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European Commission

# Study on eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the European Union

## Lot 2: Artificial Intelligence for health and care in the EU

## Final Study Report

## Internal identification

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Written by PwC

2021

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# List of abbreviations

AAL Ambient Assisted Living

AI Artificial Intelligence

API Application Programming Interface

B2B Business-to-business

B2C Business-to-consumer

BCS Bilateral Collaboration Score

DG Connect Directorate-General Connect (of the European Commission)

DSM Digital Single Market

EC European Commission

EEA European Economic Area

ehealth Electronic Health

EHR Electronic Health Records

EMR Electronic Medical Records

EPO European Patent Association

EU European Union

FC Fractional Count

GDP Gross Domestic Product

GDPR General Data Protection Regulation

ICT Information and Communications Technology

IEEE Institute of Electrical and Electronic Engineers

IoT Internet of Things

IP Intellectual Property

IT Information Technology

MCS Multilateral Collaboration Score

mhealth Mobile Health

ML Machine Learning

MS Member States

OECD Organisation for Economic Co-operation and Development

SME Small and medium-sized enterprise

VC Venture Capital

# Glossary

Unless otherwise mentioned, the definitions provided below were either used by the project team for the specific purposes of this study.

**Artificial Intelligence:** A field of science concerned with the computational understanding of what is commonly called intelligent behaviour, and with the creation of intelligent agents that exhibit such behaviour[1]

**Big Data:** Big Data represents the Information assets characterised by such a High Volume, Velocity and Variety to require specific Technology and Analytical Methods for its transformation into Value.[2]

**Healthcare system:** The collection of resources that deliver health care services to a target population

**eHealth:** to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve-health care locally, regionally, and worldwide by using information and communication technology. [3]

**mHealth**: medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.[4]

**Medical Robotics:** Medical robots are robotic machines utilized in health sciences. They can be categorized into three main classes:(1) medical devices including surgery robotic devices, diagnosis and drug delivery devices, (2) assistive robotics including wearable robots and rehabilitation devices, and (3) robots mimicking the human body including prostheses, artificial organs, and body-part simulators.[5]

**Genome Analysis:** Genomic analysis is the identification, measurement or comparison of genomic features such as DNA sequence, structural variation, gene expression, or regulatory and functional element annotation at a genomic scale. Methods for genomic analysis typically require high-throughput sequencing or microarray hybridization and bioinformatics.[6]

**Patient Monitoring:** The continuous or periodic measurement of vital signs such as blood pressure, heart rate, oxygen saturation or respiration rate of a patient.

**Disease Diagnosis:** The act of identifying a disease

1 Encyclopedia of Artificial Intelligence, 2nd Edition. Shapiro Sc, Wiley-Interscience, 1992.

2 A formal definition of Big Data based on its essential features. Andrea De Mauro, Marco Greco & Michele Grimaldi, Library Review, 2016

3 What is eHealth? Eysenbach G. Journal Medical Internet Res., 2001.

4 mHealthNew horizons for health through mobile technologies, Global Observatory for
eHealth series - Volume 3, World Health Organisation 2011.

5 Control Theory in Biomedical Engineering, Chapter 7 - Medical robotics, Olfa Boubaker, Academic Press, 2020, Pages 153-204, ISBN 9780128213506

6 Taken from Nature Research, accessed in 01/2021 at https://www.nature.com/subjects/genomic
analysis#:~:text=Definition,annotation%20at%20a%20genomic%20scale.

# Abstract

Despite a number of initiatives undertaken by the EU in the last few years towards advancing the development and uptake of AI technologies to help EU citizens better monitor their health, receive better diagnoses and more personalized treatments, as well as live a healthier and more independent life, current situation in the EU indicates that healthcare organisations are slow in implementing AI technologies in healthcare and that the level of adoption is low overall. To achieve its long-term objective of the effective implementation of AI in the healthcare sector the Commission plans to work on a common legislation and policy framework to yield the benefits that AI can bring.

Based on evidence gathered in this study, while most EU MS that have developed AI strategies identify healthcare as a priority sector, there are no policies within those strategies targeting healthcare in particular. At the same time, EU MS have made progress in proposing regulatory frameworks around the management of health data which is a foundational element for the further development of AI technologies in the healthcare sector. In terms of adoption, while healthcare organisations in the EU are open to adopting AI applications, at present, adoption is still limited to specific departments, teams and application areas. The lack of trust in AI-driven decision support is hindering the wider adoption, while issues around integrating new technologies into current practice are also prominent challenges identified by relevant stakeholders in EU MS. The scientific output of EU MS in the area of AI in healthcare is largely attributed to the larger EU MS which are also the most active in collaborating between each other and with smaller MS. Additionally, a need is identified for further financial support to support the development of AI technologies which are translated into clinical practice, including support targeting the acquisition of Intellectual Property (IP) rights for the developed technologies.

To promote the development and adoption of AI technologies in the healthcare sector, the Commission may address challenges related to policy supporting the further development and adoption of AI in healthcare, increase investment, enable the access, use and exchange of healthcare data, and develop initiatives to upskill healthcare professionals and to educate AI Developers on current clinical practices. Addressing culture issues around trust in the use of AI in the healthcare sector and creating or updating policy supporting the translation of research into clinical practice were also important insights extracted from this study.

# Contents

# 1. Introduction

Recognising the potential of Artificial Intelligence (AI) in transforming health and care in the EU Member States (MS), the European Commission (EC) has been taking steps, in the last few years, towards advancing the development and uptake of AI technologies to help EU citizens better monitor their health, receive better diagnoses and more personalized treatments, as well as live a healthier and more independent life. As a step towards achieving this goal, the European Commission adopted a plan to digitally transform the health and care system into a Digital Single Market[7] and to put EU citizens at the centre of the healthcare system.

One of this Communication's key priorities was to encourage the pooling of data for research and personalised medicine. Following this line of thought, the European Commission presented the Communication on Artificial Intelligence[8] on May 2018, and the Communication on a Coordinated Plan on Artificial Intelligence[9] in December 2018. The aim of these were to build a strategy on AI at European level, launching several initiatives to support AI adoption in the healthcare sector, as well as to mobilise all players to increase public and private investments to at least EUR 20 billion annually over the next decade. The Commission doubled its investments in AI in Horizon 2020, and plans to invest EUR 1 billion annually from Horizon Europe and the Digital Europe Programme[10], in support of common data spaces in health, transport and manufacturing, as well as large experimentation facilities, such as smart hospitals and infrastructures for automated vehicles via a strategic research agenda.

While AI has evidently become an area of strategic importance and a key driver of economic development, the current situation in the EU indicates that healthcare organisations are slow in implementing AI technologies in healthcare and that the level of adoption is low overall and differs in each country. The long-term goal of the Commission is the effective implementation of AI in the healthcare sector which is based around a common legislation and policy framework to yield the benefits that AI can bring.

However, an objective like this cannot be fully completed without having to overcome a few challenges. For instance, an important challenge is what scientific research investments must be done and what government-funded mechanisms which need to be put into place for the correct translation of this research into clinical practice. Additionally, the development and adoption of AI in healthcare relies heavily on access to high quality clinical data, therefore, the widespread adoption of Electronic Health Records (EHRs) and their interoperability within EU Member States is an important step to support progress on the AI front. Challenges such as safety of devices and applications, medical ethics, lack of information from the side of the patient and job security also need to be overcome. These challenges, and many more, need to be recognised and understood. Moreover, the socioeconomic, legal and ethical impacts of AI adoption must be carefully

7 Communication of the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Mid-Term Review on the implementation of the Digital Single Market Strategy “A Connected Digital Single Market for All”, COM(2017) 228.

8 Communication of the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, “Artificial Intelligence for Europe”, COM(2018) 237.

9 Communication of the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, “Coordinated Plan on Artificial Intelligence”, COM(2018) 795.

10 “Digital Europe Programme: Summary Report on the targeted consultation on the future of investment in Europe’s digital economy”, December 2019, accessible at https://ec.europa.eu/digital-single-market/en/news/digital-europe-programme-summary-report-targeted-consultation-future-investment-europes-digital

addressed, which requires a clear understanding of the current state of AI development, adoption, challenges, as well as stakeholders' views around it.

Towards this, the EC, via DG CONNECT, has commissioned this study, with the overarching objective to provide the European Commission with a comprehensive overview of the current situation in the EU with regards to the development, adoption and use of AI technologies and applications in the healthcare sector in the EU Member States.

To build on existing knowledge as well as to contribute to the development of a policy framework that will enable the further development and adoption of AI in the EU MS, this study aims to provide an overview and analysis of:

- Relevant legislation and policy frameworks concerning the development, adoption and use of AI technologies and applications in the healthcare sector in the EU MS.
- The scientific output of EU MS and the state of collaboration between MS in the area of AI in healthcare.
- The nature and types of AI technologies and applications developed and deployed in healthcare facilities in the EU MS.
- Social media and news awareness of each EU MS in the area of AI in healthcare.
- Stakeholders' views with regards to the development, adoption and use of AI technologies and applications in the healthcare sector in the EU MS.
- The challengers and barriers hindering the more widespread development and adoption of AI technologies and applications in the healthcare sector in the EU MS.

To retrieve information from credible online databases regarding the R&D output of EU MS in terms of scientific papers and patents, and to identify the start-ups in the EU working in the area of AI in healthcare we developed computer scripts and built queries based on combinations of keywords related to AI and healthcare. Similar tools were also developed and employed in order to collect social awareness indices from social media posts and news articles. In addition, an online survey was developed and distributed to relevant stakeholders in the EU MS, to collect information for measuring progress on the development, adoption and use AI technologies and applications in the healthcare sector and to obtain stakeholders' opinions regarding the challenges they are facing. The content of the current report was produced through a combination of the data collected via the analytical tools, the survey, as well as information extracted through desk research from a wide range of credible information sources.

# 2. Methodological Overview

A high-level description of the methodological approach is briefly elaborated below, while a detailed description of the methodology can be found in Annex I.

Our methodology was driven by the need to understand the development, adoption and use of AI technologies and applications in the healthcare sector in the EU. Therefore, our first task was to carry-out a thorough literature review based on several sources, in order to acquire a more solid understanding of the current situation.

Upon completion of the literature review and based on the issues and commonalities identified, we selected Key Performance Indicators (KPIs) providing measures of the R&D output of each EU MS in terms of scientific publications, multilateral and bilateral collaboration scores within the EU, patents granted in the area of AI in healthcare, start-ups working in the area of AI in healthcare, as well as social awareness issues around the topic of AI in healthcare. We then proceeded to develop computer scripts and analysis tools in order to obtain reliable information from credible online databases to obtain measures of the selected KPIs.

In addition, we developed a survey tool to collect data for measuring progress on the development, adoption and use of AI technologies. We divided the sampling population into three sectors: *Developers of AI technologies*, *Users of AI technologies*, and *Public Authorities*. To achieve the objective of this study, appropriate questions were selected for each group. The survey was then administered to relevant stakeholders from the three target groups in the 27 EU Member States.

The content of this study report is, thus, the combined summarisation of the results of analysis based on insights from the literature review, information retrieval from online sources, and the results from the survey carried-out, to give an overall picture of the state of development and adoption of AI in the healthcare sector in the EU, and to also identify and discuss common barriers and challenges around the deployment of such solutions. The process of information-gathering and flow for compiling the final report is shown in Figure 1.

The **sources of information** we used for the literature review were mainly focused around the categories of: Scientific Papers, EU and national publications, EU and national surveys and market and technology reports. Each of these categories offered a different type of information; for example, scientific papers provided information in terms of theoretical considerations and areas of application, whereas EU and national publications provided insights regarding past achievements, current activities and policies. Moreover, inputs regarding the methodological framework for the survey were given by reviewing EU and national surveys, while an indication of EU technology trends and digital breakthroughs was given from the assessment of numerous market and technology watch reports. During our literature search, we ensured that only high standard papers, reports and publications were taken into consideration for the subsequent analysis.

The **limitations of this study** are mainly related to its timeframe, short duration and disruptions caused by the COVID-19 pandemic.

- The timing of the survey administration (5 July – 15 December 2020) amidst the COVID-19 pandemic meant that a large number of recipients were not available to respond to the survey. While the study's sample is not statistically representative due to the impossibility of collecting a reasonable amount of responses from all Member States, an analysis of responses has been used to identify trends, draw preliminary insights and provide the basis for further exploration[11],[12]

- The survey questionnaire was only made available in English, which may have impacted the understanding of the questionnaire, and as a result limited the number of responses received.
- Misconceptions and misinterpretations on what technologies are classified as "AI" could not be avoided. As observed in this study, there appears to be a general lack of understanding about what Artificial Intelligence means in the context of healthcare.

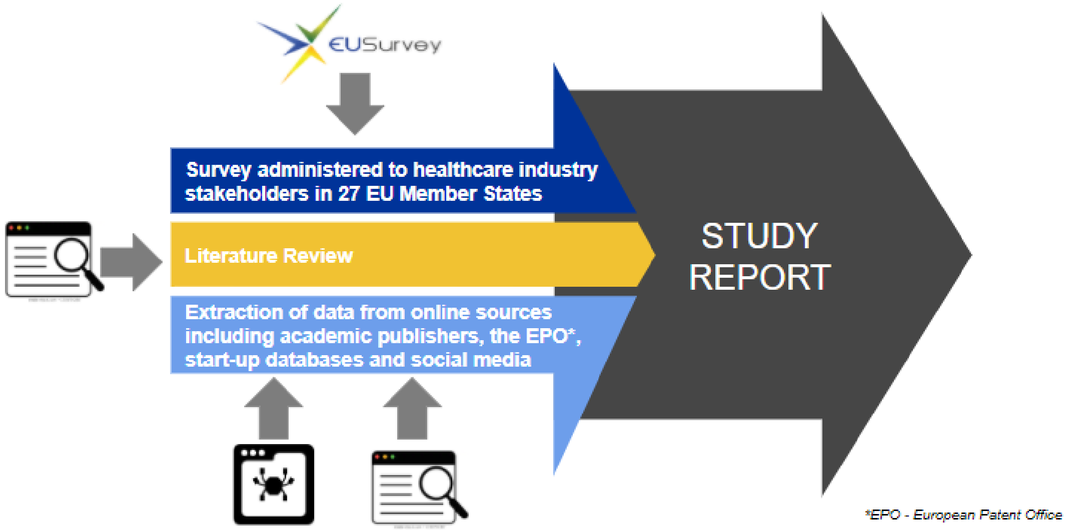


Figure 1: Overview of data sources used for compiling the Final Study Report.

### a. National-level strategies and initiatives around AI in healthcare

Despite the existence of an EU-level coordinated plan around AI, individual and national strengths will need to be joined and materialized at a European level in order to fully exploit the benefits of AI at a European level. In order to gain momentum at a European level and withstand the fierce international competition, the EU needs to overcome the fragmentation of the union and embrace collaboration.

Across the European Union, individual Member States (MS) have been working towards the development of their national AI strategies as they recognize the potential benefits these can bring to their countries, once developed and implemented. As of January 2021, 20 EU Member States have officially published reports as independent pieces of work that include various policy recommendations and planned activities to enhance the use of AI at a national level. While these studies are in some cases published using the term *National AI Strategy*, several EU countries have instead commissioned studies which will

11 To alleviate this limitation, we enhanced the collected information via the development of analytical data intelligence tools to extract information from online database which made it possible to provide reliable and statistically valid information to respond to the study's objectives.

12 The low levels of adoption in some Member States (MS), may have deterred some survey recipients from the "AI Users" and "Public Authorities" groups in participating in the survey.

form the foundation for the future development of such a strategy. Some examples include:

- Spain's Research, Development and Innovation (RDI) Strategy on AI[13], which serves as the foundation for the development of its AI strategy, and which aims, among other things, to provide guidelines for the coordination and alignment of national investments and policies as well as help improve synergies. Moreover, it will allow public and private investments to be directed at the incentivization of the use of new technologies in society and economy.
- The Austrian Council on Robotics and Artificial Intelligence's white paper on "Shaping the Future of Austria in Robotics and Artificial Intelligence"[14] which paves the way towards the development of the country's AI strategy.

Seven EU MS have not published any national-level AI strategy or mission reports. While some of these countries were expected to publish their strategies within 2020, the COVID-19 pandemic has had a significant impact on progress in various aspects, with one being the delay in finalising AI strategies.

While National AI strategies are the key documents showing the commitment of EU MS in adopting AI, MS have also taken other steps to engage with AI through other initiatives.

Such initiatives include work around policy intelligence (e.g. evaluations, benchmarking and forecasts), formal consultations of stakeholders or experts, the formation of regulatory oversight and ethical advice bodies, public awareness campaigns and other outreach activities, the availability of project grants for public research, grants for business R&D and innovation, procurement programs for R&D and innovation,

13 Ministry of Science, Innovation and Universities, 2019, Spanish RDI Strategy in Artificial Intelligence. Retrieved from: https://www.ciencia.gob.es/stfls/MICINN/Ciencia/Ficheros/Estrategia_Inteligencia_Artificial_EN.PDF

14 Austrian Council on Robotics and Artificial Intelligence, November 2018, Shaping the Future of Austria with Robotics and Artificial Intelligence (White Paper).

