation regarding IVDR - In Vitro Diagnostic Medical device Regulation (2017/746);
- Regulations related to Information Systems (e.g., e-IDAS Regulation EU 910/2014), Smartphone Applications, Devices for Wellness/fitness;

- Regulation regarding Data storage, Data protection, Data security (e.g. GDPR - General Data Protection Regulation, Regulation EU 2016/679; EU Data Act that applies from 12 September 2025; EHDS - European Health Data Space Regulation that will apply from 2027);
- Regulation regarding Artificial Intelligence (e.g. EU Artificial Intelligence Act (Regulation EU 2024/1689);
- Intellectual Property (IP) rights regime;
- Regulation related to Knowledge Transfer;
- Regulations regarding the creation of Spin-Offs by researchers;
- Regulations regarding Mobility Schemes for researchers;
- Regulation regarding Financing the Digital Health innovations;
- Policies for Public Engagement in science and research;
- Standards for technologies (e.g., ISO/IEC 30141 standard for Internet of Things; CEN ISO/TS 82304-2:2021 for Health software – Part 2: Health and wellness apps – Quality and reliability);
- Regulation regarding innovation (European Innovation Act, planned to be adopted in 2026);
- Code of Ethics (e.g., European Commission: Ethics and data protection) and code of conduct (e.g., European Code of Conduct for Research Integrity – ALLEA).

In Europe the regulation regarding Digital Health is aligned with objectives and targets established in Digital Decade Policy Programme 2030, in the realm of digital skills, digital infrastructure, digitalization of business and public services (European Union. Digital Decade Policy Programme, 2023). This governance framework is based on an annual cooperation mechanism involving the Commission and Member States.

Medical Device Regulation (MDR)

If the Digital Health product qualifies as a medical device, it must comply with EU MDR (Regulation EU 2017/745). Classification (e.g., Class I, IIa, IIb, III) depends on the intended use and risk level. For Class IIa and above, you must engage a Notified Body for conformity assessment and obtain a CE mark.

Stricter Device Classification. The Medical Device Regulation (MDR) revises the classification system for medical devices, often reclassifying previously low-risk devices as medium or high risk. This means more stringent clinical testing and post-market surveillance requirements, which can impact the development and approval timelines for new devices.

Enhanced Clinical Evaluation. MDR introduces rigorous standards for clinical evaluation and evidence. Manufacturers must provide comprehensive clinical data to demonstrate the safety and performance of their devices (REGDESK, 2025). This can drive innovation by ensuring high-quality and reliable medical devices but also poses challenges in terms of cost and time.

Transparency and Traceability. The MDR emphasizes transparency and traceability throughout the device lifecycle (REGDESK, 2025). This can foster trust among healthcare providers and patients, potentially accelerating the adoption of innovative medical technologies.

Challenges Related to MDR

Increased Costs. Compliance with MDR involves significant costs related to clinical evaluations, post-market surveillance, and certification. These rising costs can be particularly challenging for smaller manufacturers and startups.

Regulatory Predictability. Uncertainty around costs, timelines, and regulatory predictability remains a concern (MedTech Europe, 2023; MedTech Europe, 2024). This can affect Europe's attractiveness for innovative medical devices and complicate financial planning for manufacturers.

Conformity Assessment Efficiency. The efficiency of conformity assessments needs improvement, as a significant portion of the assessment time is spent outside the review phase (MedTech Europe, 2024). Streamlining these processes could reduce total assessment time and alleviate some of the regulatory burden.

Overall, while the MDR aims to enhance patient safety and product quality, it also introduces substantial challenges that manufacturers must navigate to remain compliant and competitive.

Digital Single Market

The legislation related to digital single market (DSM) aims to eliminate national barriers to online transactions and to create a safer digital space in which fundamental rights of users of digital services are protected. It enhances access to information, reduces transaction costs, and facilitates business models with less environmental impacts and able to improve access to digital goods, foster conditions for digital networks, innovative services and growth of economy. Among many norms that were established by European Commission and European Parliament (see European Parliament. The ubiquitous digital single market) are the following:

- Cross-border portability of online content services, audiovisual media services;
- Regulation on online platform
- Digital copyright (Directive EU 2019/790);

- Contract for supply of digital content and services (Directive EU 2019/770);
- End of roaming charges;
- Regulation on geo-blocking;
- Single digital gateway (Regulation EU 2018/1724);
- Rule for electronic identification (Regulation EU 910/2014);
- Data Act;
- Ethics guidelines for trustworthy AI
- Artificial Intelligence Act;
- Data protection package that include GDPR (Regulation EU 2016/679) and Directive EU 2016/680;
- Cyber Resilience Act;
- Digital Services Act (DSA)
- Digital Market Act
- European Innovation Act.

General Data Protection Regulation (GDPR)

DDPR applies to all digital health products handling personal health data. Requires explicit consent, data minimization, security measures, and data subject rights. Consider Data Protection Impact Assessments (DPIAs) and pseudonymization techniques. (GDPR. EU)

Web Accessibility Directive (WAD)

The WAD - Web Accessibility Directive (Directive (EU) 2016/2102 on the accessibility of the websites and mobile applications of public sector bodies) oblige all public sectors bodies in the EU to make their online website and mobile apps accessible. The WAD is supported by a harmonized technical standard – EN 301 549 – Accessibility requirements for ICT products and services v3.2.1. (European Union. Web Accessibility Directive)

e-IDAS Regulation

The e-IDAS Regulation EU 910/2014 that went into force on 1 July, 2016 establishes a common framework for secure electronic interaction between citizens, business and public authorities in the EU. It facilitates secure cross-border transactions and is aiming to increase interoperability in electronic transactions (European Union. EUR-Lex, 2014).

European Health Data Space (EHDS)

EHDS facilitates cross-border health data sharing (EHDS) Promotes interoperability, secondary use of health data, and patient control over data by:

- "*promoting the safe exchange of patients' data (including when they travel abroad) and citizens' control over their health data;*

- *supporting research on treatments, medicines, medical devices and outcomes;*
- *encouraging the access to and use of health data for research, policymaking and regulation, with a trusted governance framework and upholding data-protection rules;*
- *supporting digital health services;*
- *clarifying the safety and liability of artificial intelligence in health*". (European Union, 2023)

Enhanced Data Accessibility: The EHDS aims to improve the accessibility and utility of electronic health data (EHD) across EU member states, facilitating better healthcare delivery and innovation by creating the cross-border infrastructure MyHealth@EU to governing primary use and secondary use and specify and complement some of the rights of natural persons set out in GDPR (Regulation EU 2016/679) (Mondaq, 2025).

Standardization and Compliance: Digital health solutions, including digital therapeutics (DTx), must comply with stringent regulatory standards, such as CE marking for software as a medical device (SaMD) (EY, 2025). This ensures safety and efficacy but can also pose challenges for developers.

Cross-Border Data Sharing: The EHDS promotes cross-border health data sharing, which can accelerate research and development in digital health by providing access to a larger pool of data (Mondaq, 2025).

Challenges Related to EHDS

Compliance Complexity. The EHDS introduces complex compliance requirements, including data protection, patient rights, and secondary use of health data (Mondaq, 2025). Organizations must navigate these regulations carefully to avoid legal pitfalls.
Technical and Operational Implementation. The gradual application of EHDS rules due to technical and operational complexities can be challenging for healthcare providers and digital health companies (Chambers and Partners. by Bjerrum., 2025).
Overall, while the EHDS offers significant opportunities for advancing digital health innovations, it also presents substantial regulatory and operational challenges that stakeholders must address.

EU Artificial Intelligence Act (EU AI Act)

The EU AI Act - EU Artificial Intelligence Act (Regulation EU 2024/1689) introduces a uniform framework across all EU countries, based on a forward-looking definition of AI and a risk-based approach (EU Artificial Intelligence Act, 2024).

The AI Act introduces stringent requirements for high-risk AI systems, which include many medical devices.

Risk-Based Regulation. The AI Act introduces a risk-based classification system for AI applications, categorizing them into four levels: unacceptable, high, limited, and minimal risk (EU Artificial Intelligence Act, 2024). *Minimal risk*: most AI systems such as spam filters and AI-enabled video games face no obligation under the AI Act, but companies can voluntarily adopt additional codes of conduct. *Specific transparency risk*: systems like chatbots must clearly inform users that they are interacting with a machine, while certain AI-generated content must be labelled as such. *High risk*: high-risk AI systems such as AI-based medical software or AI systems used for recruitment must comply with strict requirements, including risk-mitigation systems, high-quality of data sets, clear user information, human oversight, etc. *Unacceptable risk*: for example, AI systems that allow "social scoring" by governments or companies are considered a clear threat to people's fundamental rights and are therefore banned. This framework aims to ensure that AI systems posing higher risks to safety and fundamental rights are subject to stricter regulations.

Trust and Transparency. By setting clear rules for transparency, accountability, and ethical standards, the AI Act aims to foster trust in AI technologies. This can encourage broader adoption and investment in AI innovations (EU Artificial Intelligence Act, 2024).

Global Benchmark. The AI Act positions Europe as a leader in AI governance, potentially influencing global standards and practices. This can drive innovation by providing a clear regulatory environment for developers and companies (Senior Executive, 2025).

Challenges Related to the AI Act

Compliance Burden. The stringent requirements, especially for high-risk AI systems, can be challenging for startups and SMEs. Compliance costs and administrative burdens may deter smaller companies from innovating in the AI space (Senior Executive, 2025).
Fragmentation Risk. The AI Act's extraterritorial enforcement means that AI systems developed outside the EU but used within it must comply with its regulations. This can lead to fragmentation and complexity in global AI markets (Chambers and Partners. by Lebrum &Lachguer, 2025).
Balancing Innovation and Regulation. While the AI Act aims to protect users and ensure ethical AI, there is a concern that overly restrictive regulations could stifle innovation and push AI development to regions with less stringent rules (Senior Executive, 2025).

Overall, the AI Act represents a significant step towards responsible AI development, but it also poses challenges that stakeholders must navigate to balance innovation with regulation.

Data Act

The Data Act - Regulation EU 2023/2854 (European Union. Data Act Regulation, 2023) come into play on 12th September 2025, aims to facilitate fair access to and use of data across the EU. The Act applies to EU businesses within the EU and to importers into the EU. It establishes rules for data sharing between businesses and consumers, promoting innovation and competition while ensuring data protection.

Among various norms the Data Act:

- permits connected users to access directly device-generated data (e.g., data from Internet of Things) and share it with third parties that provide benefits for users (e.g., for data-improved aftercare services);
- enable public sector entities, in exceptional circumstances, access data held by the private sector;
- introduces safeguards against unlawful third-country government access to non-personal data stored in the EU. The Act always allows the protections imposed by the GDPR to take precedence when personal data is involved.

Cyber Resilience Act

Regulation EU 2024/2847 (European Union. Cyber Resilience Act, 2024) adopted end 2024 and fully applicable by December 2027, the Cyber Resilience Act introduces mandatory cybersecurity requirements for products with digital elements, including hardware and software. The norms may improve transparency related to functionalities of Internet of Things devices (i.e., by making it easier to access clear information on the device that may contribute to better-informed purchasing decisions). By ensuring that data collected with IoT devices are secure and protected from potential breaches the Cyber Resilience Act assure protection of fundamental rights such as data and privacy protection. Manufacturers must ensure their products are secure throughout their lifecycle, conduct risk assessments, and report incidents within 24 hours.

European Innovation Act

The European Innovation Act is planned to be adopted in 2026. (European Union. European Innovation Act). It aims to create cross-sectoral legal framework conditions to remove barriers for bringing innovative ideas to market in all sectors. Various issues will be addressed: the commercialisation of research results, collaboration between the industry

and the academia, access to markets, finance, talent and infrastructures. It will also focus on creating more coordinated regulatory, policy and investment framework conditions aimed at bringing innovative solutions to the market across the EU.

EDiHTA project

EDiHTA (https://edihta-project.eu/project/) is a 4-year Horizon Europe Research and Innovation Action funded under call HORIZON-HLTH-2023-IND-06-07. The consortium has 16 partners from 10 countries. The project started in 2024 and is aiming to create a fit-for-purpose Health Technology Assessment (HTA) framework for Digital Health Technology (DHT) (e.g. telemedicine, mApps, AI) at different TRLs, territorial levels (national, regional and local) and perspectives (e.g. payer, society, hospital). It would integrate existing assessment domains and methods with new ones in order to inform decision-making. The HTA framework-platform will be developed to allow HTA assessments to be performed digitally in a standardised format that will be customised according to the type and lifecycle stage of the DHT and decision-making process at the macro (policy), meso (management providers) and micro (clinicians) levels. The digital framework will be piloted in real healthcare settings in 5 major European hospitals and through an open piloting scheme with European DHT developers.

Source of Information on Regulation related to Digital Health

Comprehensive information on regulation of medical devices and digital health solutions for Digital Health may be found at:

- EU Commission eHealth Portal: health.ec.europa.eu/ehealth;
- DiMe Society Regulatory Pathways;
- CEN. Health Informatics TC251 provide information on standards and technical specifications with relevance to the EHDS regulation: https://www.ehealth-standards.eu/documents/
- European Network of Research Ethics Committees – EUREC: https://eurecnet.eu/resources/codes-and-guidelines/
- Each EU country Competent Authorities (e.g., BfArM for Medical Devices and Digital Health Application from Germany; PECAN – Prise en Charge Anticipee framework for digital health reimbursement from France; Infarmed for Drugs and Health Products from Portugal).

The Digital Medicine Society (DiMe https://dimesociety.org) provides a structured and practical framework for navigating the regulatory landscape of digital health products in the European Union. This pathway begins with determining the regulatory classification of the product—whether it qualifies as a medical device, a wellness application, or software

as a medical device (SaMD) - as this classification dictates the applicable regulations and approval processes. Once the classification is clear, developers must map out the relevant regulatory requirements, including the European and national Medical Device Regulation (MDR), the General Data Protection Regulation (GDPR), the upcoming European Health Data Space (EHDS), and any national laws that may apply.

A strategy to comply with requirements for commercialization of products or services related to Digital Health should incorporate evaluation of reliability of technologies in clinical trials, cybersecurity protocols, and post-market surveillance plans. Engaging with key stakeholders early in the process (i.e., such as Notified Bodies, Ethics Committees, and National Health Authorities/Agencies) is essential to ensure alignment and avoid delays. Evidence generation plays a central role in this pathway, with clinical data, usability studies, and real-world evidence forming the backbone of both regulatory approval and reimbursement discussions.

To secure market access, developers must understand the health technology assessment (HTA) and reimbursement mechanisms in each target country, as these vary significantly across the EU.

Maintaining MDR or IVDR compliance over time requires implementing a robust Quality Management System, such as ISO 13485, and continuously monitoring product performance in the market. By following this step-by-step approach, digital health innovators can navigate the EU's complex regulatory environment more efficiently and position their products for successful adoption and scale. An example of Regulatory Readiness Check is presented in Annex II.

Regulatory Sandboxes

In the effort of policymakers to maintain a stable system in which consumers are protected and regulation provides the ground rules for fair competition, but also to facilitate the development of potentially disruptive innovations, the regulatory sandboxes are tools that regulatory bodies use to balance the strict regulation on public safety, competition and consumer right with rapid technological changes through innovations.
"*Regulatory sandboxes are policy instruments that facilitate small-scale, live testing of innovations in a controlled market-like environment. Sandboxes are typically employed in cases where emerging technology is potentially disruptive. It allows the testing of innovative technologies and business models that are not fully compliant with current rules and regulations, by providing temporary suspension of certain mandatory provisions or requirements for those who participate in the sandbox.*" (IDB. by Rosemberg et al., 2020).

The participants in regulatory sandboxes (i.e., innovators and knowledge providers such as large, established companies as well as startups that are testing new technologies) are allowed to test in controlled environments under oversight of regulatory entities without following all the regulatory requirements that would normally apply outside the sandbox in the regulated market. In return for this dispensation, participants are required to incorporate appropriate safeguards to insulate the market from risk from their innovative business. This gives participants a safe space for experimentation necessary for validation of technology, without running the risk of being punished for noncompliance. Regulatory authorities are responsible for monitoring and supervision of technology testing and analysing the potential regulatory needs based on data on the impact of emerging technology might be on economy and society. The framework of regulatory sandbox may differ from regulatory body for one type of technology to regulatory body for other technology and from country to country.

Examples of Digital Health regulation approach in European countries

Local regulations vary across EU member states, adding another layer of complexity. **Challenges** include:

Harmonization. Aligning local regulations with EU-wide standards.
Compliance. Ensuring that digital health solutions meet both local and EU requirements.
Adaptability. Staying updated with changes in local regulations and adapting accordingly.
National regulatory approaches to digital healthcare across the EU vary significantly, shaping how innovators enter and scale in different markets. An overview of regulatory instruments for medical devices and digital health applications (DiGA) from several European countries is presented in Annex III.

Germany stands out with its DiGA Fast-Track pathway, which allows certified digital health applications to be prescribed and reimbursed through statutory health insurance. The BfArM - Federal Institute for Drugs and Medical Devices oversees this process, enforcing strict data protection and requiring strong evidence of clinical benefit through health technology assessment (HTA).

France PECAN framework support early access and reimbursement for digital medical devices, with the Haute Autorité de Santé (HAS) playing a central role in evaluating clinical and economic impact. Great importance for approval of commercialization of digital application is given by Digital Health Agency to clinical trials and real-world evidence.

Spain presents a more fragmented landscape due to its decentralized healthcare system, where each autonomous region governs its own digital health strategy. While there is no national DiGA-like framework, regions such as Catalonia and Andalusia are more receptive to pilot programs, indicating growing interest in structured reimbursement.
Poland has a centralized digital health strategy led by the Ministry of Health and the eHealth Centre (CeZ), but reimbursement for digital tools remains limited. The country focuses primarily on infrastructure development, including electronic health records and telemedicine platforms.

Sweden is highly digitalized, benefiting from strong public-private collaboration and regional autonomy, with counties managing healthcare procurement. National efforts aim to improve interoperability across electronic health record systems.

Finland demonstrates a mature digital health ecosystem, anchored by its Kanta Services, which provide a unified infrastructure for EHRs and prescriptions. Oversight by public health and regulatory bodies such as THL and Fimea ensures compliance, while the country actively supports innovation through pilot programs and partnerships.

These national differences highlight the importance of tailoring market entry strategies to local regulatory environments while leveraging EU-wide frameworks for scalability.

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Annex I - Commitments from Ministerial Declaration on Transformative Science, Technology and Innovation Policies for a Sustainable and Inclusive Future (OECD Legal Instruments, 2024)

"*WE COMMIT to:*

- *develop and implement transformative science, technology, and innovation agendas, as appropriate, that are more inclusive, agile, anticipatory, allow for policy experimentation and reflect socially relevant directions, to help achieve the Sustainable Development Goals, including for climate and the sustainable use of the Ocean;*
- *continue investing in public research and development (R&D), including basic and experimental research, use-inspired research, mission-oriented-research, sustainable research infrastructures, and human resources, all of which are needed to advance knowledge and address global challenges;*
- *promote incentives for the private sector, including businesses and private finance actors, to invest in R&D and innovation and to engage in public-private partnerships from lab to market, especially to respond to societal and environmental needs;*
- *foster human capital and a skilled and agile workforce by promoting diverse, equitable, and inclusive access to skills training and lifelong learning programmes in science, technology, and innovation."*
- *shared values and principles in science, technology, and innovation, notably academic and scientific freedom, scientific excellence, openness, transparency, reciprocity, accountability, research ethics, integrity, and security, as well as*

diversity, equity, inclusion, and accessibility, all of which underpin responsible research and innovation;

- *open science principles and practices for data management and stewardship, including the Findability, Accessibility, Interoperability, and Reusability (FAIR) principles and frameworks for ethical data governance, such as the Collective Benefit, Authority to Control, Responsibility, and Ethics (CARE) principles, to facilitate the inclusive production of knowledge and ensure the equitable access to scientific literature and research data from public funding, across disciplines, sectors, and borders, while also respecting privacy, security, statistical confidentiality and ethical considerations;*
- *voluntary and mutually beneficial exchange of scientific knowledge and international cooperation in science, technology and innovation that is open, fair, secure, equitable, reciprocal, with respect for intellectual property rights, data protection, privacy as well as human rights, and ethical precepts, to advance knowledge and address global challenges.*

WE COMMIT to make science, technology, and innovation more inclusive, participatory, and accessible, notably by:

- *promoting measures to facilitate the engagement of all stakeholders, 'including through strengthened dialogue with relevant civil society stakeholders;*
- *strengthening the relationships and synergies among education, science, and society, by encouraging policies to promote public engagement in science and research and build public trust in science, technology, and innovation;*
- *continuing to advance diversity, equity, inclusivity, and accessibility, including through the inclusion of underserved, marginalised and underrepresented population groups, including women and girls to enable society at large to fully participate and succeed in science, technology, and innovation;*
- *promoting measures to enhance the attractiveness and availability of quality careers for research and teaching professions, notably by reducing precarity among researchers, improving their working conditions, and fostering mobility of talents and circulation of researchers across sectors and international borders.*

WE COMMIT to:

- *promote reliable, trustworthy, and internationally comparable official data in alignment with FAIR principles, statistics and empirical evidence in science, technology, and innovation;*
- *support and provide guidance on the processes needed to collect responsibly and ethically, link and leverage data in science, technology, and innovation for decision-making and policy development;*

- *promote evaluation mechanisms and strategic intelligence and foresight systems to improve the effectiveness, efficiency, transparency and impacts of research and innovation systems. "*

Annex II - Examples of Country Legal Instruments for Regulation of Digital Health Solutions

Finland

THL Regulation (Tiedonvälittäjät Tieto ja tiedonhallinnan ohjaus - Information Brokers for Information Management) provide the norms for regulation of information system and medical devices (see THL).

Examples of legislation related to Digital Health in Finland are the following:

- Medical Devices Act 719/2021 that supplements the EU regulations on medical devices entered into force on 19 July 2021
- THL/5/4.05.00/2024 - Regulation on the classification and certification of information systems and wellbeing applications in healthcare and social welfare
- THL/6/4.05.00/2024 - Regulation on essential requirements for social and health care information systems and welfare applications
- THL/4/4.05.00/2024 - Regulation on reports and requirements to be included in the information security plan
- THL/3/4.05.00/2024 - Regulation on documents transmitted outside the healthcare sector using national information system services
- THL/175/4.05.00/2023 - Regulation on the certification of wellness applications approved under previous approval criteria for the private data reserve
- THL 4274/4.09.00/2021 - Regulation on the essential requirements and certification of wellness applications that process wellness data connected to personal data reserves

Classification and Certification. THL Regulation 4, 5 and 6/2024 introduces a detailed classification and certification process for social and healthcare information systems and wellness applications. This ensures that digital health solutions meet high standards of safety and efficacy, fostering trust among users and healthcare providers.
Data Security and Privacy. The regulation emphasizes stringent data security and privacy requirements. This can enhance the protection of patient data, which is crucial for the adoption of digital health innovations.

