

SCIENCE FOR POLICY BRIEFS



How can Europe become a global leader in AI in health?

Headlines

- Al in health innovation and economic activity is rapidly increasing, reflecting the potential of AI to address the challenges of aging population and workforce shortage.
- The COVID-19 pandemic is accelerating the use of AI to monitor remotely patients, predict the spread of the virus in real-time or to develop new drugs.
- Relying on AI technologies to test and develop new drugs, the EU is a strong partner in the development of vaccines against COVID-19.
- AI in health R&I ecosystem and rich health data are Europe's key assets to transform the health sector with AI.
- Capturing the benefits of high added value services, addressing social and ethical concerns around AI in health and technological sovereignty remain Europe's challenges.

1. AI in health on the rise

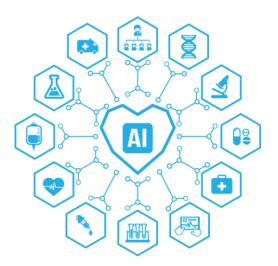
Although most AI in health projects are just at an initial stage, this is changing rapidly. Over the last decade, research and innovation (R&I) activities in AI in health have been booming. The annual number of scientific publications and inventions in this domain has significantly increased. Global Venture Capital (VC) investments in AI in health start-ups have reached approx. 5 BIn Euro per year and account for 13% of global VC investments in the health sector. These developments reflect the interest of the private and public sectors in applying AI in the health sector to address challenges related to aging population and shortage of health care professionals.

The COVID-19 crisis is accelerating the adoption of AI in health. Real-time monitoring and predicting the spread of the virus with contact tracing apps is only one AI application visible to the public during the time of the global pandemic. European pharmaceutical and biotech companies relying on AI and robotics to develop and produce new drugs, are among the first companies worldwide to develop effective vaccines against the COVID-19.

Personalised medicine represents a new approach to health. It combines information about our genome with other health information to recognise individual health risks and determine the most effective interventions to help improve our health, including personalised medications. Harnessing the power of data, AI enables this paradigm shift that allow us to benefit from tailored-made treatments.

Data analysis capacities and real time monitoring will allow to identify and react to early signals of health issues. By identifying health risks and suggesting potential interventions, AI will increase the reliance on **preventive care**.

The advancement of AI continuously reduces the challenges faced by pharmaceutical companies in the process of **new drug development**. AI does not only speed up the development time, but also improves the quality of products and the overall safety of the production process, as well as improving cost-effectiveness through a better utilization of available resources.



Joint Research Centre Al is helping transform other areas in the health sector. Promising applications include, for example, **image processing** for more accurate and faster assessment of X-rays, CT scans, **clinical decision support systems** matching symptoms to the related illnesses and suggesting both preventive and curative treatment, and **telemedicine**. Last but not least, Al can increase the efficiency of administrative and operational tasks in the health sector.

This policy brief addresses the question of **what it takes for Europe to become a global leader in AI in health**. First, it analyses Europe's position in the global AI in health innovation and economic landscape. Then, it identifies main challenges that Europe needs to address in order to leverage the strength of its health sector with AI. In addition to supporting technology commercialisation, ensuring the security and integrity of the European Health Data Space, investing in education and training, ensuring regulatory compliance, it needs to pay attention to social and ethical concerns. The document concludes by outlining a set of **actions that Europe needs to take to shape the direction of AI in health and to increase its chances of becoming a global leader in this domain**.

2. AI in health global technology landscape

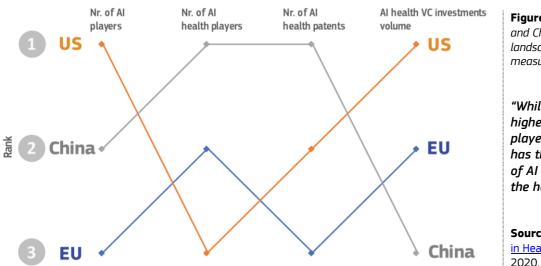
Within the global technology landscape, the EU is well **placed** in the application of AI in the health and healthcare domains, somewhat behind China but on a par with the USA. Around 2000 players worldwide are actively developing and applying AI technologies in the health sector.

These organizations represent about 6% of all global players currently active in the AI domain. While the US has the highest number of AI players in general, China has the highest number of AI players active in the health domain (see the Figure 1 here below). Chinese organizations hold the highest number of patents in the AI and health nexus. China is however considerably weaker when it comes to the level of VC investments in startups developing AI in health technologies and applications.