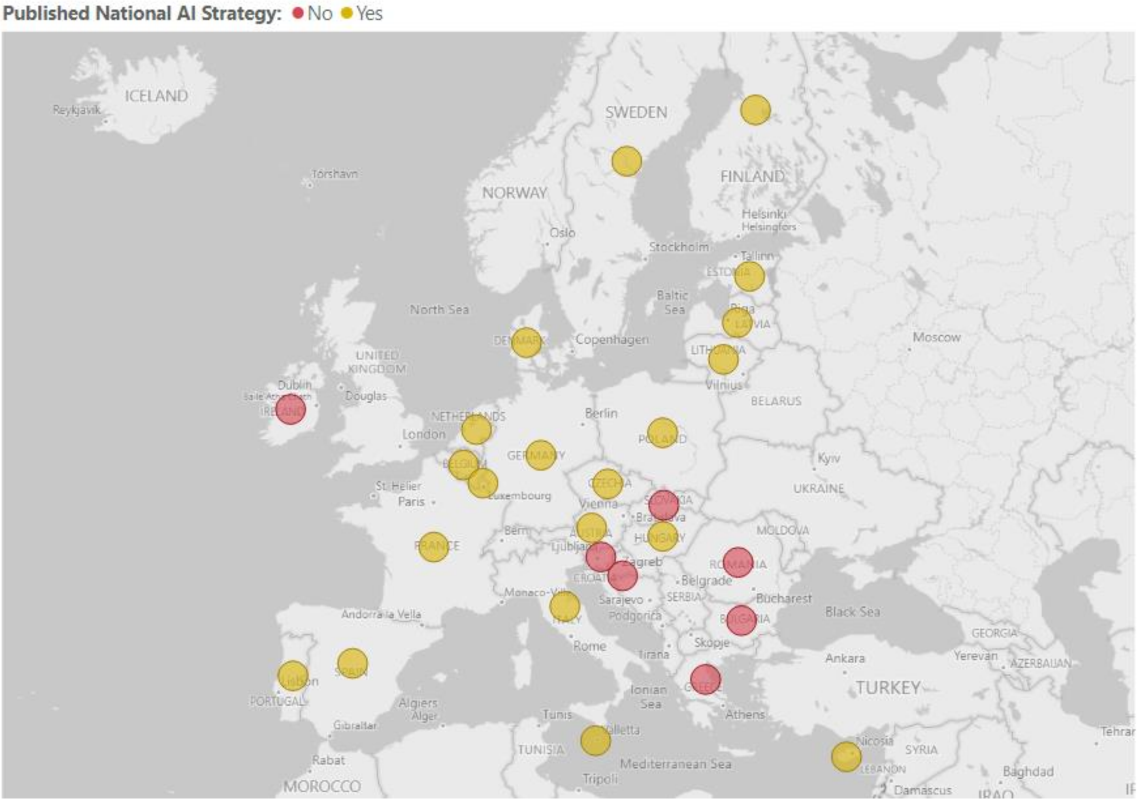


Figure 2: EU countries that have published an official AI strategy as of January 2021

fellowships and postgraduate loans and scholarships, financing, networking and collaborative platforms, dedicated support to research infrastructures, information services and access to datasets and emerging technology regulation15.

The focus of most policy instruments and strategy reports published by EU MS is the promotion of policies and initiatives to build the uptake of AI technologies for the purpose of:

- Increasing competitiveness
- Ensuring a responsible development and deployment of AI
- Integrating AI in business and society

While the issues addressed in National AI Strategies apply horizontally across sectors, we next present the way AI in healthcare is addressed particularly within these policy documents and initiatives.

15 OECD.AI Policy Observatory. National AI policies & strategies. Retrieved from: https://oecd.ai/dashboards?selectedTab=policyInstruments

### b. Policies and initiatives around AI applications in healthcare

AI-focused strategies and policy instruments include initiatives aiming to build the EU's adoption of AI across industries. With regards to healthcare, most Member States have ***identified healthcare as one of the key sectors*** that needs to be prioritized in the context of AI.

National AI strategies incorporate the field of healthcare in various ways. In these key documents there is mention of healthcare in the topics of *data*, *ethics, research and innovation* as well as *public services*.

The development of AI applications is often dependent on the availability of data as well as the quality of data. In the healthcare sector the need for data is exemplified, since good data can become the foundation for AI solutions on areas such as diagnostics and treatments. Despite the opening-up of databases, as suggested by various AI strategies, it should be noted that EU Member States are not intending to violate legislation around the protection of personal data. Making the use of AI ethical and transparent is of great relevance to the healthcare sector, with the notion of trust emerging as a significant component of this. AI-powered methods and processes used within the sector should be trusted by society.

Pilot and signature projects are expected to be launched by Member States' governments to enhance the use of AI in the public sector, including the healthcare sector. There are increasing pressures on healthcare systems arising from a growing and ageing population which call for public reforms. The opportunity to use AI to alleviate the pressure is immense. The creation of centres of excellence for R&D and national AI labs often appear in the recommendations of the AI strategies along with the reinforcement of available funding for R&D. In the highly regulated environment of healthcare, regulatory expertise may be provided in order to support and enable AI-powered applications to make it into real-life markets. Fostering R&D is expected to result in more AI-induced innovations and make nations more competitive. Additionally, most strategies stress the importance of AI being integrated to the provision of healthcare services in the future, hence, these documents are providing steps towards achieving this goal. The integration of AI will help achieve the 4 Ps of healthcare; personalised, preventive, predictive and participatory.

Steps towards the EU's vision of a more collaborative and unified Union that fully leverages the opportunities AI presents in tackling the big issues facing healthcare have also been undertaken and launched under European Commission umbrella projects, such as Horizon 2020 and include the 'AI-on-demand platform' (*AI4EU*[16]) and the network of European AI research excellence centres. The AI4EU platform, will facilitate the creation of a European AI ecosystem and will be an access point to all resources required to engage with AI. The network will focus on the mobilization of AI scientists to produce high-quality research and will promote cooperation between academics and industry.

### c. Initiatives and proposed activities from National AI-strategies and policy instruments

While not directly linked to healthcare within the documents themselves, many of the initiatives and proposed activities within these strategic documents have horizontal applications and are related to the healthcare sector, as well. These fall within the following umbrellas:

- Capability-Building and Upskilling
- Transition from Research to Application
- Data and Infrastructure

Next, we present our findings in terms of policies and initiatives included in National AI Strategies which are directly relevant to the healthcare sector.

### Capability Building and Upskilling

Recommendations under this pillar focus on promoting knowledge and capability around AI technologies, through education and up-skilling initiatives via physical and online platforms. In addition, capability building concerns the creation of cross-disciplinary and cross-border collaborations to promote knowledge exchange and enhanced innovation activities.

- Education- Policy reforms and initiatives for formal training and education, such as the creation of the 'Teach-and-learn AI' platform to develop a solid skill base in AI targeting specific user groups – as stated in the Germany AI strategy – or the creation of additional university positions focusing in the field of AI to ensure that AI has a strong foothold within the higher education system. Other examples include the National Data Science Trainee programme in the Netherlands AI strategy.
- Up-skilling- such as the creation of the National Skills Strategies to promote advanced vocational training in digital and AI-related aspects among others, including online training courses on AI for civil servants
- The formation of a cross-border networks, such as the Franco-German R&D network ("virtual centre") offering bilateral funding and training programs with bilateral AI clusters in specific industries, including healthcare.

### Transition from Research to Application

Policies under this pillar focus on AI research, programmes to foster entrepreneurship and to promote growth of startups working on AI applications. It also covers funding initiatives and the provision of infrastructure to encourage innovation and to facilitate the process of launching AI applications on the market, including in the healthcare sector. National AI strategies highlight a wide range of policy initiatives to foster networks and collaborations across the business community, academia and public research centres for the purpose of encouraging the development of multidisciplinary cutting-edge research and innovation projects. Initiatives extending from the formation of Public Private Partnerships (PPPs) and cross-border partnerships and collaborations on AI research aim to fully exploit synergies and diversities across institutional and cross-border players by promoting knowledge dissemination and transfers. In addition, under this pillar, many countries have initiated projects and policies around the dissemination of knowledge around AI to the general public, as a way of building trust and promoting adoption.

Some specific initiatives around this pillar include:

16 European Commission via CORDIS: A European AI on demand platform and Ecosystem, documents and reports accessible at https://cordis.europa.eu/project/id/825619/results

- Founding agencies for breakthrough innovations with AI as a focus.
- Developing in-company innovation spaces.
- Speeding up the process of AI innovations by launching transfer initiatives, test beds and regulatory sandboxes, as well as promoting pilot and flagship AI projects.
- The development of AI platforms to host networking between science, business community, civil society and the government.
- Further development of the Digital Innovation Hubs initiatives, particularly those related to AI, cybersecurity and other AI-related fields.
- Promoting the development of data partnerships between companies and research institutes.

### Data & Infrastructure

The focus of this pillar is around the development of new, or expansion of current, data infrastructures in order to create the optimal conditions for the development of cutting-edge AI applications. Obtaining a trustworthy data processing and analysis environment will strengthen research in AI and will support the exchange of data due to a more flexible data interoperability. Improvements in connectivity and cybersecurity also fall under this pillar.

Some specific initiatives around this pillar include:

- Promoting open access to governmental and non-governmental data.
- Improving security and performance of information and communication systems with particular focus on the resilience of AI-systems in the case of attacks.
- Building a trustworthy data and analysis infrastructure based on cloud platforms and upgraded storage and computing capacity, including investments in high performance computing.
- Setting up national-level infrastructure to provide data services to research communities.
- The promotion of FAIR principles for private data sharing and the participation into the Common European Data Space[17] is also mentioned in some of the National Strategies.

## d. Relevant initiatives within healthcare-focused national strategies

As encouraged by the European Commission, the digitisation of healthcare is a high priority for many EU Member States which in addition to horizontal AI strategies, have been preparing e-health and digital health strategies, mainly focusing on the digitisation

17 European Commission. Data sharing in the EU-common European data spaces (new rules). Retrieved from: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12491-Legislative-framework-for-the-governance-of-common-European-data-spaces.

of the healthcare sector. Within these strategies, AI is being recognised as an essential ingredient in this process. Examples include Germany's 'Digital Healthcare Act'[18] and Hungary's 'Hungarian National eHealth Platform (EESZT)'[19]. Ireland has published an 'eHealth Strategy for Ireland'[20] and has outlined its 10-year healthcare vision which incorporates digital health, while Sweden has published a strategy to implement its 'Vision for eHealth 2025'[21]. France has also adopted the 'Health Act' following the 'My Health 2022'[22] report, and Estonia has developed the 'Estonian eHealth Strategic Development Plan 2020'[23], including a strategic plan for 2020 and a vision for 2025.

Although the integration of AI in healthcare is still in its early stages, most of these documents and actions depict the momentum present in the EU regarding Electronic Health Records (EHRs), recognised widely as an important steps towards the more widespread development and adoption of AI applications in the healthcare sector.

France is one of the few Member States that explicitly includes AI in its healthcare-related documents and actions. The country's e-health readiness is also dependent on AI, and the sharing of Big Data to foster AI innovation is anticipated to give France a competitive advantage and encourage health startups to develop AI-powered solutions[24].

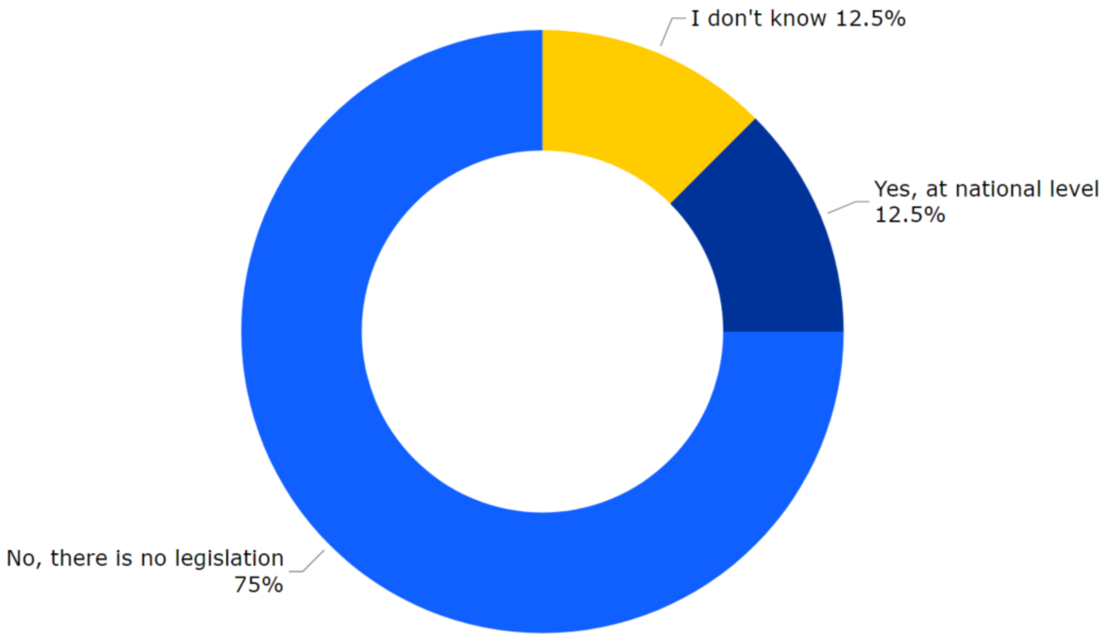


Figure 3: Responses from Public Authorities to the question "Is there national legislation in place regarding the use of AI systems in healthcare?"

18Driving the digital transfomation of Germany's healthcare system for the good of patients. Retreived from: https://www.bundesgesundheitsministerium.de/digital-healthcare-act.html

19Hungary, Health Care & Long-Term Care Systems. Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability (2019)

20Health Strategy for Ireland. AN Roinn Slainte, Department of Health

21Vision for eHealth 2025 – common starting points for digitisation of social services and health care (2016). Swedish Association of Local Authorities & Regions.

22Health System transformation Strategy. Retrieved from: https://www.gouvernement.fr/en/health-system-transformation-strategy

23Estonian eHealth Strategic Development Plan 2020 (2015)

24Reflections on Healthcare & Life Sciences Innovation. Retreived from: https://healthadvancesblog.com/2020/03/24/e-health-in-france/

### e. Refining the regulatory framework

A review of the AI-promoting initiatives from EU Member States reveals a momentum, however there are no initiatives within these strategies targeting the healthcare sector in particular.  To support the successful development and deployment of AI technologies in the healthcare sector, a targeted, well-developed and effective regulatory framework is required. Our survey of Public Responses from authorities across the EU (based on responses from 18 Member States) reveal the absence of legislation around AI in healthcare in 75% of respondents (see Figure 3). In contrast, 75% of respondents indicated that legislation around the storage and sharing of healthcare data and the protocols around it were already in place (see Figure 4). An absence of policies and legislation directly relevant to applications of AI in the healthcare sector, as well as limited strategic direction at a national level were also listed as obstacles to the widespread adoption of AI in healthcare by Public Authority respondents. Specific examples of challenges mentioned by survey respondents which may be mitigated by the presence of a refined regulatory framework and national-level strategic initiatives include:

“The lack strategic direction around the translation of R&D into wide-scale deployment”

“Lack of precise legislation around AI”

“Lack of financing for experimentation on AI in hospitals”

“The need for EHR implementation before”

“The need to find smart technical solutions while not compromising personal data protections”

“Lack of strategic initiatives and investments”

"Lack of certification mechanisms for AI"

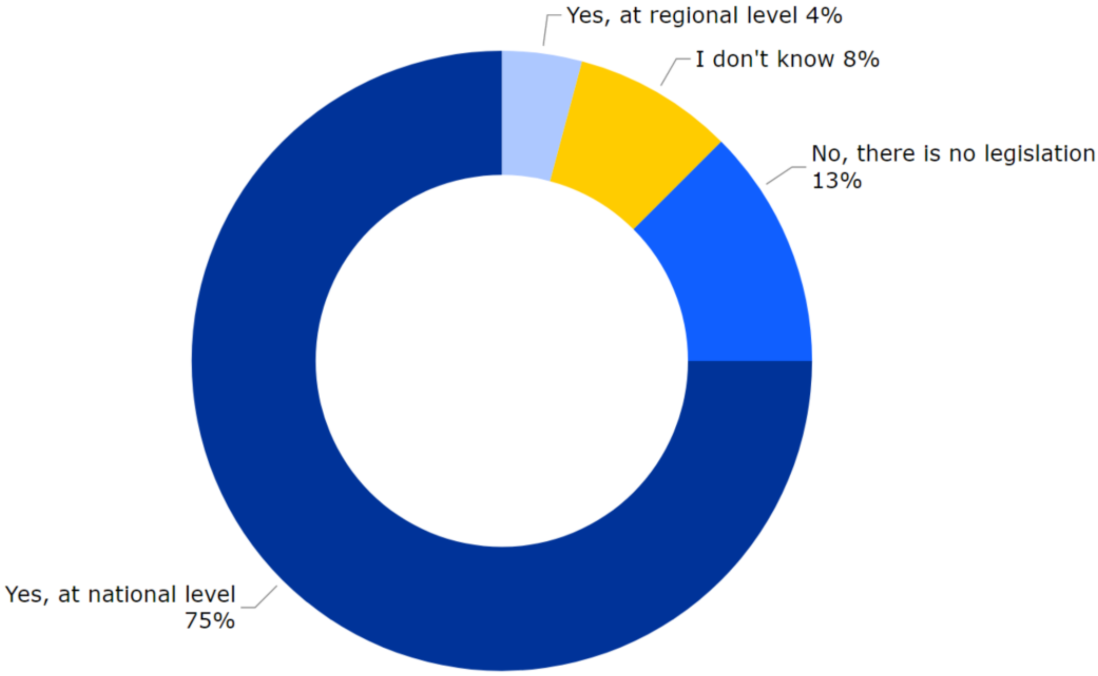


Figure 4: Responses from Public Authorities to the question "Is there national legislation in place regarding the storage and sharing of healthcare data and the protocols around it?"

"The need for benchmarking of AI solutions against existing clinical solutions"

"Long processes to acquire certification"

"The need for a legal framework that does not hinder innovation"

"Regulations for data sharing specifically for healthcare research"

"Lack of legal solutions supporting the use of AI in health facilities."

"Lack of relevant knowledge and competence among patients and health professionals."

"Resistance to change".

In addition, several respondents highlighted the uncertainty around the effect of introducing stringent regulations in the area of AI, to innovation in this area.

Similarly, as shown in Figure 5, the responses from survey respondents from the AI Developers group identify similar issues and regulatory gaps, recognising a need for stringent policies around AI testing and certification, policies supporting research and innovation and policies encouraging the deployment of AI technologies in healthcare. The need for strict regulations around data protection rules regarding the use and exchange of health data for the purpose of AI analysis, was also highlighted by survey respondents.

While the existence of regulation around health data sharing is a positive first step, it is clear that there is indeed a regulatory vacuum hindering the development and adoption of AI in the healthcare sector recognised equally by Public Authorities and AI Developers; an innovation-friendly regulatory framework is important and should tackle among other issues the integration of AI technologies into healthcare practice, issues around information management, data ownership, free flow of data, certification and standardization. Measures to promote research and innovation and the translation of research into clinical practice are also important, as well as initiatives promoting upskilling and the promotion of trust on AI in the healthcare.