Interoperability. By promoting interoperability between different health information systems, the regulation facilitates seamless data exchange and integration. This can drive innovation by enabling more comprehensive and efficient healthcare solutions.

Challenges Related to THL Regulation

Compliance Costs. The detailed certification process can be costly and time-consuming for developers. Smaller companies and startups may find it challenging to meet these requirements, potentially hindering innovation.

Technical Implementation. Ensuring interoperability and compliance with data security standards can be technically complex. This requires significant investment in technology and expertise.

Regulatory Burden. Navigating the regulatory landscape and maintaining compliance with evolving standards can be burdensome. This may deter some companies from entering the digital health market.

Overall, while THL Regulation aims to enhance the quality and security of digital health solutions, it also presents significant challenges that stakeholders must address to successfully innovate and comply.

Germany

Medical Devices Act (MPG) aligns with the EU Medical Device Regulation (MDR) 2017/745/EU and includes specific national provisions for medical devices (see BfArM).

Impact on Medical Device Innovations

Stricter Safety and Performance Requirements. The Medical Devices Act (MPG) aligns with the EU Medical Device Regulation (MDR), enforcing stringent safety and performance requirements. This ensures that medical devices meet high standards, fostering trust and reliability in innovative medical technologies.

Enhanced Clinical Evaluation. MPG mandates rigorous clinical evaluations and evidence for medical devices. This can drive innovation by ensuring that only safe and effective devices reach the market, but it also increases the time and cost associated with bringing new devices to market.

Transparency and Traceability. The act emphasizes transparency and traceability throughout the device lifecycle. This can enhance patient safety and confidence in medical devices, potentially accelerating the adoption of new technologies.

Challenges Related to MPG

Compliance Costs. Meeting the stringent requirements of MPG can be costly and time-consuming. Smaller companies and startups may find it challenging to bear these costs, which could hinder innovation.
Regulatory Complexity. Navigating the complex regulatory landscape of MPG can be daunting. Companies must invest in regulatory expertise to ensure compliance, which can be a significant burden.
Market Access Delays. The rigorous clinical evaluation and certification processes can delay market access for new medical devices. This can impact the competitiveness of companies and slow down the introduction of innovative solutions.
Overall, while the Medical Devices Act (MPG) aims to enhance patient safety and product quality, it also presents significant challenges that manufacturers must navigate to remain compliant and competitive.

Italy

Legislative Decree 46/97. Implements the EU directives on medical devices and includes specific provisions for the Italian market (see 3E).
Alignment with EU Directives. Italy's Legislative Decree 46/97, 507/92 and 332/2000 implements EU directives on medical devices, ensuring that Italian regulations are harmonized with broader European standards. This alignment helps maintain high safety and efficacy standards for medical devices, fostering innovation within a consistent regulatory framework.
National Provisions. The decree includes specific provisions tailored to the Italian market, such as linguistic requirements for labelling and instructions, and criteria for advertising and online sales (3E, 2022). These provisions address local needs and can drive innovation by ensuring that products are well-suited to the Italian healthcare context.

Challenges Related to Legislative Decree 46/97

Compliance Costs. Meeting the stringent requirements of both EU directives and additional national provisions can add some cost and delays. This can be particularly challenging for smaller companies and startups.
Regulatory Complexity. Navigating the combined EU and national regulatory landscape can be complex. Companies must invest in regulatory expertise to ensure compliance, which can be a significant burden.
Overall, while Legislative Decree 46/97 aims to enhance patient safety and product quality, it also presents some challenges that manufacturers must navigate to remain compliant and competitive.

Netherlands

Medical Devices Decree (Besluit Medische Hulpmiddelen) implements EU regulations and includes additional national provisions for medical devices. The Medical Devices Decree (Besluit Medische Hulpmiddelen) in the Netherlands does introduce some additional requirements beyond the EU Medical Device Regulation (MDR) 2017/745 (see Inspectie Gezondheidszorg en Jeugd).

National Implants Registry. The decree mandates the registration of implantable medical devices in a national registry, which is not explicitly required by the MDR.

Stricter Supervision. The Health and Youth Care Inspectorate (IGJ) has enhanced supervisory powers to ensure compliance with both the MDR and national regulations.

Additional Reporting Obligations. There are extra requirements for reporting incidents and changes related to medical devices, aimed at improving patient safety and device traceability.

Alignment with EU Regulations. The Medical Devices Decree (Besluit Medische Hulpmiddelen) aligns Dutch regulations with EU directives, such as the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). This harmonization ensures that medical devices meet high safety and efficacy standards, fostering innovation within a consistent regulatory framework.

National Provisions. The decree includes specific provisions tailored to the Dutch market. These provisions address local needs and can drive innovation by ensuring that products are well-suited to the Dutch healthcare context.

Challenges Related to Medical Devices Decree

Compliance Costs. Meeting the stringent requirements of both EU regulations and additional national provisions can be costly and time-consuming. This can be particularly challenging for smaller companies and startups, potentially hindering innovation.

Regulatory Complexity. Navigating the combined EU and national regulatory landscape can be complex. Companies must invest in regulatory expertise to ensure compliance, which can be a significant burden.

Overall, while the Medical Devices Decree aims to enhance patient safety and product quality, it also presents some challenges that manufacturers must navigate to remain compliant and competitive.

Spain

Royal Decree 1591/2009. Regulates medical devices in Spain, aligning with EU directives and adding national requirements. The new Royal Decree 192/2023 on medical devices in Spain, published on March 22, 2023, adapts Spanish regulations to the provisions of Regulation (EU) 2017/745 (see BakerMcKenzie). Key changes include:

Expanded Scope. The decree covers products similar to medical devices, such as those used in permanent or semi-permanent make-up and skin tattooing.

Licensing Requirements. It updates the licensing requirements for the manufacture, importation, grouping, or sterilization of medical devices, setting the validity at a maximum of five years.
Competent Authority. The Spanish Agency of Medicines and Medical Devices (AEMPS) is designated as the competent authority.
Documentary File. The period for maintaining the documentary file is increased to ten years for most products, and fifteen years for implantable products.
Alignment with EU Directives. Royal Decree 1591/2009 aligns Spanish regulations with EU directives, such as the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). This harmonization ensures that medical devices meet high safety and efficacy standards, fostering innovation within a consistent regulatory framework.
National Provisions. The decree includes specific provisions tailored to the Spanish market, such as requirements for labelling, advertising, and online sales. These provisions address local needs and can drive innovation by ensuring that products are well-suited to the Spanish healthcare context.

Challenges Related to Royal Decree 1591/2009

Compliance Costs. Meeting the stringent requirements of both EU directives and additional national provisions can be costly and time-consuming. This can be particularly challenging for smaller companies and startups, potentially hindering innovation.
Regulatory Complexity. Navigating the combined EU and national regulatory landscape can be complex. Companies must invest in regulatory expertise to ensure compliance, which can be a significant burden.
Overall, while Royal Decree 1591/2009 aims to enhance patient safety and product quality, it also presents some challenges that manufacturers must navigate to remain compliant and competitive.

Sweden

Medical Devices Act (Lag om medicintekniska produkter) aligns with EU regulations and includes specific national requirements. The Swedish law "Lag om medicintekniska produkter" (Law on Medical Devices) includes additional requirements beyond the EU Medical Device Regulation (MDR) (see Sveriges Riksdag).
Ethical Review. The law mandates ethical review for clinical trials and performance studies involving medical devices.
Documentation Retention. It specifies longer retention periods for documentation related to medical devices. Documentation shall be made available to the competent authorities for the period specified in the Annexes, even if the sponsor, its contact person or its legal representative is declared bankrupt, liquidated or ceases to operate. In such cases, the sponsor, its contact person or legal representative must notify the authority

determined by the government who is responsible for archiving the documents and where they are stored.

National Supervision. The Swedish Medical Products Agency (Läkemedelsverket) has enhanced supervisory powers to ensure compliance with both MDR and national regulations.

Alignment with EU Regulations. The Medical Devices Act (Lag om medicintekniska produkter) in Sweden aligns with EU directives, such as the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). This harmonization ensures that medical devices meet high safety and efficacy standards, fostering innovation within a consistent regulatory framework.

National Provisions. The act includes specific provisions tailored to the Swedish market. These provisions address local needs and can drive innovation by ensuring that products are well-suited to the Swedish healthcare context.

Challenges Related to Medical Devices Act

Compliance Costs. Meeting the stringent requirements of both EU regulations and additional national provisions can be costly and time-consuming. This can be particularly challenging for smaller companies and startups, potentially hindering innovation.

Regulatory Complexity. Navigating the combined EU and national regulatory landscape can be complex. Companies must invest in regulatory expertise to ensure compliance, which can be a significant burden.

Overall, while the Medical Devices Act aims to enhance patient safety and product quality, it also presents challenges that manufacturers must navigate to remain compliant and competitive.

United Kingdom

UK Medical Device Regulations 2002 is based on EU directives but with modifications post-Brexit to suit the UK market. Regulation for medical devices in the UK outlines the requirements for placing medical devices on the market in Great Britain (England, Wales, and Scotland) and Northern Ireland (see GOV.UK).

Certification and Marking. Devices must be certified and bear the UKCA marking for Great Britain or the CE marking for Northern Ireland.

Registration. All medical devices, including in vitro diagnostic devices (IVDs) and custom-made devices, must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) before being placed on the market.

UK Responsible Person. Manufacturers outside the UK must appoint a UK Responsible Person to ensure compliance with regulations.

Post-Market Surveillance. There are requirements for ongoing monitoring and reporting of device performance and safety.

Post-Brexit Modifications. The UK Medical Device Regulations 2002 (UK MDR 2002) have been modified post-Brexit to suit the UK market. These modifications include the introduction of the UK Conformity Assessed (UKCA) marking, which replaces the CE marking for medical devices placed on the Great Britain market. This change aims to ensure that medical devices meet high safety and efficacy standards while adapting to the UK's regulatory environment.

Alignment with EU Standards. Despite Brexit, the UK MDR 2002 still aligns closely with EU directives.

National Provisions. The UK MDR 2002 includes specific national provisions. These provisions address local needs and can drive innovation by ensuring that products are well-suited to the UK healthcare context.

Challenges Related to UK MDR 2002

Compliance Costs. Meeting the requirements of the UKCA marking will add some costs and time. This can be particularly challenging for smaller companies and startups.

Regulatory Complexity. Navigating the combined EU and UK regulatory landscape can be complex. Companies must invest in regulatory expertise to ensure compliance, which can be a significant burden (MHRA, 2025).

Annex III - Example of Regulatory Readiness checklist

Product Classification & Scope

- Clearly define the intended use of your product.
- Determine if it qualifies as a medical device or Software as a Medical Device (SaMD) under MDR.
- Identify the risk class (e.g., Class I, IIa, IIb, III).

Regulatory Frameworks

- Comply with Medical Device Regulation (MDR 2017/745).
- Ensure GDPR compliance for all personal health data.
- Align with European Health Data Space (EHDS) for interoperability and data sharing.
- Check for national regulations (e.g., DiGA in Germany, PECAN in France).

Technical & Clinical Documentation

Prepare a Technical File including:

- Risk management plan.
- Clinical evaluation report.
- Software validation (if applicable).
- Labelling and Instructions for Use (IFU).

- Conduct or reference clinical studies to demonstrate safety and performance.
- Draft a Post-Market Surveillance (PMS) and PMCF plan.

Quality & Cybersecurity

- Implement a Quality Management System (QMS) (e.g., ISO 13485).
- Appoint a Person Responsible for Regulatory Compliance (PRRC).
- Ensure cybersecurity and data protection measures are in place (consider ISO 27001).

Notified Body & CE Marking

- Select and contract a Notified Body.
- Submit documentation for conformity assessment.
- Obtain CE marking before market launch.

Market Access & Reimbursement

- Identify reimbursement pathways in target countries.
- Prepare for Health Technology Assessment (HTA) if required.
- Align with value-based procurement and public funding criteria.

Post-Market & Scaling

- Monitor product performance and report incidents.
- Submit Periodic Safety Update Reports (PSUR).
- Plan for scaling across EU markets using EHDS and MyHealth@EU infrastructure.

Chapter 6. Regulation - Intellectual Property

What is Intellectual Property

Domain of Intellectual Property – Copyright; Trademark; Trade secret; Patents

Case Study - Electrocardiograph

Annex I – Intellectual Property - Glossary

Annex II - ECG Patens (1900-1960)

Annex III - Database on patents

Digital Health innovations can help extend the reach and quality of different health services (i.e., enhance diagnosis efficiency; help to design and implement cost-effective solutions for different diseases treatment; ensure care continuity facilitating remote patient management through telemedicine; support accessibility to health care services for underserved or marginalized population; support drug development through computer-aided drug design, computational modelling for predictive toxicity; facilitate

analysis of big data from personalized medicine, systems biology, synthetic biology or omics biology). Intellectual Property related to different thought's creation is seen by many Digital Health researchers, entrepreneurs, and companies' administrators as an incentive for innovation and progress and for increasing perceived social utility (Stanford Encyclopedia of Philosophy, 2022). However, navigating in a complex legal environment surrounding technological innovation for health care and intellectual property rights related to Digital Health is difficult even for big corporations. For instance, legal battle over patents infringement of Apple, a global leader in technologies, took 14 years with VinetX, and 5 years with Masimo and AliveCor companies (Williamson, 2024) and in those patents' infringement litigations, the defendant as well as the plaintiff suffered important losses (e.g., decreased products sales revenue; high financial costs; reputational damage) (AppleInsider by Owen, 2023; AppleInsider by Neely, 2025). With evolving legal landscape in which regulators and companies seek to balance innovation and competition, the clarity of information related to Intellectual Property has great relevance for creators and Digital Health companies.

This chapter provides a starting point for understanding the domains of Intellectual Property, focusing on Patents for health systems. A key glossary related to Intellectual Property is provided in Annex I (majority of the terms were selected from European Patent Office. Glossary).

What is Intellectual Property

Intellectual Property is generally characterized as a product of original thought such as invention, literary and artistic work, design, and symbols, names and images used in commerce (European Patent Office. Glossary). Intellectual Property rights refer to intangible items and to the control of physical manifestations or expressions of ideas. In some countries (e.g., Portugal, Spain) the term intellectual property is used mainly for the copyright and related rights (i.e., related to scientific or literary publication, musical or artistic creation, software, etc.) and the term industrial property is applied to the invention, design, signs capable for distinguishing the goods or services of a company, or geographical indication of origin, therefore the intangible items produced by intellectual activity in industrial sectors. Legal protection for IP rights supports production and control of physical expression of ideas and content-creators' interest in their ideas (Stanford Encyclopedia of Philosophy, 2022). Differences are present in intellectual property law between each European countries and also between European and United States or other countries. Efforts have been and are being made to harmonize the rules, the intellectual property law within European Union. Attention to the details in legislation of each country related to intellectual property may help companies and all interested parties to efficiently

manage their intellectual property as well as to create a work environment where innovation thrives.

The Domain of Intellectual Property

The domain of Intellectual Property/Industrial Property encompass copyright, patent, trademark, trade secret and within European doctrine the moral rights granted to authors and inventors.

Copyright

The subject matter of Copyright protection (copyright symbol ©) is summarily presented in the U.S. Code (17 U.S.Code §102 – Subject matter of copyright: in general (Legal Information Institute. Cornell Law School)) "*original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device. Works of authorship include the following categories:*

- *literary works;*
- *musical works, including any accompanying words;*
- *dramatic works, including any accompanying music;*
- *pantomimes and choreographic works;*
- *pictorial, graphic, and sculptural works;*
- *motion pictures and other audiovisual works;*
- *sound recordings; and*
- *architectural works.* "

In Portugal, Decreto-Lei nº. 63/85 of 14 March - Código do Direito de Autor e dos Direitos Conexos CDADC, Decreto-Lei nº. 252/94 (based on EU Council Directive nº. 91/250/EEC of 14 May related to protection of computer program) and Decreto-Lei n.º 110/2018 of December 12 - Codigo da Propriedade Industrial indicate that copyright refer to: scientific paper; software and informatic applications (including source code, website); creation of audio or musical works; structure and scheme of reports; plan, maps; semiconductor topography; design and models; other intellectual creations. Website, computer program, blog of a company related to Digital Health may have copyright protection.
In Europe the EU copyright law consisting of 13 directives and 2 regulations protects the essential rights of authors, performers, producers and broadcasters. Following are several examples of EU norms for copyright protection (more on EU copyright law European Commission. EU copyright law)

- *Directive on the harmonisation of certain aspects of copyright and related rights in the information society ('InfoSoc Directive'), 22 May 2001*

- *Directive on the legal protection of computer programs ('Software Directive'), 23 April 2009*
- *Directive on the legal protection of computer programs ('Software Directive'), 23 April 2009*
- *Directive on the legal protection of databases ('Database Directive'), 11 March 1996*
- *Directive on certain permitted uses of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled (Directive implementing the Marrakech Treaty in the EU), 13 September 2017*
- *Regulation on cross-border portability of online content services in the internal market ('Portability Regulation'), 14 June 2017*
- *Directive on copyright and related rights in the Digital Single Market ('DSM Directive'), 17 April 2019.*

In general, the registration at national agency for copyright is voluntary but copyright protection is automatic upon the creation of a work (Creative Commons. About CC Licenses). The certificate of registration may be used in litigation and registered work is eligible for statutory damages.

The owners of copyright have the right to:

- reproduce the work
- adapt it or derive other works from it
- display the work publicly, and
- perform it publicly.

The rights of copyright owners have limited duration (established in country law of copyright) and are restricted by rule of "fair use" and "first sale". Considering the "fair use" rule anyone can use subject of copyright for such purpose of criticism, comment, news reporting, teaching, scholarship, and research (Stanford Encyclopedia of Philosophy, 2022). The "first sale" rule gives the right to the owner of copyright to sale copies of protected work but prevents him to interfere in subsequent sale of sold copies (Stanford Encyclopedia of Philosophy, 2022).

Creative Commons (CC) license

Many online content providers offer licensing agreements of a copyright work rather than selling a copy of the work. A Creative Commons (CC) license enables the free distribution of a copyrighted product of thought such as books, articles, photographs, blogs, websites, games, movies, music. There are several types of CC licenses that differ in their conditions for distribution and use (see more on Generis Global Services, 2024):

CC BY – allow distribution, adaptation and commercial use but credit must be given to creator;

CC BY-SA – similar to licence CC-BY with additional condition SA: adaptation must be shared under the same terms;

CC BY-NC – only noncommercial uses of the work are permitted;

CC BY-NC-SA – license is given for non-commercial use and adaptations must be shared under the same terms;

CC BY-ND – license enable reusers to copy and distribute the material in any medium but no derivatives or adaptations of the work are permitted;

CC BY-NC-ND – license for noncommercial use and without permission for derivatives or adaptation of the work;

CC0 (aka CC Zero) – a public dedication tool that enables reusers to use copyrighted work with no conditions.

Moral Rights

European included in legislation of Intellectual Property the “moral rights” a notion from the Berne Convention. These rights are greatly relevant for online environments of Digital Health such as digital archives, streaming services or social media. Designed to protect the personal and reputational interests of creators include the right of attribution (paternity) and the right of integrity (Legal IP Strategies Staff, 2024).
The right of attribution ensures proper attribution of authorship of a work – the obligation to indicate the authorship of the work whenever the creator work is used, the possibly of a creator to claim authorship publicly and to object if attribution is falsely assigned or omitted. (Legal IP Strategies Staff, 2024).

The right of integrity protects creators from having their works altered in a way that distorts or damages their original intent and from unfair harm to their reputation. However, rights limitation exists if changes and adaptations serve the public interest. There are variations in legislation of moral rights in different European countries reflecting differing legal traditions and cultural perspectives. Differences in national interpretations and legal protection of moral rights and jurisdictional complexities throughout the EU member state complicate enforcement efforts, particularly for digital works that are shared or remixed across different digital channels. Evolving landscape of moral rights in EU copyright law requires increased attention of stakeholders from Digital Health ecosystem for protection of creators’ personal and reputation interests (Legal IP Strategies Staff, 2024).

Trademark

According to European Patents Office the trade mark "*may consist of any signs, in particular words, including personal names, or designs, letter, numerals, colours, the shape of goods or their packaging, or sounds, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings and of being represented clearly and precisely on the register.*" (European Patent Office. Glossary) Marks may identify services rather than products and help the users of those services or products to distinguish goods from a manufacturer or merchant from goods produced by others. The subject matter of trademark is generally associated with good name or quality of a company. The trademark should be registered at national agency that confers the right to exclude others from using the same mark (e.g., INPI in Portugal).

Trade Secret

According to U.S. Restatement of the Law of Unfair Competition published in 1995, a trade secret "*is any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others*" (American Law Institute, 1995). The trade secret law confers rights and protection for private measures rather than state action to preserve exclusivity. The subject matter of trade secret is almost unlimited (e.g., a database of customers, the components of a device, the process of a service). Trade secrets are not registered with a government agency. The requirement of secrecy is mainly for competitive advantage. In litigation case the owners of trade secrets should prove that they have taken measures for preserving secrecy. The owners' rights of trade secret do not exclude independent invention or discovery. Owners of trade secrets are protected from misappropriation (e.g., courts may impose injunctive relief and damages in case of industrial espionage and employee theft of intellectual works) (Stanford Encyclopedia of Philosophy, 2022).

Patents

Patents, granted by a government agency, protect the invention and discovery of new and useful processes, machines, articles of manufacture, or compositions of a product (Stanford Encyclopedia of Philosophy, 2022, Legal Information Institute. Cornell Law School). The owner(s) of a patent has(ve) "*the exclusive right to prevent third parties from commercially exploiting - making, using, offering for sale, selling or importing the invention, which is protected by patent for a limited period of time (generally 20 years)"* (European Patent Office. Glossary). There are differences within European countries in what is patentable as well as related to the type of patents. In many countries from Europe, two types of patents are protected by law: patent and utility model. Utility model for which

different terms are used in patents regulation documents from each country (e.g., "utility innovation"; "innovation patents"; "short-term patents") "*protect new technical inventions through granting a limited exclusive right to prevent others from commercially exploiting the protected inventions without consents of the right holders…. are considered particularly suited for protecting inventions that make small improvements to, and adaptations of, existing products or that have a short commercial life* " (WIPO. Utility Model). Following are presented some differences between patent and utility model in Portugal and Spain.

