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Artificial Intelligence-based software as a medical device

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Section 1

1. Background and objectives of the report

Background

The Product Watch Reports have been developed in the framework of the 'Advanced Technologies for Industry' project and serve to identify and analyse 15 promising advanced technology (AT)-based products and their value chains, with an assessment of the strengths and weaknesses of the EU positioning.

Promising AT-based products can be defined as "*enabling products for the development of goods and services enhancing their overall commercial and social value; embedded by constituent parts that are based on AR/VR, Big Data & Analytics, Blockchain, Cloud, Artificial Intelligence, the Internet of Things, Mobility, Robotics, Security, Connectivity, Nanotechnology, Micro-and nanoelectronics, Industrial Biotechnology, Advanced Materials and/or Photonics; and, but not limited to, produced by Advanced Manufacturing Technologies*".

1.1 Background of this report

Artificial Intelligence (AI) software refers to computer programmes[1] that have the capacity to perform operations analogous to learning and decision-making in humans. This type of software can accomplish specific tasks by processing large amounts of data, recognising patterns and mimicking biological intelligence. This tool is being increasingly applied in the pharmaceutical, medical device and healthcare sectors to support various stages of research and development, as well as treatment of patients[2].

The implementation of AI essentially relates to the **level of adaptability** and **autonomy**. There are two types of AI, defined by their adaptability[3]:

1. Software that is already trained when placed on the market - *'Decision support'*
2. Software that adapts perpetually and optimises a device in order to continuously improve its outcomes - *'Autonomous decision-making'.*

A software as a medical device (SaMD) may be used to diagnose, prevent, monitor or treat a disease. SaMD also may provide suggestions for disease mitigation or assist in the diagnosis, screening, monitoring, prediction and determination of a disease[4].

Artificial Intelligence and machine learning (ML) technologies differ from other software as a medical device in the sense that they have the potential to adapt and optimise device performance in real-time to continuously improve healthcare for patients[5]. AI/ML-based SaMDs inherently change and adapt as more real-world data become available and can be incorporated.

The definition of the use of Artificial Intelligence in medical devices is still fuzzy and understood in a variety of ways which can range from simpler machine learning based algorithms to sophisticated cognitive computing. AI technologies integrated into medical devices can include big data analytics, deep learning, speech and image recognition, natural language processing, and robotics process automation among others. Standard algorithms are sometimes promoted as AI by digital healthcare startups but currently they do not represent real computer intelligence.

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[1] A software intended by the manufacturer to be used for medical purposes is considered a medical device under the Medical Device Regulation (Regulation (EU) 2017/745)
[2] Tsang et al, 2017
3 COCIR, Artificial Intelligence in Healthcare, April 2019, URL: https://www.cocir.org/uploads/media/COCIR_White_Paper_on_AI_in_Healthcare.pdf
4 COCIR published a library of use cases on its website, https://www.cocir.org/media-centre/publications/article/cocir-use-cases-artificial-intelligence-in-healthcare.html
[5] US FDA 2020

Several types of AI software can be labelled as a medical device, but manufacturers and authorities are often uncertain as to whether their software can be classified as a medical device under the respective regulations. Notified Bodies do usually provide advice. Figure 1 provides a list of examples of AI SaMD.

Figure 1: Examples of AI SaMD

	AI as a medical device	Function in healthcare	AI technology
	• AI **image analysis** of CT scans • Orthopaedic planning software • Skin disease detection AI • AI detecting diabetic retinopathy	Radiology Diagnosis Cardiac imaging analysis	Image recognition based on machine learning and deep learning models
	• AI in **monitoring** electrocardiogram (ECG) or electroencephalography signals • Medical devices for predictive analytics	Monitoring of diseases Early warning system	Big data analysis, machine learning, deep learning algorithm, neural networks
	• AI enhanced **wearables** • Glucose monitors equipped with AI	Health monitoring	Computer vision, gesture recognition, natural language processing
	• Medical **robotic** devices enhanced with AI • Personal robotic assistant	Surgery Prescription dispensing Sterilisation Elderly care	Robotics, natural language processing, speech, face recognition, machine learning, neural networks

Source: Technopolis Group, 2020

To use AI/ML technology safely, it needs to be verified and validated in terms of its reliability, accuracy and cost-utility. The current classification models established by the Medical Device Regulation (MDR) and In-Vitro Diagnostic Regulation (IVDR) regulate software as a medical device and are applicable and suitable to the AI/ML medical software. However, the current EU regulatory framework does not address a self-learning AI system specifically. In general, AI algorithms are regarded as Class II (medium risk). AI/ML software applications can fall into Class IIa or Class IIb, and for high-risk devices are classified in the most highly regulated Class III.

Currently, there are few actors that have managed to obtain a CE mark for their decision-making AI system (one example is the French company Diabeloop).[6] As it is often pointed out, the regulations might not fit the rapid, iterative nature of Artificial Intelligence.

AI is increasingly used in various stages of research and development, as well as patients' care pathways. The two main benefits of SaMDs are:

- *Faster research and production of drugs and medical devices to drive faster innovation*
  - To identify possible drug treatment, the application of AI software can be key, as it has the power of increasing efficiency. For example, AI presents the industry (especially pharmaceutics) with an opportunity to revolutionise research and development programmes, especially at the earliest stages of product development in screening for potential drug targets and the corresponding drug candidates. Since there is no hardware involved, there are fewer constraints to using fast feedback loops for product improvement.
  - AI can be exploited post-market in the life science sector. There is an increasing demand by regulatory authorities for manufacturers to generate and analyse a significant amount of data relating to safety, quality and clinical effectiveness after product approval. AI has the potential to streamline this process[7].