Furthermore, based on survey responses, issues around AI ethics, transparency and interpretability do not appear high in the agenda of stakeholders, who appear to be prioritising more basic practical hurdles that need to be overcome.

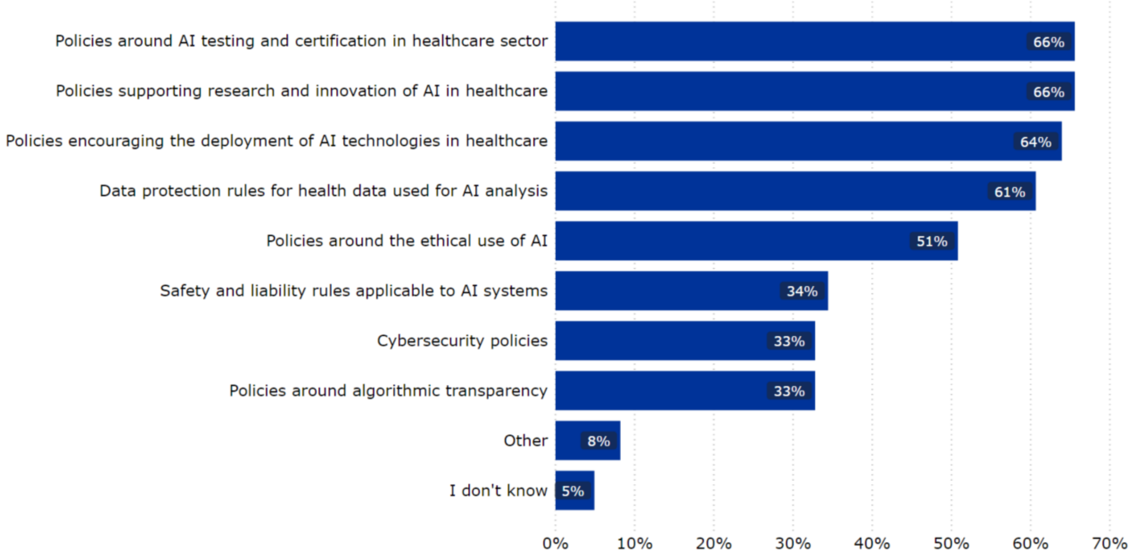


Figure 5: Responses from AI Developers to the question "Which of the following areas of legislation/policy with regards to the development and usage of AI-enabled healthcare tools would you like to see in place?" (multiple selection).

Measures to promote research and innovation and the translation of research into clinical practice are also important, as well as initiatives promoting upskilling and the promotion of trust on AI in the healthcare sector were also issues highlighted by survey respondents and should be addressed from a regulatory aspect. Some policy recommendations and initiatives emerging as important, include:

- Policies around the development of competition and copyright law.
- Policies around the introduction of certifications for the use of AI in healthcare.
- Legislations providing reskilling opportunities and support to employees whose job is at risk due to AI technologies.
- Data protection rules regarding the use and exchange of health data, which at the same time safeguards the control on personal data, compliant with EU law.
- Amendments in current legislations concerning the use of non-personal data as well as copyright.
- Accelerating the implementation of cyber security directives locally as required by the EU Directive on security of network and information systems (NIS) requires Member States to adopt a national cyber-security strategy.
- Ethical requirements to ensure transparency, verifiability and predictability of AI systems, especially for critical sectors, such as healthcare.
- Funding for the development of data standards and formats to encourage EU-wide collaborations.

- Funding for experts, particularly from SMEs and startups in order to support their participation in international standardization processes.
- Funding to SMEs for obtaining IP on their innovative products around AI in healthcare.
- Improving access to innovation funding and venture capital through different schemes focusing mainly on SMEs targeting individual and collective R&D projects.

It is worth noting that many of these issues emerging as important from a policy perspective in the context of AI in healthcare are issues which have been identified as important in the wider context of digital transformation in the healthcare sector. The results of the public consultation on transformation of Health and Care in the Digital Single Market[25] identified most of the above issues as barriers, from a policy and legislation perspective, for the wider adoption of digital healthcare, referring in particular to the need for addressing risks of privacy breaches, cybersecurity risks, and the lack of infrastructure, as well as policies to promote the standardization of EHRs, development of harmonised standards for data-quality and reliability, introduction of health-related cybersecurity standards, and support for cross-border interoperability through open exchange formats. To address the low level of adoption of digital health solutions in health care, the same report concluded that there is a need for sustained EU investment in research and innovation, the transfer of knowledge and practices between Member States and regions, as well as common approaches for feedback mechanisms about quality of treatment. The issues that appear to be more directly related to AI in particular, are those of ethics and transparency and the need for AI-specific certifications.

### f. Investments in the area of AI in healthcare

Showcasing its commitment to the promotion of AI for a better Europe, the EU also proposed an investment of at least EUR 7 billion in AI for the period of 2021-2027. This strengthening will come through the Horizon Europe and Digital Europe programmes. More specifically for healthcare, following the COVID-19 pandemic, the 'EU4Health'[26] programme, discussed earlier, aims to stimulate the digitalisation and strengthening of health systems and to boost innovation in the field of medicine and pharmaceuticals. Both targets will enhance the outlook of the EU with regards to AI and healthcare.

As indicated by survey responses from public authorities, figures around AI investments particularly targeting applications in healthcare are not available. Respondents from only two MS provided figures for planned funding around the development of AI in healthcare. This may be attested to the following:

- Most public research funding programmes are either focusing on
  - Applications of AI without specifying a particular sector or
  - Applications of ICT in healthcare

As a result, the funding awarded at the intersection of these two areas (AI applications in healthcare) is not precisely known.

25 European Commission via DG CONNECT and DG Health, 2018, Consultation:Transformation Health and Care in the Digital Single Market, Synopsis Report. Retrieved from https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_consultation_dsm_en.pdf

26 EU4Health- A vision for a healthier European Union, 2021-2027, retrieved from https://ec.europa.eu/health/funding/eu4health_en

- There is ambiguity in defining health technology applications as AI-based or not. Indeed, it was evident from some of the survey responses that, often, healthcare applications utilising automation or rule-based decision support, or applications around medical robotics are often wrongly considered AI applications, even though they are not using AI methodologies.
- There were cases of public authorities that responded that they could not provide numbers of public investments in the area of AI in healthcare because the distribution of funds was not done at a national level but instead at a federal or regional level.

Looking at the survey responses from AI Developers working on healthcare applications, most respondents received funding for the development of AI technologies in healthcare via public funding initiatives, either from national (29%) or European Commission (28%) funding schemes. Only 15% of AI developers have used private funding and of those, only 6% have received both public and private funding, indicating that despite an increase in private investment to support the startup ecosystem across Europe, research and innovation in the area of AI in Healthcare **is still heavily reliant on public funding**.

Based on survey responses, most AI developers have received funding in excess of EUR 500K (29%), followed by EUR 100-500K (21%), and less than EUR 100K (14%). Most privately funded start-ups have received less than EUR 100K in private funding, while, as expected, AI developers that have received funding from multiple sources have received a higher total amount of funding. Additionally, looking at the responses of AI Developers regarding the **challenges identified in moving their products to the market**, 56% of the AI Developer respondents identified the **lack of financial resources** as a barrier to the adoption of AI technologies in healthcare. Furthermore, seeing as 26% of AI Developers indicated receiving funding from multiple sources (public national, public European or private), the Commission may need to dive further into the per-project budgets allocated, to ensure that innovative companies can obtain sufficient funds for translating their research into applications and for taking them to industry without having to dedicate a large amount of time and resources in multiple, and often cumbersome, funding application processes. This point was further highlighted by Public Authorities in responses to an open-ended question regarding the most important barriers to AI adoption in healthcare, e.g., “Lack of funding (especially from private resources)”, “Insufficient Funding” and “Resource capacity to sustain innovative solutions and technologies and available funding”.

More so in the case of SMEs, stronger financial support and dedicated funding schemes targeting AI in healthcare are evidently necessary to support organisations in translating their innovative products into the market. Limited funding schemes provide only short-term support to innovative companies, and do not support the translation of products outside the lab, instead they may be tying-in researchers into dead-end cycles of R&D which does not make it to the market and does not sustain innovation in the longer-term development.

It should be noted that responses from the AI Developers group included only start-ups which are eligible for national and EU funding under national and European SME-instrument funding schemes. As evidenced by our study around patent applications in the area of AI in healthcare in the EU, in the last three years, approximately 80% of patents in the area of AI in healthcare have been granted to just two large healthcare technology corporations (Siemens Healthcare GMBH in Germany and Koninklijke Philips in the Netherlands). This means that **most innovation around AI in healthcare in the EU which makes it to the market stems from large private organisations** and consequently from private funding. It is evident that further support is needed for SMEs for obtaining intellectual property rights (IP) for their innovative AI products. As discussed in 4iP's study on "The Exploitation of Intellectual Property for Industrial Innovation"[27], European SMEs focus mainly on the in-house development of their own technical solutions and the use of third-party inventions and patents remains low. Possible reasons for this are the lack of awareness and effective IP strategies on the part of SMEs, budget constraints, transaction costs and the complexity of processes. The insights provided

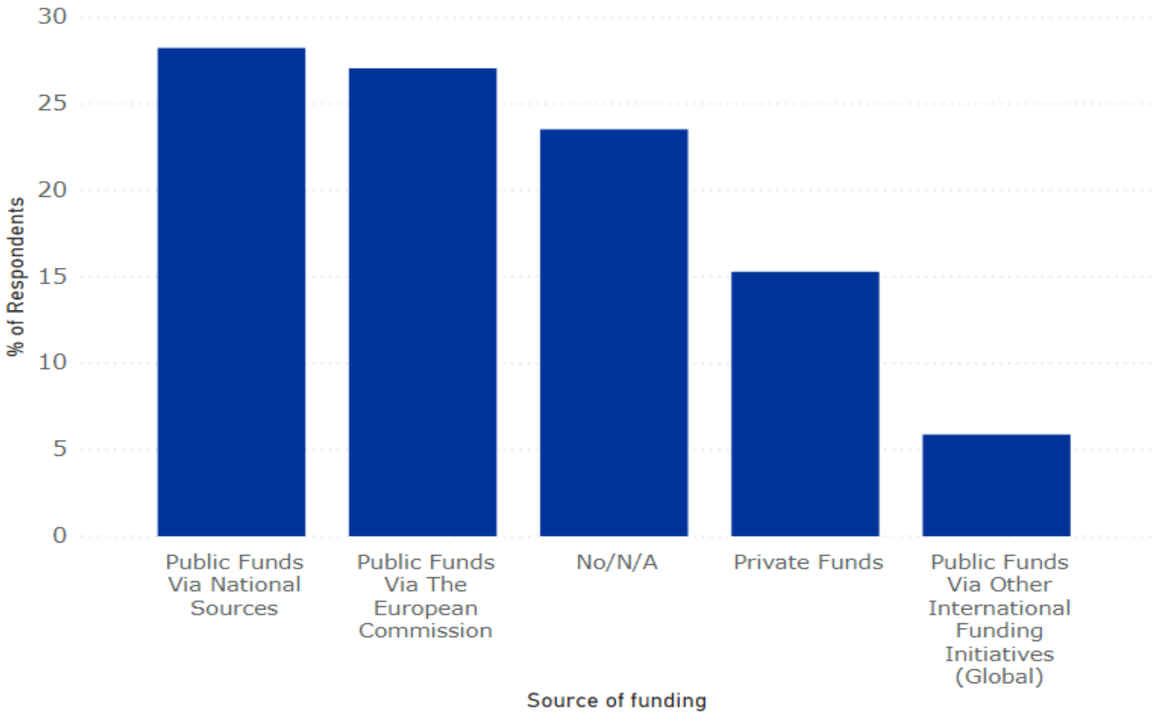


Figure 6: Responses from AI Developers to the question "Have you received any private or public funding for the development of AI-enabled healthcare tools?" (multiple answers)

27 Exploitation of Intellectual Property for Industrial Innovation (2018). Retrieved from: https://www.4ipcouncil.com/application/files/8015/3486/9872/Summary-INNO_AG.pdf

from the 4iP study included the need for the introduction of several schemes and tools to support SMEs in their external IP acquisition, including the provision of funding in the form of vouchers for obtaining IP, as well as the enhancement of support, via current SME instrument schemes for obtaining IP and for the use of third-party IP, something relevant also to the area of AI in healthcare.

In terms of funding opportunities towards innovative products in the area of AI in healthcare, the EU may have a disadvantage compared to the US since in the last few years, all Big Tech corporations (Amazon, Apple, Google, Facebook and Microsoft) have invested in the development of AI technologies with applications in the healthcare sector and have provided industrial funding to SMEs for developing their innovative products. Market reports indicate that this funding has been mostly distributed to US-based SMEs indicating the need for the development of strategies with the EU for channelling VC funds to EU-born ideas, and for considering initiatives to bring Big Tech corporations closer to EU-based SMEs so as to maintain the competitiveness of EU-based SMEs in the area of AI in healthcare. Additionally, investments such as those enabled through the European Investment Fund (EIF)[28], indicate that VC investments, especially in areas of lower economic development within the EU, spur further VC investment and development thereafter and supports the continuity and longerity of SMEs across-sector.

28 Helmut Kraemer-Eis, Simone Signore and Dario Prencipe, EiF Research and Market Analysis, Working Paper 2016/34 on The European venture capital landscape: an EIF perspective Volume I:The impact of EIF on the VC ecosystem, accessible at https://www.eif.org/news_centre/publications/eif_wp_34.pdf

# 3. Level of development, adoption, awareness and use of AI technologies in the healthcare sector in the EU

## a. Level of development of AI in the healthcare sector in the EU

To assess the level of development of AI applications in the healthcare sector in the EU, we measured the output of EU MS in terms of scientific publications, patents granted, as well as the startup ecosystem in the EU as a whole, and per MS.

### Scientific Publications

While many R&D activities in the area of AI in the healthcare sector takes place within the startup ecosystem, the first stage of the technology-innovation cycle is well-captured by gaining an understanding of the research output, in terms of scientific peer-reviewed publications from universities and research institutes.

To provide a measure of the level of development of AI in the EU, we applied an elaborate methodology, explained in detail in Annex I, aiming to obtain a valid and representative sample of the EU's scientific output in the area of AI in healthcare. We then used this sample in order to develop KPIs describing the share of scientific contribution for each MS in the area of AI in healthcare, as well as a measure of the level of collaboration between MS, resulting in original and innovative scientific work around AI in healthcare. To obtain a representative sample, several sources of peer-reviewed publications were selected, and two sets of keywords, defined for the two fields of interest (AI and healthcare) were applied. The results presented next, represent scientific publications published between the 1st of January of 2015 and the 31st of August of 2020. While the papers used to extract these indices do not represent the entire body of published research papers in the area of AI in healthcare (which would be nearly impossible to obtain due to limitations in accessing scientific publication databases and in ambiguity in the definition of AI and/or healthcare), the sample we obtained is a representative one and it provides an indication of the state of development of AI in the healthcare sector as a measure of comparison between the EU Member States.

Following the Nature Index approach[29], which is considered to be a valid scientific approach for deriving individual scientific contributions of institutions or countries in this instance, as well as multilateral and bilateral collaboration indices, three indices were defined and calculated:

- The **Fractional Count (FC) Share** index, used as an appropriate and validated proxy for the Scientific Output of each of the EU-27 Member States.
- The **Bilateral Collaboration Score** (**BCS**), adopted in order to portray the extent of collaboration across the EU-27 Member States. The BCS is a measure of the collaboration between any pair of two countries that have contributed to a scientific paper.
- Lastly, the **Multilateral Collaboration Score** (**MCS**), adopted in order to portray the extent of collaboration across the EU-27 Member States. The MCS attempts to measure the overall collaborative character of each country.

29 A guide to the Nature Index. Nature 551, S26 (2017).

The scientific output of each EU Member State in the area of AI in healthcare is shown in Figure 7. The collaborative performance of each country as measured by the MCS is shown in Figure 8. Figure 9 shows a visual mapping of the countries based both on their MCS index and the total number of collaborating countries.

Table 1: The list of EU-27 Member States, sorted by the number of collaborating countries, alongside their individual Multilateral Collaboration scores.

| | Member State | Number of Collaborating Countries | Multilateral Collaboration Score |
|---|---|---|---|
| 1 | Italy | 22 | 38.7 |
| 2 | France | 20 | 31.1 |
| 3 | Germany | 20 | 34.9 |
| 4 | Portugal | 20 | 19.8 |
| 5 | Netherlands | 18 | 28.1 |
| 6 | Spain | 18 | 41.9 |
| 7 | Austria | 17 | 10.7 |
| 8 | Denmark | 17 | 9.9 |
| 9 | Greece | 17 | 19.5 |
| 10 | Czech Republic | 16 | 7.0 |
| 11 | Sweden | 16 | 12.3 |
| 12 | Poland | 15 | 10.1 |
| 13 | Finland | 14 | 6.7 |
| 14 | Hungary | 13 | 0.9 |
| 15 | Belgium | 12 | 11.7 |
| 16 | Cyprus | 10 | 1.9 |
| 17 | Ireland | 10 | 6.5 |
| 18 | Romania | 8 | 5.3 |
| 19 | Slovenia | 8 | 1.0 |
| 20 | Croatia | 6 | 1.6 |
| 21 | Luxembourg | 5 | 2.2 |

| | | | |
|---|---|---|---|
| 22 | Lithuania | 4 | 1.5 |
| 23 | Slovakia | 4 | 2.9 |
| 24 | Latvia | 3 | 0.8 |
| 25 | Estonia | 2 | 0.4 |
| 26 | Bulgaria | 1 | 1.2 |
| 27 | Malta | 0 | 0.0 |

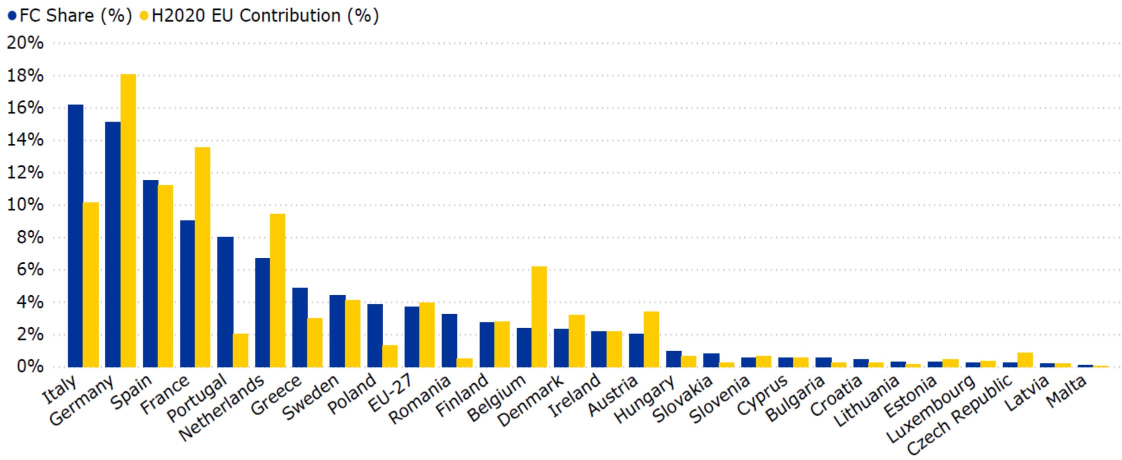


Figure 7: The Fractional Count (FC) Share for each of the EU-27 Member States (blue bars), compared with the percentage of the Horizon 2020 EU Contribution for each country (yellow line).