In Europe, European patent can be granted by European Patents Office (EPO) based on European Patents Convention (EPC) (European Patent Office. Patent Convention). The EPC rules are applied both to patents and utility models (art. 140 National utility models and utility certificates, of EPC, Part VIII, Chapter III (European Patent Office. Patent Convention)).

Table 3. **Patent and Utility Model difference in legal characteristics**. Source: Dominguez

Requirement	Patent PT	Patent ES	Utility Model PT	Utility Model ES
Novelty	worldwide	worldwide	national	National
Inventive Step/Activity	maximal: invention shall not be obvious to a person skilled in the art	maximal: invention shall not be obvious to a person skilled in the art	maximal (but more flexible): invention shall not be obvious to a person skilled in the art, and whether it is a practical technical advantage, it shall not be obvious to the manufacture, use or process in question	minimal: invention shall no be so obvious for a person skilled in the art
Subject Matter	products, processes, substances, their use (including biological products or products that	products, processes, substances, their use (including biological products or products that	protection is not granted for inventions related to biological products, processes, chemicals,	consist on providing to a product a structure or configuration from which may results a utilization or

	may have biological compounds or processes for production, transformation or utilization of biological compounds)	may have biological compounds or processes for production, transformation or utilization of biological compounds)	pharmaceutical substances	practical advantage is permitted only a protection of such objects as devices, apparatus, or tools
Maximal Period of Protection	20 years	20 years	*6 years+2+2	10 years
Supplementary Protection Certificate	only for the drugs and phytosanitary product (up to maximum 5 years)	only for the drugs and phytosanitary product (up to maximum 5 years)	is not permitted	Is not permitted
Procedure	more demanding, more expensive	more demanding, more expensive	may be made also without examination	less demanding, less expensive

"*A European patent application may be transferred or give rise to rights for one or more of the designated Contracting States*." (art. 71 Transfer and constitution of rights, of EPC Part II, Chapter IV (European Patent Office. Patent Convention)). The rights conferred by a European patent are those conferred by the Contracting State in respect of which is granted (art. 64 Rights conferred by a European patent, of EPC Part II, Chapter III (European Patent Office. Patent Convention)). "*A European patent application may be licensed in whole or in part for the whole or part of the territories of the designated Contracting States*." (art. 73 Contractual licensing, of EPC Part II, Chapter IV (European Patent Office. Patent Convention)). The conditions for revocation of European patent is expressed in Article 138 Revocation of European Patents, of EPC Part VIII, Chapter II (European Patent Office. Patent Convention)). The owner of a patent may request revocation or limitation of a patent by amending the claims. For instance, revocation of a patent can be carried out "*if does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*". Each country patents agency and the European Patent Office communicate to each other "any useful information regarding European or national patent applications and patents and any proceedings concerning them" (art. 130 Exchange of information, of EPC Part VII, Chapter II (European Patent Office. Patent Convention).

Patentable/non-patentable

Each country's legislation defines what inventions may be patentable. For instance, in Portugal may be protected by a patent any invention of products and processes in all technological domains (Decreto-Lei n.º 110/2018 of December 12 - Codigo da Propriedade Industrial) such as invented objects or instruments, apparatus, systems, scientific research results, processes, substances, their utilization, respecting conditions to be new, to involve an inventive step and have industrial applications. In U.S. patentable may be "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement" (35 U.S. Code§101 (Legal Information Institute. Cornell Law School)). According to article 52(1) of the European Patent Convention (EPC) (European Patent Office. Patent Convention)) the European patent "*shall be granted for any inventions, in all fields of technology, provided that they are* ***new, involve an inventive step*** *and* ***are susceptible of industrial application***". These conditions/requirements for a patent are also used in many European country patents' agencies and are applied also for utility model. In U.S. Code the main requirements for patentability are novelty, non-obvious subject matters and industrial applications of invention (35 U.S. Code§101; 102; 103 (Legal Information Institute. Cornell Law School)).

Novelty

Novelty shall be presented in the description of patent and is subject of examination by a person skilled in art. The novelty requirement generally invalidates patent claims if the invention was "*patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention*" (35 US Code § 102 (Legal Information Institute. Cornell Law School)).

Inventive Step

Considering the state of the art an invention must be non-obvious to a person skilled in the field (see European Patent Office. Glossary – Inventive step). The claimed invention should not be a mere aggregation of features. Inventive step requirement in European patents is similar with non-obviousness requirement in US code. The examination of inventive step should consider the question "*Would this invention be obvious to an expert in the relevant field*?" (Stanford Encyclopedia of Philosophy). Therefore, in relation to any claim defining the invention, analysis of background art related to invention should be performed to establish whether before the filing or priority date valid for that claim, it would have been obvious to the person skilled in the art to arrive at something similar falling within the terms of the claim or does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art (PCT-EPO Guidelines, Part G, Chapter VII. 4 Obviousness (European Patent Office. PCT-EPO Guidelines. Obviousness)). If so, the invention is not patentable as the claim lacks the inventive step.

Susceptible to Industrial Application

To be patentable an invention "*shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture*." (art. 57 Industrial Application of EPC, Part II, Chapter I (European Patent Office. Patent Convention)). The usefulness of an invention for any kind of industry is required also in US Patent Act *"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."* (35 US Code § 101 (Legal Information Institute. Cornell Law School)).

Recently, health care industries have been witnessing transformative changes induced by artificial intelligence (AI) that reshaped the ways of human-machine interaction and decision-making processes. Patents related to artificial intelligence have great complexity as claims can be on physical hardware, computer program or applied technology. To be patentable an AI computer program should have a "technical character". The computer program that provides artificial intelligence should have "further technical effect" when executed on a computer, which has to go beyond the normal physical interactions between the program and the computer (Kunda, 2024), such as new functioning of the computer or new interfaces.

Where to apply for a patent?

Patents are territorial, which means if you have a patent for an invention in Portugal, the rights are not protected in Germany. Examples of national agency from Europe that provide services related to patents are INPI – Portuguese Institute for Industrial Property; OBI - Hellenic Industrial Property Organisation; PRH – Finnish Patent and Registration Office. In Europe is possible to apply for European patent at EPO - European Patent Office, and patent may be granted in different countries from Europe under European Patent Convention (EPC). By filing a single application at EPO a protection for an invention in up to 44 European countries can in each of a large number of countries, under Patent Cooperation Treaty (PCT). The contracting states (currently, 158 PCT membership) allow the filing of a single patent application that is called PCT application (WIPO. PCT – The International Patent System). A PCT application itself does not result in the grant of a patent, as the grant of patent is a prerogative of each national or regional authority.

Inventor versus Applicant

Inventor(s) shall be indicated in patent application. Applicant may be other than inventor in patent application. The applicant can be an individual (inventor or not) or entity (the employer or a legal assignee such as an investor) that owns the invention and apply for patent protection for the invention. In case of unlawful patent filing in Europe the lawful person(s) shall institute proceedings before a national court before reclaiming ownership

of the patent based on art. 61 of European Patent Convention (art. 61 European patent applications filed by non-entitled persons, of EPC Part II, Chapter II (European Patent Office. Patent Convetion)). Examples of unlawful patent filing are: an employee invent something and by disregarding the contractual clause had filled a patent in their own name and not the name of employer, as stipulated in contract; a team member files a patent application disregarding other contributors; a third party filled a patent application for an invention without the inventor's consent based on confidential disclosure, or stealing information on invention; a consultant or contractor violates a consultancy agreement by filing a patent application jeopardizing the company's ownership rights. Therefore, the company shall define clearly ownership terms in employment, consultancy or contract agreement and maintain a detailed records of the invention process to safeguard innovation by patent protection (Moreira, 2024).

What is Person Skilled in the Art?

According to Article 83 of European Patent Convention (art. 83 Disclosure of the invention of EPC Part III, Chapter I (European Patent Office. Patent Convention)) the applicant for a patent "*shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*." In U.S. Code one of the requirements for patentability is non-obvious subject matter as such "*differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains*." (35 US Code § 103 (Legal Information Institute. Cornell Law School). The concept of person skilled in the art (PSA), a legal concept in patent law does not represent a person with constant skills. PSA is an adjustable concept considering the continuous progress in science and technology. According PCT-EPI Guidelines, part G, Chapter VII.3 Person Skilled in the Art "*should be presumed to be a skilled practitioner in the relevant field of technology, who possesses average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date. They should also be presumed to have had access to everything in the "prior art", in particular the documents cited in the search report, and to have had at their disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem. The skilled person is involved in constant development in their technical field*." (European Patent Office. PCT-EPO Guidelines. Person Skilled in the Art).

The patents agency may invite the applicant to provide more information on prior art concerning an invention. If the applicant fails to reply in due time to the request on information on prior act the patent application can be rejected.

Date of Filing

"*The date of filing of a European patent application shall be the date on which the requirements laid down in the Implementing Regulations are fulfilled.*" (art. 80 Date of Filing, of EPC, Part III, Chapter I (European Patent Office. Patent Convention). From the date of filing of the first application for the patent is granted the right of priority during a period of twelve months. "*A European patent application which has been accorded a date of filing shall, in the designated Contracting States, be equivalent to a regular national filing, where appropriate with the priority claimed for the European patent application*" (art. 66 Equivalence of European filing with national filing, of EPC Part II, Chapter III (European Patent Office. Patent Convention).

Date of Publication

Date of publication is the date when patent is granted, and the application of patent is first made available to the public. From that date the patent is part of the state of art for other patents.

Patent Application

According to Article 78 of EPC (art.78 Requirements of a European patent application, of EPC Part III, Chapter I (European Patent Office. Patent Convention) a patent application shall contain:

- a request for the grant of a European patent;
- an abstract
- a description of the invention;
- one or more claims;
- any drawings referred to in the description or the claims.

Many national patents agency require the same structure of a patent application as for European Patent.

Abstract

The abstract shall be a short summary of the invention.

Description of the Invention

Description of the invention shall be made "*in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*" (art. 83 Disclosure of the invention, of EPC, Part III, Chapter I) (European Patent Office. Patent Convention)).
According to Rule 42 from Implementing Regulations to Part III of the EPC (EPO-European Patent Office. European Patent Convention. Rule 42) the content of description shall include:

- the technical field to which the invention relates;
- state of the art related to invention, useful to understand the invention, which include European and international public patents related to invention and citation of the scientific documents reflecting such art;
- novelty of the invention;
- description of the invention in such terms that allow understanding of the technical problem and its solution, and presentation of any advantageous effects of the invention with reference to the background art;
- briefly description of the figures in the drawings, if any;
- description in detail of at least one way of carrying out the invention claimed, using examples where appropriate and referring to the drawings, if any;
- presentation of usefulness of the invention, when it is not obvious from the description or nature of the invention, using example of the way in which the invention is industrially applicable.

Form and content of claims

The claim(s) define(s) the legal boundaries of the invention and distinguish the technical features of the invention from prior art. Their formulation should obey the rule stipulated by national or regional agency. For European Patents the Rule 43 from Implementing Regulations to Part III of the EPC (EPO-European Patent Office. European Patent Convention. Rule 43). indicates the form and content of claims. According to that rule:

- "*a statement indicating the designation of the subject-matter of the invention and those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, form part of the prior art;*
- *a characterising portion, beginning with the expression "characterised in that" or "characterised by" and specifying the technical features for which, in combination with the features stated under sub-paragraph (a), protection is sought*"

A patent application generally shall include one independent claim in the same category (product, process, apparatus or use) that states all the essential features of the invention.

Each independent claim may be followed by one or more "dependent" claims concerning particular technical characterization of the invention.

Formulation of "dependent" claim is also regulated by Rule 43 from Implementing Regulations to Part III of the EPC "*Any claim which includes all the features of any other claim (dependent claim) shall contain, if possible at the beginning, a reference to the other claim and then state the additional features. A dependent claim directly referring to another dependent claim shall also be admissible. All dependent claims referring back to a single previous claim, and all dependent claims referring back to several previous claims,*

shall be grouped together to the extent and in the most appropriate way possible." (EPO-European Patent Office. European Patent Convention. Rule 43).
Claims should not describe the technical features of the invention using references to the description or drawings (e.g., expressions as "*as described in part ... of the description*", or "*as illustrated in figure ... of the drawings*" are not allowed) (EPO-European Patent Office. European Patent Convention. Rule 43).
The claims shall be followed by reference signs that were included in the patent drawings, placed in parentheses, only if they supports easier understanding of the claim.
In US patent application a multiplicity of independent claims is allowed but in European patent more than one independent claim in the same category is allowed only if the subject-matter of the application involves: "*a plurality of interrelated products; different uses of a product or apparatus; alternative solutions to a particular problem, where it is inappropriate to cover these alternatives by a single claim*" (art. 2 of Rule 43 from Implementing Regulations to Part III of the EPC) (EPO – European Patent Office. European Patent Convention. Rule 43).

A claims fee is charged for each additional claim after the 15th claim in European patent application and after 20th in US patent application.

Patent Infringement

In dispute cases related to patents, administrative and judicial ways are provided in legislation of each European country for enforcing or invalidation of a patent and criminal sanction for patent infringement. For instance, each country's legislation and European Patent Office provide information on rules for opposition after publication of a patent (e.g., any person may give notice of the opposition to a European patent based on the fact that invention disclosure is not made "*in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*" - art. 99 Opposition and art. 100 Ground for opposition, of EPC Part V (European Patent Office. European Patent Convention). When opposition is related to a European patent, the opposition document should be filled in the country that granted the patent or at European Patent Office.

In many European countries patent infringement is considered a criminal offense. According to Portuguese legislation (art. 318 from Decreto-Lei n.º 110/2018 December 12) the activity that may be considered as an "*exploitation of the invention*" claimed in a patent, (i.e., the manufacture, store, offer, market or use of the patented product, or the importation or possession thereof, for any of the mentioned purposes, without the consent of the owner) that is carried out by any unauthorized third parties is the matter of dispute in patent infringement. Patent litigation generally takes place before the national Intellectual Property Court ("IP Court") that may handle all actions concerning industrial property in all forms as provided in law, including both patent enforcement and invalidation

proceedings (Nazare & Lima, 2021; Lexology, 2020). A complaint may be lodged with the administrative authorities (e.g., government patents' agency, customs authorities) or the

Public Prosecutor's Office. Customs institutions may be involved in patents protection by preventing the import of the products resulting from patent infringement. Legal proceedings (civil or criminal) can be initiated by a patent owner or licensee at a state court or arbitration court.

Information on proceedings related to patent infringement is provided by each governmental agency empowered for patents protection. The law of State(s) that granted patent is applied to European patent infringement. According to European Patents Convention each State shall "*ensure at least that, from the date of publication of a European patent application, the applicant can claim compensation reasonable in the circumstances from any person who has used the invention in that State in circumstances where that person would be liable under national law for infringement of a national patent*" (art. 67 Rights conferred by a European patent application after publication, of EPC Part II, Chapter III (European Patent Office. European Patent Convention)). The courts may protect the value of innovation through remedies such as injunctions and damages when patent rights are infringed. However, patent infringement litigations significantly inhibit the defendant micro and small-sized companies' innovation performance at different levels and even after winning they can only engage in short-term breakthrough innovation (Deng et al., 2024).

The citizens continuous information and the improvement on the efficiency of intellectual property rights protection are crucial to combat falsification of products or piracy.
The recommendations of Portuguese Patents Agency (INPI) for efficient innovation management are (Dominguez):

- very good knowledge of interested parties on patents system and his function;
- continuous training of researchers on intellectual property;
- efficient management of patents documents database to avoid duplication of protection;
- continuous alertness of innovation and inventions in technologies;
- adequate protection of partial and final results in research and innovation projects;
- seeking professional advice on patents and IP rights for innovation administrative management.

Case Study - Electrocardiograph

Electrocardiogram (abbreviated ECG or EKG) is one of the simplest and fasted tests used for heart function assessment and the most used diagnostic tool for identification of cardiovascular diseases. The abbreviation EKG comes from German term *Elektro-*

KardioGraphie and ECG is from English *Electro-CardioGraphy*. The apparatus that enables electrocardiogram recording is named electrocardiograph. There are currently a multitude of different ECG devices, differing in their capacity of recording changes in features of ECG or in their purpose (i.e., in hospital patient heart activity monitoring; in home patient heart monitoring; remote patient health monitoring; wellness or fitness). The information on discovery, the progress in technologies and role of innovation and patent protection related to electrocardiograph can help for understanding important issues related to innovation and intellectual property, mainly patent protection in Digital Health ecosystem.

Who discovered/invented the electrocardiograph?

In many teaching materials or scientific articles, Willem Einthoven is presented as inventor of electrocardiograph receiving for this invention Nobel Prize. However, the Nobel Prize for Physiology or Medicine in 1924 was awarded to Willem Einthoven "*for his discovery of the mechanism of the electrocardiogram*" (NobelPrize.org. The Nobel Prize in Physiology or Medicine 1924). The Nobel Prize for Physiology or Medicine award in each year the person/people that made "*discovery of major importance in life science or medicine. Discoveries that have changed the scientific paradigm and are of great benefit for humankind are awarded the prize, whereas life time achievements or scientific leadership cannot be considered for the Nobel Prize*" (NobelPrize.org. Nomination and selection of medicine laureates).

The contribution of W. Einthoven to the development of electrocardiogram apparatus was highlighted in speech delivered by Professor J.E. Johansson, Chairman of the Nobel Committee for Physiology or Medicine of the Royal Caroline Institute, at Nobel Prize award ceremony (NobelPrize.org. Award ceremony speech):

"*To construct a self-registering measuring instrument which records directly and truly the potential variations of this order of magnitude was a problem which Einthoven has solved with his string galvanometer (1903). In constructing this, he started from the well-known Deprez-d'Arsonval «moving-coil galvanometer» and had herein replaced the moving parts – coil and mirror – with a fine, silver-plated quartz wire, which was stretched in the field between the poles of the magnet and at the same time between an optical illumination system, and another one for projection. The reduction in mass of the moving parts, achieved in this way, allows at the same time high sensitivity and short adjustment time.*"

The above information suggests that W. Einthoven may be considered as the inventor of electrocardiograph – an apparatus/device that records the electrical activity of the heart. Detailed history of electrocardiography could be found in many publications (e.g., Fish, 2000; Grob, 2006; Rivera-Ruiz et al., 2008; AlGhtrif & Lindsay, 2012; Cadogan, 2025).

Willem Einthoven (1860-1927) a Dutch physician and physiologist was professor and researcher at Leinden University, Netherland (from 1886). The term 'electro-

kardiogrammem' (the German term for electrocardiogram) was presented by W. Einthoven at a meeting of the Dutch Medical Association in 1893 (Einthoven, 1893) and in a research article in 1985 (Einthoven, 1985). However, the term was not entirely new at that time. In 1887 physiologist Augustus D. Waller published the term "electrogram" and "cardiograph" (Waller, 1887) and a year later the term "cardiogram" that was registered with Lippmann's capillary electrometer (an equipment invented by Gabriel Lippmann in 1872 and published in his doctoral thesis from 1873) (Burche & DePasquale, 1964). August D. Waller made several demonstrations of recording electrical activity of the heart with Lippmann's capillary electrometer (e.g., at St. Mary's Hospital, London and at Basel International Physiological Congress) (Cadogan, 2025; Burche & DePasquale, 1964) in which he used his dog 'Jimmy' that stood with paws in glass jars of saline (a copyrighted image of a demonstration to the Royal Society by Waller's pet bulldog 'Jimmy' is Illustrated in London News, May 22nd 1909, which could be found at British Newspaper Archives www.britishnewspaperarchive.co.uk).

W. Einthoven decided to initiate research on heart electrical activity after participating at a A.D. Waller demonstration of cardiography with Lipmann's capillary electrometer, in the first International Physiological Congress in Basel in 1889 (Grob, 2006). Lippmann's capillary electrometer, is a device able to detect small changes in voltage (to within 0.1 mV). It consists of a tube, open at both end, which have the lower end very thin (approximately 50 micrometres). The tube is filled with mercury and the capillary point of tube is immersed in dilute sulphuric acid of other tube with larger diameter that has at bottom mercury. A platinum wire is put into connection with the mercury in each tube. An applied voltage produces electrical polarization of mercury surface, changing its "capillary constant" (Stock, 2004) that can be observed at level of capillary tube by using a microscope (Sella, 2015). Einthoven performed experiments with Lipmann's capillary electrometer and with the Jacques D'Arsonval and Marcel Deprez galvanometer (Arsonval &Deprez, 1882; Nature, 1884) and the William Thomson galvanometer (Trainer, 2004) (later named Lord Kelvin that invented the "mirror galvanometer" patented in 1858) (Grob, 2006). He made experiments with two galvanometer in order to detect with higher velocity the changes in electrical activity of heart, as was evidence at that time from different research data (Marey, 1876; Burdon Sanderson, 1878; Burdon Sanderson & Page, 1884; Burch, 1890; Bayliss & Starling, 1891; Bayliss et al., 1892) that column of mercury from capillary electrometer would not react quickly enough to the actual time process of the potential changes in the heart muscle during heart beat. "*The standard principle of the galvanometer recording is that when current flows toward the positive electrode of the bipolar lead it generates a signal with positive deflection from isoelectric line, whereas when it flows away it inscribes a negative deflection under the isoelectric line.*" (Padeletti et al., 2019). Observing the differences between the signals obtained with capillary electrometer and galvanometers and with the help of Hendrik A. Lorentz (1853–1928), the

well known nowadays Leiden professor of physics * W. Einthoven estimated the real shape (as is known nowadays) of individual electrocardiogram. Based on adaptation of Clement Arder string galvanometer (invented in 1897) he develops his instrument for recording cardiac electric activity and firstly published in a scientific article the recorded electrocardiogram with string galvanometer in 1903 (Einthoven, 1903). At Chelsea Clinical Society on March 19th, 1912, Einthoven described different features of electrocardiogram and outlined his schema of the equilateral triangle (Einthoven triangle) formed by his standard leads I, II and III (Cadogan, 2025). The Einthoven triangle reflect the spatial orientation of the heart's electrical axis – an important parameter for identification of abnormalities in electrocardiogram associated to different heart diseases as well as the incorrect placement of leads.