[6] https://www.diabeloop.com/
[7] Tsang et al. (2017). The Impact of Artificial Intelligence on Medical Innovation in the European Union and United States.

- *Improved health outcomes powered by data*
  - Diagnosis timelines can be improved through faster data analysis (e.g. autonomous diagnostic decision-making systems help detect signs of certain diseases, and ML algorithms can identify patterns in datasets to assess risks). This is used especially in medical imagery[8].
  - Developments in the areas of patient care and disease management (e.g. using AI to personalise diabetes management solutions and to set up mobile-based coaching systems for pre- and postoperative patient care). Remote monitoring, coaching and empowerment of patients can reduce the burden of noncommunicable diseases such as asthma[9].

Other benefits of the use of SaMD include the following[10]:

- Greater efficiency and optimisation in healthcare delivery (e.g. predictive techniques allow the prioritisation of patient flow; data mining can help predict falls in elderly patients);
- Predict the need for medical supplies before the end user runs out of stock and help distributors identify when products need to be sent to distribution centres, and when the products with short shelf life need to be promoted to reduce inventory waste;
- Access to health services and shortage of healthcare professionals can be overcome by using algorithms to perform time-consuming tasks (e.g. computer-aided detection (CAD) systems to interpret medical images);
- In public health, predictive modelling could analyse data to provide information such as severity, location and date of a disease outbreak.

Interest in AI/ML applications has been growing rapidly. In medicine, devices based on machine learning have proliferated, especially for image analysis. AI/ML SaMDs are seen as opportunities for physicians to gain time for diagnostics and plan for the consumption of supplies based on previous purchases, as well as for industry to improve product testing during the R&D phase, etc.

In a 2018 survey, 82% of medical technology company leaders and 88% of executives in the software industry indicated that AI is important to their company[11]. These results tend to show that SaMD professionals at the intersection of these two fields tend to recognise AI as a very important technology.

AI technology is regarded as a golden opportunity for the medical technology (MedTech) sector. MarketsandMarkets forecasts that the global AI-in-healthcare market will grow from €4.3 bn in 2020 to reach €40 bn by 2026. The European AI-in-healthcare market is estimated to grow with a compound annual growth rate (CAGR) of 35.45% during 2020-2028[12]. In the EU, **research in genomics and DNA sequencing in particular is generating a large amount of digital healthcare data and is expected to drive AI SaMD.**

The main obstacles to use AI in healthcare, and therefore of AI-based medical software are the following:

- Access to data and data governance

AI and ML technologies require secure access to a large amount of high-quality data. The management and access to high-quality data is an important obstacle to the current use of AI/ML software as many healthcare services do not offer publicly available data.

- Systems interoperability

Achieving interoperability of systems has become essential. Ensuring the interoperability of systems allows for hospitals to make use of the software on their machines. In a 2019 survey, healthcare and life sciences executives stressed their concerns related to data privacy, data standards, normalisation and disparate software platforms as being the main barriers to interoperability[13].

- Reimbursement of medicine and device expenses

Current reimbursement systems do not recognise AI SaMD as the reimbursable expenses, and AI solutions are not covered by health insurance premiums. Reimbursement schemes are country-specific with no clear and unified criteria for AI-based medical software.

[8] MedTech Europe 2019
[9] Sennaar, 2019
[10] MedTech Europe, 2019, Jha, 2020
[11] Russel Reynolds Associates, 2018
[12] https://www.inkwoodresearch.com/
[13] Deloitte, 2019

- User acceptance of AI

Reluctance to adopt AI by physicians and health professionals, whether in terms of training or accepting to work with AI-enhanced medical devices and robots, is still a significant barrier. A knowledgeable workforce that is comfortable with using AI technologies is key to enabling AI technologies to become more sophisticated.

- Ethical framework

AI tools are developed by humans who may transcribe their own bias to the algorithm and functions of the software and therefore cause unethical outputs. The use of data on which AI is trained has important ethical implications. If the results of AI are generated by biased and skewed datasets, affected stakeholders will not be adequately protected from discriminatory harm[14]. In order to limit this issue, the European Commission published in 2019 its Ethics Guidelines for Trustworthy AI[15].

US vs. EU regulatory framework for AI/ML-based software as a medical device

US and EU professionals need to adapt to the ever-changing regulatory landscape.

Under EU law, software can be considered a medical device. Guidelines were published in 2016 within the regulatory framework for medical devices.[16] They define the criteria for the qualification and application of classification criteria for stand-alone software, when used in healthcare setting (European Commission, 2016). AI in MedTech is already subject to a well-developed safety and performance regulatory regime for their development and use, mainly the Medical Device Regulation (MDR), In-Vitro Diagnostics Regulation (IVDR) and General Data Protection Regulation (GDPR). The MDR enters into force on 26 May 2021. The application date for the IVDR is 26 May 2022. While not all software used in the healthcare setting is considered to be a medical device, the classification may change. Of particular relevance, software with a medical purpose of "prediction and prognosis" will be considered SaMD.[17] Moreover, the EU is currently working on the unique liability risks associated with the specific features of AI (e.g. opacity) that can make the application and enforcement of the existing legislation more difficult[18].

In the US, the FDA's traditional paradigm of medical device regulation was not designed for adaptive Artificial Intelligence and machine learning technologies. Under the FDA's current approach to software modifications, the FDA anticipates that many of these Artificial Intelligence and machine learning-driven software changes to a device may need a premarket review. Therefore in 2019 it published a discussion paper that describes the administration approach to premarket review of these products. The approach takes into account the specificities of AI/ML SaMD by embracing the iterative improvement power of Artificial Intelligence and machine-learning-based software as a medical device, while ensuring patient safety (US FDA, 2020).