The Bilateral collaboration performance is illustrated in the chord diagram of Figure 10, where each country is connected to its paired country with a line, the width of which represents the strength of the pair’s collaboration.

Analysis of the scientific output of the EU-27 Member States reveals that the top-4 performing countries (Italy, Germany, Spain, and France) contribute more than half (51.8%) of the total EU-27 FC Share. The same countries, with a slightly different ranking (Spain, Italy, Germany, and France), outperformed the rest of the EU-27 Member States in terms of the MCS and the BCS indices.

Apart from the size of these four countries, we noted the multidisciplinary consortia involved in many of those countries' publications, which include, in many cases, university hospitals collaborating with ICT departments for the development of technologies directly applicable to the clinical sector. Some examples of such hospitals who appear in scientific publications in the area of AI in healthcare identified in our search, include University Hospitals of Fuenlabrada, Getafe, Asturias, Barcelona, Murcia and Seville in Spain, Ruggi D'Aragona and Pisa in Italy, Regensburg, Aachen and Heidelberg in Germany and Clermont-Ferrand, Dijon, Rouen and Lyon in France. Another observation is the collaborations in many cases of university departments in scientific publications with large technology corporations, such as Siemens and Philips which are

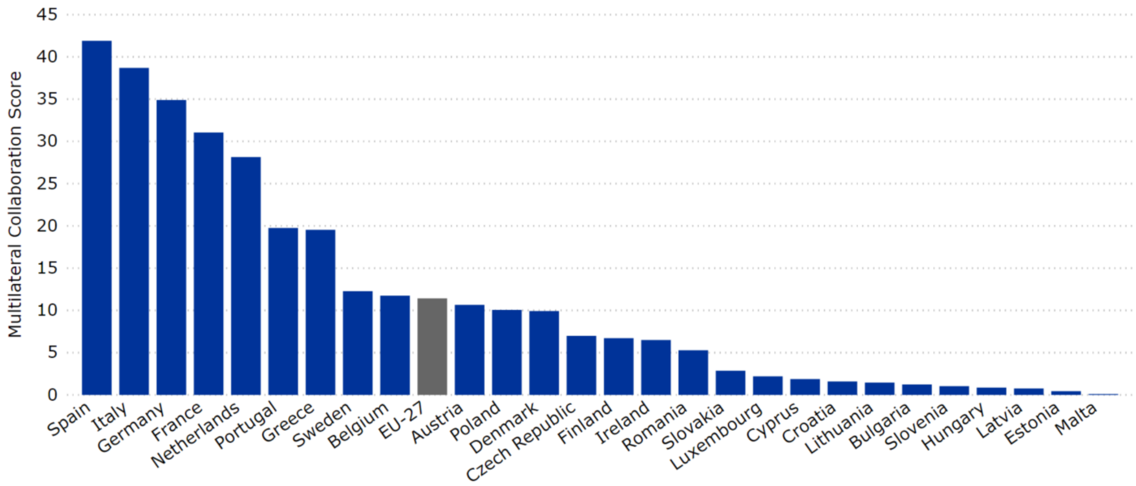


Figure 8: The Multilateral Collaboration Score for each of the EU-27 Member States.

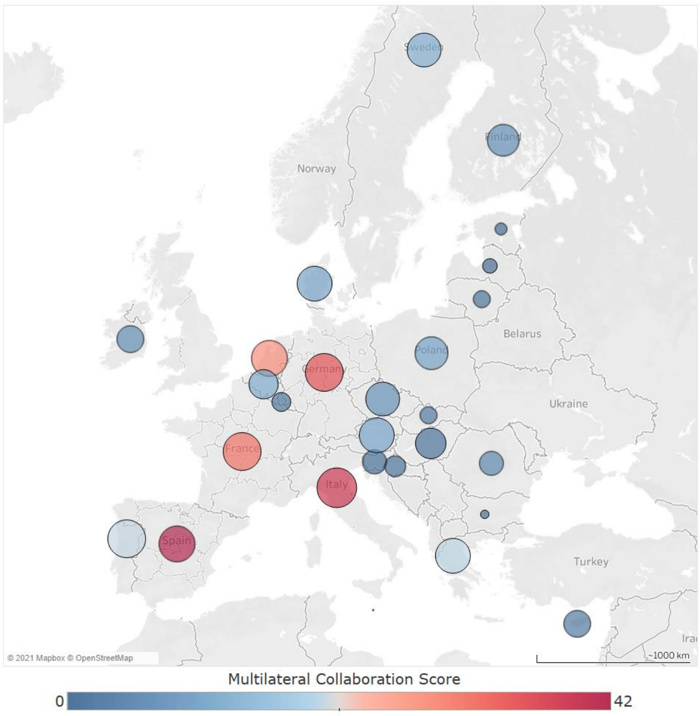


Figure 9: EU-27 Member States map of the Number of Collaborating countries (bubble size) and the MCS (bubble colour).

most likely tied with industrial funding projects between the research institutes and the technology corporations.

Potential correlations were explored between the EU-27 Member State's abovementioned performance and other publicly available indicators[30], like the GDP, R&D contribution (Horizon 2020[31]), size of Population and the Digital Economy and Society Index (DESI)[32]. The data comparison reveals that the EU's largest economies, namely Germany, Spain, France and Italy, which are ranked in the top four places in terms of the FC Share, also come first in terms of the EU funding received for Research & Innovation via the Horizon 2020 programme (cumulative values for the period 2014-2020). This correlation is far from perfect, as Figure 7 shows some countries performed better in the FC Share compared to the received H2020 funding (e.g. Portugal, Greece, Poland, Romania and Italy), and vice versa for countries like the Netherlands, Belgium and Austria, where ranking in terms of received H2020 funding was better than their FC Share. No correlation between the number of publications and the DESI index was found which indicates that the differentiators are more relevant to research-related factors, rather than general societal digitalisation indices.

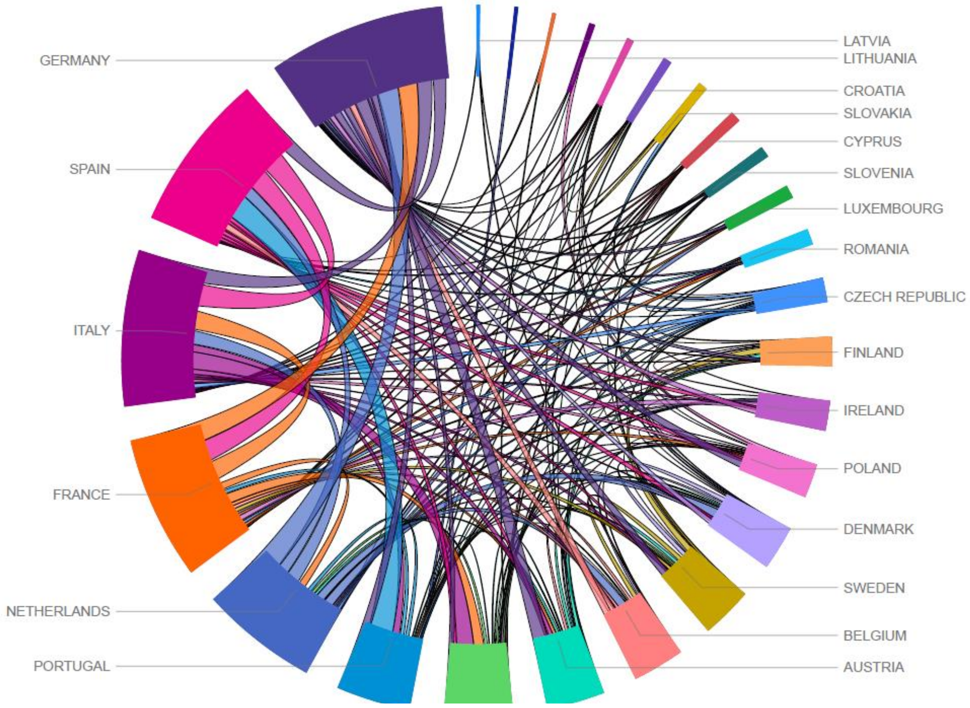


Figure 10: Chord diagram illustrating the Bilateral Collaboration Scores of each of the EU-27 Member States.

In terms of multilateral collaborations, interestingly, the eight countries with the highest FC Shares also have the eight higher MCSs. **The top eight countries in the share of authorship of scientific papers in the field of AI in healthcare are also the top eight multilateral research collaborators.** These highly ranked countries have relatively large populations and some of them also share borders. The formation of cross-border networks, such as the Franco-German R&D network ("virtual centre") offering bilateral

30 Eurostat Main Page. Retrieved from: https://ec.europa.eu/eurostat/web/main/home

31 EU Research & Innovation programme webpage. Retrieved from: https://ec.europa.eu/programmes/horizon2020/en

32 The Digital Economy and Society Index (DESI) 2020. Retrieved from: https://ec.europa.eu/digital-single-market/en/digital-economy-and-society-index-desi

funding and training programmes with bilateral AI clusters in specific industries, including healthcare, may be contributing to the formation of cross-border collaboration patterns between the largest and richest Member States. Another example of such initiatives is the 2019 Baltic Research Programme operated by the Latvian Ministry of Education and Science[33], which aims to support, via a EUR 14.5 million research fund, collaborative research projects between the Baltic countries and Norway, Iceland and Liechtenstein, with a view to building a regional research hub and strengthening the impact of the funding via the pooling of cross-border resources. Due to the recency of these programmes, the effect is not yet be visible in the bilateral collaboration scores, thus, the measures need to be recalculated once some time passes in order to provide a better assessment of the impact of these initiatives.

The chord diagram in Figure 10 incorporates the Bilateral Collaboration Scores of EU Member States in order to depict the research collaborations taking place between the Member States. Table 2 shows the top collaborating country for each EU Member State, ranked by Bilateral Collaboration Score.  It is evident that the strongest cross-border collaborations occur between countries which are either neighbouring, or share strong cultural ties (e.g., Italy-Spain and Cyprus-Greece). In addition, countries with a smaller rank in FC share such as Austria and Ireland appear to be benefiting from strong collaborations with a bigger country, such as Germany, to boost their scientific output in the area of AI in healthcare.

Table 2: A list of the top collaborating country for each EU Member State, ranked by the Bilateral Collaboration Score.

| | Member State | Top Collaborating Country based on BCS | Bilateral Collaboration Score (BCS) |
|---|---|---|---|
| 1 | Portugal | Spain | 25 |
| 2 | Spain | Portugal | 25 |
| 3 | Germany | Netherlands | 22.8 |
| 4 | Netherlands | Germany | 22.8 |
| 5 | Italy | Spain | 22.7 |
| 6 | France | Spain | 21.3 |
| 7 | Greece | Italy | 17.9 |
| 8 | Austria | Germany | 14.6 |
| 9 | Denmark | Netherlands | 9.5 |
| 10 | Belgium | Netherlands | 8.3 |
| 11 | Poland | Germany | 8.1 |

33 Programme agreement signed for the Baltic Research programme in Latvia. Retrieved from: https://eeagrants.org/news/programme-agreement-signed-baltic-research-programme-latvia

| | | | |
|---|---|---|---|
| 12 | Sweden | Germany | 7.4 |
| 13 | Finland | Sweden | 5.9 |
| 14 | Romania | France | 5.9 |
| 15 | Ireland | Germany | 5.7 |
| 16 | Czechia | Italy | 5 |
| 17 | Luxembourg | Netherlands | 4.2 |
| 18 | Lithuania | Poland | 3.2 |
| 19 | Slovakia | Czechia | 3 |
| 20 | Croatia | Slovakia | 2.8 |
| 21 | Bulgaria | Portugal | 2.3 |
| 22 | Cyprus | Greece | 2 |
| 23 | Slovenia | Sweden | 2 |
| 24 | Estonia | Italy | 1.3 |
| 25 | Hungary | France | 1.2 |
| 26 | Latvia | Belgium | 1 |
| 27 | Malta | n/a | n/a |

In order to gain a more holistic picture of the collaborations between Member States, we also list the origin country and the respective number of collaborating countries. In the field of AI in healthcare, Italy is the most outward looking country, ranking first in terms of the number of countries (22) with which it collaborates for its scientific output. Despite that, Germany appears as the top collaborating country for five Member States (the Netherlands, Austria, Poland, Sweden, and Ireland) indicating stronger collaboration links between German research institutions and ones in other EU Member States.

Outside the EU, the top collaborating countries for EU Member States in terms of scientific publications in the area of AI in healthcare are the UK and the USA, with joint publications with 22 EU MS each, followed by Switzerland (11 MS) and China (8 MS). USA appears in the top 5 collaborating country list of Austria, Cyprus, Finland, France, Germany, Hungary, Ireland, Luxembourg and Poland, while it is the number one collaborator of Belgium in this area. On the other hand, the UK appears in the top 5 collaborating country list of Austria, Belgium, Denmark, France, Ireland, Italy, Latvia, Netherlands, Spain and Sweden and is the number one collaborator of Cyprus in the area of AI in healthcare. In the recent years, an increasing number of collaborations can be observed between research institutions in EU MS and corresponding ones in Asia (mostly China, Japan and India), however these collaborations are still not prominent in terms of the overall scientific output of individual EU MS in this area with only one case of an Asian country (China) appearing in the top 5 collaborating country list of a single EU MS (Lithuania).

## Patents granted on AI technologies and applications in healthcare

The European Patent Organization (EPO) database was used to analyse the number of patents granted from each Member State. As before, a search was conducted using combinations of AI and healthcare related keywords and data mining approaches were applied to further refine the dataset used.

After conducting the search for patents granted in the period between 2017 and 2020 relating to AI and healthcare, Germany was ranked first with 62% of total patents granted, the Netherlands second with 22% and Sweden third with 2.8%. Following, Ireland had 15 patents (2.2%), Belgium and France with 13 patents each (1.9%), followed by Italy with 10 patents (1.47%) and Finland with seven patents (1%). Furthermore, Greece, Denmark and Spain had six patents each (0.88% each), Romania and Portugal at four patents each (0.58%) and Austria, Poland and Lithuania at three (0.44%), two (0.30%) and one (0.15%), respectively. The sample used in this study did not find patents in the field of AI in healthcare submitted by the rest of the EU-27 countries.

Analysis was further conducted on Germany and the Netherlands, the top two countries in the sample in terms of AI in healthcare patents. The analysis proved that in countries where the number of patent applications is significantly higher, certain companies are causing this distinction. For instance, in Germany, approximately 96% of total AI in healthcare patents are owned by Siemens Healthcare GMBH, while only 4% of the patents are owned by other companies. Likewise, in the Netherlands, approximately 92% of the total patents identified are owned by Koninklijke Philips and only 8% are owned by other companies. Therefore, it could be argued that, while these countries are technologically developed, this type of technological development is mainly driven by large private corporations. This might restrict the competition of other companies trying to enter the market. In the rest of the countries, we consider that the patents in AI healthcare could be a result of startups. While this is not a direct indication of the actual technology developed from each MS (since not all technology proceeds with patenting), it is an indication of the current trends in obtaining IP protection for technology developed which, in turn, is a deciding factor for the commercialisation potential and long-term viability of companies working on the development of AI technologies in the healthcare sector.

Moreover, the results of this study were compared to the publicly available patent statistics and data provided by the World Intellectual Property Organization (WIPO) and European Patent Organization (EPO) respectively.

By looking at the average number of total patent applications for the period of 2015-2018, calculated by adding the patent applications submitted by residents and non-residents as provided by the WIPO, Germany again ranks first among EU Member States. From the average number of patent applications per country of residence of the applicant for the period of 2017-2020, provided by the EPO, it is also evident that Germany is the leader among EU countries. In both databases, France is ranked second and both the Netherlands and Italy are within the top five countries of the EU.

## Start-up ecosystem relevant to AI technologies and applications in healthcare

A national startup ecosystem consists of various stakeholders and as the concept "ecosystem" suggests, there is interdependence between these stakeholders. One can easily understand that startups are not created overnight, nor do they operate by themselves or in a vacuum. The factors that contribute to successful startups are numerous and can range from financial to sociological factors. The presence of supportive governments, educational institutions, research organisations, funding opportunities, incubators and accelerators, coworking spaces, mentors and related events are some of the main enablers for the creation of a successful startup ecosystem. Through this report, it has become evident that improving one's startup ecosystem is the key to one's growth and development.

The improvement of a country's start-up ecosystem is the result of various changes. One factor observed among EU countries is the **creation of start-up platforms and national start-up facilitators** which are responsible for raising awareness, acting as the key start-up network of Member States and offering support in the form of funding or training. A country's startup ecosystem is more visible and understandable in the presence of **'one stop shop' initiatives** which are found online in the form of easily accessible and informative websites.

In many countries, these platforms are usually developed by government agencies or through partnerships which may include the government. The Czech Republic, Estonia, France, Greece, Latvia, Lithuania, Luxembourg, Portugal, Slovenia and Sweden have government-funded platforms and their aim is to have a national platform to support their startup ecosystems and serve as a network between the various stakeholders of these ecosystems.