The first document published on his string galvanometer (that contains only several physical characteristics of equipment and schematic drawings) was in 1901 (Einthoven, 1901).

Note:

* H Lorentz was awarded by Nobel Prize in Physics 1902 for his research into the influence of magnetism upon radiation phenomena; he describe the Lorentz force – a force exerted on a charged particle by electric and magnetic fields.

In that document he mentioned in a footnote "*Mr. Ader has already built an instrument with a wires stretched between poles of a magnet. It was a telegraph receiver"* (Einthoven, 1901).
The more detailed description of string galvanometer that he coined Saitengalvanometer (the German for string galvanometer) and the registered electrocardiogram with this instrument was presented in 1903 (Einthoven, 1903).

The first document on the electrocardiogram obtained with Einthoven galvanometer was published in 1902 in a commemorative book for the Dutch Professor S. S. Rosenstein (1831–1906) (Einthoven, 1902). In his presentation at Chelsea Clinical Society (1912) he acknowledged the contribution of Augustus D. Waller and Thomas Lewis to the knowledge of electrocardiogram *"It gives me an especial pleasure to bring to remembrance here that the human EKG was first recorded by a London physiologist, Augustus D. Waller, who also introduced the term "electrocardiogram" into science; and that Dr. Thomas Lewis, whose extensive researches have been crowned with such exceptional success, was the first man in England who applied electrocardiography to clinical investigations."* (Einthoven,

1912; Cadogan, 2015). The key inventions that contributed to the development of the Einthoven galvanometer is presented in Figure 1.

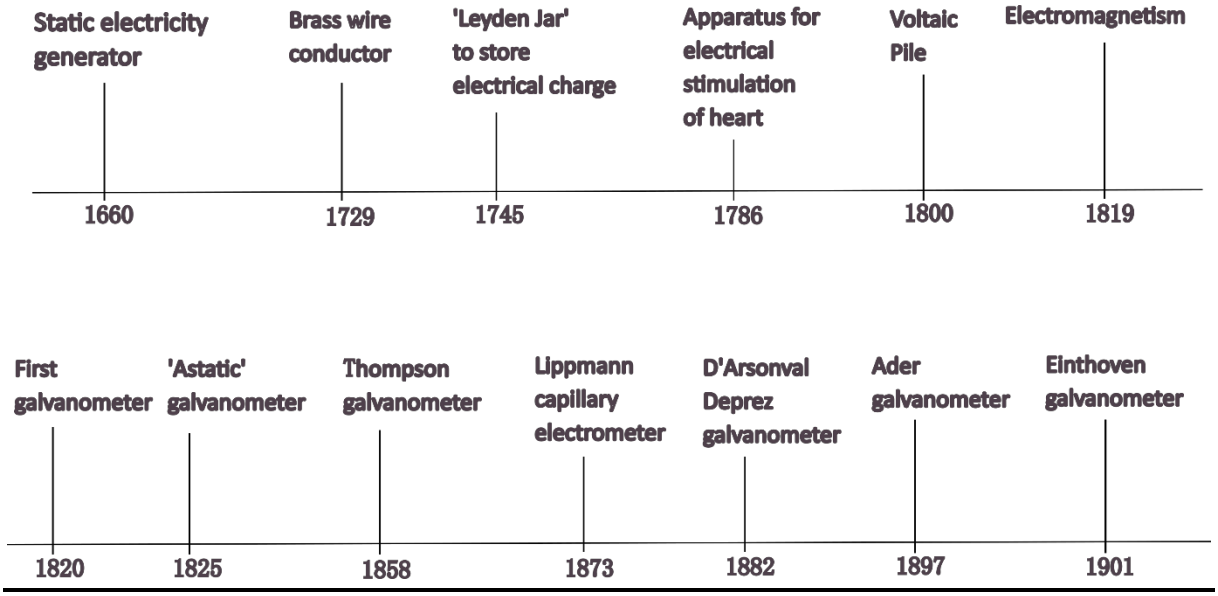

Figure 2. **Evolution of technologies that contribute to Einthoven galvanometer invention**

1660 – Otto Von Guericke invented static electricity generator; 1729 – Stephen Grey invented brass wire conductor; 1745 – Pieter van Musschenbrock, Ewald Georg von Kliest of Pomerania invented 'Leyden Jar' an apparatus for electrical charge storing; 1786 – Luigi Galvani (Galvani name was used for naming galvanometer) develop an apparatus for electrical stimulation of heart, nerve and muscles for experiments with frogs; 1800 - Alessandro Volta invented voltaic pile; 1819 – Andre Marie Ampere described the electromagnetism; 1820 – Johann Schweigger invented first galvanometer; 1825 – Leopoldo Nobili invented 'astatic galvanometer'; 1858 – William Thompson invented "mirror galvanometer"; 1873 – Gabriel Lippmann invented Lippmann capillary electrometer; 1882 – Jacques D'Arsonval and Marcel Deprez invented D'Arsonval - Deprez galvanometer; 1897 – Clement Ader invented string galvanometer; 1901 – Einthoven invented Einthoven galvanometer.

Soon after having knowledge on "electrogram" recorded by A.D. Waller W. Einthoven had the intuition that it would have great importance in future physiological studies, and his focus was on turning this tool efficient and largely utilized for electrophysiological research. His first research was on estimation of real electrical signal of heart trough experiments with Lippmann's capillary electrometer and galvanometer and by mathematical modelling of electrocardiogram (Einthoven, 1895), then he adapted string galvanometer to increase sensitivity of recording electrocardiogram (Einthoven, 1903) and by analysing different human ECG features obtained with electrodes positioned in different body parts he introduce the standard lead I, II and III and Einthoven triangle that is utilized to estimate heart electrical axis (Einthoven, 1912), and not less important he put a lot of effort to convince a number of instrument makers for the production of his

galvanometer as he expected that this instrument would support research of all kinds of electrical phenomena, such as retina, nerve or muscle function (Grob, 2006). Data from his correspondence has shown that W. Einthoven contacted several instrument makers from Netherland (Nederlandse Instrumenten Fabrick; P.J. Kipp en Zonen J.W. Giltay Opvolger), Germany (Max Edelmann), and United Kingdom (Cambridge Scientific Instruments Company) (Grob, 2006). In 1905 he assigned an agreement with Cambridge Scientific Instruments Company (that functioned until 1919) and with Max Edelmann (the agreement was cancelled unilaterally by Edelmann in 1907) for production and commercialization of the instrument holding his name and to receive 10% of every galvanometer sold (Grob, 2006). The first string galvanometer electrograph was sold by Cambridge Scientific Instruments Company (CSI) to a physiological laboratory from Sheffield in 1905. During W. Einthoven collaboration with CSI various improvements in the apparatus were introduced by technical engineers William DuBois Duddel and Bernard A. Robinson (i.e., the lighter and smaller design; smaller electromagnet that generate less heat; a new string carrier; a silver plated glass fibres instead of the quartz fibres) (Grob, 2006). Max Edelmann (that after 1907 had sold string galvanometer with his name instead of W. Einthoven) also made changes to the instrument (the electromagnet was replaced with a permanent magnet that reduced the weight and size of the instrument) (Grob, 2006). The first string galvanometer for cardiography that was sold in United States was a Max Edelmann equipment, in 1909 to Mt. Sinai Hospital, New York and was used by Dr. Alfred Cohn (Fish, 2000; Burnett, 1985). The instruments sold in United State were used both in physiological and clinical studies and contributed for development of cardiology as a medical specialization. The string galvanometer made a great contribution in clinical studies and affirmed the importance of ECG for heart diseases diagnosis. Great impact had the monograph written in 1911 by Thomas Lewis on "*The Mechanism and Graphic Registration of the Heartbeat*" (Lewis, 1911)] and his 10 000 ECG collected from soldiers during First World War (1916-1918) at the Military Heart Hospital in London (Grob, 2006). This research had underscored the relation between electrocardiogram features and heart dysfunctions and the importance of ECG tests in heart diseases diagnosis.

Considering the current information on background art related to W. Einthoven research and information on innovation in Digital Health and Intellectual Property, reflection on several questions is necessary.

Each question may bring clarity and insight into the content presented in the Guide for Digital Health Innovation.

- **Was the W. Einthoven inventor or innovator?**
- **Where could W. Einthoven have applied for a patent?**

- **What were the incentives for innovation in electrocardiography for W. Einthoven, Cambridge Scientific Instruments and Siemens Companies?**
- **If W. Einthoven had applied for a patent, could he have obtained protection for his invention?**
- **What about innovation in electrocardiography in the last 120 years?**
- **What about innovation related to the use of electrocardiography?**
- **What about patent infringement related electrocardiography?**

Was the W. Einthoven inventor or innovator?

Considering the definition of an inventor "*someone who designs or creates something that did not exist before*" (Cambridge Academic Content Dictionary) the literature search for apparatus that records electrical signals from heart, before W. Einthoven published his data, is required to understand if was **inventor** or **innovator** (check for definition of inventor and innovator in (Innovation4EU).

- What he invented?
- What he innovates?

Where could W. Einthoven have applied for a patent?

Up to 1910 no law on patents was in Netherland (Grob, 2006). However, patent protection of invention was in France, Germany, United Kingdom, United State. It is not clear why W. Einthoven not applied for a patent considering his knowledge of instrument makers from those countries, as is reflected in his correspondence that is preserved in the Einthoven archives, which are kept at the Museum Boerhaave (Grob, 2006). The analysis of the information provided in the paper "*Willem Einthoven and the Development of the String Galvanometer. How an Instrument Escaped the Laboratory*" (Grob, 2006) could support reflection on the following questions:

- Why could W. Einthoven have applied in Germany for a patent?
- Why could W. Einthoven have applied in United Kingdom for a patent?

What were the incentives for innovation in electrocardiography for W. Einthoven, Cambridge Scientific Instruments and Siemens Companies?

Part of the information on the incentives for innovation in electrocardiography for W. Einthoven, Cambridge Scientific Instruments and Siemens Companies could be also found in the paper "*Willem Einthoven and the Development of the String Galvanometer. How an Instrument Escaped the Laboratory*" (Grob, 2006). In addition, by following the patents related to electrocardiography owned by Cambridge Scientific Instruments and Siemens Companies presented in Annex II of this Guide for Innovation in Digital Health, and analysing the history of products developed by Cambridge Scientific Instruments ** and Siemens *** the answer for this complicated question (i.e., considering various theoretical and practical issues related to incentive for innovation) shall be organised by responding at the questions:

Note:

**see Cattermole, M.J.G. (1989). *The early history of the Cambridge Scientific Instruments Company: 1878-1968*. In Sixteenth I.E.E. Week-End Meeting on the History of Electrical Engineering, at Twickenhaun, UK, 1-8; and Connelly, C., Chang, H. (2019). *Galvanometers and the many lives of scientific instruments*. In: Nall, J., Taub, L., Willmoth, F., eds. The Whipple Museum of the History of Science: Objects and Investigations, to Celebrate the 75th Anniversary of R. S. Whipple's Gift to the University of Cambridge. Cambridge University Press, 159-186)

***see Siemens. History and Heritage. *Siemens - a technology company since 1847.* https://www.siemens.com/global/en/company/about/history.html; and Britannica Money. *Siemens AG. German company*. https://www.britannica.com/money/Siemens-AG

- What was the expectative of the W. Einthoven when he developed string galvanometer?
- What was the research environment that promoted electrocardiography innovation in the W. Einthoven lab and in Europe health and research systems?
- What contributes for innovation in electrocardiography in Cambridge Scientific Instruments Company? Trained people, competitive environment, marketing, financial investment – **what** and **how** they contribute?
- What contributes for innovation in electrocardiography in Siemens Company? Trained people, competitive environment, marketing, financial investment – **what** and **how** they contribute?

If W. Einthoven had applied for a patent, could he have obtained protection for his invention?

Thinking on a hypothetical application for a patent by W. Einthoven in 1903:

- What could he claim for invention protection? The string galvanometer, the component(s) of string galvanometer, the operational process of electrocardiography, the mechanisms of electrocardiogram or the utilization of string galvanometry for electrophysiological studies?
- What about novelty requirement in this hypothetical patent?
- What about inventive step requirement in this hypothetical patent?

What about innovation in electrocardiography in the last 120 years?

Nowadays, most of electrocardiograph producers or ECG service providers are from United State. However, there are also many companies in Europe that produce or provide services related ECG.

Examples of European trade mark of ECG equipment or software for ECG analysis for hospital, existing in 2024 (in alphabetic order) are: *Aktiia,* Switzerland; *Cardiologs*, France; *Cardiolyse*, Finland; *Cardiomatics*, Poland; *CathVisio*n, Denmark; *ECG-Excelence*, Netherlands; *FibriCheck*, Belgium; *FineHeart*, France; *Happitech*, Netherlands; *Hato*

Medical Technologies, Denmark; *Idoven*, Spain; *Implicity*, France; *my mHealth*, United Kingdom; *OneProjects*, Ireland; *Philips*, Netherlands; *Sky Lab*, Norway; *Shift Bioscience*, United Kingdom; *Ultromics*, United Kingdom; *Volta Medical*, France; *XOresearch*, Latvia. Examples of ECG trade mark for in home or personal use are: *Omrom*, United States, *AliveCor KardiaMobile*, U.S.A.; *FitBit*, United State; *Huawei*, China; *Samsung*, South Korea; *Apple Watch*, United State.

As could be observed from Figure 1. the progress in ECG technology was mainly towards miniaturization of the equipment.

The ECG equipment sold by Cambridge Science Instruments between 1930-1940 was significantly smaller than Einthoven galvanometer (an image of the Einthoven galvanometer was published in 1906 paper (Einthoven, 1906)). The Einthoven electrocardiograph weighted about 270 Kilogram. By 1930 the weight of ECG equipment was reduced at about 14 Kilogram (the approximatively the weight of nowadays ECG workstation). Some integrated analog front end for ECG acquisition have currently dimensions of millimetres and weight a few grams. A technology that mainly contributed for reduction of ECG dimension and weight was electronic vacuum tube amplifiers (invention from 1906 of Lee De Forest). The amplifier technology was introduced in electrocardiograph devices since 1920. The capacity of electrocardiograph to communicate data at other location than that of examined person was explored by Einthoven (Grob, 2006) but first ECG equipment able to broadcast the electrocardiogram was developed by Norman J. Holter by attaching a radio transmitter and charging ECG equipment with batteries.

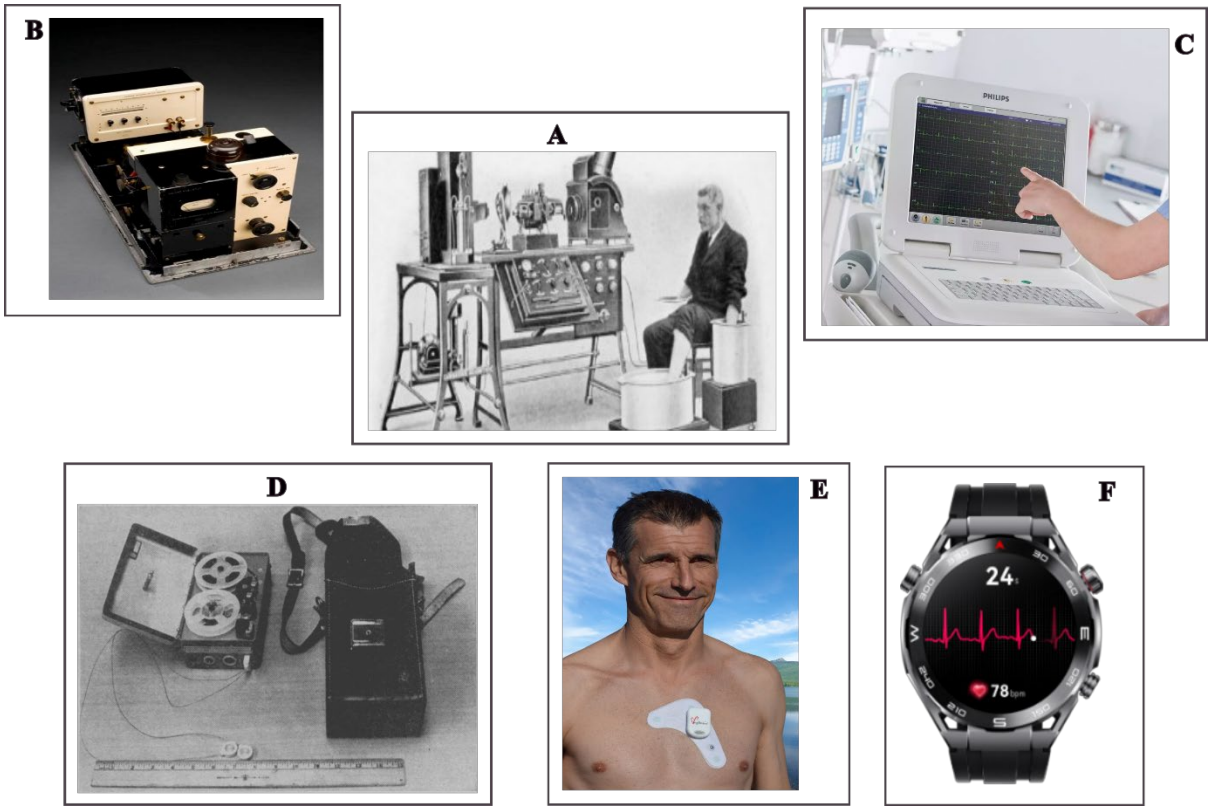

Figure 3. **Evolution of Electrocardiograph' technology.**

A - Photo with W. Einthoven recording electrocardiogram with his string galvanometer (1912). Source: Burche & DePasquale, 1964; B - Portable electrocardiograph produced by Cambridge Scientific Instrument. Source: Science Museum Group; C - Philips ECG workstation. Source: Philips; D - Holter, 1965. Source: Corday et al., 1965; E - myPatch®sl Holter monitor. Source: DMS Service LLC; F - Huawei Watch with ECG app. Source: Huawei.

The portable ECG equipment able to communicate remotely electrocardiogram signal is currently named Holter. The first Holter that was developed in 1949 weighted 38 Kilogram. Nowadays, the majority of Holter has the size of centimetres. The wearable ECG technology (ECG device attached to a chest belt, clothes, a patch or wristwatch) had great development in the last decade. For instance, in 2010 a U.S. patent was granted for the wireless device CardioBip (developed by NewCardio) that record and transmit synthesized, accurate 12-lead ECGs at physician prescribed intervals of time, during ordinary daily activity of monitored person or when ischemic heart symptoms or atrial dysfunction develop. Small ECG device is included in pacemakers' technology (a device that helps the heartbeat in a regular rhythm). The dimension of a pacemaker is nowadays in some company product "about the size of a large vitamin capsule" (see Medtronic Micra pacemaker). Several other inventions were related to electrodes for ECG (see patents from Annex II). Technologies for processing electrocardiogram for heart rate variability (HRV) estimation have also a great importance in turning electrocardiograph in one of the

most used diagnostic tests for different heart and body diseases. Nowadays inventions are mainly related to integration of Artificial Intelligence (AI) technology in processing and communication of ECG data.

Important progress in ECG technology was produced from 1900 to 1960. There are several public and private patents database, where may be found the patents related to ECG, the database services differing by services they provide (see Annex III. Example of Patents Database). In Annex II is presented a list of patents related to ECG selected from European Patent Office database - Espacenet (Espacenet, https://worldwide.espacenet.com) considering the period 1900-1960. Espacenet had retrieved a list of 163 patents related to electrocardiograph from which 84 are presented in Annex II, 28 having the name Electrocardiograph. By analysis of the listed patents from Annex II, related to electrocardiograph a reflection on the following questions is required:

- Why the first patent related to electrocardiograph that was listed in European database was a patent applied by Siemens? What was the relation of W. Einthoven with this instruments maker? (see Grob, 2006).
- When Cambridge Scientific Instruments obtained protection for a patent related to ECG?
- Why many of the listed patents are named Electrocardiograph if a requirement of a patent is to be something new?
- From the listed names of patents what are the three countries with the larger number of ECG related patents?
- From the listed name of patents in Annex II what are the three invention that are more relevant today?

What about innovation related to the use of electrocardiography?

Nowadays, there are electrocardiograph equipment for hospital use (i.e., for in hospital diagnosis of heart disease, for monitoring critical ill patients, for implant ECG, for ambulatory monitoring of patients, for remote monitoring and treatment of patients) or for in home or personal use (i.e., portable or wearable technologies for ambulatory treatment, for ambient assisted living, for fitness). Heart rate variability technology that supports the detection and monitoring of the autonomic nervous control of the heart and also for characterization of several diseases evolution is affirmed each day as a great tool both for clinicians as well as for other professionals (e.g., psychologists, sportive) or general population (e.g., use of HRV for evaluation of body stress). The integration of Artificial Intelligence (AI) technology in processing and communication of ECG data support development of precision medicine and fitness technologies. Philips introduced in July 2025, the ECG AI Marketplace a platform that support health care professionals to find in one place the vendors of AI products/services related to ECG. It may help clinicians to enhance their capacity to use ECG as diagnostic tool.

It is helpful for understanding the progress in ECG technology reflection on:

- What are some examples of innovation related to ECG use for improvement in health care for old people?
- What are some examples of contribution of Artificial Intelligence technology for ECG use in clinical or wellness setting?

What about patent infringement related electrocardiography?

"As the framework surrounding emerging technology and intellectual property continues to develop, with courts and regulators seeking to balance innovation and competition, it is more important than ever that technology companies and relevant stakeholders pay close attention to this evolving legal landscape." (Williamson, 2024)

The most disseminated information on ECG patent infringement is related to Apple and AliveCor dispute. Information on this dispute may be found at AppleInsider platform (AppleInsider by Owen, 2023; AppleInsider by Neely, 2025) and Williamson J paper (Williamson, 2024).

Searching for more information that is provided in the following text, on the dispute between Apple and AliveCor over ECG patents:

"In 2020, AliveCor claimed that Apple infringed on its intellectual property by using patented information when creating the AFib detection feature in Apple Watch Series 4 and onward. Just a few months later, AliveCor sought out an Apple Watch ban.

In 2022, the US Patent Office's Trial and Appeals Board sided with Apple, claiming the company did not infringe on AliveCor's patents. However, shortly after, an ITC judge sided with AliveCor, recommending that the ITC conduct a full review of the case.