R&I AI in health among key strengths of the EU. What is noticeable is that, in the EU, almost two thirds of all players in the field of AI in health are involved in research, against approximately one-third in China. In the US, the number of research institutions involved in AI and health is negligible compared to the commercial players. The US accounts also for nearly 70% of global VC funding in AI in health start-ups. In contrast, European start-ups account for less than 20% of the total VC funding in AI in health.

Europe's underdeveloped technology commercialisation capabilities is a very well-known fact. In spite of considerable improvements in this respect and increases in the overall levels of funding of technology commercialisation, including VC funding, Europe risks that the results of its research efforts will remain either unexploited or, if acquired by foreign companies, will be appropriated by non-European actors.

differences Great in terms of technological specialisation between major global regions. In the EU and the USA, most of the activity concentrates on diagnostics and health technology assessment. In China, over 50% of activities in AI in health focus on diagnostics, which includes image recognition technologies for which China is a worldwide leader, and 21% are in the field of medical devices development. China enjoys this leadership because of, among others, the strong governmental support for companies through favourable economic and regulatory conditions, and a multiple role as strategic investor, consumer of digital technologies, and provider of access to key data. The state control on user data has been key in developing the lead in facial recognition technology, which then supports the lead in medical diagnostic technology.



Ranking of EU, US and China by AI in health landscape performance measure

Figure 1: Ranking of EU, US and China by AI in health landscape performance measures

"While the US has the highest number of AI players in general, China has the highest number of AI players active in the health domain"

Source: <u>AI Watch: AI Uptake</u> <u>in Health and Healthcare</u>, 2020, EC JRC.

3. Europe's key challenges for the uptake of AI in health

In order to seize the opportunities AI offers in the health domain, Europe needs to address a number of issues. The key challenges include: exploiting existing **research capabilities**, capitalising on its **high-quality data**, retaining the economic **benefits of high value-added activities and addressing social and ethical concerns** that slow down the adoption of AI in health. The following sections discuss these challenges and potential policy responses.

3.1 Exploiting existing research capabilities

From the lab to the market. The EU Framework Programme (FP) constitutes an important element of the European research and innovation landscape in this domain. Until today, 146 projects in AI in health have been launched under the H2020 FP. Starting with less than 10 Mln Euro, their funding has been increasing and reached over 100 Mln Euro in 2020 (see Figure 2 below).

EU-funded research projects produce cutting-edge technologies that have potential to help us to solve societal challenges and improve our lives. <u>An analysis of the</u> innovations stemming from EU FP projects reveals that 35% of them show market creation potential. Innovations in eHealth or medical diagnostics, i.e. domains that heavily rely on digital and AI technologies, show the highest levels of market creation potential among EU FP innovations.

BioNTech, one of the first companies worldwide that has developed an effective vaccine against COVID-19, illustrates the disruptive potential of EU-funded research in the nexus of health and AI (see Box 1 on next page).

The EU R&I funding kick-starting disruption. The case of BioNTech illustrates also the contribution of the public sector as a lead investor providing funding to risky, novel and uncertain projects that have the potential to generate breakthrough innovations and revolutionise the industry.

Europe needs to make efforts to exploit and capitalise on its existing research capacities and, like in the case of BioNTech's new technology, translate them into marketable products. One part of this strategy may include scaling-up of existing initiatives that are aiming at attracting private investors to provide capital for commercialisation of technologies and innovations developed within the EU FP projects.

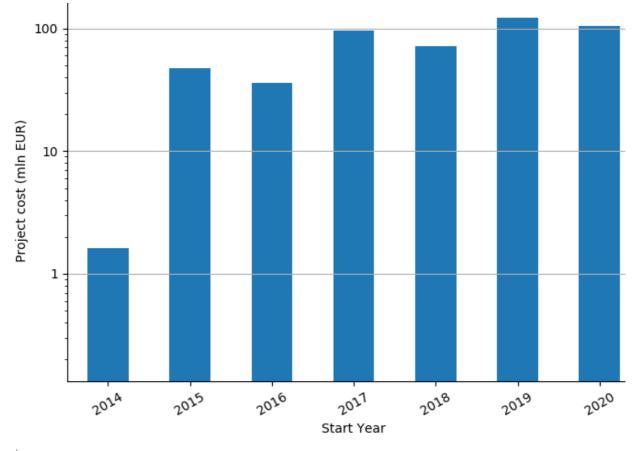


Figure 2: H2020 AI in health total project funding, Mln Euro

"Until today, 146 projects in AI in health have been launched under the H2O2O FP. Starting with less than 10 Mln Euro, their funding has been increasing and reached over 100 Mln Euro in 2020"

Source: AI Watch: AI Uptake in Health and Healthcare, 2020, EC JRC.