Other Member States have seen the development of similar platforms through private initiatives. Austria, Belgium, Bulgaria, Cyprus, Hungary, the Netherlands, Poland, Romania and Slovakia are such examples, with some platforms being led by the private sector and entrepreneurs. The nature of these platform is usually informative.

Many EU Member States looking to enhance their startup and entrepreneurial ecosystems are encouraging foreign talented entrepreneurs to develop their business ideas in these countries. This is often achieved through the provision of special visa schemes and, more specifically, start-up visa schemes. These start-up visa schemes are provided to non-EU and non-EEA citizens usually as a form of temporary residence and are based on their business plans. Countries with such schemes include Italy, France, Denmark, Estonia, Cyprus and Lithuania.

Following a specified methodology explained in Annex I, our findings indicate that Germany has the most start-ups relevant to AI technologies and applications in healthcare, followed by France and the Netherlands in that order. Based on our findings, Germany hosts around 16.5% of start-ups in the field of AI in healthcare. At the other end of the spectrum there are many Member States which have only a couple of start-ups in this field. These countries include Croatia, the Czech Republic, Hungary, Latvia, Luxembourg, Malta, Romania and Slovenia.

One important development affecting the start-up ecosystem of Germany and contributing to its success is the recent introduction of the Digital Healthcare Act[34]. This initiative is driving the digital transformation of the healthcare system of the country and provides specific directions for various aspects such as digital health innovations, online consultations, electronic prescriptions and IT security. The most relevant law is the one encouraging the use of digital healthcare apps by both patients and health professionals, which will also be reimbursed by the state insurance[35]. This may be one of the factors that result in the high number of startups in Germany.

## Level of awareness of topics around AI technologies and applications in healthcare in news and social media

In the past few years, is has become evident that online news and social media play an important role in increasing public awareness and in collecting the views, information and attitudes toward certain issues[36]. That is why social media platforms are now being widely relied on for the promotion of ideas, social causes and products; they are an efficient and inexpensive approach to address barriers such as a lack of engagement, awareness, and finances. The level of social media awareness on AI technologies in healthcare in the EU MS provides an indication of how informed citizens are and may provide insights to governments and individual organisations for using social media in order to increase citizen trust in these new technologies and, thus, increase adoption.

The methodology employed for measuring the level of awareness on AI in the healthcare sector, measures the following two metrics on the basis of combinations of keywords related to the words “AI” and “healthcare” (see Annex I):

1) The number of mentions of a specific topic (i.e. number of times a specific set of keywords assumed to define the topic are mentioned online from a specific type of source - online News or Social Media);

2) The level of engagement on a specific topic (i.e. number of times such an online publication has been forwarded, shared or commented on);

For creating the index presented here, we summed up the mentions for each country during the time period considered, i.e. we use the total mentions and total engagement over a period of 13 months. These were then standardised by dividing by the number of internet users, in order to account for each country's size, and normalised to have comparable index values. The standardised index ranges from 0-100 where a value of over 70 is considered high.

When looking at the level of awareness raised around AI for health and care across national online news sources, the EU27 average of 20.63 over a 13-month period indicates a rather low level of mentions on this topic. 12 EU MS have an index score above average, e.g. particularly news publications in Portugal, Austria, Sweden, Malta, Spain, Cyprus, Luxembourg, Ireland, France, Finland, Germany and Italy yet reveal a comparatively higher awareness.

34 Driving the digital transformation of Germany’s healthcare system for the good of patients. Retrieved from: https://www.bundesgesundheitsministerium.de/digital-healthcare-act.html

35 The guinea pigs of Germany’s new healthcare revolution. Retrieved from: https://sifted.eu/articles/germanys-healthcare-apps/

36 Dwivedi, P. K., & Pandey, I. (2013). ROLE OF MEDIA IN SOCIAL AWARENESS. Humanities & Social Sciences Reviews, 1(1), 67-70. Retrieved from https://giapjournals.com/hssr/article/view/hssr1110

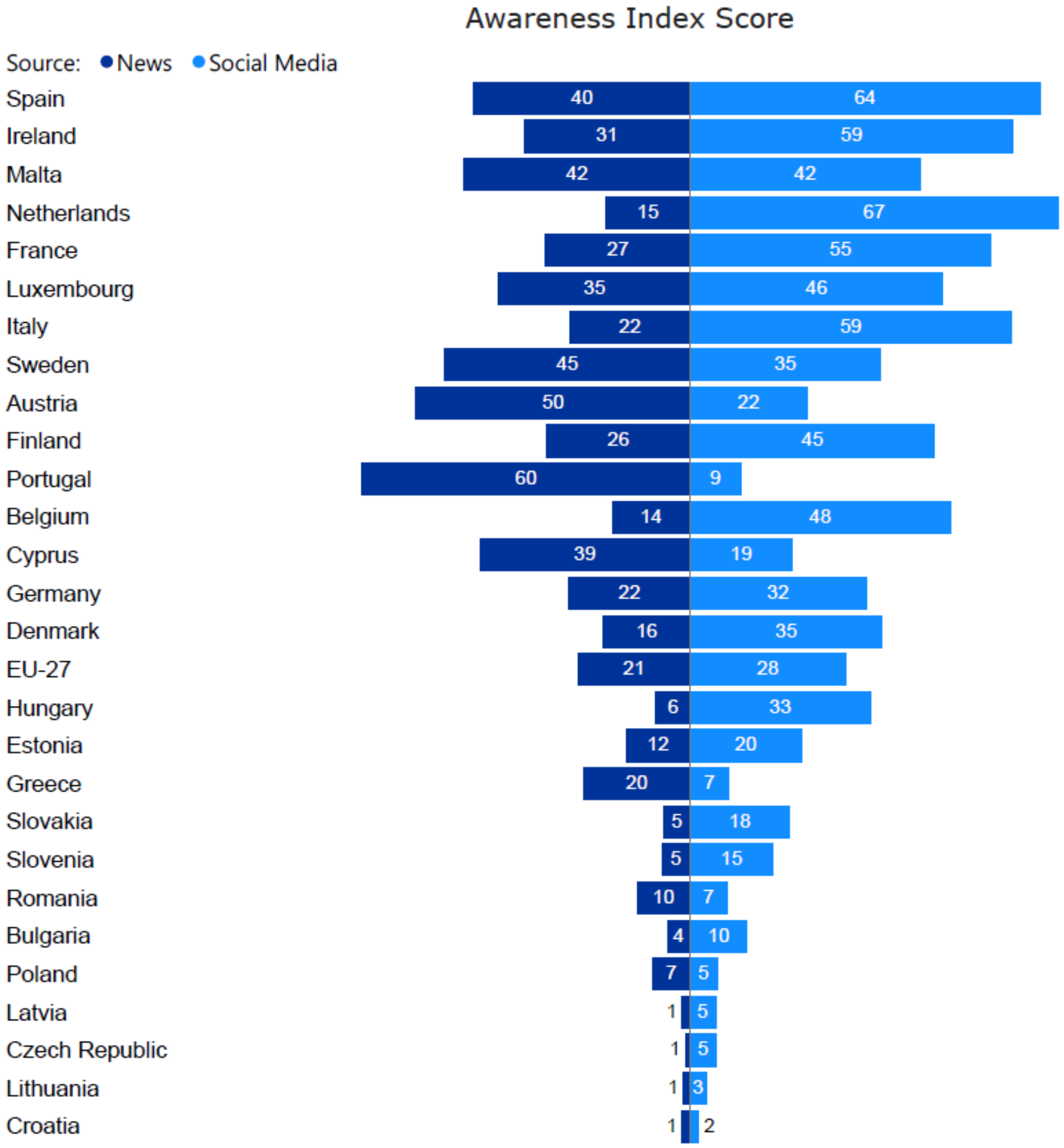


Figure 11: AI in healthcare Awareness Index Score for online news and social media.

Overall, news publications are very much **event-driven**, e.g. linked to summits or EU-wide conferences in the field of AI for health. The importance of **patient-centeredness** in AI technology development is particularly noteworthy in all countries, i.e. the case of chatbots. It becomes evident that news topics are centred around patients' interest in recent innovations, accelerations in clinical trials for the treatment of chronic or widespread diseases, rather than direct impact on health outcomes.

The contextual analysis of spikes in news publications in all EU Member States has resulted in four main thematic clusters:

- Spikes of mentions between March and June 2020 in all EU Member States are first of all due to the **Covid-19 pandemic** and a resulting rise in awareness regarding new ways of mitigating the virus through novel AI applications and technologies. For instance, users show interest in the use of AI applications to detect Covid-19 via symptoms checkers, to ensure social distancing and help tracing/ tracking the spread of the virus. In that sense, there are mentions of using AI and ML to investigate genetic factors. A general observation eventually relates to European citizens' interest in big data usage to control the spread of the coronavirus in Asian countries.

- The second cluster relates to publications about the use and development of AI applications for the **detection and further prevention** of diseases or dysfunctions.
- The third cluster focuses on the **oncological indication**. Potential cancer treatments through means of novel technologies, such as AI-powered cancer screening tools, appear of special interest. Users also discussed automatic assistance systems that could detect potential cancerous tissue patterns of gastroenterological type.
- Awareness in the press is finally raised around the use of AI-based solutions **for different medical treatments**. Thus, there are EU-wide mentions of the relevance of AI technologies for radiology and cardiac imaging, robotics for surgical intervention, the use of AI and Virtual reality to support remote monitoring of patients. In this context, the role and positioning of multinational technology companies (i.e. Samsung, Philips) is stressed.

Eventually, other topics mentioned cover elderly people care and mental health treatment.

Awareness raised across social media channels, particularly Twitter, point out a similarly moderate EU27 average scoring 28.45 mentions over a 13 month period. A slightly higher score yet stresses out the relevance of social media discussions on civil society's perception of the use and development of AI in healthcare. Comparably to the total number of countries above EU27 average regarding news publications, with overall 13 countries above-average awareness, there is a clear tendency for six countries that are leading thru both categories: These comprise France, Ireland, Luxembourg, Malta, Spain and Sweden. In general, there is a correlation between the usage of national social media platforms and awareness around this specific topic.

Whereas **sentiments** about this topic are rather **positive**, hashtags are broadly used to describe the disruptive potential of AI technologies, ML and blockchain. Yet, negative connotations about that topic appear in tweets and retweets criticizing pressing **ethical issues** around AI in health parallel to human intelligence and pointing out mistakes of robotics in medical interventions.

Twitter users in different EU Member States show involvement around four streams of discussion, as listed below:

- Tweets and retweets around AI for health and care are predominantly **event-driven.** Thus, spikes of publications go along with conferences, congresses and digital summits providing internet users with insights shared about latest AI technologies, progress with treatments and highlighting ambitions (i.e. Digital Summit Berlin, FINnovation Events, conference held by the European Economic and Social Committee in Helsinki).
- Posts are associated with **political decisions and actions on national governmental or EU level**. Concerning this matter, key opinion leaders' publications coincide with the European Commission's publication of the White Paper on AI, announcements regarding the Horizon2020 funds, to name a few.

These refer to novel uses of AI and ML in health-related fields or rather the impact on personalized medicine. Users express their opinions around national governments' announcements of new AI-related activities in different fields, including ambassadors of those developments.

- **Multinational (high-)technology players** (i.e. Philips, Google Health) and their innovative market offerings in this field appear of relevance and influence users' online awareness. With this regard, users show keen interest in technological breakthroughs allowing for better accuracy in surgical and radiographic approaches.
- **Covid-19** has likewise enhanced awareness thru Twitter. Users discuss different streams of innovation that AI offers to **mitigate impacts of the pandemic**, such as predictive diagnosis, statistic modeling to forecast peaks of contamination, AI-based technologies to trace contacts or rather personalized treatments. Moreover, tweets in most of the EU Member States highlight the positioning and relevance of **high-tech and med-tech start-ups** when managing the Covid-19 crisis.

While is it not possible to correlated news and social media awareness with levels of adoption on citizen's sentiments towards the use of AI in the healthcare sector, it is clearly evident that social media channels can now be utilized by the European Commission, and EU MS alike as channels for increasing awareness around the use of AI and other technologies in the healthcare sector in order to enhance citizens' understanding of these technologies and to build the necessary trust that will lead to improved adoption.

### b. Level of adoption of AI in the healthcare sector in the EU

While our survey of users of AI technologies in healthcare, constituting of hospitals and other healthcare providers, has not yielded statistically significant results, we can analyze responses to obtain *an indication* of the level of adoption of AI in the healthcare sector and the factors that may be affecting adoption.

Our survey indicates that most organizations who responded to the survey are either currently using or planning to use AI technologies in the next three years with 11% of them using AI technologies across the entire spectrum of applications included in the survey, i.e., Medical Robotics, Disease Diagnosis, Patient Monitoring and Genome Analysis. The technology most widely used or planned to use in the next three years is Patient Monitoring (72%) followed by Disease Diagnosis (61%), Medical Robotics (53%), Other (33%) and Genome Analysis (31%)[37].

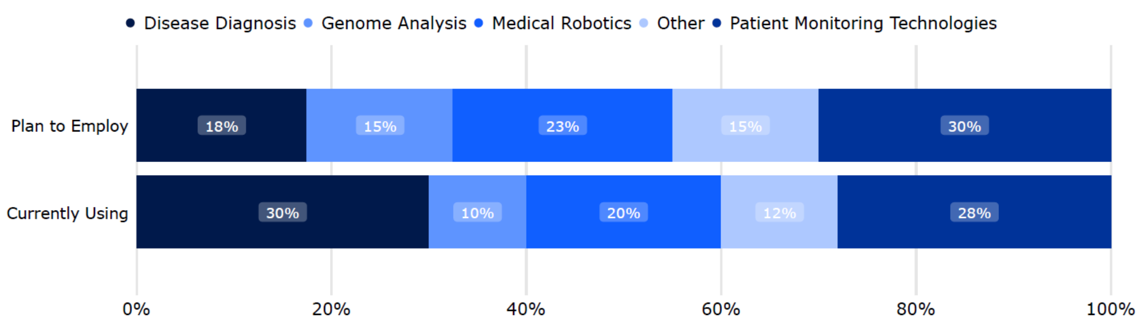


Figure 12: Adoption of AI applications by Hospitals and Healthcare Service Providers

37 Genome Analysis is not a technology traditionally used in hospitals as it is mainly a scientific discipline so the result in terms of responses is to be expected.

Despite the encouraging numbers of organisations already using or planning to use AI, responses regarding the number of departments and users of AI technologies within the organisation were limited, with most respondents indicating that the applications were not still widely used within the organization, with use limited mostly to 1 and up to 3 departments only and used only by specialized staff (a common answer included “pathology doctors”). It is evident that while some healthcare organisations within the EU are gradually becoming open to the use of AI technologies, use is still limited within hospitals and healthcare providers and measures to promote more widespread use are needed.

In terms of R&D activities taking place within hospitals and healthcare providers, 50% of respondents indicated that they are either actively (39%) or sporadically (11%) collaborating with research institutions, start-ups or the government for the purpose of translating AI research into practice within their own institution. There was no difference in responses between public and private hospitals. The types of initiatives included in the responses included collaborations with start-ups, universities (e.g., for joint PhDs), as well as own research on AI technologies within the hospitals themselves. In addition, 55% of organisations indicated that they had received either local of European funding for purchasing or using AI technologies.

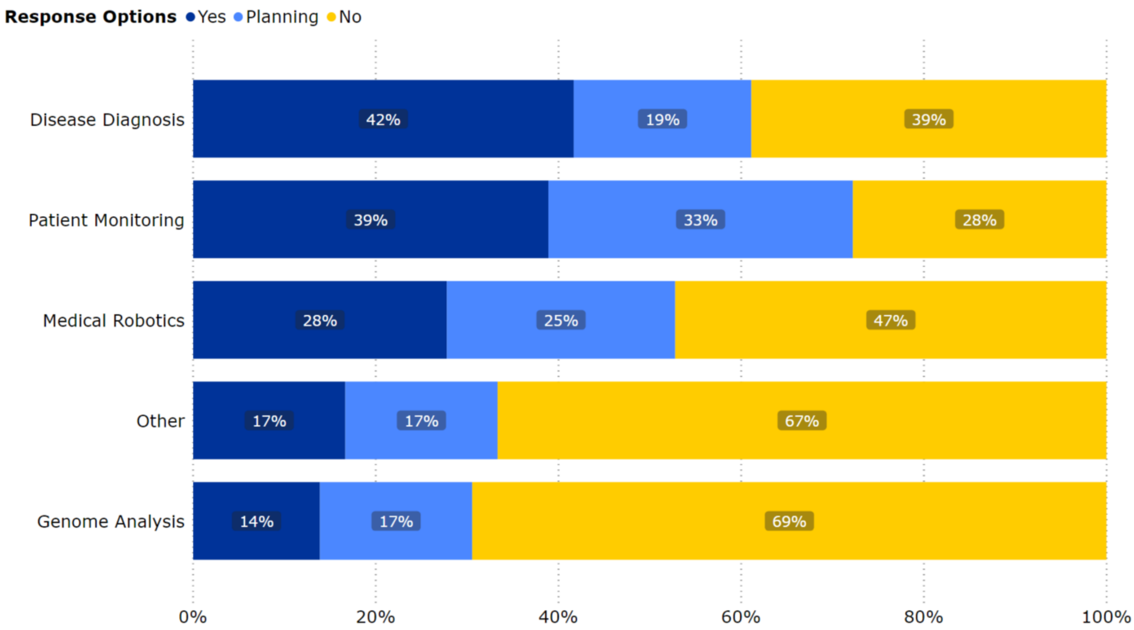


Figure 13: Level of adoption of AI tools by the users of AI technologies in healthcare.

In terms of where AI Users heard about potential AI technologies to use in their organisations, healthcare technology agents came out top, followed by technologies developed internally and government initiatives next. This indicates the need for targeted initiatives for engaging healthcare technology agents with developers and products in the area of AI in healthcare for promoting products and applications in interested organisations.

An extra point of view on the level of adoption of AI technologies, may be derived from the survey answered by the developers AI technologies who were asked to indicate whether their AI-enabled products were already being used by healthcare organisations or individuals. 44% of respondents replied that their products were already in use by organisations and individuals while the rest (56%) were still in the development phase. Of the organisations that had purchased AI-enabled technologies, over 90% on average appear to be actively using them. In terms of B2C applications, the most widely used technologies were in the area of mhealth. Instead, the highest adoption in applications for use by healthcare professionals were in the area of radiology (Disease Diagnostics). Lastly, the majority of AI in healthcare developers have acknowledged that they are actively collaborating with other research institutes/companies/healthcare delivery centers for the translation of AI-related research into healthcare applications.