When the ITC found Apple guilty of patent infringement in December 2022, it imposed a Limited Exclusion Order on Apple. The order would set a $2.00 bond per infringing Apple Watch imported or sold during the Presidential review period." (AppleInsider by Neely, 2025).

Reflect on questions:

- Was an injunction order in the dispute AliveCor-Apple Watch and what type of injunction? (see type of injunction (Juristopedia by Brinkley))
- What about objectivity/subjectivity of Person/People Skill in the Art involved in the patents dispute?
- What the importance of details in the invention description and patents claims to prevent patent infringement?
- What are the steps in the process of proving patent infringement?
- What are the modalities that you know for management of intellectual property from one company or organization or centre having or not research activity?

- What example(s) you know of the activity of the knowledge transfer or intellectual property management department from an institution?

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Annex I - Intellectual Property – Glossary

Majority of terms are from European Patents Office Glossary.

Applicant - is the individual or the company who files an application for registration of an IP right (e.g., a trademark, a patent or a design) with the relevant IP office. The applicant will become the owner of the IP right once it is registered upon the conclusion of the application process.

Blocking Patents - patent applications which are strategically used as a barrier to pre-empt rivals from getting their patents granted and entering markets and technologies.

Brand - identifies a specific product or name of a company as a sign of quality recognised by customers. A brand can be a trademark if registered, but can also exist without being a trademark.

Certification Mark - (also called guarantee mark) is a trademark capable of distinguishing goods or services which have been certified by the owner as meeting certain requirements for certification. Unlike collective marks no membership to an association is necessary and all that is required is compliance with the standards in respect of material, mode of manufacture, quality or other characteristics set by the owner of the mark. A certification mark may not be owned by a natural or legal person currently engaged in the supply of goods or services which the trademark seeks to certify.

Collective Mark - is a trademark capable of distinguishing the goods or services of the members of an association from those of undertakings external to the association. The trademark is owned by the association which must ensure that the standards required for its use are respected by all its members who use the mark in the course of trade.

Circumvention Devices - are primarily designed, produced or adapted for the purpose of enabling or facilitating the circumvention of technical measures that prevent unauthorised copying or restrict unauthorised access to copyright works.

Computer-Implemented Invention (CII) - is an invention which involves the use of a computer, computer network or other programmable apparatus, where one or more features are realised wholly or partly by means of a computer program.

Confidential Information - is information of a confidential nature that may include information of a personal, scientific, industrial, business, or commercial nature, that is not available to the public.

Confidentiality Agreement - also known as non-disclosure agreement (NDA), refers to the written agreement that parties use when they wish to disclose information and ideas in confidence. This agreement therefore establishes the obligation of the recipient (i.e. the legal person to whom the information is disclosed) to not disclose the information and

ideas to third parties. A confidentiality agreement is crucial for an inventor or any other party that needs to protect confidential information.

Copyright - is the legal right granted to an author, composer, playwright, publisher or distributor to the exclusive publication, production, sale, or distribution of a literary, musical, dramatic, or artistic work.

Counterfeiting - a practice of intentional imitation of a genuine article and selling it under a genuine article's brand name without the brand owner's authorization with the intent to take advantage of the superior value of the imitated product.

Customs Actions - are the measures taken by customs authorities against counterfeiting and piracy when goods suspected of infringing intellectual property rights are entering a customs territory in the EU. Such measures can be taken on the authorities' own initiative or upon explicit request from a right holder. When goods suspected of infringing its intellectual property rights enter the territory of a Member State, the right holder may file an application for action at the relevant customs authorities. Customs actions are an important instrument for the enforcement of IP rights.

Database - a collection of independent components (information, works, data or other materials) arranged in a methodical or systematic way and according to specific criteria, and made individually accessible by electronic or other means. Under EU law, the cumulative protection of databases is possible under copyright (if the arrangement of data meets the conditions of originality and creativity) and more broadly, under a sui generis right (provided that the arrangement of data has involved a qualitatively or quantitatively substantial investment).

Disclosure - The first public disclosure of details of an invention. If the disclosure is made before the patent application has been filed (in a deliberate form or otherwise), the invention will in most cases be unpatentable. In return for a patent granted (exclusive rights for a limited time period), the applicant must make a full disclosure of the invention for which protection has been solicited.

Domain Names - A combination of typographical characters corresponding to one or several numeric IP addresses which is registered with an accredited Registrar and used to identify a particular website on the internet. Each domain name consists of two parts: a top-level domain (TLD – .com, .net, .org, .eu) and a second level domain, which represents the entity that owns the domain name. Although a domain name is unique and may be a valuable commercial asset, a domain name registration is not an intellectual property right.

Economic Rights - are a set of exclusive rights granted to a copyright owner (to authorize the reproduction, distribution and communication of a work to the public), which allow the owner of these rights to derive financial reward(s) from the use of his works by others. These rights may be transferred or licensed, usually for a sum of money or royalties depending on the proposed usage of the work.

Enforcement (IP Enforcement) - legal actions, remedies, measures and procedures taken against IPR infringement. This includes, among others, stopping unauthorized use, deterring future infringements, and obtaining recovery for damages resulting from the infringing act.

European Patent - is obtained by presenting a single application and following a European centralized procedure in the EPO, where a patent granted turns into a bundle of as many national patents as countries chosen in the application. The holder of this patent is conferred the same rights as would be conferred to a patent granted in the respective countries designated in the application.

European Patent Office (EPO) - The European Patent Office (a regional patents office) was created by the European Patent Convention (EPC) to grant European patents, based on a centralized examination procedure.

European Union Trademark - is a trademark which is registered at the EUIPO in accordance with the conditions contained in Regulation 2017/1001 on the European Union trademark, as a result of which protection is obtained in the whole territory of the European Union.

Exclusive License Agreement - is a contract licensing intellectual property to another party for its exclusive use and/or economic benefit.

Filing Date (patents) - is the date at which all necessary requirements for filing of a patent application have been complied with. In case of multiple applications for one same patent in several country the filing date of the first application will also act as the priority date.

Harmonised Database - is a multilingual database of descriptions of goods and services that have been agreed to be acceptable classification terms by the EUIPO and national IP offices in the EU, used when applying for a trademark.

Industrial Applicability - is one of the three basic patentability requirements under the European Patent Convention. An invention will be considered capable of industrial application if it can be made or used in any kind of industry. This requirement is to be understood in a broad sense: it includes for instance applications in the agricultural field. See also: Inventive step and Novelty.

Industrial Design - is an intellectual property right aimed at protecting the appearance of products, in particular resulting from its lines, contours, colours, shape and materials. It consists of the right to prevent any third party from making, offering, selling, importing, exporting or using a product in which the design is incorporated or to which it is applied, or stocking such a product, without the design owner's consent, when such acts are undertaken for commercial purposes.

Infringement - a violation or infraction of the terms of an agreement, encroachment, trespass, or disregard of others' rights. Intellectual property infringement will refer to a breach of rights resulting from a patent, copyright, database right, performer right, design, trademark, etc.

Injunction - An injunction is a court order that compels or restrains an individual, entity, or government body from taking specific actions, often issued to prevent irreparable harm or enforce legal rights. It is a remedy in the form of a command instead of monetary relief. They are typically sought when monetary compensation isn't deemed sufficient to remedy the harm. (Juristopedia by Brinkley)

Innovation Action - in Horizon 2020, refers to an action primarily consisting of activities directly aimed at producing plans and arrangements or designs for new, altered or

improved products, processes or services. For this purpose, they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

Intellectual Property (IP) - refers to the creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

Intellectual Property Rights (IPRs) - are private legal rights that protect the creation of the human mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. They are commonly divided into two categories: Industrial Property Rights (e.g. patents, trademarks, industrial designs, geographical indications) and Copyright and Related rights (e.g. rights of the authors/creators and those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programmes).

Intellectual Property law protects a content-creator's interest in their ideas by assigning and enforcing legal rights to produce and control physical instantiations of those ideas. (Stanford Encyclopedia of Philosophy, 2022)

International Patent Application - is a patent application filed through the Patent Cooperation Treaty.

Inventive Step - is one of the three basic patentability requirements under the European Patent Convention. It means that an invention must be non-obvious to a person skilled in the field, having regard to the state of the art, in order to be patentable. See also: Industrial applicability and Novelty.

Inventorship - the quality or state of being an inventor (a person who conceived an invention). In order to be considered as an inventor it is generally acknowledged that a certain level of contribution to the development of the creative elements of an invention (technical creativity) must be met. Inventors are always entitled to be designated on the patent, regardless of who files the application. An inventor is not necessarily always the owner of the rights in his invention, as the rights to patent grant might have been assigned to a different subject.

IP Due Diligence - Intended as the exercise to gather as much information as possible on the value and the risks of a company's intangible assets, with a view to acquiring IP, raising capital and seeking financial assistance (e.g. bank loans). Although IP due diligence is a precondition for any capital investment, it can be helpful for enforcing IP rights and reducing the IP-related costs as well. In a few words, IP due diligence can be considered as an essential process when developing an IP strategy.

Know-How - means a package of non-patented practical information (of a technical, commercial, administrative, financial or other nature), resulting from experience and testing, which is secret, substantial and identifiable.

License Agreement - The contract under which the owner of an intellectual property right ('licensor') gives permission to another individual or entity ('licensee') to use this right for a period of time and within a defined territory. Without such permission, this use would infringe patent or trademark rights. Therefore, the license can allow the licensee to legitimately use, sell, offer to sell, and import the invention protected by intellectual property rights (in this case, by patent). In return, in the majority of cases, the licensor

receives royalty payments. Signing a license agreement does not transfer the ownership of the invention to the licensee.

Likelihood of confusion - is a concept, which will be applied in a situation of trade mark registration (opposition) or infringement proceedings in order to determine, if an entity's sign is similar to another entity's registered trade mark, identifying similar goods and services and therefore leading the relevant consuming public to believe that these goods and services originate from that other entity.

Locarno Classification - is an international classification system used to classify goods for the registration of industrial designs and is administered by World Intellectual Property Organization (WIPO). This classification is currently used by more than 50 national offices and by organisations such as EUTM and WIPO.

Madrid System - is an international system, managed by the World Intellectual Property Organization (WIPO), for obtaining and maintaining trademark protection in multiple countries with a single application, in one language and under payment of one set of fees.

Material Recipient - the person or legal entity receiving research material under the terms of a material transfer agreement (MTA).

Material Transfer Agreement (MTA) - is a contract governing the transfer of one or more materials, such as tangible research property (TRP), from the owner or authorized licensee to a recipient. This agreement is usually signed for research purposes only. MTAs usually prohibit the recipient from using the transferred materials for commercial purposes or outside of the agreement purposes. Some MTAs state that modifications to the material transferred to the recipient shall be treated as still being property of the provider of the materials. The transfer of physical samples of materials (such as cell lines, plasmids, transgenic animals, chemicals, etc.) does not mean the transfer of ownership of the materials or intellectual property rights.

Nice Classification - is an international classification system for goods and services that is used for the registration of trademarks. The system is administered by WIPO and updated regularly. It currently comprises 45 classes in total: 34 for goods and 11 for services. The Nice Classification is used in around 150 IP offices worldwide, including organisations such as EUIPO and WIPO.

Novelty - is one of the three basic patentability requirements under the European Patent Convention. It means that the invention must not form part of the state of the art, that is, that it must never have been disclosed to the public in any way, anywhere, before the date of filing of the patent application (or before the priority date). See also: Industrial applicability and Inventive step.

Originality - is one of the requirements for copyright protection. The test to determine whether a work will be considered original is to ask if it can be defined as the author's own intellectual creation.

Ownership of IP rights - the state or quality of being an owner of a proprietary right. It enables its holder to exercise exclusive rights of use in relation to the subject matter of the IP and to restrict others from using these IP rights.

Patent - is granted by a government agency which, as a result, grants the recipient intellectual property rights, which confers on its owner the exclusive right to prevent third parties from commercially exploiting - making, using, offering for sale, selling or importing the invention, which is protected by patent for a limited period of time (generally 20 years).

Patent protection - is granted for inventions, which are products or processes, provided that they are new, involve an inventive step and is capable of industrial application. In order to obtain patent protection, technical information about the invention must be disclosed to the public in a patent application.

Patent Attorney - is a professional qualified in a scientific discipline and qualified to act in the obtainment of patent and design registrations.

Patent claim - defines the subject matter and technical features of the invention which are 'claimed' by the applicant/owner for exclusivity. Claims are expected to be short and supported by description section of the patent.

Patent Pool - a portfolio of patents in the same technology domain, generally owned by different parties who agreed to jointly license them.

Patentability - Patentability is the ability of an invention to satisfy the legal requirements for obtaining a patent. The invention must be novel, contain an inventive step (or be non-obvious), be capable of industrial application and not be in certain excluded fields (e.g. scientific theories and mathematical methods, these inventions cannot be patented at the EPO).

Piracy - an unauthorized copying, use, reproduction and/or distribution of materials protected by intellectual property rights for commercial purposes.

Prior Art - is a legal term referring to information previously disclosed to the public in any form (e.g. publications, documents, written articles, devices known, on sale, or used by the public, etc.) and any place (inside the national territory and outside) relating to the invention before its priority date.

Priority Country - is the country where the patent is first filed before being extended to other countries.

Priority Date - Priority date is the first filing date of a patent application, anywhere in the world (normally in the applicant's domestic patent office), to protect an invention. The priority date is used to determine the novelty of the invention, which implies that it is an important concept in patent procedures.

Proprietary Software - refers to any computer software that is owned by an individual or a company and cannot be copied, used, modified or distributed by the others without having permission of its owner; its source code is almost always kept secret.

Public Domain - is referred to when expired exclusive intellectual property right is made available for unrestricted use to the public.

Registered Community Design - is a design registered with the European Union Intellectual Property Office (EUIPO). Throughout the European Union a new design with an individual character can be protected as a registered Community design, valid in all 28 EU Member States, renewable every 5 years up to a maximum of 25 years.

Related Rights (or neighbouring rights) - are rights related to the protection of works of authorship under copyright but are not granted to the author. The purpose of related rights is to protect the legal interests of certain persons and legal entities who contribute to making works available to the public. They include those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs.

Royalty - is a payment made to a right holder for the use of the intellectual property which it owns, such as a patent, trademark, or copyrighted work. Royalties can be freely negotiated but usually constitute a percentage of the revenues obtained by using the owner's right. They are the most used remuneration method in the context of licence agreements.

Spin-off - a new, separate and independent company created from an existing company or organisation. The creation of spin-off is also one of the technology transfer mechanisms through which knowledge and/or intellectual property are transferred and commercially exploited.

Standard Essential Patents (SEPs) - patents on technologies that are comprised in an industry standard and that would be necessarily infringed by implementing standard specifications.

Supplementary Protection Certificate (SPC) - is the extension of the duration of a patent right after its expiration date, applicable to some biologically active agents such as medicinal products. SPCs usually last for a maximum of 5 years; furthermore, the total market exclusivity duration of the patent and the SPC cannot together exceed 15 years. SPCs are justified by the long waiting time for regulatory approval of these products, which delays their introduction on the market.

Technology Transfer - in the terms of the Enterprise Europe Network, it can be described as the successful application and/or adaptation of a technology developed in one organisation to meet the needs of one or more other organisations. The transferred technology shall be innovative for the recipient. A technology transfer not only includes transfer between organisations but also between different industrial sectors. A technology transfer is deemed to have been achieved once a licensing agreement, a joint venture agreement, a manufacturing agreement, and/or a commercial agreement with technical assistance has been signed.

Technology Transfer Agreement - is the assignment of technological intellectual property, developed and generated in one place, to another through legal means such as technology licensing or franchising.

Trade mark - may consist of any signs, in particular words, including personal names, or designs, letter, numerals, colours, the shape of goods or their packaging, or sounds, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings and of being represented clearly and precisely on the register.

Trade Name - a name used to identify a business, as distinguished from a trademark which identifies goods or services as produced or marketed by a particular undertaking. A trade

name does not have to be identical with the corporate/legal name entered in a commercial register.

Trade Secret - refers to information which meets the following requirements: it is secret, meaning that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; it has commercial value because it is secret; and it has been subject to reasonable steps under the circumstances, by the person in control of the information, to keep it secret.

Unitary Patent - is a single European patent with unitary effect for the EU Member States involved in an enhanced cooperation. In order to obtain a unitary effect, patent holders need to request the unitary effect at the European Patent Office (EPO) within one month of the date of publication of the grant of the patent in the European Patent Bulletin. The unitary patent will be a third option for companies or inventors seeking patent protection in Europe in addition to national patents and 'classical' European patents (i.e. without unitary effect).

Unregistered Community Design - is a form of protection for industrial designs fulfilling the conditions of protection – novelty and individual character. The protection lasts for a period of three years and is acquired through the first disclosure or use in trade of a design within the European Union. The Unregistered Community design constitutes a right to prevent the commercial use of the design only if the use results from copying.

Utility Model - is one of the intellectual property rights that protects technical solutions such as an invention, with a lower level of inventiveness required than for a patent. The protection period is shorter than for patents (often 6 to 10 years).

WIPO (World Intellectual Property Organization) - is an agency of the United Nations that functions as a global forum for IP, providing several services including arbitration and mediation (e.g. domain names disputes), international registration systems for patents, trademarks, designs and appellations of origin), policy discussion, technical infrastructure, cooperation programs and information on intellectual property. WIPO administers 26 treaties and occupies a prominent role in the global IP landscape.

Annex II - ECG Patents (1900-1960)

Espacenet: https://worldwide.espacenet.com/

Apparatus for checking electrocardiographs, oscillographs, and the like	1913-04-08	1915-08-24	SIEMENS AG	US1151118A
Facility to prevent interference in the measurement of body currents	1923-07-11	1924-09-10	SIEMENS AG	AT97773B
Portable electrocardiograph		1925-03-17	HORACE EDWARDS NICHOLS	CA247702A
Improvements in or relating to portable electrocardiographs and the like apparatus	1924-07-09	1925-10-09	HORACE EDWARDS NICHOLS	GB240919A
Electrical Indicating instruments	1925-01-15	1931-12-22	HARRY B MARVIN and JOSEPH K LEIBING	US1837913A
Electrocardiograph	1926-09-16	1928-08-21	No applicant available	US1681628A
Interference eliminator for electrocardiographs	1928-07-16	1932-11-15	CLINICAL DEV LAB INC	US1888139A
Apparatus for recording electric currents produced by living organisms	1929-01-12	1931-10-27	ROBERT LUTHI	US1829267A
Device for regulating the sensitivity of electrocardiographs	1930-10-28	1932-11-25	SIEMENS AG	AT130400B
Electrocardiograph	1931-12-15	1932-10-11	R.H. KRUSE	US1882402A
Interlocking control for cardiographs	1933-02-23	1934-10-09	WESTINGHOUSE ELECTRIC & MFG CO	US1976594A
Improvements in or relating to electrocardiographic apparatus	1934-04-12	1936-01-13	COSSOR LTD A C	GB441057A
Electrocardiograph apparatus	1934-11-06	1937-11-09	No applicant available	US2098695A
Improvements in cinematographic apparatus combined with apparatus for recording sound and physiological phenomena	1935-06-04	1937-01-04	OTTO KURT KOLB	GB459714A

Improvements in or relating to devices for oscillographically recording the action voltages of the human hear	1935-08-14	1937-08-04	HANS ERICH HOLLMANN	GB469857A
Device for oscillographically recording the action voltages of the human heart	1935-08-14	1939-03-14	RADIO PATENTS CORP	US2150223A
Apparatus for investigating temporarily variable electrical fields	1936-08-18	1938-04-19	SIEGFRIED HELLER	GB483547A
Improvements in or relating to the production of electro-cardiograms and to electro-cardiographs	1936-08-12	1938-08-19	HANS ERICH HOLLMANN	GB490717A
Improvements in or relating to electro-cardiographs and to the production of electro-cardiograms	1936-10-26	1938-07-07	SIEMENS AG	GB488465A
Electrocardiograph	1936-10-26	1941-01-28	RADIO PATENTS CORP	US2229698A
Electrocardiograph	1936-12-03	1941-11-18	RADIO PATENTS CORP	US2262936A
Improved electrocardiograph	1937-09-13	1939-03-10	EDWARD THOMAS BOTH	GB502072A
Electrocardiograph	1937-10-02	1940-03-12	BOTH ELECTRO CARDIOGRAPH LTD	US2193471A
Electrocardiograph		1940-09-24	BOTH ELECTRO CARDIOGRAPH LTD	CA391472A
Galvanometer	1938-11-26	1942-11-03	No applicant available	US2300497A
Potential recording mechanism	1939-02-17	1941-11-18	No applicant available	US2262958A
Electrode	1941-04-07	1943-05-04	No applicant available	US2318207A
Method and apparatus for conducting electrocardiographic examinations	1942-05-22	1946-05-21	No applicant available	US2400583A
Electrocardiograph	1942-08-27	1948-03-23	GEN ELECTRIC X RAY CORP	US2438341A
Method of and means for treating heart ailments	1943-03-23	1945-01-09	No applicant available	US2366799A
Electrocardiograph	1944-06-02	1946-12-17	ELECTRO PHYSICAL LAB INC	US2412639A

Electrically actuated recording unit	1945-02-03	1950-04-04	WESTERN UNION TELEGRAPH CO	US2502419A
Instantaneous tachometer method and apparatus	1945-03-19	1949-12-27	WATERS CONLEY COMPANY	US2492617A
Device for calculating deviations of the heart axis from electrocardiograms	1945-06-09	1946-11-30	MAVRODIADI V G	SU68734A1
Device for calculating the deviation of the heart axis from the electrocardiogram data	1945-10-19	1946-11-30	GOLDMAN L N	SU68735A1
Electrocardiograph	1946-08-23	1951-10-16	No applicant available	US2571223A
Improvements in electrocardiograms	1946-11-29	1950-03-22	ELECTRO PHYSICAL LAB INC	GB634575A
Electrical recording instrument for electrocardiographs	1946-12-04	1952-03-25	TECHNICON CARDIOGRAPH CORP	US2590554A
Multiple-lead electrocardiographs	1947-07-22	1953-02-03	TECHNICON CARDIOGRAPH CORP	US2627267A
Multiple-lead electrocardiograph recorder	1947-07-22	1953-72-14	TECHNICON CARDIOGRAPH CORP	US2645550A
Electrocardiograph		1948-12-28	ELECTRO PHYSICAL LAB	CA453658A
Electro-cardiograph		1949-09-06	ELECTRO PHYSICAL LAB	CA459473A
Improvements in or relating to electro-cardiographs	1948-02-18	1950-10-18	FORTIPHONE LTD	GB644934A
Direct writing electrocardiograph	1948-04-21	1953-07-21	No applicant available	US2646336A
Electrocardiovectographic device	1948-08-03	1953-11-17	USINES GALLUS SOC	US2659363A
Interference reducing circuit	1948-08-18	1950-03-21	SANBORN COMPANY	US2500994A