At international level, there is also guidance such as the International Medical Device Regulators Forum's SaMD guidance documents.[19]

1.2 Objectives of this report

While SaMD represents a niche market, it constitutes a valuable addition to the hardware and services provided by the MedTech industry. Moreover, because software design and improvement are much less resource intensive than hardware development, the area is rapidly growing and maturing. Big players from the software industry and the healthcare industry have developed products and there are many examples of the benefits of SaMD.

This report aims to provide an overview of relevant stakeholders to see how advanced technology-based products can help EU industry to stay ahead of global competition. The objective is to map the key players in the SaMD value chain, as well as to identify their strengths and weaknesses. Analyses were based on desk research and interviews.

[14] Leslie, D. (2019). Understanding artificial intelligence ethics and safety
[15] https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top
[16] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices
[17] Tsang et al, 2017
[18] European Commission (2020). White Paper on Artificial Intelligence - A European approach to excellence and trust.
[19] N12 Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Consideration; N41 Software as a Medical Device (SaMD): Clinical Evaluation)

Section 2

2. Value chain analysis

2.1 Value chain structure

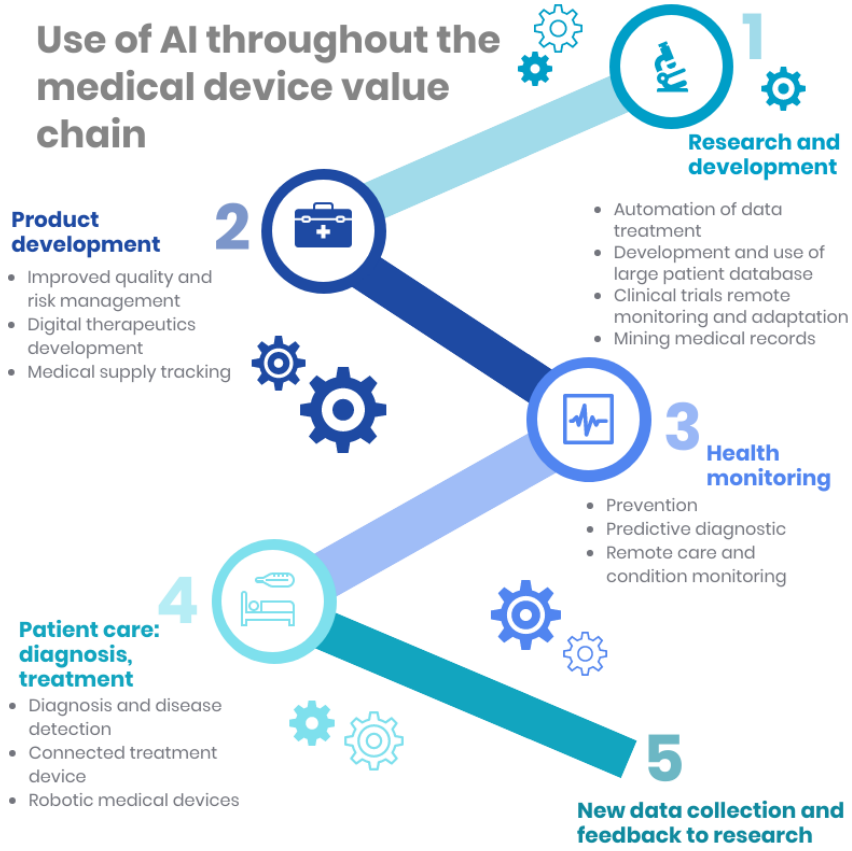
Due to its versatility, AI/ML-based SaMD can be found in all segments of the health value chain and has a potential utility for all actors and in all phases of the care pathway.

AI/ML-based SaMD exists as stand-alone software but is often included in hardware devices. AI/ML-based SaMD can be useful in prevention, diagnosis, treatment or monitoring, and it can also support healthcare services such as supply chain or note taking. It is also powerful when coupled with big data for research and development. Therefore, all healthcare manufacturers tend to have an interest in developing AI/ML-based software. However, because the algorithm for AI is developed by IT companies, these have been entering increasingly the medical devices value chain.

The greatest potential of AI software is currently identified in the R&D and patient care delivery stages, which are also the highest value-added activities along the healthcare value chain[20]. There is a lot of potential in these two areas because the use of real-time patient data will enable researchers and health providers to identify and respond to patients' needs more quickly. Moreover, interviewees stressed that the possibilities of AI in healthcare are endless.

Figure 2 below showcases where AI/ML-based SaMD bring value in the healthcare value chain.

Figure 2: Examples of AI/ML-based software utility along the healthcare value chain