Box 1: Vaccine against COVID-19 enabled by EU-funded research and AI made in Europe

Founded in 2009, BioNTech is a European biotech unicorn developing novel RNA-based technologies for personalised cancer therapies. In the midst of the COVID-19 global crisis, it was among the first firms worldwide to announce the successful development of a vaccine against the COVID-19.

At the core of BioNTech's approach is to develop to develop individual therapies. Discovering and developing new drugs and setting up a production and supply system providing hundreds of thousands of patients with personalized medications requires the development and convergence of innovations in a range of different advanced technologies, such as big data, AI, and fully automated analytics and production lines. BioNTech has been investing in digital capabilities by collaborating with small and large European digital firms. These efforts allow it to develop highly digitalized and automated manufacturing technologies and quality controlled processes enabling fast delivery of customized therapies comprising off-the-shelf drugs, on-demand immunotherapies, and combinations thereof.

BioNTech has benefited from the EU R&I support since its early days (see Figure 3 below). Until today, BioNTech and its subsidiaries have participated in ten EU FP projects and received nearly 10 Mln Euro of funding. As early as in 2009, the German start-up participated in an FP7 project where it explored the use of highly innovative gene-modifying technology in developing new therapies. In 2013, it set-up and coordinated the MERIT FP7 project aiming at clinically translating and industrially validating the pioneering RNA-based immunotherapies. BioNTech's mRNA technology, co-funded by the EU R&I FP, is at the core of the vaccine against the COVID-19. Today, we can say that the European funding to BioNTech was a well-placed investment.

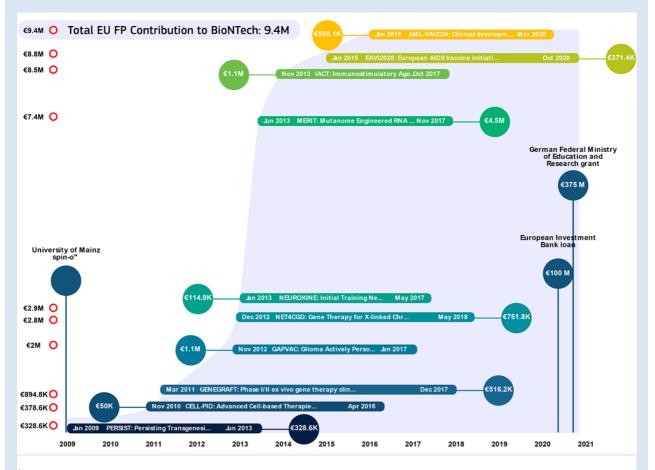


Figure 3: EU Framework Programme contribution and public support to BioNTech

"BioNTech has benefited from the EU R&I support since its early days. Until today, BioNTech and its subsidiaries have participated to ten EU FP projects and received nearly 10 Mln Euro of funding"

Source: Source: EC CORDIS database, compiled by JRC.

3.2 Capitalizing on high quality data

It's the data, stupid! The quality of AI models depends on large volumes of good quality, semantically-structured data, labelled to provide information-rich context. The European health sector has been already identified as a sector where Europe has world-leading industry and a wealth of industrial, research, and public sector data. The richness of these data is the focus of the European Strategy for Data that envisages the establishment of a health data space. Its objective is to support "advances in preventing, detecting and curing diseases as well as for informed, evidence-based decisions to improve the accessibility, effectiveness and sustainability of the healthcare systems".



The European health data policy needs to address the issue of **sovereignty**. Maintaining control over data and technology, will have direct implications for the ability of European companies to capitalise on their value, while maintaining high standards of protection.

The road to the European Health Data Space is far from easy. One of the main challenges is the current fragmentation of data repositories, with different formats and definitions. Their integration will likely face regulatory challenges. In addition, access to health data may indeed prove challenging as the General Data Protection Regulation (GDPR) restricts the processing of sensitive personal data. Therefore, there is great uncertainty in the industrial sector on the use of health data within the strict boundaries of GDPR. SMEs are particularly affected by the difficulty to assess compliance of AI solution with GDPR (EASME, 2019).

Do I own my DNA data? Regulators need to clarify the question of ownership of health data. This is particularly relevant for genomic data, which is often shared among individuals.

Data needs to be AI-ready. Although high quality health data is seen as one of the Europe's biggest assets for the roll out of AI in health, most of existing medical data is either not "AI-ready" for algorithm development, not exchangeable, or difficult to process and interpret. The development of a European Health Data Space may become a game changer only if it succeeds in bringing together these different data sources, and making them interoperable and reusable, particularly to start-ups and SMEs. In this context, the main challenge is the security and the integrity of the data space, its underlying infrastructure and all data-enabled products and services, including AI-based systems.