Success stories from European SMEs developing AI technologies, include:

- The Austrian SME, Symptoma, a digital health assistant and symptom checker that is currently being used by 10 million patients monthly according to the survey.
- The Estonian SME Velmio which is actively used by 10,000 patients in more than 90 countries.
- The Estonian SME, Healthcode AI, which reaches 4000 patients through its AI Leia Physician.
- Another example includes Danish SME, Livalife, which also estimates that 5000 are purchasing and using their digital health coaching programmes.

Another insight obtained through the survey of AI Developers concerned **awareness-of and collaboration-with organisations aiming to support the translation of their products into clinical practice and widespread use**. The answers to the question “Are you aware of public/private organisations within your country that provide support for the

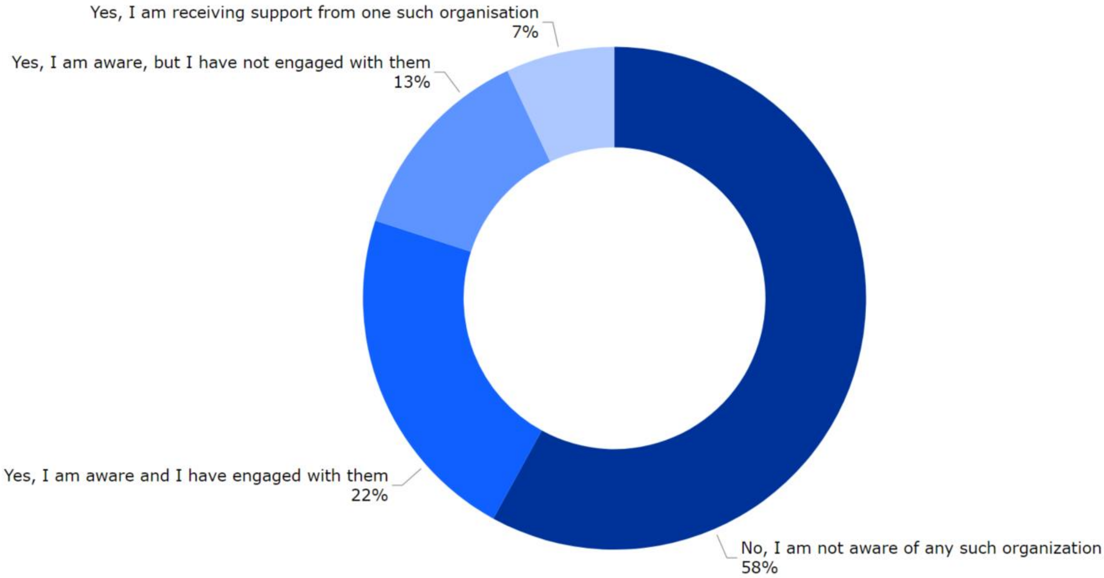


Figure 14: Awareness or engagement with organisations to support the translation of AI research into applications.

translation of your AI-enabled healthcare tools into applications?” showed that most AI Developers (56.7%) were not aware of any public or private organisations that could support them for taking their products to market and only 6.7% were actually receiving any support for this. This kind of support mechanisms, usually facilitated through research councils, are very important since moving from R&D to application is often reported as a major hurdle in the success of such innovative technologies. Despite the attention the European Commission has placed in developing programs and support mechanisms for taking products to market[38], it appears that developers in the area of AI in healthcare are still not aware of these schemes or actively engaging with such schemes and this may be a factor hindering both R&D around this area, as well as widespread adoption.

### c. Technical Aspects

#### Major areas of application of AI in the healthcare sector in EU Member States

The literature review conducted at the beginning of this study revealed the extent of the research and innovation activity around AI in healthcare in the EU Member States which focus mainly in the following broad categories:

- Patient Monitoring
- Genome Analysis
- Disease Diagnosis
- Medical Robotics

We proceeded to classify the volume of scientific publications and start-ups around these 4 broad areas in order to get a picture of the distribution of technologies in the EU as a whole.

Figure 15 shows the share of scientific publications in each category from the scientific papers' sample used in this report. Likewise, Figure 16 shows the share of start-ups in each category. In the case of start-ups it is worth mentioning that, unlike in the case of scientific papers, most companies are working on innovative products which cut across areas and many companies also focus on treatments and end-to-end products that provide AI-enabled monitoring, diagnosis and decision support. The classification in the case of start-ups was thus more challenging and results should only be taken as indicative.

It is evident that the scientific output of the EU as a whole within the field of AI in healthcare is dominated by the category of Disease Diagnostics by around 42%. This is then followed by Patient Monitoring (34%), Other (16%), Medical Robotics (6.6%) and Genome Analysis (2.4%), in that order.

On a more granular level, in almost all EU Member States the category of Disease Diagnostics is again dominant. The only exceptions are Greece, Portugal and Romania where Patient Monitoring and Disease Diagnostics have an equal share and Ireland where the category of Patient Monitoring dominates slightly.

Approximately 35% of start-ups applying AI in healthcare within the EU work in the area of Patient Monitoring. Nevertheless, Disease Diagnostics is a close second with 33%. The opportunities presented by patient monitoring applications are numerous with time and cost savings being two of them. Developing a remote patient monitoring software is an ambition of many start-up companies in the field of AI in health and care. Remote patient monitoring is not limited to the management of certain chronic illnesses but can

38 Europe go to market support for enterpreuneurs-Online tool, accessed at https://ec.europa.eu/digital-single-market/en/go-to-market support?g2m_support_types_tid=All&g2m_subtopics_tid=All&g2m_geo_focus_tid_1=74930

also be focused on elderly patients, patients with mobility problems, patients with limited access to healthcare facilities and post-surgical patients.

On the other hand, the use of artificial intelligence (AI) in diagnosing diseases through medical imaging has become more common and more accurate through the years. According to a study in the literature, when deep learning models (part of AI technologies) were compared to healthcare professionals in studies of any disease, the diagnostic performance of the two was found to be equivalent[39]. In another study an AI system's performance was compared to that of 101 radiologists in the topic of cancer detection accuracy and was found to be similar and non-inferior to that of the healthcare professionals[40]. Although these studies are retrospective, they both show that incorporating AI in disease diagnosis in highly promising.

Image recognition and analysis through AI and in particular, through deep learning has been transforming healthcare by introducing automation, accuracy and accessibility improvements and cost reductions.

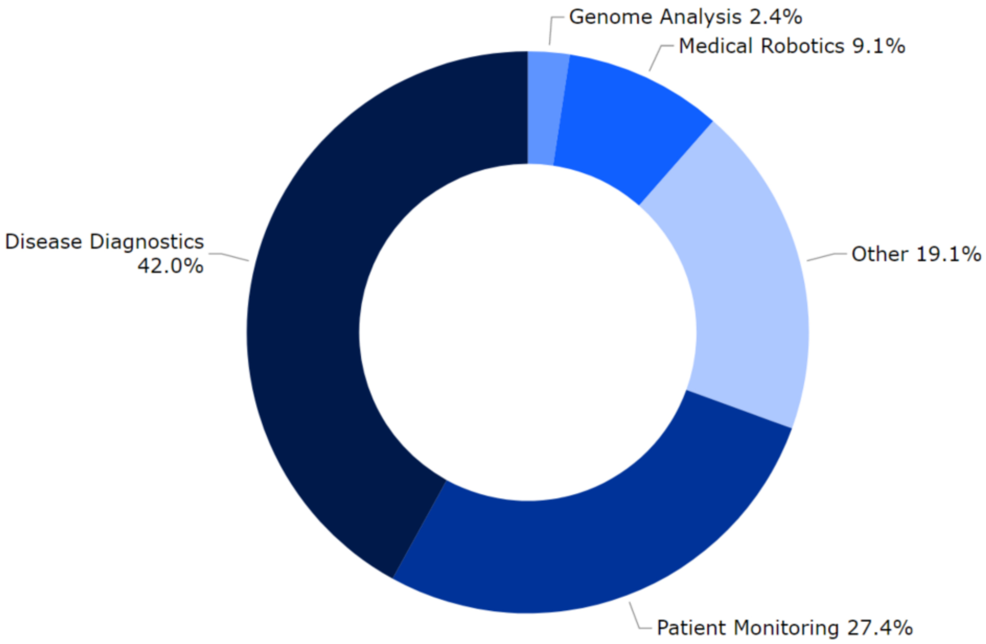


Figure 15: Scientific papers areas of application of AI in healthcare.

On the other hand, it is widely accepted that remote monitoring is expected to be one of the most transformative AI applications in the field of health and care. Remote patient monitoring has the potential of reducing hospitals' personnel costs by reducing the number of hospital rooms needed and by allowing patients to receive healthcare in the comfort of their own space and by minimizing the risk of nosocomial infections[41]. Frail patients will be able to avoid the possibility of hospital-acquired infections, hospital-

39 Liu, X., Faes, L. & Kale, A. A comparison of deep learning performance against health-care professionals in detecting diseases from medical imaging: a systematic review and meta-analysis (2015). The Lancet Digital health, Volume 1(6).

40 Rodriguez, A., Lang, K., & Broeders, M. Stand-Alone Artificial Intelligence for Breast Cancer Detection in Mammography: Comparison With 101 Radiologists (2019). Journal of the National Cancer Institute, Volume 111(9), Pages 916–922

41 Eric Topol: EHRs have 'taken us astray,' but AI could fix healthcare in a 'meaningful and positive way'. Retrieved from: https://www.healthcareitnews.com/news/eric-topol-ehrs-have-taken-us-astray-ai-could-fix-healthcare-meaningful-and-positive-way

induced delirium and other transport complications through telemedicine and remote monitoring[42].

The European Commission is co-financing the Active & Assisted Living (AAL) program. This programme has been funding projects that can result in better quality of life for the EU's older population and an enhanced market regarding healthy ageing technology and innovation[43].

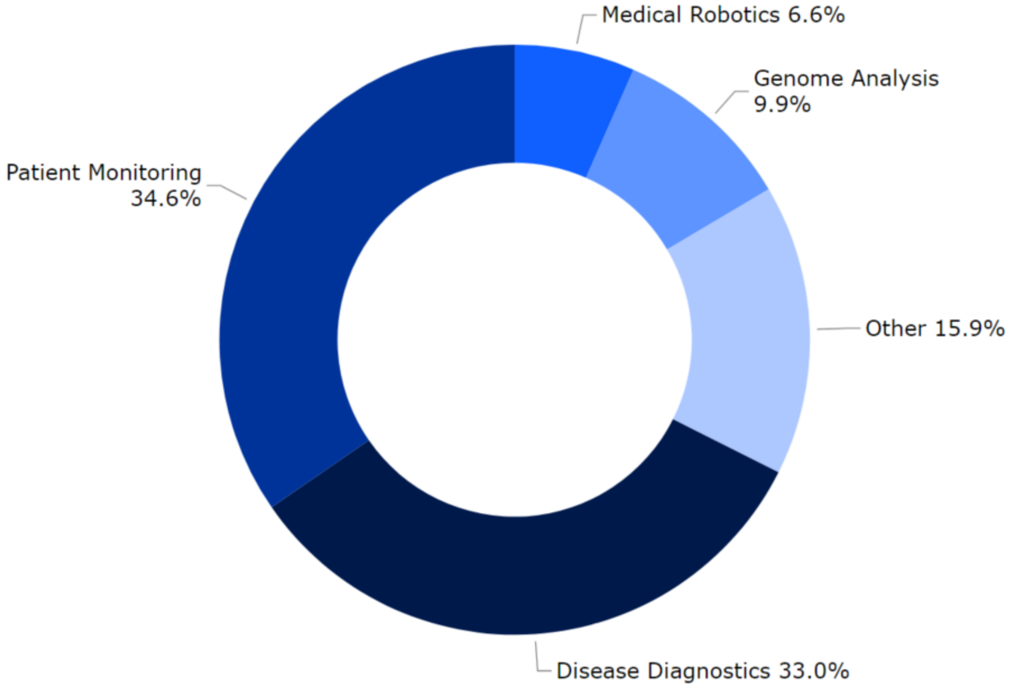


Figure 16: Start-ups areas of application of AI in healthcare.

The AI developers included in the survey were asked whether their AI developments are in the field of healthcare and if so, they were asked to respond according to the areas of application within healthcare.  It is evident that the two dominating areas of application within healthcare among AI developers are Disease Diagnostics and Patient Monitoring. More than 50% of the respondents and organizations represented in the survey are developing AI tools relating to Disease Diagnostics and Patient Monitoring. The two less popular categories within healthcare among AI developers seem to be Medical Robotics and Genome Analysis. This finding is mainly in line with the classification of total EU scientific output and start-ups in these 5 different areas of application. There is, however, a contrast in terms of responses received from hospitals and healthcare providers who

42 Healthcare's Digital Future: Telemedicine & Remote Monitoring. Retrieved from: https://ai-med.io/ai-med-news/future-healthcare-digital-telemedicine-remote-monitoring/

43 Ageing well in a digital world. Retrieved from: http://www.aal-europe.eu/about/

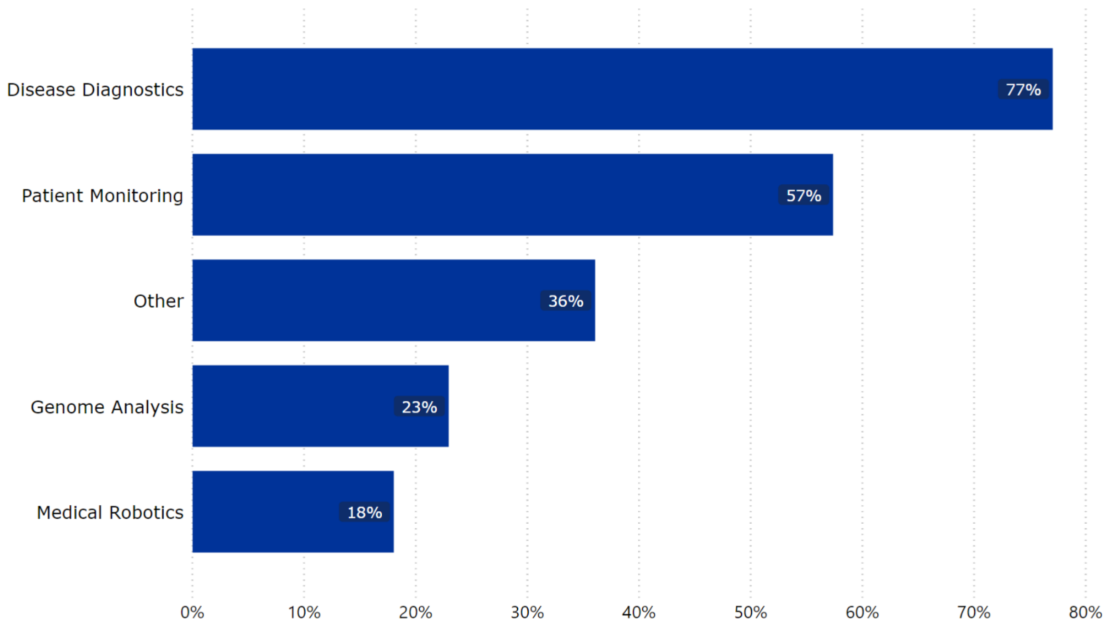


Figure 17: Areas of application for AI Developers.

have mainly adopted disease diagnostic applications in their organizations, albeit mostly in a pilot phase. This contrast may be attributed to

- A lack of distinction around the terms *diagnosis* and *monitoring*.
- A lack of trust in the use of AI or automation for decision-making compared to the use as part of a process (Patient Monitoring). It is much easier for both clinicians and patients to trust a medical procedure which is assisted by software and automation than to trust a machine-based diagnosis. This is a possible reason for the contrast between the level of development and adoption of AI-enabled diagnostic and patient monitoring tools.

## Sources, types and characteristics of data used by AI technologies and applications deployed in the healthcare sector

The developers of AI technologies and applications in the healthcare sector rely heavily on good quality data and therefore, were asked to indicate the sources and types of data they utilize in their developments.

67.2% of the survey responses indicate that the data required for the development of AI technologies and applications in healthcare are obtained through the organizations' own collections via clinical trials or other data collections. However, a lot of responses indicate that AI developers are using private data collections alongside public ones. In particular, 52.5% respondents state that they utilize openly available research databases whereas, 36.1% respondents also list hospital EHR systems as their data sources.

Healthcare organizations may find it easier and cheaper to source and access data that belongs to them when they develop AI technologies.

One of the European Commission's policies is to enhance the interoperability and exchange of Electronic Health Records across borders within the EU, to digitalize healthcare. Improving access to health data across borders in a secure way will enable continuous and improved patient care across the EU and will reduce healthcare costs. Enhancing the availability of data further encourages the development of AI applications for healthcare, as it is the main foundation for their development. For example, due the efforts of the EU, by 2025 most Member States will have introduced ePrescriptions and Patient Summaries before the full health record will be implemented[44].

Regarding the types of data used, **60.7% of the developers included in the survey use Imaging data**. This corresponds to the high level of AI technologies and applications being developed in the specific field of disease diagnosis, where the use of imaging data is essential. There are 3 types of data which have relatively similar popularity among the survey's AI developers, and these are: **vital sign data, pathology data and unstructured data (text)**. On the contrary, the least popular type among our sample is that of Biochemical data. Lastly, when asked about their attitude towards the use and sharing of Open Data, AI developers do not depict clear preferences. 77% of respondents do not share their data, of which 52% use other open data. **Only 23.0% of the survey's AI developers is using open data from open databases and is, at the same time, willing to contribute to open databases**. Work still needs to be in order to educate people on the importance of Open Data and the subsequent benefits such as its need in the development of AI technologies and applications for healthcare.

'Shaping Europe's digital future' includes among others, increased access to high-quality data in the most secure way possible and the creation of a European health data space to encourage research, diagnosis and treatment[45]. Envisioning the creation of a single market for data in the EU has tremendous potential and can transform the European economy into an attractive, secure and dynamic data economy.