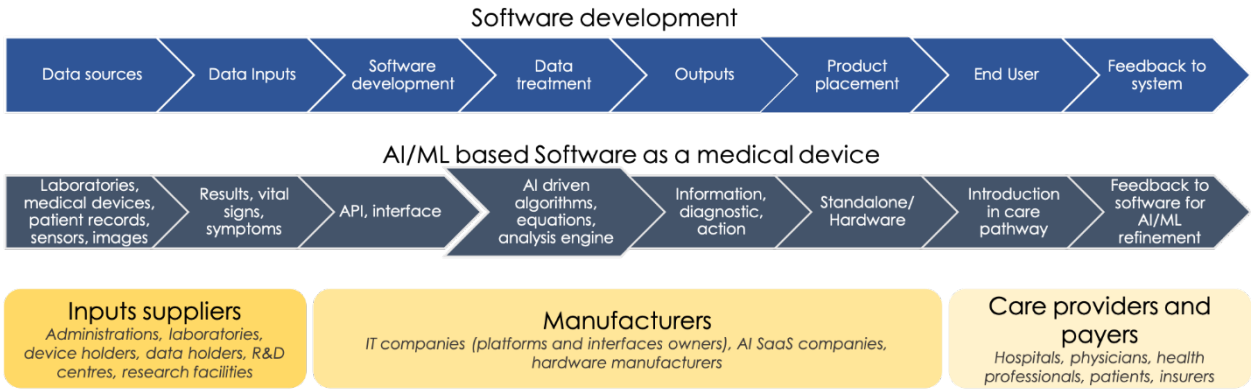
Source: Technopolis Group, 2020

[20] Torsekar, 2018

Figure 3 shows how a standard software and an AI/ML-based SaMD is being developed (showcasing in the zoomed-in arrow where AI is developed). The yellow boxes indicate where the different stakeholders play a specific role in the process. The figure shows development in a linear manner, it does not reflect, however, the continuous nature of software development.

Beyond the simple value chain, **it is very important to look at the development of AI/ML-based SaMD through a lens of the entire value ecosystem, where hospitals, clinicians and patients play a crucial role** not just as the final users of such products but as a source for innovation and proof of concept. In particular, regional and local innovation and healthcare ecosystems need to be considered, where clinicians and tech companies can work together on specific patient-oriented solutions in a focused local setting.

Figure 3: Software as a medical device - linear development



Source: Technopolis Group, 2020

The specificity of AI/ML-based SaMD lies with the iterative process at the core of their development, market introduction and overall lifecycle.

The software development is typically led by an IT company that has expertise in AI/ML. The development is based on data fed continuously to the system to form the basis of the software decision making ability. The AI engine is developed, integrated to the software which, along its lifetime is improved continuously based on users' needs and feedback, through an application programming interface (API) system.

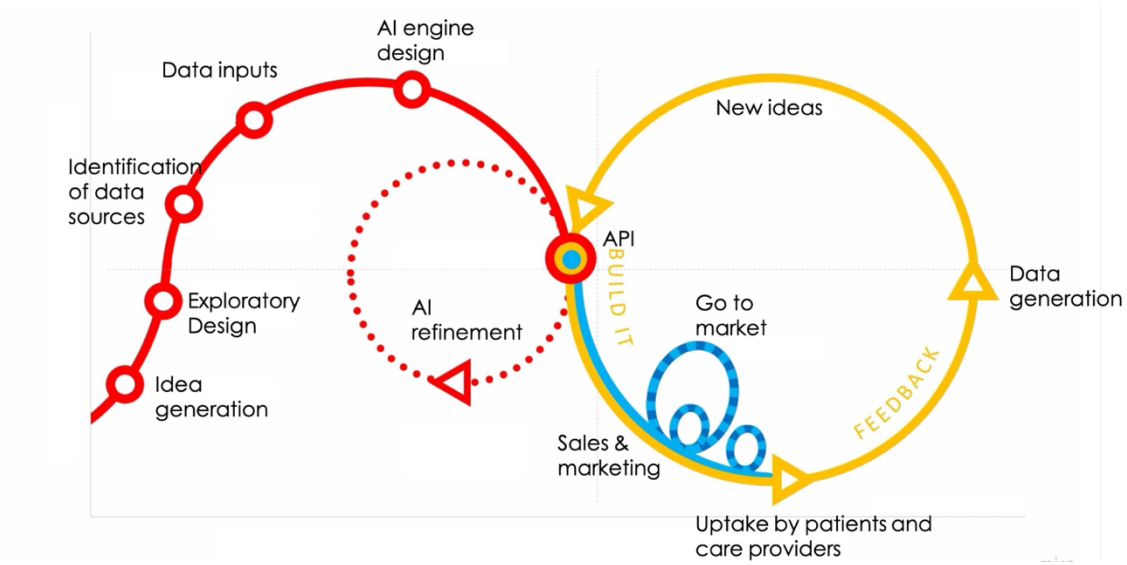
Once it is sufficiently refined, and approved by the regulatory authorities, the software is put on the market to reach end users, including care providers and patients. At this stage, it may also be embedded in a hardware device. The "go to market" of a software supposes the existence of a delivery platform, which is typically owned and managed by a tech company. This means that IT companies tend to own several elements of the value chain: software development and distribution.

Beyond the core development process of AI-based SaMD, companies often need to acquire expertise in the Internet of Things (IoT) in order to develop AI-driven connected medical devices and to improve clinical outcomes. Cybersecurity is another technology that is tightly linked to AI-based SaMD that can allow for the highest security against hackers and malicious software.

The figure below presents visually the ongoing improvement system (e.g. inclusion of new features, bug resolution, inclusion of rules and criteria for outputs) that takes place. The iteration is central to the development of the AI/ML-based SaMD and therefore impacts the value chain which requires the IT engineers (UX designers, mathematicians, data scientist and developers) to be included during the lifecycle of the product. In summary, the value chain of an AI/ML-based SaMD revolves around the development and refinement of the software and its AI/ML capabilities.

The linkages with the rest of the medical devices industry happen during the research phase but also once the software goes to market where it may be embedded into a hardware device (for clarity this is not shown in the figure below, which rather shows a stand-alone software).

Figure 4: AI/ML-based SaMD continuous innovation



Source: Technopolis Group, 2020 based on The lean start-up (Eric Ries)

2.2 Key actors in the value chain

The AI/ML-based SaMD value chain is composed of a series of key actors relevant for each segment including the following:

- Software development - technology/IT companies
- Data infrastructure
- Integrating software and hardware - manufacturers, electronics and medical devices companies
- Regulators
- Distribution and sales - end users
- Payers

Software development:

Today, tech companies are the main actors and drivers of the value chain. IT companies leverage their extensive data handling and storage capacities. Moreover, IT specialists have a central role in the development of AI/ML-based SaMD algorithms. They are behind the technology, the technical aspects of the software architecture (the algorithm as the set of rules to be followed in the calculations) and the training and/or conception of the AI/ML system.