Past success is no guarantee of future success. The richness and diversity of European health data does not automatically translate into economic benefits. The history of digital transformation shows us that assets that were sources of competitive advantage in the past are becoming obstacles in the digital world. European firms have been losing against digital newcomers in sectors in which they enjoyed unchallenged positions.

The example of the current race to build electric autonomous vehicles illustrates this well. In spite of their leading position in the car sector, European manufacturers find it difficult to keep up with Tesla, a newcomer in this new market niche. With the number of software developers nearly twice as high as that of Tesla, the biggest challenge for Volkswagen, the world's largest car manufacturer, is to integrate digital technologies into its products and transform its cars them from purely means of transport into digital data platforms providing mobility and other high-value services. The market valuations of Tesla and Volkswagen reflect these capabilities to seize the emerging opportunities. With car sales of only 3% of the number of cars that Volkswagen sells, current market capitalisation of Tesla already exceeds that of Volkswagen by



"A common European Health Data Space will promote better exchange and access to different types of health data (electronic health records, genomics data, data from patient registries etc.), not only to support healthcare delivery (so-called primary use of data) but also for health research and health policy making purposes (so-called secondary use of data)."

Page5

Source: European Health Data Space, FC

10%. The context of the health sector is very different from the car-manufacturing sector. The process of digitalisation and roll out of AI technologies in this domain faces different conditions and hurdles. Nevertheless, the story of Tesla vs. VW can serve as a potential case study illustrating how Europe needs to leverage its assets in traditional industries with the help of digital and AI technologies.

Summing up, high quality heath data creates a very good opportunity for Europe to transform its health system using AI and to bring tangible benefits to European society. However, when looking at the other sectors in which Europe has lost its leadership as the digital transformation has been progressing, there is a risk that it may fail to benefit from the opportunities that AI offers without clear action to sustain innovation and increase our sovereignty over both technology and data.

3.3 Capturing the economic benefits of European investments

Foreign competition for Europe's health assets and markets. Excellent research capabilities in AI in health and the richness and diversity of European health data are likely to attract considerable interest from non-European firms. This creates an issue of data sovereignty and security of the European Health Data Space. In addition, this raises the question of whether non-European players are able to appropriate the benefits of European investments in AI in health.

As the digital revolution is unfolding, Europe's economic interests and sovereignty are at stake. The COVID-19 lockdowns triggered a massive and rapid migration of all possible social and economic activities into the digital world. As every business, government, education, research, and social activity moved online, we all came to rely exclusively on non-European collaborative platforms. Consequently, while traditional European retailers suffered from decreased sales, Amazon was expanding its operations at a fast pace.

US big-tech's eyes on the European health market. Amazon is extending its activities into the healthcare sector and other large online platforms follow suit. Bringing nontraditional business models, technology, infrastructure in logistics and computing, and a large customer base, they are expected to transform the entire health sector from the pharmaceutical supply chain to healthcare management. Armed with a growing volume of data and AI, genomics and monitoring technologies they are likely to leapfrog the existing European players, which are struggling to make a transition from the traditional to the digital world.

European policy makers are already taking steps to address the issue of dependence on large international big-tech companies. For example, France decided to reverse its decision to rely on Microsoft's cloud hosting services in the health domain and to build a platform to store health data at the national level. Also Gaia-X, a Franco-German initiative for a federated data infrastructure for Europe, includes health among its priority sectors. Appropriating the benefits of Europe's AI in health assets allows to re-invest the profits in future technologies. In parallel, Europe needs to pay close attention to foreign firms entering the European health sector. Leveraging their dominant position in other sectors, equipped with capacities to collect process and exclusively use personal data, they may stifle innovation and competition and increase their dominance in the European economy.

3.4 Addressing social and ethical concerns

Trust in AI can accelerate its adoption. The uptake of AI in health does not depend only on the availability of technology. Because of its far-reaching consequences, the introduction of AI in health raises a number of social and ethical concerns. They belong to three groups: common aspects to the use of AI at large (e.g. cybersecurity, robustness, transparency and explainability, fairness and biases, and data protection), aspects of particular relevance for healthcare (e.g. empathy) and ethical issues related to applications such as gene editing and its potential for bioterrorism.

Still in experimentation phase. The first group includes concerns related to the fact that many studies featuring AI health applications are in an early stage, carrying a number of methodological flaws. AI models that are frequently based on small and statistically biased datasets, which can critically hinder their accuracy and reliability.