44 Electronic cross-border health services. Retrieved from: https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en

45 Shaping Europe's digital future (2020). Retrieved from: https://ec.europa.eu/commission/presscorner/detail/en/fs_20_278

# 4. Stakeholders' views regarding the development, adoption and use of AI technologies and applications in the healthcare sector

## a. Views regarding the use of AI in healthcare

Patient sentiment is crucial in order to understand the impact of incorporating AI-based technologies and applications in healthcare holistically. Patients are key stakeholders in the healthcare sector and their perceptions regarding AI can have a trickle-down effect in society. Since no data from patients was collected as part of our survey, we focused on extracting information from a number of studies in literature which depict patients' perceptions either on the use of AI in healthcare in general or on the use of specific AI tools.

A common theme that emerges from literature relates to the notion of trust and whether humans and, especially, patients can trust AI-powered medicine and healthcare services. Despite the hype surrounding AI and the potential benefits it can bring to the healthcare sector, patients tend to question whether AI will harm human engagement, empathy and involvement. As suggested[46], resistance to AI stems from the idea that such technologies cannot understand and process patients' unique characteristics and will thus not provide personalized outcomes. Disbelief among patients has also been observed in the context of mental illnesses, where they believe that complex mental illnesses cannot be understood by machines.

The EU's focus on creating a strong link between AI and trust is highly relevant in the healthcare sector. As indicated by literature, patients and other stakeholders are not convinced that they can foster a relationship of trust with AI-powered tools and machines.

In the context of skin cancer screening for example, although patients are receptive to the use of AI, they highlight the importance of a symbiotic relationship between humans and AI[47]. This point of view is further exemplified by the fact that when asked about the creation of an AI-power virtual nurse assistant, the majority of patients assert that doctors are the ones who should be trusted for this task[48]. Moreover, only half of a group of patients with chronic conditions believe that the use of AI in healthcare represents an exciting opportunity and only a minority would be willing to integrate biometric wearable devices and AI into their care plans[49].

Interestingly, in another study, both the public and the patients empower the clinician and would prefer it if the clinician oversaw the final decision-making process rather than machine learning algorithms[50].

46 Longoni, C., Bonezzi, A. & Morewedge, C. Resistance to Medical Artificial Intelligence (2019). Journal of Consumer Research, Volume 46 (4)

47 Nelson, C. & Creadore, A. Patient Perspectives on the Use of Artificial Intelligence for Skin Cancer Screening A Qualitative Study (2019). JAMA Dermatol 156(5), 501-512

48 How Should Healthcare Make Use of AI? Ask the Patient. Retrieved from: https://invivo.pharmaintelligence.informa.com/IV005288/How-Should-Healthcare-Make-Use-of-AI-Ask-the-Patient

49 Tran, V.T., Rieros, C. & Ravaud, P. Patients' views of wearable devices and AI in healthcare: findings from the ComPaRe e-cohort. NPJ Digital Medicine, Volume 2, Article number (53)

50 Future data-driven technologies and the implications for use of patient data Dialogue with public, patients and healthcare professionals. Retrieved from: https://acmedsci.ac.uk/file-download/6616969

Nevertheless, one cannot deny that there are positive connotations associated with the incorporation of AI in health and care. In a cross-sectional study, the majority of patients

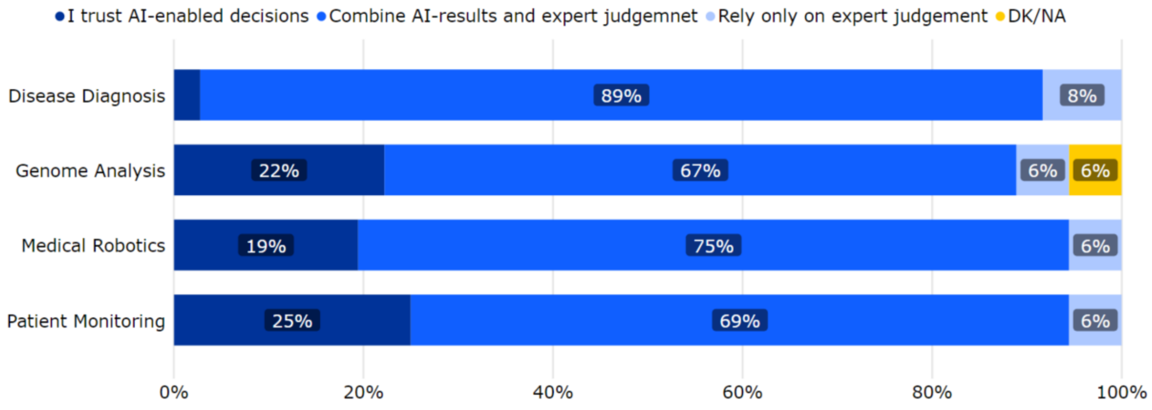


Figure 18: Potential users' attitude towards the use of AI tools with respect to the balance between AI-enabled decisions and expert judgement.

Despite the excitement of heart and circulatory patients regarding AI and its use in diagnosis and treatment, it is also found that only 17% of these patients are actually aware of the current uses and applications of AI in this field[51]. Therefore, one may infer that the public's awareness regarding artificial intelligence tools and applications in the healthcare is insufficient. Negative public or patient perception may be driven from misinformation of the topic or lack thereof.

Responses from our survey, confirm the issues of trust and the need for collaborative machine-clinician decision-making for increased acceptance of AI technologies in the healthcare sector, even by healthcare professionals. When potential users of AI technologies were asked to indicate their attitude towards the use of AI tools within their organization, with respect to the balance between AI-enabled decisions and expert judgement the overwhelming majority responded that they trust AI results in combination with expert judgement. AI-enabled decisions were trusted mostly for applications of Patient Monitoring (25%), followed by Genome Analysis (22%), Medical Robotics (19%). Only 3% of respondents would trust an AI-enabled diagnostic decision. In contrast, 89% of respondents would "trust AI-results in combination with expert judgment" in the case of Disease Diagnosis, 75% in the case of Medical Robotics, 69% for patient monitoring and 66% for Genome Analysis. This indicates that individuals are more likely to trust AI when they associate it to a process rather than with a decision.

### b. Views regarding barriers to adoption

The survey identified specific barriers related to the utilization and implementation of AI systems by health professionals in the health sector and asked AI developers to provide their own opinions on the relevance of these barriers. Around 80% of the AI developers agree, either strongly or somewhat agree, that the lack of understanding of AI technologies slows down the rate of implementation and utilization of AI systems by health professionals in the healthcare sector. Moreover, AI developers strongly believe that the lack of trust in AI and the lack of IT knowledge and competencies are two barriers

51TechUK WEBPAGE. Retrieved from: https://www.techuk.org/insights/reports/item/15353-putting-patients-at-the-heart-of-artificial-intelligence which significantly impede the uptake of AI systems by health professionals. On the Users side, while they acknowledge the benefits that AI can bring to their everyday work (See figure 19), lack of training and lack of trust are also acknowledged as barriers to the more widespread adoption of AI.

Via the survey, it is also evident that developers of AI technologies and applications in healthcare believe that these technologies and applications can have a positive impact on various aspects and stakeholders of the sector. Many identify a link between better diagnostic accuracy, timely detection of various diseases, enhanced therapy and better treatment plans for patients, which directly affects the quality of healthcare they receive and their lives. These benefits are also linked with the ability of AI technologies and applications to support doctors in their decision making and hence, improve quality. Automation and improved efficiency of processes can help free up time from doctors and other healthcare professionals, who will be able to devote more time for productive tasks and human interactions, according to AI developers. These changes will also have a positive impact on the quality of healthcare received by patients. Moreover, it is commonly stated that such technologies and applications will manage to reduce costs, impacting healthcare organizations' finances and making healthcare more accessible. Most of the responses are focused on the impact accruing to the patient and hence, again exemplify the concept of patient centricity.

Users of AI technologies in the healthcare sector agree that the use of AI systems by healthcare professionals is useful for their jobs and task, enhance the effectiveness of their job and improve quality of care.

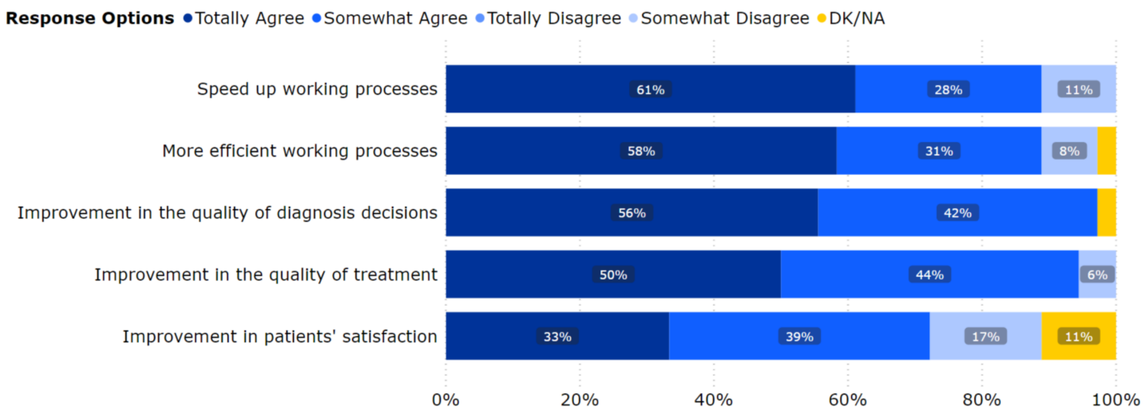


Figure 19: AI Users' statements regarding the use and impact of AI technologies in healthcare.

Regarding the barriers of using these AI systems within the healthcare sector, more than 80% of respondents agree, either totally or somewhat, that the lack of financial resources and lack of training are two such barriers. When asked about the potential positive impacts of AI systems in the healthcare sector, around 95% of respondents agree that these systems can lead to an improvement in the quality of diagnosis decisions. Also, more than 90% of AI users agree, either totally or somewhat, that AI systems in healthcare can improve the quality of treatment and more than 80% agree that they can make working processes much faster and more efficient.

Despite having fewer responses from Public Authorities, it is useful to understand the perspectives coming from Ministries, Public Authorities and National Funding Bodies regarding the topic of AI in healthcare.

When the respondents were asked to list some of the barriers, challenges and enablers regarding the adoption of AI technologies in healthcare across all healthcare delivery centers, some common patterns are identified from their answers. Approximately 50% of respondents list the lack of relevant policies and legislation as well as, strategic direction at a national level as the obstacles to the adoption of AI in healthcare. More than 50% also list the increased need for funding and investments. Another observation derived from the responses is that without good quality digital infrastructure and healthcare data it is very difficult to develop and adopt these technologies in the healthcare sector.

# 5. Insights

Analysis of the findings of our study with regards to the level of development and adoption of AI in the healthcare sector in the EU provides insights into the factors which are hindering the wider adoption of AI in the healthcare sector and which may provide a basis for policy development and strategic planning. These fall under six categories on which we elaborate next.

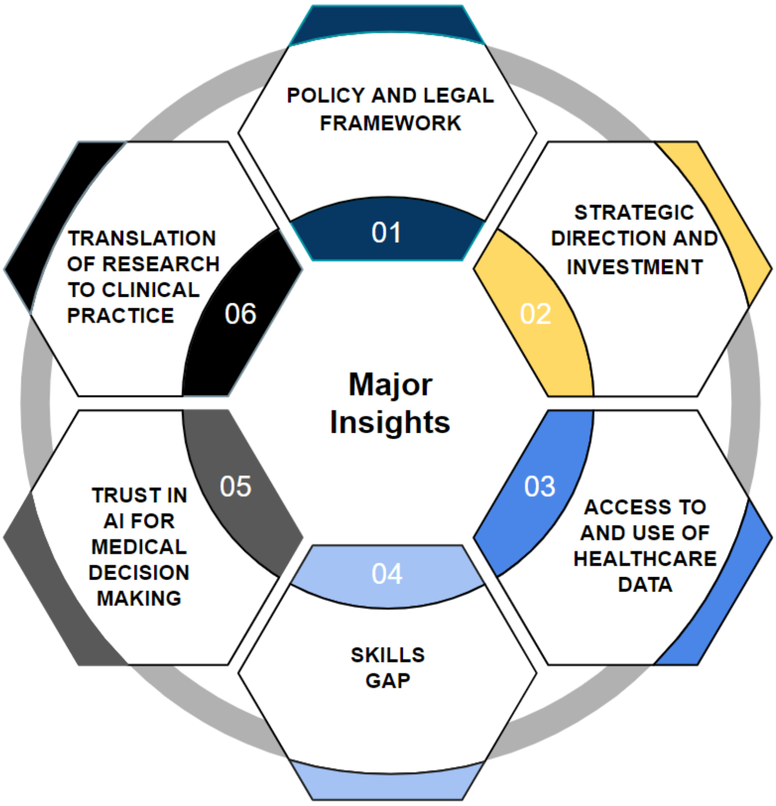


Figure 20: Insights related to the development and adoption of AI in the healthcare sector.

## Policy and Legal Framework

While aspects of the use of AI in healthcare may be covered by existing legislation around the data protection, the use of EHRs, as well as trademark laws. The nature of applications of AI in healthcare, as well as the risks and ethical aspects relevant in the use of AI for medical decision making requires special attention and a possibly more stringent regulatory framework and legislation. Based on our findings, the priority areas for the development of legislation around the use of AI in healthcare concern ethical requirements to ensure transparency, verifiability and predictability of AI systems, policies around the introduction of certifications for the use of AI in healthcare, as well as amendments to existing laws around competition and copyright, in addition to data protection laws regarding the use and exchange of health data, in particular for the use in research and innovation in the area of AI in healthcare.

## Strategic Direction and Investment

Despite 20 EU Member States having already published an AI strategy, there is little mention of strategic initiatives targeting applications in healthcare, in particular. At the same time, research organizations working on the development of AI applications in healthcare are still largely reliant on public investments and the calls targeting AI in the healthcare sector in particular are limited. Stakeholders identify a need for strategic direction for the improvement in the development and adoption of AI technologies in the healthcare sector. National-level strategic initiatives are needed to **foster cross-border collaboration in R&D** (since especially for smaller EU MSs, as it is evident that close collaboration with larger more technologically advanced MSs provides a benefit), to **increase citizen awareness and trust** in AI technologies and to **support the translation of AI research into clinical practice**. On the funding side, there is a need of specialized funds for the **development of data standards and formats** (to encourage EU-wide collaborations) and for participation in international standardization processes, as well as funding (and improved processes) for SMEs for **obtaining IP on their innovative products** so that the market is not monopolized by the large technology corporations. Strategic initiatives supporting networking and providing **access to innovation funding and venture capital** are also initiatives which will improve the prospects of AI technologies making it to the market and to clinical practice thereof.

## Access to and use of healthcare data

There is momentum around the establishment of legislation and standards for the use of EHRs, however, these apply only to public-lead initiatives, and stakeholders highlight access to and sharing of data in the private sector as a major hurdle for the further development of AI technologies in the healthcare sector. Our study revealed that **only a small percentage of AI developers (23%) are willing to share their own data** with other developers, while almost 50% of developers use publicly available open data for their own work. Data is still viewed as a competitive advantage by AI developers and it is likely that a better **regulatory framework around IP** and the use of third-party data would improve this attitude. On a national level, delays in the implementation of EHRs in some Member States, as well as common infrastructures for the cross-border exchange of such data presents a hurdle. To facilitate this, accelerating the **implementation of cyber security directives** locally as required by the EU Directive on security of network and information systems (NIS) is a necessity.

## Skills Gap

Stakeholders identify a skills gap which hinders the widespread adoption of AI in the healthcare sector in the EU. Lack of training, IT knowledge and competencies in both patients and health professionals, as well as a lack of understanding of AI have been highlighted by respondents as challenges. At the same time, looking at the responses of public authorities and health professionals, **the skills gap goes both ways** in that a need is identified to create AI technologies which are easy to integrate into current clinical workflows and clinical practice. Success models reveal the need for collaborative R&D activities involving **multi-disciplinary teams of AI experts and clinicians** such that technologies are built in a way that they can be integrated, and thus accepted, by health professionals and such that clinicians are equipped to use them. As way to foster this, is the establishment of **University Hospitals**. Indeed, the existence of university hospitals in EU Member States has been shown to be a factor contributing to the scientific output in the area of AI in healthcare. Initiatives and legislation providing **reskilling opportunities** and support to employees in the health sector whose job is at risk due to

AI technologies is a way to address the skills gap and to build more confidence and acceptance of the new status.

### Trust in AI for medical decision-making

While the majority of respondents indicated that they would trust AI-enabled medical decisions in combination with expert judgement across applications, there is a lack of trust in AI-only systems, more so for systems of disease diagnosis. The issue of trust and the need for culture-building is a prominent response when stakeholders were asked to identify challenges to adoption. The introduction of **legislation around ethical use, transparency and explainability**, as well the introduction of **AI certifications and benchmarking** for medical use are initiatives which may help towards the acceptability of AI technologies in healthcare but it is also acknowledged that **understanding of AI technologies through education and reskilling initiatives** may prove decisive for the more widespread acceptance.

### Translation of research to clinical practice

The translation of AI research into clinical practice is a major hurdle, attested by the fact that over 50% of SMEs have still not taken their products to market. Additionally, even in the case that AI technologies have made it into hospitals and medical practices, use is confined to single departments and a limited number of users. At the same time, the long and laborious process of obtaining IP is a hindering factor for SMEs for protecting their products and gaining a market advantage. While there are a number of initiatives for supporting organisations for taking their innovative products to market, SMEs are not aware of the support mechanisms available very few are actively engaging with them for support. **More awareness** is therefore necessary. The establishment of **improved legislation around copyright and IP**, as well as **funding support** for obtaining it will improve the translation of R&D into applications. Additionally, consortia consisting of industry, universities/research institutes and hospitals for the translation of research into clinical practice seem to be very beneficial in cases that they have been used and **such schemes should be further established and supported** by the EC and local governments. In most cases, these collaborations are mostly possible between big technology corporations via industrial funding but funding should be provided to further support the development of such relationships for SMEs as well so that the innovation pool around AI in healthcare widens. Related to both the skills gap and issues of trust, technology transfer will be further supported through the digital upskilling of healthcare professionals so that they acquire the competence, trust and acceptance of AI systems. At the same time, **cultural variations across nations and organizational or domain culture-based differences are factors that influence the success of technology transfer** and these should also be addressed through EC-level and national-level initiatives. The establishment of cross-disciplinary and cross-cultural consortia are initiatives that have been shown to cultivate a common understanding and to support the transfer of technology into clinical practice.