These tech companies cover both IT and software. Some of them offer SaaS, PaaS, IaaS (Software, Platform, Interface as a service) and many have been making the leap towards AI, such as Alphabet, Apple or Microsoft. Others are AI experts by design such as Arterys (France), Greenfinch (Ireland), Blackford (US) or IBM Watson (US).

Major actors at the forefront of AI innovation are generally not healthcare companies. Nevertheless, **medical device manufacturers can reverse this current situation, if they find talent and staff with the right digital skills** and get access to the data in healthcare institutions as interviewees stressed. A survey from Rock Health, an incubator that invests in digital health startups, revealed that only 11% of people would be willing to share their health data with a tech company, compared with 72% for doctors and 49% for health insurers[21].

There is often a tension between IT companies that develop innovative AI and companies from the healthcare sector that have access to the data, as pointed out by the interviewees. To develop products, the former often need to partner with the latter, specifically to access hospital databases. As a result, there is uncertainty regarding which of these will become the central actor of the value chain. Similarly, according to an interviewee[22], there are about 700 AI startups in Europe, and

[21] Day and Zweig, 2018
[22] Please see list of interviewees in Annex.

while many have developed modules useful for healthcare, there are only a few that work uniquely on AI for medical devices.

European firms are active all along the value chain and they are not concentrated in a specific area. Nevertheless, they are mostly positioned in high-value areas of the value chain, such as research and service provision, while assembly and sub-components manufacturing (when needed) are usually taken up by Chinese actors. One interviewee pointed out that at first European actors tended to focus on radiology and imaging technologies. Today, the AI market is very crowded, and a lot of companies are trying to find their niche, which allows the ecosystem to become more diversified.

The software development segment is dominated by US firms and no European companies are among the top 10 in terms of revenue and size. These firms have invested heavily in supporting AI development, including in healthcare and medical technology.

On the one hand, some experts fear that if AI becomes widespread in healthcare, there is a risk of seeing one of these companies take over the market. On the other hand, it is also **a possible scenario that AI tools will become commodities, like programming languages, and "domain know-how" will decide the winners,** notably what quality data is available and for what specific medical purpose. Europe does not need to follow the US technology-driven perspective that is prevailing at the moment but rather adopt a solution-oriented and patient-centred strategy as highlighted by interviewees.

Therefore, while the tech companies have strong added value for the AI/ML-based SaMD market, there is an evident lack of trust from patients.

Table 1: The ten largest tech companies in the world active in AI for health (in billion eur) - 2019

Rank	Company	Headquartered	Market Value	Assets
1	Apple	United States	838	325
2	Samsung Electronics	South Korea	237	265
3	Microsoft	United States	825	225
4	Alphabet	United States	753	202
5	Intel	United States	229	110
6	IBM	United States	108	113
7	Facebook	United States	446	84
8	Cisco Systems	United States	216	89
9	Tencent Holdings	China	412	91
10	Oracle	United States	162	95

Source: Technopolis Group, 2020 based on Forbes 2019

Examples of large IT companies' entry in healthcare

- Despite not being listed by Forbes, Google is a key player. In particular, its life sciences unit called Verily is working with pharmaceutical companies on drug discovery and develops devices such as 'smart nappies', which alert parents when their child's nappy needs changing.
- Apple is trialling a device that can detect the tremors afflicting sufferers of Parkinson's disease, enabling them to monitor the progress of their condition.
- Samsung has introduced breast screening solutions and AI algorithms to assist diagnosis in each of its imaging modalities.
- Microsoft leverages the ubiquity of the Windows operating system among hospitals and rolling out new software and data-storage solutions powered by its cutting-edge cloud computing technology.

Besides the large tech companies, startups are also active in this segment. Crunchbase, a database of investment-backed innovative firms includes 33 EU and 56 US firms that combine Artificial Intelligence and medical devices as a core business[23]. Some EU companies have been specifically focusing on AI for

[23] www.crunchbase.com; accessed in March 2020

healthcare, such as Promaton (NL), Thirona (NL) or Mediktor (ES). Below is a short list of interesting young companies developing AI as the core of their healthcare product.

Table 2: Examples of AI-based healthcare startups in Europe

Country	Name	Description	Year founded
Austria	SteadySense [24]	SteadySense is an innovative start-up that aims to set new standards in medical data collection.	2016
Denmark	Corti[25]	Corti uses AI to analyse emergency calls in real-time and identify signs of cardiac arrest.	2016
France	Volta Medical[26]	Volta Medical is an innovative start-up that develops artificial intelligence software as a cardiac mapping assistance tool. It is designed to provide information to electrophysiologists so that they can treat complex arrhythmias such as atrial fibrillation.	2016
Hungary	Hand in Scan[27]	Hand in Scan has innovative new tech to reduce nosocomial infections. They do this by monitoring hand hygiene performance, using digital image processing.	2012
Italy	Patch AI[28]	Patch is a virtual assistant used in clinical trials to help collect data in real time. The platform engages the patient by mimicking real human conversations. It can also evaluate clinical trial performance.	2018
Latvia	Ardora	Ardora offers early-stage, digital assistance for relatives of dementia patients. They use AI algorithms on audio patterns to track various care metrics to ultimately reduce care hours and alleviate stress for informal caregivers.	2019
Netherlands	Aidence[29]	Using deep learning AI, Aidence allows computers to analyse medical images and provide detailed reports.	2015
Spain	Biel Glasses	Biel Glasses develops smart glasses to improve mobility and personal autonomy of people with low vision.	2017

Source: Technopolis Group, 2020, based on Crunchbase

Data infrastructure:

A crucial element of developing AI/ML-based software is data input, since without access to high-quality and accurate big data the AI software cannot be adequately trained. Large health datasets can be accessed via electronic health records, clinical trials, registries, but data can be also generated and collected through sensors on wearable devices.