The AI doctor will see you now. The second group considers the human aspects of medical practice such as the relationship between doctor and patient that is based not just on professional knowledge but also on empathy and trust, both of which are possibly affected by the introduction of AI in clinical practice.

The impacts can be either positive or negative depending on how the process is handled: for instance, streamlining cumbersome and repetitive administrative tasks and freeing up time for face-to-face interaction with the patient can enhance empathy. On the other hand, telemedicine, where long-distance monitoring and assistance reduces human contact, may reduce empathy.

How dark is the dark side of AI in health? The third group of issues focuses on the ethical dilemmas of applications that have potentially dual effects. They include, for example, the possibility of reading and decoding human brain signals, which may challenge the very definition of free will, but also offers impaired patients the possibility to directly control their prosthetic limbs through interfaces with their neural system.

Overall, these early stage shortcomings as well as potential misuses of AI in heath may undermine the trust in the technology and slow down its adoption. It is up to policy makers to find appropriate solutions that will guarantee the security, transparency and trust around AI in health. The riskbased approach of the forthcoming AI regulatory framework is an important step in this direction.

4. The way forward

Compared to other world's economies, Europe enjoys strong assets that are necessary conditions for transforming the health sector with the help of AI.

First, **Europe's high standard health system** provides a strong foundation for the roll out of digital and AI technologies. Its high-quality standards guarantee that the implementation of AI-enabled health innovations will generate the highest possible benefits, while minimising potential costs. By introducing the GDPR, Europe was the first in the world to set the rules and standards helping to reduce uncertainty in the uncharted digital world. While compliance can be perceived at first as a cost, the lack of mechanisms governing operations in an increasingly connected and complex environment can be even more costly. Similar to the case of personal data protection, **Europe can lead in setting the benchmark for global standards of AI in health in terms of liability, transparency, security and trust.**

Second, **high-quality health data** are a by-product of the strengths of European health systems. Being the oil of the digital economy, it can fuel the development and implementation of AI for health in Europe. The European Health Data Space is the first step in the right direction. The implementation of this initiative is likely to prove crucial in attracting actors in the AI and health sector able to introduce and develop innovations. Creating such an innovative ecosystem is particularly important, considering that the already dominant large digital platforms are entering into the health sectors. Armed with vast volumes of data and AI technologies, they have all the prerequisites to become new players in the health sectors providing highly profitable services and capturing the largest part of the economic rents generated in the sector.

Third, Europe enjoys a strong and diversified R&I AI in health ecosystem. Its particular strength lays in diagnostics, health technology assessment, medical devices and pharmaceuticals. This diversification offers opportunities for exploiting complementarities and creating synergies between different domains. For example, the field of medical devices is closely linked to robotics and advanced manufacturing, i.e. other areas in which Europe has a strong comparative advantage. Beside deepening and exploring multidisciplinary opportunities, Europe needs to reinforce its technology commercialisation capabilities. It needs to create a system allowing for the translation of research results into marketable products and solutions and to capture the economic benefits they create. This includes training and empowering the healthcare workforce to master the use of AI products and help their development.

In parallel to reinforcing its data, technological capabilities and skills, Europe needs also to address a range of **social and ethical concerns** around AI in health. Solving the issues of data protection and transparency of AI technologies and ensuring their security properties will increase the trust in AI in health and accelerate its adoption. Making AI in health

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secure and preventing its controversial or unethical use will reduce the negative costs to the society.

Al will transform the health sector in the short- and mid-term future. The digitally driven creative destruction offers vast opportunities for those who have the courage and capacity to seize them and leaves behind those who are either too late or too slow to adapt. With the help of AI, Europe has a chance to build on and leverage its scientific, research and industrial base in the health sector. In addition to Europe becoming a global leader in AI in health, our future wellbeing and health are at stake.

Related and future JRC work

The analysis presented in this brief builds on the following JRC reports:

- <u>AI Watch: AI Uptake in Health and Healthcare</u> (2020),
- Artificial Intelligence and Digital Transformation: early lessons from the COVID-19 crisis (2020),
- <u>Artificial Intelligence in Medicine and Healthcare:</u> <u>applications, availability and societal impact</u> (2020).

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The brief is part of a broader set of activities conducted within the <u>AI Watch project</u>, an initiative of the European Commission jointly developed by the JRC and DG CONNECT. AI Watch monitors industrial, technological and research capacity, policy initiatives in the Member States, uptake and technical developments of Artificial Intelligence and its impact in the economy, society and public services.

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