German silver electrocardiograph contact electrode	1950-01-10	1952-09-23	No applicant available	US2611368A
Calibrating apparatus, particularly for an electrocardiograph	1950-02-25	1953-05-20	CAMBRIDGE INSTR COMPANY INC	GB691880A
Electrocardiograph	1950-02-25	1953-10-13	CAMBRIDGE INSTR COMPANY INC	US2655425A
Electrocardiograph	1950-03-23	1956-03-20	CAMBRIDGE INSTR COMPANY INC	US2739030A
Electrical recording instrument, particularly for an electrocardiograph	1950-03-23	1953-03-04	CAMBRIDGE INSTR COMPANY INC	GB688235A
Electrocardiograph	1950-05-02	1954-04-13	BURDICK CORP	US2674992A
Electrocardiograph	1950-05-02	1957-01-15	BURDICK CORP	US2777747A
Esophageal switch for electrocardiograph apparatus	1950-05-06	1953-08-04	TECHNICON CARDIOGRAPH CORP	US2647508A
Electrical calibration system	1950-06-16	1953-11-24	SANBORN COMPANY	US2660165A
Improvements in and relating to electro-cardiograph apparatus	1950-06-30	1953-04-08	COSSOR LTD A C	GB690052A
Electrocardiographic electrode	1950-09-19	1952-12-16	No applicant available	US2621657A
Electrocardiograph	1951-06-05	1954-05-18	BURDICK CORP	US2678867A
Electrocardiograph		1953-05-12	J LUKACS	US2638401A
Electrocardiograph electrode	1951-08-10	1953-11-24	No applicant available	US2660175A
Means for detecting and recording electrical changes in the body resultant on its physiological processes	1952-02-16	1954-11-10	CHARLES CLAYTON BREAKELL	GB718131A

Miniature direct-writing electro-cardiograph	1952-07-01	1955-09-20	No applicant available	US2718224A
Spatial vectometer for vectorcardiography	1953-04-03	1955-08-02	No applicant available	US2714380A
Electrocardiographic card mount	1953-10-22	1958-09-23	No applicant available	US2852878A
Record trace identification device	1953-12-24	1957-05-07	ELECTRO PHYSICAL LAB INC	US2791482A
Electrocardiograph		1954-03-30	HOWARD N FAWCETT	US2673559A
Safety ground connection for electrical testing devices	1954-04-08	1957-05-07	ELECTRO PHYSICAL LAB INC	US2791728A
Electrocardiograph	1954-07-23	1958-12-23	BURDICK CORP	US2865366A
Improvements in electric voltage measuring circuit arrangements	1954-08-16	1959-01-14	PHILIPS ELECTRICAL LTD	GB807373A
Improvements in or relating to supersonic wave-impulse cardiographs	1954-09-11	1957-02-13	SIEMENS REINIGER WERKE AG	GB782547A
Apparatus for indicating or recording simultaneously, an ultrasonic impulse cardiogram, and the cardiogram of a cardiograph incorporating an oscillograph loop	1954-09-11	1958-08-20	SIEMENS REINIGER WERKE AG	GB800173A
Recording with audible and visible monitoring	1955-02-28	1958-04-09	CAMBRIDGE INSTR CO INC	US2986606A
Electrocardiograph electrode with absorbent contact surface	1955-10-10	1957-02-26	No applicant available	US2782786A
Recording cardiotachometer	1955-11-30	1960-03-08	AMERICAN CYANAMID CO	US2927573A
Operating arrangement for single-curve electrocardiographs	1956-02-27	1958-01-25	SIEMENS AG	AT195030B
Electrocardiograph		1956-07-10	CAMBRIDGE INSTR COMPANY	CA527576A

Single-channel electrocardiograph	1956-04-07	1956-11-30	PUSHKAREV A A	SU107868A1
Device for large-scale measurement of electrocardiographic waves	1956-07-11	1956-11-30	NIKOLSKIJ B S	SU106474A1
Electrocardiograph		1957-08-20	CAMBRIDGE INSTR COMPANY	CA545074A
Electrocardiograph		1957-08-27	CAMBRIDGE INSTR COMPANY	CA545362A
Adaptation to electrocardiographs of all systems to record the reliable duration of the temporal indicators of the heart's electrical activity and its dynamics	1957-01-30	1957-11-30	SYSOEV V F	SU108847A1
Pad for skin preparation for electrocardiography and the like	1957-08-15	1959-05-19	SANBORN COMPANY	US2887112A
Electrocardiograph electrode	1957-09-13	1959-07-21	No applicant available	US2895479A
Electrocardiograph	1960-03-19	1960-11-30	No applicant available	SU137229A1

Annex III - Database on Patents

European Patent Office – https://worldwide.espacenet.com
World Intellectual Property Organization (WIPO) – PATENTSCOPE Simple Search – https://patentscope.wipo.int/
Portuguese Intellectual Property Agency – www.inpi.justiça.gov.pt
Hellenic Industrial Property Organisation (OBI) – https://www.obi.gr
Finish Intellectual Property (PRH) – www.prh.fi
Deutsches Patent -und Markenamt – https://www.dpma.de
Japanese Patents Agency - www.jpo.go.ip
Thomson Innovation – https://thomsoninnovation.com
Free Patents Online – www.freepatentsonline.com
Google Patents – https://patents.google.com
Patent Lens – www.patentlens.net
PriorSmart:Tracking Patent Documents – https://patentlyo.com
Derwent World Patent Index (DWPI)/Clarivate – https://clarivate.com

Chapter 7. Mobilization for continuous innovation

Innovation in the workplace

Incentive, rewards for innovation

Digital Health ecosystems

Knowledge transfer

Recognizing commercially viable Digital Health solutions

Guidance for putting a Digital Health product/service on market

Annex I - Guide for planning for conformity assessment of a medical device

Annex II - Example of stages for market access in EU

Innovation in the Workplace

Schumpeter (1934) initially posed **innovation as the force behind economic growth**, explaining how new products, processes, markets, sources of supply, and organization forms revolutionize industries. Years later, March (1991) emphasized that innovation involves juggling exploration—experimenting to find new things—and exploitation—**pushing efficiency** and drawing on what already works. Christensen (1997) went on to

apply these principles to the corporate environment, showing how the established firms usually collapse because they ignore **disrupting innovations** when they pop up in niche markets. All these three additions sum up intellectual foundation: innovation is creating systems that **incorporate disruption, enable exploration, and combine purpose and execution**.

In Digital Health, constant innovation cannot rely on single projects or pilot projects. It requires a system where **incentives**, **governance**, **rapid prototyping**, and **regulatory foresight** are continuously integrated into daily operation.

There are factors that help people to innovate and other factors that help to put and scale an innovative product/service in the market.

Human Factors for Innovation

Embracing "human-centred systems" by focusing on the human experiences and perceptions has great importance for products/services innovation in today's rapidly evolving technological landscape (Professional&Executive Development. HARVARD DIVISION OF CONTINUING EDUCATION, 2025). The best firms create an environment for daily innovation endeavour, in which employees view innovation as an ongoing process and not an occasional task or a one-time achievement (Tushman & O'Reilly, 1996). Among various human factors can be mentioned:

- **Intellectual stimulation** (i.e., meaningful discussion around significant challenging issues or ideas, meaningful tasks, freedom to question the status quo) (LEADERONOMICS, 2015);
- **Positive interpersonal cohesion** (i.e., working toward shared goal or objective, or absence of emotional conflict) (LEADERONOMICS, 2015);
- **Perception that learning from error creates opportunity for innovation.** (LEADERONOMICS, 2015);
- **Perception that creativity in doing the work is recognized and rewarded** (Forbes.a.,2025; LEADERONOMICS, 2015);
- **Perception of autonomy in doing the work** (i.e., sense of control over the work and a feeling of responsibility for the final project) (LEADERONOMICS, 2015);
- **Perception that organization is willing to invest the time and money necessary to support innovation and implementation of innovative product/service** (i.e., many innovative product/service are originated from small companies or team although they struggle with tight budget have higher difficulty on investing in new technologies or ideas) (LEADERONOMICS, 2015);
- **Long-term job security** (FasterCapital, 2025).

Organisational Environment for Innovation

To ensure sustainability and resilience leaders of organizations shall build and encourage an innovation culture "*an organizational environment that encourages creativity, experimentation, and continuous improvement. It involves fostering a mindset where employees feel empowered to explore new ideas and take calculated risks without fear of failure.*" (Professional&Executive Development. HARVARD DIVISION OF CONTINUING EDUCATION, 2025). Important roles on environment for innovation in organizations are:

- **Organization mission clarity** (e.g., setting clear, specific goal and model of business compelling innovation) (LEADERONOMICS, 2015);
- **Management practices** (e.g., ISO 56000:2020 Innovation management) may empower employees to suggest improvements and challenge outdated practices. Leaders should demonstrate innovative thinking by encouraging new ideas, being open to change, and ensure appropriate resources, including funds, materials, facilities, and information (Professional&Executive Development. HARVARD DIVISION OF CONTINUING EDUCATION, 2025). Risks evaluation and mitigation play an important role in innovation management. Effectively managing these risks requires companies to identify potential uncertainties, assess their potential impact, and implement strategies to mitigate adverse outcomes. (StartUs Insights). An innovation environment should support employees to learn from failures without fear of retribution (Edmondson, 1999; Professional&Executive Development. HARVARD DIVISION OF CONTINUING EDUCATION, 2025). Studies demonstrate that creativity flourishes in environments where autonomy, mastery, and purpose are dominant, and in which reward is linked to effect as much as (possibly more than) to quantity (Amabile, 1998).
- **Cross functional collaboration between different departments** fuels knowledge sharing and activates collective intelligence. Collaborative workspace enables employees to share ideas, pool resources, and build upon each other's strengths to drive collective success. Creation of cross-functional innovation labs that bring together employees from different departments to collaborate on solving complex challenges may foster creativity and accelerate problem-solving through different specialists' perspective on challenges and solutions, often leading to breakthrough ideas that might not arise in siloed teams (Forbes.a., 2024)
- **Investment in employees training** builds capacity to adjust quickly to new tools, technologies, or industry trends without losing focus or productivity (e.g., Apple University for training their employees). Upskilling through gamification is incorporated in several companies that use game mechanics like points, levels, and rewards, companies encourage employees to develop new skills while enhancing motivation and knowledge retention (Forbes.b., 2024).

- **Reward and recognition of creativity**. Acknowledgement and celebration of innovative efforts, both big and small through formal awards ((e.g., Genesis Grants from 3M, IBM innovation fund to support the best ideas which might emerge during the year), recognition programs, or even a simple thank-you for contributing new ideas (Forbes.a., 2024).
- **Time for creativity**. Ensuring a realistic workload pressure or a time that stands apart from regular duties that enable employees to work on innovative projects or explore new ideas (e.g., Google's "20% time" is an example of allowing employees to spend part of their time on creative endeavors outside of their daily tasks) may also foster innovation (Forbes.a., 2024).
- **Identification, understanding the obstacles, innovation barriers in each workplace and implementation of solutions to overcome these,** is also decisive for creation an efficient environment of innovation at workplace. Barriers in fostering innovation include: superficial adoption of innovation symbols without genuine empowerment; prioritizing short-term gains over long-term strategic priorities; failing to align innovation initiatives with a compelling narrative (Professional&Executive Development. HARVARD DIVISION OF CONTINUING EDUCATION, 2025).

Systematic approach of innovation may ensure that mobilization for innovation in Digital Health is not necessarily improvisation, but rather orderly designed. Incentives, governance, quick prototyping, regulatory preparedness, and people capacity need to converge. Unleashing European assets and linking them with organizational purpose creates innovation from scattered projects into a continuous stream of change.

Incentive, rewards for Innovation

While countries tend to use similar sets of policy instruments to support knowledge transfer, differences exist across countries in terms of value accorded for each type of policy instrument (e.g. in terms of budget or number of initiatives), and in the detailed design or implementation of each policy instrument (e.g., eligibility criteria, monitoring methods). The impact of one instrument depends also on other policies in place in the country (OECD, 2019). The policy for supporting knowledge transfer and it expected outputs in innovations can be ensured by a mix of policy instruments (OECD, 2019):

- **Financial** - subsidies/grants for industry-science research; tax incentives for companies purchasing research from universities; grants for IP applications from universities; financial support to academic spin-offs; financial support to firms to recruit PhDs & post-docs; financial support for collaboration between universities; public-private partnership creating joint research laboratories; performance bases funding systems for university linkages with industry; etc.

- **Regulatory –** intellectual property regulations regarding publicly-funded research; regulation of spin-offs; awards and mobility scheme for people engage in knowledge transfer and innovations; open access & open data provisions for publicly-funded research.
- **Soft –** activities that raise awareness on products and services resulted from research & industry collaboration; collective industry-science road mapping & foresight exercises for innovation; networking support to build industry-science linkages; training programs on knowledge-transfer; guidelines, standards, code of conduct for industry-science collaboration (OECD, 2019).

Digital Health ecosystems

Research&development institutions, universities, innovations centres and companies are the entities that generate most of innovations related to Digital Health. The **collaboration** between different stakeholders and **knowledge transfer** in a Digital Health **ecosystem** creates conditions for innovations in Digital Health.

Digital Health ecosystem can be understood as dynamic collaboration between academic, research, regulatory, business, industry, healthcare, wellness entities and civil society with shared strategic objectives that provides supports or coordinates services and/or activities at the level of their institutions collaboration, while the individual institution remains responsible for their own governance, strategy and business.

Different stakeholders can be involved in a Digital Health ecosystem: higher education institution(s); research & development institution(s) with expertise in e-Health technologies; healthcare provider(s); companies/enterprises with digital health products or services; health insurance institution(s); innovations centres; organization(s) that promote digital health; pharmacies; wellness institution(s); welfare institution(s); policy makers; regulatory agencies. The logic and mutual value creation through services which may be established between different organizations in Digital Health ecosystem may contribute to creation, development and implementation of different e-Health technologies or e-learning technologies that improve the healthcare procedures, the management information system and data-driven decision making in healthcare systems, or may support people health management. The successful development of Digital Health ecosystem is not dependent only on a robust operational organization of the stakeholders. Policymakers and funders play a critical role in ensuring an environment for innovations addressing the complex scientific and societal challenges related to populations health.

World Health Organization provides several guidelines and tools that may support countries in implementing interoperable digital health ecosystem that may ensure seamless and secure exchange of health data by and between users, health care

providers, health systems managers, and health data services (WHO, 2021; WHO. Smart Guidelines; Saban et al., 2024; WHO. Global Initiative on Digital Health).

Europe is creating an **environment conducive to innovation in all domains of Digital Health**. A few examples can illustrate how mobilization of organizations and money create the environment for boosting innovation on Digital Health.

EIT Health (https://eithealth.eu/) is demonstrating how pan-European consortia power innovation with cross-border pilots and start-up projects. EIT Health network connects world-class organisations across Europe from the three worlds of business, research and education.

EIT Health Regional Innovation Scheme (RIS) (https://eithealth.eu/in-your-region/eit-regional-innovation-scheme/). The programme that started in 2015 supports fast-tracking healthcare entrepreneurs with the skills, network, and resources needed to take their ideas from vision to reality, in the European regions where the pace of innovation is moderate. EIT Health supports business development at each and every stage to shorten the time-to-market for the most promising projects. It links talent pools and creative organizations in RIS regions with healthcare innovators from the EIT Health network. As part of this ecosystem, the RIS Academy trains healthcare professionals, entrepreneurs, and innovators to give them the skills they need to succeed in the healthcare innovation ecosystem.

Several ecosystems supporting innovation in Digital Health were created in Europe. European Digital Innovation Hubs (EDIHs), living labs, and niche clusters provide access to infrastructure, people, and testing facilities that reduce the experiment cost and ensure interoperability. These entities allow organizations to "*test before they invest*" reskill their workforce and try solutions with clinicians and patients in real-world settings.

European Digital Innovation Hubs (EDIHs). The **EDIHs** that is a result of Digital Europe Programme enable hospitals and SMEs to pilot AI-based solutions and more advanced digital tools before scaling up extensively. EDIHs are one-stop shops that help businesses and government agencies adapt to digital issues and boost their competitiveness (European Commission. EDIHs). Among the services they offer are:

- access to technological know-how and testing facilities allows you to test before you invest;
- training and skill development (i.e., providing public services and SMEs with training sessions to help them reskill and upskill their workforce);
- financial guidance and assistance for digital transformation are examples of innovation services.

Since May 2025, the EDIH Network encompasses 168 hubs supported by the Digital Europe Programme, which comes from all EU Member States, Albania, Iceland, Kosovo,

Liechtenstein, Montenegro, North Macedonia, Norway, Serbia, Türkiye and Ukraine (European Commission. EDIHs).

Living Labs based ecosystem. Different companies producing product/services related to Digital Health, patients, clinicians collaborate in Living Labs based ecosystem for testing and developing Digital Health solutions. Digital Health solutions may be tested and validated in real-world settings thanks to the many health-focused labs hosted by the European Network of Living Labs (ENoLL). By including patients, medical professionals, and researchers in the creation process, these labs promote user-centric innovation (ENoLL, 2018). Horizon Europe's Cancer Mission has led to MAYA Living labs connecting the research world with the clinic in bridging the discovery-to-application gap (https://maya-horizon.eu/living-labs/).

Cluster of Health organizations. Regional networks known as health clusters encourage cooperation between healthcare providers, academia, and industry. (WHO. Health Cluster). Examples of European health clusters are:

Health Cluster Portugal (https://www.healthclusterportugal.pt/) is a private non-profit association that currently brings together more than 220 members, including R&D institutions, universities, hospitals, organisations from civil society, and companies in the areas of pharmaceuticals, biotechnology, medical technologies, and services.

Digital Health PORTUGAL (https://www.digitalhealthportugal.eu/) is a civil society initiative that congregates founders, guest CXOs and top managers from a mix of Portuguese organizations comprising patient associations, health services and technology providers and the Ministries of Healthcare in mainland Portugal and the autonomous regions of Madeira and Azores.

HealthTech cluster (https://healthtech.teknologiateollisuus.fi/en/association/member-services) is Finnish association that provides regulatory support, growth and internationalization, information and tools, model contracts, and training for developing corporate responsibility and communication competence to companies having products or services related to technologies for health.

Hellenic Digital Health Cluster (HDHC) is a dynamic initiative of the Foundation for Research and Technology – Hellas (FORTH) that aims to include Greece among the leading countries in the field of digital health internationally. HDHC includes 30 innovative and dynamic companies of the digital health ecosystem in Greece and internationally, as well as FORTH.

Innovation hubs and technology parks. Startups and SMEs in the Digital Health can get infrastructure and support from technology parks and innovation hubs.

***DigiHealth*PT** (https://european-digital-innovation-hubs.ec.europa.eu/edih-catalogue/digihealthpt-digital-health-portugal-website) - is a Portuguese innovation hub

dedicated to support the digital transformation in the Health sector, namely the SmartHealth segment, which includes the application of a wide-spectrum of technologies for improved cost-effectiveness and health provision. DigiHealthPT focuses on the application of Artificial Intelligence and Cybersecurity in Health to respond to the emerging needs of startups and SMEs, supporting innovation and digital transition, and of the public sector, promoting the adoption and use of digital solutions. The hub is also devoted to empowering the population and health professionals in the digital transformation process by providing training related to digital technologies, fostering digital and health literacy. The hub is providing access to experimentation and testing; training; support to find investment; innovation ecosystem building and networking.

European Health Data Space (https://healthdataspace.eu/). Compliance with the European Health Data Space (EHDS) supports cross-border scalability, data sharing.

The *EDiHTA European project* (https://edihta-project.eu/project/) will develop in 4 years, a framework-platform for Health Technology Assessments (HTA). The European HTA platform that started in 2024 will enable HTA to be performed digitally in a standardised format that will be customised according to the type and lifecycle stage of the DHT and decision-making process at the macro (policy), meso (management providers) and micro (clinicians) levels.

European Innovation Act. European Commission plans to adopt the European Innovation Act in 2026 (European Union. European Commission.a.). Issues like the commercialization of research results, collaboration between the industry and the academia, access to markets, finance, talent and infrastructures will be addressed. It is aiming to create more coordinated regulatory; policy and investment framework conditions aimed at bringing innovative solutions to the market across the EU. European Innovation Act may help overcoming the innovation gap in relation with Europe's main global competitors, as well as boost Europe competitiveness and growth.