Data infrastructure and data platforms that can provide such health data play a critical role in the AI/ML-based SaMD value chain. Data infrastructure has, however, high costs in terms of installation and ensuring data security. Firms and organisations that have access to large, high-quality and trustworthy datasets will be in a more competitive position to develop AI SaMD.

With their larger pools of interoperable data, the US and China might have an advantage over Europe currently, although interviewees also stress that it is not the volume of data that matters but the level of quality and its standardised format. In this regard, Europe might be better to focus on developing an effective process to collect a smaller set of highly standardised health data.

Another solution to the need for large data sets is to test and use emerging data synthesis methodologies (for instance, through generative adversarial networks) to overcome the limitations of available real-world data.

[24] https://www.steadysense.at/
[25] https://corti.ai/
[26] https://www.volta-medical.com/
[27] https://www.handinscan.com/
[28] https://patchai.io/en/
[29] https://www.aidence.com/

There are significant, ongoing efforts in the EU to create a wide and interoperable European Health Data Space.

In terms of private efforts, Philips Healthcare unveiled its IntelliSpace Discovery 3.0 platform[30] in 2018, which facilitates the development of AI training data. It is an advanced visualisation and analysis platform designed specifically to support imaging research. Various institutions and startups are already using the Discovery 3.0 version to prepare patient data to train and validate deep learning algorithms.

Some other examples of pan-European, patient-centric health data infrastructures and initiatives include the following:

- *European Health Data Evidence Network - EHDEN*[31] has developed a health infrastructure in a federated network at scale across Europe.
- *Meaningful Integration of Data Analytics and Services* - MIDAS[32] investigates how to connect patient data from European health authorities with individual data collected from apps, sensors and social media.
- *European Institute for Biomedical Imaging Research* supports researchers and industry partners in the coordination of biomedical imaging research.
- *BBRMI-ERIC*[33] a European research infrastructure for biobanking, which currently includes 20 countries and one international organisation, making it one of the largest European research infrastructures.
- *European Medical Information Framework* (EMIF) was a public-private consortium with 57 partners and ran for 5.5 years, ending June 2018. During this time span, EMIF has successfully improved access to human health data by providing tools and workflows to discover, assess, access and (re)use human health data.

Integrating software into medical devices:

Hardware manufacturers. While traditionally MedTech companies have focused on hardware development, partnerships with consumer technology companies could help them tick the software box as well. Besides, they invest in developing capabilities and interfaces necessary to integrate data collected from connected devices with other internal and external datasets. Finally, MedTech companies can leverage their knowledge and position in the healthcare system to ease the burden of care providers through data management and operation[34].

While hardware companies externalised software development in the past, it is expected that the development will become reintegrated into hardware again and as a result hardware companies will obtain their own AI/ML systems as pointed out during the interviews. Nevertheless, AI/ML-based SaMD is not only about data and AI algorithms, but also how AI fits into the medical device and supports a better medical outcome. In this respect, **putting the focus back on the know-how of medical device manufacturers should be better leveraged in Europe.**

The product placement on the market depends on the usage of the software which can be stand-alone or embedded in a hardware device. In the second case, electronics manufacturers become a key element of the value ecosystem.

Electronic manufacturers make the essential electronic components for the functioning of hardware products associated with AI/ML-based SaMD. In this market, Original Equipment Manufacturer (OEM) outsourced software development to larger contract manufacturing firms when possible. Reasons included financial stability, fewer vendors to coordinate in product manufacturing and confidence in larger firms' abilities to invest in new facilities, equipment and quality systems.

Basic engineering is also necessary for the production of medical devices (moulding, coating) as well as the development of new materials and manufacturing technologies.

The **largest global medical device manufacturing** companies are found in the US, with just a handful of European companies represented (in bold below), all of which have experienced a revenue decrease

[30] https://www.philips.com/a-w/about/news/archive/standard/news/press/2018/20181120-philips-launches-intellispace-discovery-research-platform-at-rsna-to-support-the-development-and-deployment-of-artificial-intelligence-assets-in-radiology.html
[31] https://www.ehden.eu/
[32] http://www.midasproject.eu/
[33] https://www.bbmri-eric.eu/
[34] Deloitte, 2019

or slow increase over the fiscal year 2018-2019. However, as underlined by interviewees, even US-based companies are active across the globe and are important actors in Europe too, such as GE healthcare which tops the operating room market.

Table 3: Top 15 Medical device manufacturers in the world (converted into billion €) - 2019

Rank	Company	Headquartered	Revenues	% change 2018-19
1	**Medtronic**	**US/Ireland**	**27**	**+2**
2	Johnson & Johnson	United States	23.9	+1.5
3	GE Healthcare	United States	17.52	+4
4	Abbott	United States	16.76	+17
5	**Philips**	**The Netherlands**	**14.25**	**-1.2**
6	Becton Dickinson	United States	14.15	+32.1
7	Cardinal Health	United States	13.8	+15
8	**Siemens Healthineers**	**Germany**	**13.8**	**-2**
9	Stryker	United States	12.04	+9.3
10	Baxter	United States	9.85	+5.3
11	Boston Scientific	United States	8.7	+8
12	Danaher	United States	8.05	+5.8
13	**EssilorLuxottica**	**France**	**7.55**	**+0.8**
14	Zimmer Biomet	United States	7.02	+1.7
15	**B. Braun**	**Germany**	**7.00**	**-2.8**

Source: Medical Product Outsourcing, 2019

Startups and young firms that develop medical devices and integrate AI technology into their products are still few in number but are growing dynamically. Some examples are listed in the table below.