# ANNEX

# Annex I: Detailed Methodological approach

### g. Methodological approach for determining scientific peer-reviewed publications in area of AI in healthcare

To provide a Specific, Measurable, Attainable, Relevant, and Time-Bound (SMART) KPI indicative of each Member States' scientific peer-reviewed publications output related to Artificial Intelligence technologies and applications in healthcare we selected the "Percentage of scientific publications contributed by authors from each EU Member State" and the corresponding rank amongst the EU-27.

To collect publication data, we developed computer scripts in Python and used them with APIs available by scientific publishers in combination with web crawling tools.

## Sources

To derive a statistic regarding the respective contribution of each EU Member state to the peer-reviewed publication output related to AI technologies and applications in healthcare we selected a number of sources of peer-reviewed publications based on the following criteria

- Relevance of academic publishers with the topic of AI in healthcare based on literature review performed as part of Task 1.1.
- Relevance of academic publishers with the topic of AI in healthcare based on top 1000 articles identified by Google Scholar[52].
- Accessibility to full article information via the publishers' search engine including title, abstract, list of authors and respective academic affiliations.

The publishers' which were thus selected for performing the publication search were:

- Institute of Electrical and Electronic Engineering (IEEE) Publishing via IEEExplore[53]
- Elsevier Academic Press via Science Direct[54]
- Springer International Publishers via SpringerLink[55]
- Sage Journals[56]

### Approach: Definition of keywords, sampling approach and quality review

With regards to **definition of the keywords and designing and translating queries**, an iterative review and validation process was used to retrieve the data from the different search engines.

52 It was not possible to use "Google Scholar" as a single source for performing the journal article search because of limitations in the accessibility to journal article information since only 1000 papers are available for each search query which limits the ability to process the data satisfactorily for deriving the selected KPIs.

53 Advancing Technology for Humanity. Retrieved from: https://ieeexplore.ieee.org/Xplore/home.jsp

54 Science direct webpage. Retrieved from: https://www.sciencedirect.com/

55 Springer webpage. Retrieved from: https://link.springer.com/

56 Sage Journals webpage. Retrieved from: https://journals.sagepub.com/

- First, two sets of English **keywords** were defined for the two fields of interest, e.g. related to AI and healthcare, based on a review of literature, articles and social media posts, as well as input from the team's experts. While the list is not exhaustive, the list was deemed adequate for providing a measure of the respective scientific output in the area of AI in healthcare.
    - The final set of English keywords used in the query related to AI were: "artificial intelligence" or "AI" or "A.I". or "machine learning" or "deep learning" or "neural networks" or "natural language processing" or "predictive analytics" or "machine intelligence" or "knowledge engineering" or "robotics" or "decision support" or "image processing" or "machine vision" or "novelty detection" or "anomaly detection" or "bioinformatics" or "data mining" or "early warning systems".
    - The final set of keywords used in the query related to healthcare included the following: "health" or "health care" or "health-care" or "healthcare" or "care" or "patient" or "health" or "nurse" or "nursing" or "public health" or "medic*" or "disease" or "patient monitoring" or "treatment" or "radiology" or "medical imaging" or "ambient living" or "diagnos*" or "early prediction" or "smart alert" or "electronic health records" or "electronic medical records".
- The queries constructed in each search engine consisted of a combination of the AI and Healthcare keywords divided by the word "and".
- In the construction of the query we limited the time period of search to papers published between the 1st of January of 2015 and the 31st of August of 2020.
- After running the query on each search engine using our scripted python code papers were extracted and stored in a database with the following information stored: Title, keywords, author names, author affiliations.
- After the papers were assigned to a country of origin 5482 papers were left which were assigned to authors from the EU-27.
- We then proceeded to filter the database to include only publications originating from EU-27 academic institutions based on the assigned country of origin.
- We then proceeded to manually review the remaining list of papers and removed papers which were not relevant to the topic and were included in the list as a result of relevance to some keywords in the search query, ending up removing a total of 22% of publications, leaving a list of 4264 papers which were the most relevant papers to AI in healthcare originating from EU-based authors[57].
- As a last step, we calculated three indices from the final list of papers all of which were based on the Nature Index approach, which is considered to be a scientific valid approach for deriving scientific contributions between institutions or countries in this instance. The three indices were calculated as follows:

57 Despite the different number of publications extracted from each academic publisher's search engine, we did not perform a stratified sampling approach and kept the filtered database intact based on the fact that some academic publishers were more directly relevant to the topic of AI in healthcare compared to some others and were thus expected to publish a larger number of papers on the topic than others.

- ***Fractional Count (FC)*** for which we assigned a fractional contribution of each paper to each country based on the ratio of authors from that country compared to the total number of authors. The total FC for a county is calculated by summing the relative contributions over all papers. As this FC index is derived from a representative sample of papers and not from a complete population, we then converted this number into a percentage contribution per EU Member State (**FC Share**).
- ***Multilateral collaboration score (MCS),*** which was derived by first dividing the total fractional contribution for each country by one less than the total number of institutions which collaborated on the article. This is done for each collaborating country and the values are summed for each pair of countries to give the total MCS for that pair on an article. The MCS for each country is the sum of the values from each of its pairs of countries over all papers.
- ***Bilateral collaboration score (CS)*** was calculated any two countries co-authoring at least one article. It is derived by summing the fractional contributions from articles with authors from both countries. The collaboration score between two countries is the sum of each of their fractional contributions on the papers to which both have contributed

### h. Methodological approach for determining granted patents in the area of AI in healthcare

To provide a Specific, Measurable, Attainable, Relevant, and Time-Bound (SMART) KPI indicative of each Member States' scientific granted patents related to Artificial Intelligence technologies and applications in healthcare we selected the "Percentage of granted patents contributed by authors from each EU Member State" and the corresponding rank amongst the EU-27.

#### Sources and timeframe

To derive a statistic regarding the respective contribution of each EU Member state to the peer-reviewed publication output related to AI technologies and applications in healthcare we used the Espacenet[58] patent search tool which is an online service for searching patents and patent applications developed by the European Patent Office (EPO) together with the Member States of the European Patent Organisation. We selected this tool since it contains information on published patent applications and granted patents from over 100 patent-granting authorities, it is thus considered to provide a comprehensive overview of the patent applications submitted and granted worldwide.

#### Approach: Definition of keywords, sampling approach and quality review

With regards to **definition of the keywords and designing and translating queries**, similarly to the peer-reviewed journal applications search, a concise review and validation process was used to retrieve the data.

- First, two sets of English **keywords** were defined for the two fields of interest, e.g. related to AI and healthcare, based on a review of literature, articles and social media posts, as well as input from the team's experts. While the list is not

58 Espacenet webpage. Retrieved from: https://worldwide.espacenet.com/patent/

exhaustive, the list was deemed adequate for providing a measure of the respective scientific output in the area of AI in healthcare.

- The final set of English keywords used in the query related to **AI** were: “artificial intelligence” or “AI” or “A.I”. or “machine learning” or “deep learning” or “neural networks” or “natural language processing” or “predictive analytics” or “machine intelligence” or “knowledge engineering” or “robotics” or “decision support” or “image processing” or “machine vision” or “novelty detection” or “anomaly detection” or “bioinformatics” or “data mining” or “early warning systems”.
    - The final set of keywords used in the query related to **healthcare** included the following: “health” or “health care” or “health-care” or “healthcare” or “care” or “patient” or “health” or “nurse” or “nursing” or “public health” or “medic*” or “disease” or “patient monitoring” or “treatment” or “radiology” or “medical imaging” or “ambient living” or “diagnos*” or “early prediction” or “smart alert” or “electronic health records” or “electronic medical records”.
    - The query constructed consisted of a combination of the AI and Healthcare keywords divided by the word “and”.
    - In the construction of the query we limited the time period of search to patents granted between the 1st of January of 2017 and the 31st of August of 2020[59].
- After running the query using our scripted python code patent information was extracted and stored in a database with the following information stored: Title, keywords, author names, author affiliations.
- We then proceeded to assign a country or origin to each publication in the following way by assigning to each paper the country from which *the majority of authors were affiliated with via the academic or business affiliation stated in the paper*. In the case that there was no majority, the patent was assigned to the country of affiliation of the *1st author of the patent*.
- After the papers were assigned to a country of origin 845 patents were left which were assigned to authors from the EU-27.
- We then proceeded to filter the database to include only patents originating from EU-27 organisations based on the assigned country of origin.
- We then proceeded to manually review the remaining list of papers and removed papers which were not relevant to the topic and were included in the list as a result of relevance to some keywords in the search query, ending up removing a total of 24% of patents, leaving a list of 642 papers which were the most relevant papers to AI in healthcare originating from EU-based authors.
- As a final step, we calculated the percentage of papers originating from each EU country and ranked them in by percentage.

59 We used the 1st of January of 2017 as the starting date of our query based on the knowledge that the period of time for a patent application to be submitted and processed is approximately three to five years (https://www.epo.org/service-support/faq/procedure-law.html#faq-274) so this time period for granted patents includes innovation produced in the 3-5 years prior to granting.

### i. Methodological approach for identifying start-ups working on AI technologies and applications in healthcare

To identify start-ups working in the area of AI in healthcare in the EU Member States we ran searchers on well-known and credible start-up search portals and enhanced the information using local knowledge in each Member State and desk research.

#### Sources and timeframe

To develop a first list of start-ups working in the area of AI in healthcare we used a combination of sources as follows:

- The crunchbase[60] company search platform which provides business information about private and public companies, and specifically the *advanced search engine* of Crunchbase which allows searches to be performed using specific keywords and by specifying the country where the company headquarters are.
- Tracxn[61], a market intelligence platform for tracking start-ups and private companies spread across 300+ technology areas.
- Desk research

#### Approach: Definition of keywords, sampling approach and quality review

Our approach for creating a comprehensive list of start-ups in EU Member States working on AI in healthcare consisted of the following steps:

- First, two sets of English **keywords** were defined for the two fields of interest, e.g. related to AI and healthcare, based on a review of literature, articles and social media posts, as well as input from the team's experts. While the list is not exhaustive, the list was deemed adequate for providing a measure of the respective scientific output in the area of AI in healthcare.
- The final set of English keywords used in the query related to **AI** were: "*artificial intelligence" or "AI" or "A.I". or "machine learning" or "deep learning" or "neural networks" or "natural language processing" or "predictive analytics" or "machine intelligence" or "knowledge engineering" or "robotics" or "decision support" or "image processing" or "machine vision" or "novelty detection" or "anomaly detection" or "bioinformatics" or "data mining" or "early warning systems".*
  - The final set of keywords used in the query related to **healthcare** included the following: "health" or "health care" or "health-care" or "healthcare" or "care" or "patient" or "health" or "nurse" or "nursing" or "public health" or "medic*" or "disease" or "patient monitoring" or "treatment" or "radiology" or "medical imaging" or "ambient living" or "diagnos*" or "early prediction" or "smart alert" or "electronic health records" or "electronic medical records".
  - For our search in the Crunchbase we used combinations of the above keywords specifying the country where the company was headquartered, and that the status of the company was "active".
  - We then proceeded to extract in a database the list of companies headquartered at each Member State together with the company url and keyword description.

- We then ran a different search in Tracxn using in each case the search "AI in healthcare start-ups in Austria/Belgium/etc" and extracted the company information which we added to the existing database.
- As a last step we proceeded to perform three rounds of desk research using combinations of the AI and healthcare related keywords described above and the name of the country to identify additional start-ups which had not already been identified using the previous two searches.
- For every start-up in the database we manually reviewed the company website to verify
  1. That the company was still active
  2. That the company worked in an area related to AI technologies and applications in healthcare.
  3. That the company was indeed headquartered at an EU Member State.

- The resulting filtered and verified list consisted of 210 start-ups working on AI technologies and applications in healthcare whose headquarters are at an EU Member State.
  - As a final step, we calculated the percentage of start-ups in each EU country.

## j. Annex I.V Methodological approach for news and social media listening

We selected a type of metric commonly used in news and social media monitoring for measuring awareness of AI in the healthcare sector within the EU, e.g. "*Number of mentions of a specific topic*" (i.e. number of times a specific set of keywords assumed to define a specific topic are mentioned online).

To collect web data, a social listening tool was required. The tool had to be able to scan all public news articles and public social media (e.g. Twitter, Facebook, YouTube) sites, across the 27 EU Member States. The selected tool, the Digital Intelligence Platform, collects data from 150 million public sources and covers sources in over 180 languages. The tool uses keywords and Boolean operators, along with advanced analytics with artificial intelligence capabilities, to allow for the extraction of the most relevant data.

### Sources and timeframe

Two types of sources were included, e.g. news and social media (i.e. Twitter, Facebook, YouTube, with most results coming from Twitter). While typically covered by the platform, for the current analysis, Instagram results were excluded. Instagram produced higher levels of irrelevant results compared to the other sources. Additionally, its content (mainly visual in nature, i.e. images, drawings) was found to differ highly from the other web sources (news sites, blogs, Twitter), which were mainly text.

60 Crunchbase webpage. Retrieved from: https://www.crunchbase.com/home

61 Tracxn webpage. Retrieved from: https://tracxn.com/

With regards to the timeframe, 13 months' worth of data was extracted from the platform for each country. All data were published online between May 4, 2019 and June 24, 2020.

### Approach: Definition of keywords and "queries" to retrieve pertinent and coherent real time data within the scope of the study

Using the Digital Intelligence Platform to retrieve data requires the development of queries, which are requests for information from a database written in a specialized language (which in this case involves using Boolean operators).

With regards to **definition of the keywords and designing and translating queries**, an iterative review and validation process was used to retrieve the data from the Digital Intelligence Platform.

- First, two sets of English **keywords** were defined for the two fields of interest, e.g. related to AI and healthcare, based on a review of literature, articles and social media posts, as well as input from experts using the platform.
- This list was reviewed and edited by subject matter experts and then tested by a linguistic expert on the platform in order to increase the relevance of results and reduce the amount of "noise" as much as possible.
- The keywords were **translated into 22 additional languages** (cf. listed below) corresponding to the 27 EU Member States and revised by Native speakers in order to ensure quality. Maltese was excluded.

| | | | | | | |
|---|---|---|---|---|---|---|
| Bulgarian | Croatian | Czech | Danish | Estonian | Finnish | French |
| German | Greek | Hungarian | Italian | Latvian | Lithuanian | Luxem-bourgish |
| Dutch | Polish | Portuguese | Romanian | Slovak | Slovenian | Spanish |
| Swedish | | | | | | |

  - The final set of English keywords related to AI included the following: artificial intelligence, AI, A.I., machine learning, deep learning, neural networks, natural language processing, predictive analytics, machine intelligence, knowledge engineering, robotics, clinical decision support, image processing, machine vision, novelty detection, anomaly detection, bioinformatics, data mining, early warning systems.
  - The final set of keywords related to healthcare included the following: health, health care, health-care, healthcare, care, patient, health, nurse, nursing, public health, medic*, disease, patient monitoring, treatment, radiology, medical imaging, ambient living, diagnos*, early prediction, smart alert, electronic health records, electronic medical records.
  - Based on keyword translations, we created an automation that generates automatically the **query in each language**. We performed a **quality check** on queries results for each country within the defined time period.
  - If results were not related to the use of AI in the healthcare sector, we decided to exclude the problematic keyword that caused the noise or link this word to another word related to healthcare or AI in order to get only relevant results. The following example is illustrative of the important results of this exclusion step. A keyword first selected for the healthcare

dimension included “treatment”: The output for Cyprus showed that most of the results not related to health were a result of the keyword “treatment”. Thus, we had to be link “treatment” to other words related to health, e.g. (treatment NEAR/10 (patient OR disease OR medicine)).

- After validation of all keywords, **queries** were constructed using special Boolean operators stipulating that a set of keywords must be near certain others. The AI-related keywords were connected to the healthcare dimension keywords with an allowed distance of 20 or fewer words in between. Furthermore, the “treatment” related keyword was connected to the other possible keywords in healthcare with a distance of 10 or fewer words (cf. above). These Boolean operators allow a higher probably for relatedness between two sets of keywords, and thus higher likelihood for the result to be relevant to the dimension.
- The final element of the query was the geo-localization operator. The location is determined by the platform based on the metadata available for the result, according to the following order:

1) the geo-location of the article/post, if enabled by user;

2) location found within the contact/profile section (i.e. a company address or a Twitter profile’s selected location);

3) if news or website, the IP address or if social media, the posting language (designated to the country with the most speakers of that language).

For all queries in languages other than English, the geo-localization was applied only for the countries which have that language an official language, i.e. German language query was appended only with the country filters for Germany and Austria.

- Once the quality check and exclusion were completed and geo-location added, we triggered the historical data on the platform for the indicated time period.
- We finally performed a review on the data we collected from the platform for each country, focusing on peaks. We looked at the top authors (in terms of volume of results) and assessed the relevancy and quality of their content. In this instance, we decided to exclude 3 authors that produced a large amount of low-quality data and that appear to be bots, or automated spam accounts.

Once the inserted queries were finalized and tested, we examined the results over time for both news and social media sources to describe and analyse the trends per country.

# Annex II: Survey

The sample. Considering the objectives of this study, the timeline and resources available, all the healthcare stakeholders in the EU could not be surveyed. Therefore, a sample from the population was selected and surveyed. As the topic of AI in healthcare included multiple stakeholders with different relevant indicators, we developed three different questionnaires, targeting three different stakeholder groups:

- **AI developers**: this group included universities, research organisations and companies working on the development of AI technologies and applications in the healthcare sector.
- **AI users**: this group included hospitals, medical centres and healthcare services providers.
- **Public Authorities**: this group included Health Ministries, National Health Authorities and Public Funding Organisations.

To obtain a representative sample of responses, our aim was to obtain at least 5 responses in each group for each EU Member State. The table below indicates the number of responses obtained for each stakeholder group. We had a minimum of x answers obtained from each EU MS.

| Stakeholder Group | AI Developers | AI users | Public Authorities |
| --- | --- | --- | --- |
| Number of Responses | 61 | 36 | 24 |

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