ManagiDiTH ecosystem (https://managidith.eu/). The ManagiDiTH ecosystem includes three European Universities (ISCTE – Instituto Universitario de Lisboa, Portugal; LAUREA – Ammattikorkeakoulu Oy, Finland; AUTH – Arristotelio Panepistimio Thessalonikis, Greece), the research&development institute – Instituto de Telecomunicações, Portugal, various companies inside research project consortium (Whymob, Portugal; Clinipower, Finland, Mundiconsulting, Portugal) and in collaboration with project consortium, a health cluster (Health Cluster, Portugal), a European Network of Living Labs, and various patients and healthcare associations. The purpose of the ManagiDiTH project is to design and implement an innovative Master program that qualifies the graduated students for efficient management of digital transformation of health services. The project purpose is in line with the vision of The Digital Education Action Plan (2021-2027) - a renewed European Union (EU) policy initiative adopted in 30 September 2020, for a high-quality, inclusive and accessible digital education in Europe. The Action Plan calls for greater

cooperation at European level on digital education and aims to support the adaptation of the education and training systems of Member States to the digital age. It creates opportunities for the education and training community (teachers, students), policy makers, academia, and researchers on national, EU and international level (European Union. Digital Decade Policy Programme 2030). The project promotes engagement of stakeholders from the quadruple helix (public sector, research, private sector and civil society) throughout the strategy of smart specialization of personnel of the health and care organizations. Smart Specialization Strategies (S3) for improvement of health services is embedded in the *Policy Objective 1* of the European Regional Development Fund – *A smarter Europe by promoting innovative and smart economic transformation* (European Union. European Commission.c.). The project will contribute to the four main targets of Digital Decade policy program for 2030: skills; digital transformation of businesses; digitalization of public services; secure and sustainable digital infrastructure (European Union. Digital Decade Policy Programme 2030.). The interdisciplinary themes for Master's curricula are based on recommendations for teaching biomedicine and health information management of the International Medical Informatics Association (IMIA) (see International Medical Informatics Association), and HITComp competencies (see HITComp). The program will be aligned with the Council of Europe's EQF Recommendation (2017 / C 189/03) on the European Qualifications Framework (EQF) for lifelong learning and the National Qualifications Frameworks (NQFs) (Official Journal of the European Union, 2017), as well as qualifications systems that are defined as equivalent to the EQF, as they support existing recognition practices. The targeted population for the new Master are graduates' students on: Healthcare, Social & Welfare, Information and Communication Technology, and Business Administration. The master's will work as a conversion course, with graduates from each background learning complementary skills. The graduated students of Master program would have knowledge of the healthcare sector and the main pillars within the sector (e.g., evidence-based practices; value-based healthcare) as well as the skills and competences to create, implement and manage new digital service in a regional and/or European health ecosystem that promote social innovation. Social innovation is defined as "*new ideas (products, services and models) that simultaneously meet social needs (more effectively than alternatives) and create new social relationships or collaborations. In other words, they are innovations that are both good for society and enhance society's capacity to act*" (European Union. European Commission, 2012). Therefore, the project contributes to European Digital Agenda (see European Parliament) by promoting digital transformation of health services, social innovation through e-Health and e-government, as well as the New European Innovation Agenda (adopted in July 2022) (European Union. European Commission.e), by supporting deep tech innovation and cooperation between companies for innovative solutions in health services.

Such initiatives show not just that Europe is investing in innovation but much more importantly that it **is constructing the systemic bricks towards sustained mobilization**.

Knowledge transfer

Formal channels for knowledge transfer in a Digital Health ecosystem may be:

- collaborative and contract for research;
- researchers mobility/ academic consultancy;
- intellectual property transactions;
- academic spin-offs;
- workforce mobility.

Among informal channels of interaction may be:

- research publications, conferencing and networking;
- facility sharing;
- geographic proximity;
- and continuing education/training provided by universities to enterprises.

In the report of OECD *University-Industry Collaborations* (OECD, 2019) the formal channel that may be established between research centres, universities and industry were being identified as:

- **Collaborative research** – refers to research projects carried out by teams from different institutions. It can be fully or partly funded by industry, and can range from small-scale projects to strategic partnerships with multiple stakeholders (i.e., public-private partnerships).
- **Contract research** – refers to research that a private firm commissions to other institutions (e.g., university or research lab) to perform. It generally involves the creation of new knowledge in line with the specifications or goals of the client. It is frequently used in relations between university and industry.
- **Academic consultancy** – refers to research and advisory services provided by public researchers to industry clients.
- **Intellectual property (IP) transactions** – refers to the licensing and selling of IP generated by different entities.
- **Research mobility** – refers to both university researchers working in industry and the converse, including temporary assignments.
- **Academic spin-offs** – refers to the entrepreneurial route to turn commercial the product or service generate by knowledge developed by public research.
- **Labour mobility** – refers to university graduates that join industry.

Informal channels of interaction identified in the OECD report (OECD, 2019), which facilitate the diffusion of knowledge from research to industry and vice versa include the following:

- **Publication of public research** in scientific journals and other specialised media.

- **Conferencing and networking** – conferences, workshops, other events (e.g., meetings of former classmates who are employed in public research and industry) may facilitate interaction between public researchers and industry actors.
- **Networking facilitated by geographic proximity** – that is, informal interactions between public research staff and industry researchers facilitated by location of the institution near other institutions that produce science or technology (e.g., locating science parks near university campuses, or firms' laboratories within university campuses).
- **Facility sharing** between industry and public research (e.g. laboratories, equipment).
- **Courses and continuing education** provided by universities to enterprises, and lectures at universities held by industry employees.

Although there is no reliable instrument to measure the impacts of university-industry knowledge transfer, it may be assessed using case study evidence, patent data and publications data, data on innovative start-ups and venture capital deals, workforce survey, signed contract agreement, IP licenses, the hired researchers, academic spin-off, etc. (OECD, 2019).

Recognizing commercially viable Digital Health solutions

Digital transformation of health is no longer just scanning paper charts into electronic records. It's now a force reshaping the way care is delivered, paid for, regulated, and understood. Advances in technologies for medical devices, technologies for exchange of health information, data analytics, Big Data are contributing for cost-effective healthcare interventions and quality services in health systems. Wearables technologies, smartphone applications, and patient portals allow individuals to track vital signs, get personal recommendations, and give informed consent more freely. True engagement occurs when people have access to information and also have some level of control over decisions. From a technology perspective Digital Health encompasses a broad range of technologies aiming to improve health. It does not refer only to technologies from hospitals or clinics. They span the entire ecosystem of stakeholders, each with distinctive needs and possibilities related to health. The patient and the citizen is and shall be at the centre of focus. Innovation in this context refers to digital tools that can facilitate prevention, care and self-care, and also digital health literacy. The main questions that should be made when wanting to put an innovative Digital Health product/service into market are:

- Who wants it?
- What real problem solves?
- Would the innovative product/service survive in the market?

According to the digital health and innovation team from World Health Organization:
"*Digital health will be valued and adopted if it: is accessible and supports equitable and universal access to quality health services; enhances the efficiency and sustainability of health systems in delivering quality, affordable and equitable care; and strengthens and scales up health promotion, disease prevention, diagnosis, management, rehabilitation and palliative care including before, during and after an epidemic or pandemic, in a system that respects the privacy and security of patient health information. The vision further seeks to enhance research and development, innovation and collaboration across sectors*." (WHO, 2021).

Product viability is a dynamic process in which iterative testing and prototyping may ensure that a product/service delivers the value that is desirable. When the product/service is at mature phase, the signs of decline or stagnation should be registered for creating a new environment that puts high value on innovation.
Having an innovative product/service is necessary to identify: the size of the market, what customers demand, the competitive landscape, market trends, company's capabilities to support putting product or service in the market. For instance, for a digital health application is necessary to identify and describe well the novelty of their features in comparison with other applications, the number of potential customers, the norms/legislation, standards, code of ethics related to that type of digital application (e.g., understand the differences on regulation for wellness product/service and diagnostic or therapeutic product/service), the economic viability of product/service, identify the potential risks and the ways to mitigate the risks, the scalability potential, understand the competitive landscape.

"*Every product team is flooded with ideas — feature requests from sales, wild bets from leadership, feedback from support, user suggestions, personal pet projects. Without a structured idea management process,* ***it's easy to confuse volume*** *with* ***value.***" De Villambrosia, C.G. 2025).

"***Ask the right questions***!" was the mantra of Aaron Antonovsky the author of salutogenic model of health, **as a key to relevant answers**.

A systematic approach of innovation and of the strategies to put the innovative Digital Health product/service to market may increase the likelihood of successful commercialization.

Guidance for putting new Digital Health product/service on market

Discovery, proof of value and scaling are the key stages of producing and commercialization of an innovative product/service**.** These stages may further be divided into idea generation, evaluation of feasibility, product development or service implementation, and scaling. Each may be managed by binary decision gates (Stage-Gate methodology of innovation) based on **problem size, value of evidence, adoption signals, and delay cost** (Cooper, 2019; McGrath & MacMillan, 1995). **Portfolio discipline, enforced by multidisciplinary governance boards, prevents allowing resources to be squandered on poor-performing projects.**

Stage-Gate's governance, **Agile** methodology, user centricity from **Design Thinking**, rapid hypothesis testing from **Lean Startup**, and knowledge flows from **Open Innovation** and **Innovation Intelligence** (see Chapter 1 for terminology explanation) can be blended to accelerate putting a Digital Health product/service digital in the market. Stage-Gate is necessary for decision making in the processes of innovation management and regulatory compliance and CE marking, Agile methodology to accelerate the processes by efficient planning of team tasks, Design Thinking to engage clinicians and patients for a user-centered design of Digital Health solution, Lean Startup for rapid hypothesis testing with rapid prototyping, and Open Innovation and Innovation Intelligence to obtain data necessary for decision making using innovation scouting, startup scouting, technology scouting, trend intelligence, open innovation, business intelligence, market intelligence, customer intelligence, competitor intelligence (see chapter 1). Agile methodology enables teams to shift from hypotheses to functional prototypes in weeks. In medical devices, “day-one” bench prototypes, ISO 14971 risk analysis, and planning for rules reduce CE certification failure. Standards for interoperability such as FHIR (Fast Healthcare Interoperability Resources), cybersecurity, and data privacy must be incorporated in the digital solutions for health from the start.

Regulation (e.g., reimbursement process) should be considered for rapid entry in the market of a Digital Health solution. Innovation testbeds and regulatory sandboxes facilitate health technology assessment (HTA) in secure settings. Pre-emptive preparation of evidence on clinical validation and on cost-effectiveness of new product/service increases the chances of take-up the new Digital Health product/service across Member States.

Human factors are decisive. **Continuous training, communities of practice, and the digital literacy of health-care workers** are decisive for turning prototypes into adopted solutions.

Innovation mobilized consistently in digital **health is not necessarily improvisation, but rather orderly design**. Incentives, governance, quick prototyping, regulatory preparedness, and people capacity need to converge. Unleashing European assets and linking them with organizational purpose creates innovation from scattered projects into a continuous stream of change.

Guidance in the process of putting a Digital Health product/service in the EU market rests on ten pillars. It's important to treat them as interconnected, not sequential. Strength in each pillar multiplies the effect of the others.

The ten pillars:

1. EU Regulatory Framework
2. Financing and Incentives
3. Market Strategy for Fragmented Systems and Scale
4. Focus on High-Impact Areas
5. Multidisciplinary Agile Teams
6. Interoperability and Digital Infrastructure
7. Capacity Building and Organizational Change
8. Mobilization for Innovation in the Ecosystem
9. Scalability and Sustainability
10. Early Clinical and Economic Evidence

1. EU Regulatory Framework

For a new Digital Health product/service to entry into the EU market, is necessary to prove that innovative technology is safe and can be trusted.

Core device rules: The Medical Device Regulation (MDR, Regulation (EU) 2017/745) and the In Vitro Diagnostic Regulation (IVDR, Regulation (EU) 2017/746) are the European instruments for evaluation of medical devices and in vitro diagnostic technologies (see Chapter 5). Regulation regarding software differs from country to country and are differences in the type and component of software that are regulated. A Notified Body (in each country) will audit technical files and quality system for class IIa and above. Misclassification in MDR Annex VIII is not an error—it is months of delay, redesign, and cost (European Parliament and Council, 2017).

Quality and risk management: MDR requires each manufacturer to have a quality system, and a properly defined risk management process. ISO 13485 for quality and ISO 14971 for risk management are standards that might be used. These are those that Notified Bodies would like to see, and in their absence the procedure doesn't go any further (ISO, 2016, 2019).

Technical documentation and evidence: Technical file has great importance for conformity assessment. It includes Clinical Evaluation Report, risk management file, validation and documentation of software lifecycle, labelling, Instructions for Use, and Post-Market Surveillance (PMS) and Post-Market Clinical Follow-up (PMCF) plans. Implant and Class III devices require a Summary of Safety and Clinical Performance (SSCP) but not for all. Transparency of technical file is now also requested by payers and hospitals (European Parliament and Council, 2017).

Data protection: Health data include sensitive data (personal data). The General Data Protection Regulation (GDPR, Regulation (EU) 2016/679) is European regulatory instrument for personal data privacy and security. Processing health data on a large scale requires a Data Protection Impact Assessment (DPIA). In the absence of DPIA, no regulator or hospital IT platform will approve integration (European Parliament and Council, 2016).

European Health Data Space: European Health Data Space (EHDS) will transform access and exchange of health data across the EU. EHDS regulation refers to primary use (for healthcare) and secondary use (research, innovation, policy) of data. Interoperability and audit trails won't be an option—it'll be within a procurement requirement (European Commission. 2022; EDIHs).

Artificial Intelligence Act: The AI Act introduces a risk-based classification system for AI applications, categorizing them into four levels: unacceptable, high, limited, and minimal risk (EU Artificial Intelligence Act). Many AI systems in the healthcare sector would be "*high-risk*." (see Chapter 5 on Artificial Intelligence Act). Businesses would have to prove good risk management, high-quality training data, transparency for users, human intervention, and post-market surveillance (European Parliament and Council, 2024; Muehlematter et al., 2021).

National pathways and sandboxes: Some Member States, like France, Spain, and Portugal, currently have working regulatory sandboxes (see Chapter 5 on regulatory sandboxes). These allow companies to test digital health products in a safe mode, avoiding uncertainty and gaining early regulator and customers/people trust.

Checklist – 1. EU Regulatory Frameworks

- Determine purpose of use and check MDR or IVDR classification.
- Create a QMS; ISO 13485 as the harmonized standard is recommended.
- Implement risk management; ISO 14971 is the standard reference.
- Appoint a Person Responsible for Regulatory Compliance (PRRC) as required by MDR.
- Conduct a GDPR DPIA and further enhance privacy and security practices.
- Consider ISO 27001 for formal information security.
- Get consulting from a Notified Body in advance for Class IIa or more.
- Plan in alignment with EHDS interoperability requirements.
- Track responsibilities under the AI Act for high-risk AI.

2. Financing and Incentives

Financing or funding new Digital Health product/service financing require raising capital by matching the degree of product maturity to the right financing instrument and blending public and private funds to reduce risk and accelerate uptake. Europe has among the broadest set of health innovation financing instruments available anywhere, but the key is to navigate it well.

EU-level programs: There are several European frameworks for financing and funding research projects or business development (e.g., Horizon Europe, European Innovation Council (EIC) Accelerator, EU4Health; see Chapter 4).

National programmes: The Member States contribute to the ecosystem through national programmes (e.g., PECAN, Bpifrance from France, PER TE Salud, Spain). The Germany's DiGA fast-track, providing national reimbursement for digital applications such as digital therapeutics has high credibility for innovators and investors. France has the PECAN programme with an early reimbursement pathway, and the Nordic countries of Sweden and Finland have advanced digital maturity and stable public–private partnerships (Hägglund & Scandurra, 2017). Spain, despite its decentralized system, offers regional opportunities in Catalonia and Andalusia, while Poland's centralized e-Health record investments offer the infrastructure for future scaling (Gobierno de España, 2022).

Strategic alignment: There is evidence on faster development and sustainable growth of companies that combine European and national tools with private capital. Public subsidy reduces perceived risk for private investors, and reimbursement schemes offer an avenue to sustainable revenue. Germany's DiGA is an excellent example of how reimbursement framework contributes both to the adoption of digital solution and investor confidence (Gerke et al., 2020). Membership in a Horizon Europe consortium has also been shown to increase credibility and facilitate follow-on financing (European Commission. Horizon Europe, 2021). Such an alignment of public finance and private investment is an essential link from policy through to market entry at scale.

Checklist – 2. Financing and Incentive

- Match Technology Readiness Level (TRL) and risk profile to the most suitable EU programme.
- Prepare regulatory documentation (CE marking plan, GDPR compliance) to strengthen proposals.
- Build or join consortia for Horizon Europe or EIT Health calls.
- Combine EU instruments with national schemes to finance early pilots.
- Blend public grants with private investment to reduce exposure.
- Map reimbursement schemes to secure long-term sustainability.

3. Market Strategy for Fragmented Systems and Scale

Healthcare within the European Union is marked by a paradox. On one side, EU-level policy such as the Medical Device Regulation (MDR), the In Vitro Diagnostic Regulation (IVDR), the General Data Protection Regulation (GDPR), and soon the European Health Data Space (EHDS) provides a harmonized space. On the other side, reimbursement systems, procurement pathways, and adoption pathways remain firmly in the control of individual Member States or even regions. This fragmentation complicates scaling yet offers multiple points of entry for innovators (Wong et al., 2022; Greenhalgh et al., 2017).

Start local, become European: Most successful innovators start in one or two strategically chosen markets (e.g., Belgium, France, Germany, UK, Nordic countries) that combine good reimbursement with digital readiness.

Interoperability as a prerequisite: Scaling at the European level requires more than regulatory approval or reimbursement, the technical and semantic interoperability. Standards such as HL7 FHIR for data exchange, SNOMED CT for terminology, and IHE profiles for workflows are necessary to ensure seamless integration into electronic health record systems. The EHDS regulation requires these standards for rendering data portability and interoperability (European Commission. European Health Data Space, 2022; Wong et al., 2022).

Engaging payers, providers and regulators: Payers and health technology assessment (HTA) bodies have great importance in every market. Without their support, even clinically effective products can be excluded from market. Healthcare providers (e.g., hospital) play an important role both for collaboration on validation of the new technology as well as for feedback on difficulties for new product/service integration on workflow. Evidence has shown that co-development with providers significantly improves the chances of long-term success and extended utilization (Shaw et al., 2018).

Table 4. **Examples of entry approaches in Member States**

Country/Region	Framework/Programme	Strategic Value
Germany	DiGA fast-track	National reimbursement and credibility
France	PECAN, HAS	Early access and reimbursement pathway
Spain	PERTE + regional pilots	Regional autonomy, strong pilot regions (Catalonia, Andalusia)
Nordics	Vinnova, Business Finland	High digital maturity and public–private pilots
Poland	Centralised digital health strategy	Strong EHR infrastructure, growing pilot opportunities

Checklist – 3. Market Strategy for Fragmented Systems and Scale

- Choose initial markets with positive reimbursement or digital maturity.
- Design for interoperability with HL7 FHIR, SNOMED CT, and IHE profiles.
- Align with EHDS requirements for data portability and governance.
- Involve national payers and HTA bodies early.
- Co-design solutions with providers and hospitals to deliver a workflow fit.
- Package local clinical and economic evidence for replication in other EU markets.

4. Focus on High Impact Areas

Not all Digital Health innovations are created equal when it comes to their chances of success. Those whose solution places them within the most pressing health priorities of Europe attract funding, regulatory acceptance, and take-up more rapidly. Policy maps and evidence track a few priority areas with robust demand.

Chronic disease: Chronic conditions such as diabetes, cardiovascular disease, and obesity drive a considerable percentage of EU health spending. Digital interventions improve monitoring, adherence, and lifestyle change. Multimorbidity and ageing raise concerns both for payers and providers. There is evidence on significant benefits on care when digital tools are combined with traditional care (Marcolino et al., 2018).

Mental health: The pandemic uncovered service gaps in mental health. Moreover, evidence exists on increase prevalence of mental disorders in the youth population. Cognitive Behavioral Therapy apps, telepsychiatry play now a relevant role in European and national agendas. Dropout from teletreatment, less engagement in using the apps remains a problem. Solutions must be clinically effective and engaging in nature to retain users in the long term (Torous et al., 2020).

Artificial intelligence in diagnostics and decision support: AI, properly designed, can reduce workload and speed up diagnosis (Topol, 2019). AI is moving from pilots to practice in radiology, pathology, and clinical decision support. AI can potentially improve accuracy and throughput but is tightly regulated in Europe. Many AI-enabled medical devices will be classed as high risk, adding to the need for validation and monitoring (Muehlematter et al., 2021).

Virtual and hybrid care models: Rural and underserved groups still face access barriers. Virtual and hybrid models bring care to patients without adding complexity for clinicians. When combined with primary care, the models increase continuity and patient-oriented outcomes (Shaw et al., 2018).

Digital therapeutics (DTx): Digital therapeutics offer evidence-based therapies through software. Europe is creating formal mechanisms for them. Germany's DiGA fast-track allows national prescription and reimbursement, driving adoption and investor optimism (Gerke et al., 2020). France's PECAN guidance also provide reimbursement. Comparative evidence suggests that those countries with clearer reimbursement rules have faster take-up and volume (van Kessel et al., 2023). To be successful, DTx developers are integrating strong clinical outcomes with early health economic models that address a payer's most elementary question: what improves, at what cost, for whom, and in which setting.

Why this emphasis matters

Placing these areas top of mind aligns development with public health objectives, enhances funding requests, and is the language of payers. It also improves the chances that pilots become standard care, rather than stand-alone projects.

Checklist – 4. Focus on High-Impact

- Link product use cases to EU health priorities: chronic disease, mental health, AI, DTx, hybrid care.
- Show how the solution is cost saving or improves outcomes.
- Uncover real-life proof to cement long-term benefits.
- Track EU calls and national policy on the chosen subject.
- Forge clinical partnerships in the target area.

5. Multidisciplinary Agile Team

Digital health innovation is dependent on individuals. Technology drives it, but teams turn ideas into safe, useable products. A good team has specialists with clinical experience, regulatory expertise, engineering nous, data science, and human-centred design. All together, they drive up adoption and reduce rework.

Clinicians at the centre: Clinicians need to be involved when a new Digital Health solution for healthcare system should be validated. Their feedback grounds the problem statement, creates relevant results, and informs plans for evaluation. Clinician

engagement boosts adoption and long-term use because solutions are based on real workflows and challenges (Greenhalgh et al., 2017; Ross et al., 2016).

Regulatory and data privacy experts. The team needs GDPR capability and MDR and IVDR literacies. A regulatory specialist anticipates classification, requirements for evidence, and technical documentation. When privacy of data leads to the design of consent flows, data minimisation, and security controls, it inspires confidence with providers and

patients. Trust is not a slogan but a design of important feature in health software (Adjekum et al., 2018).

Experts in data science, engineering and design: Data scientists and engineers work with service and UX designers. They facilitate small batches, user iteration, and friction reduction. Human-centred design makes it more enjoyable and usable. Patient and clinician co-design generates implementation and real-world effectiveness (Kilfoy et al., 2024; Lyon et al., 2024; Sanz et al., 2021; Wang et al., 2022).

Experts on user experience, usability and patient-centred design: Patient experience is not a surface. It is a design driver. Open language, open interfaces, and open use of data drive engagement. Greater engagement preserves outcomes and supports reimbursement case. Reviews suggest patient-centred design and co-design improve effectiveness and sustainability of digital interventions (Kilfoy et al., 2024; Wang et al., 2022).

Agile methodology: Agile and regulation do coexist. Short sprints can be planned, and keep traceability, verification, and risk management. This does comply with adjusting direction and frameworks for medical device software in EU regulations (Khan et al., 2024; Association for the Advancement of Medical Instrumentation, 2023).