Table 4: Examples of medical devices startups with AI technology in Europe

Country	Name	Description	Year founded
Finland	Cerenion	Cerenion is a medical company working on a technology that monitors the brain function of intensive care patients.	2017
Germany	DeepSpin	DeepSpin is a company developing an Artificial Intelligence-powered MRI imaging machine.	2019
Italy	Omnidermal	Omnidermal is specialised in the realisation of devices equipped with Artificial Intelligence algorithms applied to dermatology.	2017
Lithuania	Oxipit	With a team of award-winning data scientists and medical specialists, the company aims to introduce innovative Artificial Intelligence/Deep Learning breakthroughs to everyday clinical practice.	2017
Poland	Aether Biomedical	Aether Biomedical is a rehabilitation robotics startup focused on building bionic limbs for upper limb amputees.	2017
Spain	Biel Glasses	Biel Glasses develops smart glasses to improve mobility and personal autonomy of people with low vision.	2017

Source: Technopolis Group, 2020

Integrating AI and IoT through wearables: The Internet of Things connects smart medical devices and implies the generation of very large volumes of data that AI software can meaningfully analyse. The integration of AI software and IoT technology enables in particular the development of a new range of wearable products, and hence the development of a new value chain segment. AI-enabled IoT can be used for chronic disease management, drug management and remote health control. Such medical devices combine not only AI software and IoT but also clinical decision-support algorithms, cloud applications and cybersecurity technologies.

Wearables are devices that have been rendered portable thanks to advances in electronics and wireless connectivity. Data collected by a wristband can be streamed directly to a cloud-based platform and the wearer's behavioural pattern can be analysed by an AI software in the cloud. For instance, Philips Healthcare developed solutions that continuously monitor patients in a critical condition. Philips Healthcare's IntelliVue Guardian uses AI to predict when a life-threatening crisis may occur, and it allows early intervention.

The rising adoption of IoT in healthcare is expected to significantly influence the growth of the Software as a Medical Device market over the coming years, where cloud-based SaMD is projected to hold a significant share, owing to the rising popularity and greater functionality and scope in comparison to on premises-based devices[35].

Regulators:

Regulators have a responsibility to ensure safety, high-quality, appropriate standardisation and to promote interoperability. Privacy regulations are also critical and have to be fully in place in order to unlock the potential in AI algorithms that rely on big data. Given the adaptive character of AI-based SaMD, transparency is key, and developers/manufacturers need to ensure performance monitoring. AI/ML-based SaMD is based on continuous optimisation from real-world data. However, with modifications there is a risk that the device will change in terms of its functions and effects. AI algorithms that constantly retrain do not fit well with current medical device regulation. The EU MDR/IVDR and harmonised standards do not account for the dynamic change that some machine-learning models represent[36]. In addition, it has to be kept in mind that developers are not obliged to adhere to a harmonised standard. The MDR is about essential requirements, where procedures and quality management rules ensure that essential requirements are being met over time. In the US, the FDA is expecting manufacturers to track what modifications have been incorporated and how the device is performing. These are to be used to mitigate risks and to provide the FDA with periodic updates. The frequency and types of these reports are to be based on risks associated to the device, the number and types of modifications, and the maturity of the algorithm[37].

Distribution and sales

End users of the AI/ML-based SaMD are first and foremost healthcare professionals. They are the main users of the technologies at hand. They operate the AI software-embedded hardware but also work with the results produced by standalone software. This is especially clear in the detection and diagnosis phases of a condition, by using tools such as imagery reading and sorting software. Health administrators, specifically hospitals and clinics managers, can use intelligent software to help manage stocks and supplies. Researchers work with AI-driven software at the R&D stage, e.g. for drug development or using large datasets to identify future needs. Patients are and will be important users of AI software through their devices (mostly smartphones) and in the monitoring of their condition, especially in the case of chronic disease that require a constant influx of data to revise the treatment or dosage. The end users are connected to the other actors of the value chain, such as with their physician for the diagnostic or management of a condition, since while the software may help take decisions and gain knowledge of the evolution of a condition, the physician makes the treatment decisions. They interact with the AI which sends back information to the software developer.

Payers:

Insurance companies, and national (or regional) governments operating healthcare reimbursement schemes, are important actors in the healthcare value chain. They are vital to the reimbursement of health expenses related to AI-based solutions and to the sustainability and growth of this subsector. Without health insurance reimbursement, many solutions are unlikely to go to market. However, these

[35] Knowledge Sourcing Intelligence, 2019
[36] Algorithms as medical devices, PHG Foundation (2019)
[37] https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf

actors do not necessarily have the same perspective as patients. A useful product for patients and clinical care may lack traction from payers, and this will limit its adoption. Similarly, an AI/ML-based SaMD may be highly relevant to payers and not useful to patients. In the context of a shift from a 'fee-for-volume' (where the emphasis is on the amount of care received) to a 'fee-for-value' model (with a focus on quality and value), the importance of AI-driven healthcare solutions is growing.

There are other economic incentives to adopt these new technologies for consumers and payers[38]. Indeed, the new models of outcomes-based reimbursement push to find solutions to the three main issues of healthcare systems: cost, quality and access to care. Across Europe, regulations are updated to address the new AI-based solutions and expand reimbursement for these (e.g. Germany enacted a law that enables state health insurance schemes to reimburse costs related to the use of digital health applications). However, the process of changing regulations is slow and appears to be country specific. In 2019, the eHealth Stakeholder Group[39] issued "Proposed Guiding Principles for Reimbursement of Digital Health Products and Solutions[40]", which includes recommendations regarding criteria for reimbursement and funding sources.