Operating model and roles: All high-performing teams share well-defined roles and strict coordination. A notified-body preparedness and documentation on regulation should be carried out by experts in the domain. Outcomes and safety alerts should be handled by a clinician. DPIAs and vendor diligence should be handled by a data protection expert. Product manager coordinates evidence plans, reimbursement objectives, and scope. Engineers and design specialists should be involved in quality and usability assessment. Post-market learning and risk identification and mitigation are the duty of everybody in the team. Scaling in European market has currently high degree of difficulty due to the heterogenous regulation of market in different countries. Teams should learn from pilot studies of implementation of a technology in different countries. The use of standardized clinical protocols, economic templates, and integration in EHRs may facilitate the market entry. Team discipline compresses time for scaling a product/service.

Checklist – 5. Multidisciplinary Agile Team

- Clinical lead engaged from day one, with time and decision rights.
- Regulatory plan mapped to MDR or IVDR, with clear evidence strategy.
- Execute a DPIA and privacy-by-design in place to meet GDPR and buyer expectations.
- Agile delivery with traceability from user stories to risks and tests.
- Co-design sessions completed with patients and clinicians, and insights implemented.
- Usability and accessibility tested with target populations, not only staff.

- Documentation sprinted in parallel, not after the fact, to avoid delays at conformity assessment.
- Post-market plan ready before launch, with feedback loops into the backlog.

6. Interoperability by Design

Every day across Europe, the same inefficiencies are duplicated. Doctors retype already filed results elsewhere. Nurses ask patients the same questions again and again. People get duplicate scans simply because an institution is unable to access another's records. These are not minor irritations—they waste time, increase cost, and erode faith in healthcare systems. Researchers affirm that this interoperability gap is one of the most persistent challenges to the implementation of digital health across Europe (Wong et al., 2022).

The building blocks: Interoperability is where health information may safely travel and retain its meaning system to system. HL7 FHIR is the basis for transferring structured data. SNOMED CT provides consistent medical terminology across borders. IHE profiles impart reproducible patterns to transactions and workflows. Such standards are not optional accessories. As Hägglund and Scandurra (2017) illustrated in the Swedish electronic health record implementation, semantic and technical interoperability are essential to integrated care. Without them, even the most advanced product is at risk of being trapped in a silo.

The European Health Data Space: As of 2025, the EHDS will establish interoperability and portability as legal requirements (European Commission. European Health Data Space, 2022). The new product/service that do not follow the standard for interoperability would struggle to get adopted but may even be excluded from procurement or cross-border pilots by law. Anticipating EHDS requirements avoids costly redesign in the future.

Real-world adoption: Some Digital Health solution may work in small pilot study as being based on local needs. When project get bigger, cracks may appear associated with missing standards, incompatible systems, and workflows that collapse under pressure. This is why so many digital tools get stuck at pilot stage (Hoerbst & Ammenwerth, 2010). On the other hand, when data moves cleanly, clinicians save time, patients miss less testing, and confidence in the system builds. Interoperability is not merely a technical facilitator but a confidence facilitator, as Adjekum, Blasimme, and Vayena (2018) remind us.

Checklist – 6. Interoperability By Design

- Map how the product integrates with hospital and national systems.
- Use HL7 FHIR, SNOMED CT, and IHE profiles from the start.
- Build secure APIs with authentication, identity checks, and audit logs.
- Test implementation in real hospital environments, not only controlled demos.

7. Capacity Building and Organizational Change Management

Health care change is actually all about people. Digital technologies won't improve care unless health professionals, nurses, managers, and patients are engaged to use them and enabled while doing so. Evidence shows that failed change management is among the leading causes of digital programs not scaling (Shaw et al., 2018).

Training and literacy: Different professional groups have different interests. Doctors are interested in the impact on diagnosis and treatment by a new tool. Nurses are interested in integration into regular practice. Administrators are interested in compliance, reporting, and effectiveness. Tailored training enhances confidence and reduces anxiety. Research confirms that structured training and electronic literacy initiatives greatly improve acceptance and long-term use of eHealth solutions (Ross et al., 2016).

Communities and champions: Influences travel faster when respected colleagues lead by example. Communities of practice—typically bounded by clinical champions — establish trusting conditions for professionals to exchange lessons and help each other solve problems. Research shows that these bottom-up influences build stronger trust than top-down orders and are instrumental in sustaining transformation (Greenhalgh et al., 2017).

Patient involvement: Patients do not have to be asked at the end of poduct/service development. Their perspective reveals usability problems which are bound to be overlooked by experts, such as unclear information, difficult-to-use interfaces, or inadequate privacy protection. Patient co-design has been shown to improve usability, trust, and adherence of digital health interventions (Torous et al., 2020).

Incentives that matter: Adoption is stronger when there are actual gains observed by professionals. Earlier discharge, reduced readmissions, and better compliance mean real returns for staff as well as patients. European pilot initiatives confirm that explicit incentives associated with quantifiable progress increase motivation and speed adoption (Wong et al., 2022).

Checklist – 7. Capacity Building and Organizational Change Management

- Provide role-specific training targeted to clinicians, nurses, and administrators.
- Build communities of practice and empower clinical champions.
- Engage patients early in design and testing.
- Track adoption and tie incentives to visible improvements in workflows and outcomes.

8. Mobilization in the Ecosystem

It is very difficult for a single organization to put in European market a Digital Health solution. The path is affected by regulators, investors, universities, SMEs, and hospitals. Examples of the healthcare ecosystem illustrate that the co-operative partnership reduce the time taken for development, lowers the costs, and increases adoption (Pikkarainen et al., 2017; Konopik, 2023).

Innovation hubs and living labs: European Digital Innovation Hubs (EDIHs) and Living Labs offer in situ, real-life settings where solutions are tested in vivo within clinical or community settings. This "test-before-invest" mitigates risk, moves more quickly, and achieves regulators' and payers' confidence earliest. Living Labs have proven to speed technology transfer and provide sustainable uptake (van Limburg et al., 2011).

Health clusters and networks: Health clusters connect universities, companies, hospitals, and state institutions. They share resources and expertise that each would not be able to have on its own. Evidence shows that firms in such networks grow faster, share more, and benefit more from their innovations (Pikkarainen et al., 2017).

Cross-border pilots: Health is largely national, but EU programs encourage collaboration among Member States. Cross-border pilots allow for stronger evidence and the ability to create solutions for European-wide application. Cross-border pilots also shape EU agendas, so projects compete for funding sources such as Horizon Europe and EU4Health (European Commission. EU4Health programme, 2023).

Checklist – 8. Mobilization in the Ecosystem

- Work with EDIHs and living labs to pilot in real-world settings.
- Engage in health clusters to access expertise, funding, and talent.
- Develop cross-border pilots to strengthen evidence and EU market readiness.
- Collaborate early with regulators and payers to raise adoption potential.

9. Scalability and Sustainability

Most Digital Health solutions prove successful during pilot trials but fail upon scaling. The reasons are predictable. Lack of long-lasting business model, high running costs, low ability to adapt to specific contexts. Clinical, organizational, environmental, and social elements determine whether an innovative Digital Health product/service would survive in the market and would reach sustainability (Greenhalgh et al., 2017; Schlieter et al., 2022).

Economic viability: Health systems need evidence of value - lower total cost or better outcomes for an equivalent spend. Robust business models forecast streams of reimbursement, unit costs at scale, and can prove financial resilience. Evidence is linked to robust cost-effectiveness arguments and higher adoption and utilization over the long term (Elton & O'Riordan, 2016).

Flexibility between settings: Europe is diverse. What works in Sweden will not be appropriate for Spain or Poland without language, workflows, and regulation tuning. Scalable products localize the wrapper but protect core architecture and evidence assertions. Scaled-up reviews demonstrate that it is usually flexibility and fit rather than pure technical complexity that matters (Greenhalgh et al., 2017; Schlieter et al., 2022).

Environmental and social impact: Sustainability also means greener and fairer care. Digital technologies must minimize unnecessary travel, underpin lower-carbon transitions, and bridge gaps in access. Innovations that tackle inequities are more likely to have policy and public support throughout Europe (Kickbusch et al., 2021).

Checklist – 9. Scalability and Sustainability

- Define a clear business model aligned with reimbursement pathways.
- Stress-test costs and revenues under EU-scale scenarios.
- Plan for localization across workflows, regulations, and languages.
- Track environmental footprint and equity outcomes.
- Demonstrate both clinical value and financial sustainability.

10. Early Clinical and Economic Evidence

Most Digital Health technologies are more likely than not to be demos' stars but failures at scale. A chronic culprit is the lack of early and strong evidence. Regulators, payers, and providers must do more than see a strong prototype. They require assurance that the product is safe, clinically relevant, and economically sustainable. Otherwise, even technology-driven innovations rarely escape pilots (Ross et al., 2016).

Early clinical validation: When a Digital Health product/service is developed for healthcare system, clinical validation and reliability of the measurements should be considered. Early clinician and hospital contacts may guide study protocols, influence outcomes that matter, and provide valid data. Systematic reviews had shown that Digital Health solutions based on strong clinical evidence are significantly more likely to be adopted and scaled up (Marcolino et al., 2018).

Economic evidence as a driver for decision: Decision-makers weigh not only clinical but also economic results. Cost-effectiveness analyses, budget impact analyses, and evidence of economic advantages are increasingly required by payers and HTA agencies. Evidence of a solution's positive effects on reducing hospitalization, preventing unnecessary care duplication, or reducing waiting times can be decisive in decisions regarding reimbursement (Elton & O'Riordan, 2016).

Integration with regulatory and reimbursement streams: In Europe, clinical validation and economic proof for advantages of new Digital Health product/service for healthcare system are required in national reimbursement program eligibility (i.e., such as Germany's DiGA pathway, France's PECAN program). Generation of the appropriate type of proof strengthens regulatory credence and minimizes time to reimbursement (Gerke et al., 2020).

Trust and usability as evidence: Evidence on a Digital Health technological advantages, usability data, patient-reported outcomes, and adherence data are important for payers,

healthcare providers and patients. When professionals and patients see evidence of safety and usability, trust in digital health systems rises (Adjekum et al., 2018).

Checklist – 10. Early Clinical and Economic Evidence

- Define economic and clinical endpoints from the outset.
- Create a Clinical Evaluation Report (CER) in accordance with MDR.
- Carry out usability testing and pragmatic trials before scale-up.
- Develop HTA and cost-effectiveness models for target countries.
- Gather real-world evidence through pilots and post-market surveillance.
- Incorporate patient-centred outcomes to encourage compliance and trust.

11. Overcoming Obstacles to EU Market Entry of New Digital Health Solution

Different regulatory instruments were implemented in Europe to build a Digital Single Market. However, innovators continue to face different obstacles. There is harmonization in legislation but in practice regulation is interpreted differently in each European country. Reimbursement varies between Member States. Integration of a new Digital Health product/service in hospitals workflow(s) requires a lot of administrative efforts to align with regulation and for overcoming barriers of new product/service adoption. Furthermore, investors are risk averse. These barriers exist and each of them should be known to plan for its overcoming.

Fragmented regulations: The General Data Protection Regulation, the Medical Device Regulation, and the European Health Data Space all seek to create one set of common rules for all Member State but at national level interpretations still exist. Something permitted in one country often needs further effort in another. Early engagement with Notified Bodies and participation in cross-border pilot studies reduces friction and speeds progress (Wong et al., 2022; Bogaert et al., 2021).

Reimbursement gaps: Reimbursement is the most important bottleneck. Starting in a market with reimbursement framework for Digital Health provides momentum and increases trust in further markets. Major country differences in the reimbursement framework and the reason why strategy must be phased by market was shown in a recent study (van Kessel et al., 2023).

Implementation challenges: Hospitals employees see currently new digital product/service as more work. In the absence of workflow fit, the Digital Health product/service is less adopted. Pilot study in real environments and co-design with clinicians reduce resistance and build trust. Evidence suggests solutions co-designed with frontline staff spread better (Shaw et al., 2018).

Investor caution: Health innovation is risky. It is time-consuming to review. Reimbursement is not guaranteed. Blending EU grants and venture capital reduces

exposure and increases credibility. Public money de-risks pilot upscaling. Private capital funds scale-up. Mission-led programmes in the EU provide an excellent template for filling the gap from pilot to scale (Mazzucato, 2018).

Table II. **Examples of common challenges and how to address them.**

Barrier	Solution
Fragmented regulations	Use harmonised frameworks (MDR, EHDS) and engage in pan-EU pilots
Lack of reimbursement	Target countries with clear reimbursement
Implementation hurdles	Partner with health systems for co-design and workflow integration
Investor caution	Blend public grants with venture capital to de-risk

Checklist – Overcoming Obstacle to EU Market Entry of Digital Health Solution

- Map the main barriers for each target market before entry.
- Align early with EU-level frameworks to reduce national friction.
- Enter markets with reimbursement schemes to build traction.
- Co-design with hospitals and frontline staff.
- Combine EU grants and private capital to reduce investor risk.

Summary: Mobilization for Innovation

The European Union (EU) stands at the forefront of digital transformation of health and healthcare, offering a fertile yet complex environment for innovation. As the region embraces data-driven care, artificial intelligence, and cross-border health services, entrepreneurs and developers must navigate a multifaceted landscape of regulation, funding, and market dynamics. Preparing to develop an innovative digital healthcare product in this environment requires strategic foresight, regulatory literacy, and a collaborative mindset.

Innovation environment. To create an innovation environment the organization should consider human factors (i.e., intellectual stimulation, positive interpersonal cohesion, perception that learning from error creates opportunity for innovation, perception that creativity in doing the work is recognized and rewarded, perception of autonomy in doing the work, perception that organization is willing to invest the time and money necessary to support innovation and implementation of innovative product/service, long-term job security) and organizational environment (i.e., organization mission clarity, management practices, cross functional collaboration between different departments, investment in employees training, time for creativity, identification, understanding the obstacles,

innovation barriers in each workplace and implementation of solutions to overcome these).

Innovation Intelligence. Technologies that anticipate trends, identify opportunities, and optimize innovation processes enable organizations to adapt strategies for development and to meet future demands. Tools like Artificial Intelligence based Analytics, Big Data, Market Intelligence for strategic, efficient, and impactful outcomes would have great importance for fostering innovations in organizations.

Knowledge Transfer. Formal channels for knowledge transfer (i.e., collaborative and contract for research; researchers' mobility/academic consultancy; intellectual property transactions; academic spin-offs; workforce mobility) and informal channels (i.e., research publications, conferencing and networking; facility sharing; geographic proximity; and continuing education/training provided by universities to enterprises) should be considered to enable innovation in Digital Health ecosystems.

EU Regulatory Framework: European regulation is a standard by which all other national regulations are judged. The MDR not only ensures safety and performance of the medical device but also his clinical validity. GDPR, European Health Data Space, AI Act, Data Act are key regulatory instruments that should be considered when developing a Digital Health product/service for European market. Planning the QMS, DPIA, and technical file in advance is reducing process time for reimbursement and enhance credibility in the conformity assessment process.

Financing and Incentives: Europe is rich in funding opportunities. Management plan should align the level of maturity of the Digital Health product/service with the right financing or funding instrument. Horizon Europe and EU4Health are financing digital product/service development and clinical validation, and promote collaboration between research centres, companies, healthcare providers and patients' associations. The EIC Accelerator is funding visionary SMEs willing to scale up, by mixing grants and equity. Digital Europe investments in digital skills, AI, cybersecurity are incentives that support innovation in digital technologies. Member States subsequently fill in the gaps with their own schemes of financing and incentives. Achievement is obtained by integrating public vehicles with private capital to mitigate risk and release investor confidence.

Market Strategy for Fragmented Systems and Scale: Europe is continuing its pathway to harmonize regulation from 27 Member States related to digital product/service development and commercialization. To enter a new Digital Health product/service in European market is better currently to start small (in a country with reimbursement framework for Digital Health solutions and scale smartly in other countries). It is necessary to select the market, show value, and scale from there. Interoperability standards like HL7 FHIR and SNOMED CT may ensure rapid adaptation to the requirements of new healthcare provider.

Focus on High-Impact Areas: Digital Health solutions addressing Europe's greatest health priorities may increase adoption and move forward more rapidly by aligning companies' goal with European and national financing programmes priorities and regulation. Chronic diseases drain health budgets. Digital technologies that support compliance with treatment or health monitoring are required. Mental health is priority in many European countries' strategic plan for healthcare. It is currently necessary to increase the adoption of online therapies by tackling the dropout factors. Innovation based on AI may have great impact on healthcare systems. Digital therapeutics and hybrid care models already have channels for reimbursement established in different European countries. It is better to target market where policy, demand, and money already converge.

Multidisciplinary Agile Teams. Great teams bring together clinicians, engineers, data scientists, regulatory experts, and designers. Clinicians keep the work anchored in reality so that solutions solve actual problems. Specialists in regulatory instruments may provide clear information on requirements related to conformity assessment. Different professionals and patients may turn a pretty demo product/service, in an efficient product through co-design. Defining each role in a team has great importance for rapid prototyping and implementation of a Digital Health solution.

Interoperability: Europe is still wasting time and money because systems don't talk. Doctors retype lab results, patients repeat scans, hospitals struggle to connect. Interoperability is the main solution - HL7 FHIR carries the data, SNOMED CT ensures the language is consistent, IHE profiles make workflows predictable and by 2025, the EHDS will make interoperability and data portability mandatory. By integrating interoperability standards in the design of Digital Health solution the compliance costs are reduced, and market opportunities increase.

Capacity Building and Organizational Change: Clinicians, nurses, and administrators need tailored training that solves their problems—workflow fit, compliance, reporting, patient care. Internal champions inside hospitals are a faster driver of adoption. Engaging patients in testing Digital Health product/service may reveal usability and trust barriers that professionals should address to increase the likelihood of large-scale adoption.

Ecosystem Partnerships: Breakthroughs of disruptive innovation depend on partnerships—with regulators, hospitals, payers, universities, and investors. EDIHs and Living Labs help innovators "test before they invest" in real-world settings, lowering risk and creating evidence. Health clusters bring together expertise and unlock the route to finance and people. Cross-border pilot study do more than offer better evidence, they put projects into competition for EU tenders. The rule is straightforward: the healthier the ecosystem, the faster is innovation process and entering in the EU market of new Digital Health product/service.

Scalability and Sustainability: A new digital product/service may succeed in pilot studies but fail at scale when is lacking adaptability, flexibility, sustainability. Digital Health solutions need to demonstrate value (i.e., better outcomes for less or the same cost). Product/service must be flexible enough to bend to many languages, processes, and regulations without breaking their core. Scalability requires not only technology but also finance, efficient operations, and market opportunities. Sustainability of society (i.e., meaning social and environmental footprint) may be ensured by Digital Health products/services by minimizing travel, minimizing carbon release, and closing equity divides but require support of policy.

Early Clinical and Economic Evidence: Evidence breaks or makes adoption. Regulators, payers, and hospitals do not embrace prototypes, they embrace proof. Early clinical validation with real endpoints has great importance when Digital Health product/service is for healthcare system. Cost-effectiveness and budget impact analysis strengthen reimbursement cases. Usability and patient-reported outcomes build trust. Evidence-based validation of a Digital Health solution is key factor that facilitates EU market entry.

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Annex I - Guide for planning for conformity assessment of a medical device

Stage A: Strategic Planning & Feasibility

Define Intended Use & Classification

With medical devices, confirm the product's risk class under MDR Annex VIII rules (e.g., short-term invasive, active non-hazardous devices) and identify applicable classification rule.

Market & Regulatory Feasibility

Conduct a gap analysis: assess internal capabilities, budget, and regulatory readiness (European Commission, 2020).

Choose initial launch countries based on reimbursement potential (e.g., Germany's DiGA, France's PECAN).

Stage B: Regulatory Preparation

Quality Management System (QMS)

Implement or upgrade to ISO 13485-compliant QMS.

Appoint a Person Responsible for Regulatory Compliance (PRRC) as per MDR Article 15.

Technical Documentation

Prepare documentation per Annex IX or XI:

Clinical evaluation plan

Risk management file

Software validation (if applicable)

Post-market surveillance (PMS) plan

Labeling and IFU (Instructions for Use)

Notified Body Engagement (when needed)

Select and contract a Notified Body for conformity assessment.

Submit technical documentation for review and obtain CE marking.

Notified Body is required in medical device CE certification in risk classes IIa and higher.

Stage C: Product Development & Clinical Validation

Clinical Evaluation

Conduct clinical studies or literature reviews to demonstrate safety and performance.

Prepare a Summary of Safety and Clinical Performance (SSCP) if required.

Cybersecurity & Data Protection

Ensure GDPR compliance and implement robust cybersecurity measures.

Consider ISO 27001 certification and GDPR sandbox testing (disrupting.healthcare by Wrzosinski, 2025).

Stage D. Funding & Commercial Strategy

Secure Funding

Apply for EU-level grants:

- EIC Accelerator (up to €2.5M grant + €15M equity)
- EU4Health (for infrastructure and interoperability)
- Horizon Europe (via consortia) (disrupting.healthcare by Wrzosinski, 2025)
- Explore national programs (e.g., Bpifrance, HTGF, Business Finland).

Reimbursement Pathways

Prepare for digital reimbursement frameworks (e.g., DiGA in Germany).

Engage early with payors and HTA bodies.

Stage E: Market Launch & Scaling

Launch in Pilot Market

Choose a digitally mature country with clear reimbursement (e.g., Germany, Nordics).

Partner with hospitals or clinics for pilot deployment.

Post-Market Surveillance

Implement PMS and Post-Market Clinical Follow-up (PMCF) plans.

Submit Periodic Safety Update Reports (PSUR) as required.

Scale Across EU

Align with European Health Data Space (EHDS) standards for interoperability.

Expand to additional markets using CE mark and shared infrastructure.

Annex II - Example of stages for market access in EU.

Stage A: Planning

Define intended use and confirm Class IIa classification.

Complete market and regulatory feasibility study.

Stage B: Regulatory

Implement ISO 13485-compliant QMS.

Prepare technical documentation.

Engage Notified Body and submit for CE marking.

Stage C: Development

Conduct clinical evaluation.

Ensure GDPR and cybersecurity compliance.

Stage D: Funding

Apply for EU and national grants.

Develop reimbursement strategy.

Stage E: Launch

Pilot launch in initial EU market.

Implement post-market surveillance (PMS) and PMCF.

Scale across EU markets.