2.3 Linkages along the value chain

The main collaboration between stakeholders along the AI/ML-based SaMD value chain is through the "give and take of expertise between MedTech and consumer tech companies". This is a speciality-based collaboration, such as the one between Novartis and Microsoft[41] to develop the AI capabilities they offer. Therefore, each company develops and retains its expertise, but they collaborate in order to integrate AI into the medical offer. As highlighted earlier, however, the tech and software companies tend to be big US players, joining forces with big European players or acquiring innovative European startups and SMEs.

It is important to underline that mergers have become a defining characteristic of the medical sector, with an increase in mergers and acquisitions (M&A) in the past three years. As one example, Microsoft announced a partnership with OpenAI worth €0.89 bn, to enhance capabilities of its Azure platform and help build the next generation of AI applications[42]. As another, in 2018, Roche Holding acquired US cancer startup Flatiron Health for €1.68 bn – one of the largest M&A deals in Artificial Intelligence. Across all economic sectors, AI acquisitions multiplied by more than six times between 2013 and 2018, led by the tech companies and in particular Apple and Google[43].

M&A transactions in the MedTech sector are increasingly taking place in related areas such as wearables. In 2017, Johnson & Johnson Medical announced the acquisition of the software company Surgical Process Institute (SPI). SPI is one of the global pioneers in the digitalisation and structuring of medical processes in hospitals. The same year, Philips announced the acquisition of the Germany-based Tomtec Imaging Systems. Tomtec produces image analysis software and systems[44].

The collaboration can also link together IT companies with care providers on a service-based model such as the agreement between Philips and Jackson Health System. The first provides the second with patient monitoring technology. Rather than buying technology outright with an upfront payment, Jackson pays Philips a per-patient fee in return for monitoring services over the 11-year duration of the agreement. In addition, Apple and Johnson & Johnson just completed the largest heart data study in history using the Apple Watch as highlighted during the interviews.

[38] Demark, 2020
[39] https://ec.europa.eu/digital-single-market/en/news/call-expression-interest-ehealth-stakeholder-group-members-2019-2022
[40] https://www.medtecheurope.org/wp-content/uploads/2019/04/30042019_eHSGSubGroupReimbursement.pdf
[41] https://www.novartis.com/news/novartis-and-microsoft-announce-collaboration-transform-medicine-artificial-intelligence
[42] Deloitte, 2019
[43] CBS Insights, 2019
[44] Deloitte, 2019

Section 3

3. Analysis of EU competitive positioning

An indication of the EU competitive positioning can be outlined according to the strengths and opportunities, and the risks and challenges faced. Figure 5 depicts an overview of these key strengths, opportunities, challenges and risks for the AI/ML-based SaMD value chain.

Figure 5: Strengths, opportunities, challenges and risks for the AI/ML-based SaMD value chain

Source: Technopolis Group

3.1 Strengths and opportunities for EU companies

Strength: Catching up based on EU specificities

The overall market trend for SaMD in Europe (and also globally) is currently positive and growing. By 2025, North America is projected to hold the largest market share followed by Europe, which is expanding dynamically, while the Asia Pacific is projected to grow with the highest compound annual growth rate (CAGR) over the forecast period of 2020-2025. The main reasons for high growth in Asia are the ageing population of Japan and the appetite of citizens (especially educated citizens) in emerging economies such as China and India for monitoring and managing their health[45].

The EU has its own specificities that are considered as strengths by the interviewees. Complying with the strict data privacy rules of the GDPR constitutes a competitive advantage for the EU in the long term, compared to Asia or America where regulations are less concerned with data protection. Several interviewees underlined that European companies tend to join new markets after the US, but they do so with more mature solutions (i.e. solutions that respect the privacy of the patients, are un-hackable, etc).

By the same logic, the difficulty of working internationally in only one language is also highlighted by the interviewees, especially for codifying data. While the multiplicity of languages in Europe is an issue at first (the market is fragmented and the growth potential of companies is limited compared to countries with a large internal market), the product is de facto adapted to all languages later on and can be exported more easily.

The EU is also strong in subject-matter expertise (biology, medicine, etc.), which plays a key role when developing AI software for healthcare and is very important, just as computer science skills are. In order to successfully commercialise AI/ML-based SaMD, the developers have to have a deep understanding of how it can best fit the medical condition to be addressed. In this sense, European players are well-placed to deliver high-quality and well-defined products.

[45] Knowledge Sourcing Intelligence, 2020

Strength: An already well-established industry

Countries like Germany, France, Italy or Ireland can build upon a well-established large MedTech industry and workforce. There are 27,000 medical technology companies in Europe[46]. Most of them are based in Germany, followed by Italy, France and Spain. Small and medium-sized companies make up almost 95% of the MedTech industry. Smaller companies tend to invest more intense R&D efforts to innovate because products typically have a lifecycle of only 18-24 months before an improved product becomes available. For example, BioMérieux, a French company, is expected to invest substantially more in R&D as a percentage of its MedTech sales than the other top 20 companies, with an R&D investment rate of nearly 16% in 2024[47]. Having a wealth of small companies is a strength in a market that favours agile and innovative companies moving quickly from design to implementation. Moreover, an interview emphasised that the European field is more diverse than that in the US.

Well-known European companies from the industry, such as Medtronic or Philips, are already cooperating with companies from the AI sector to develop innovative solutions for the healthcare market[48]. There are clear opportunities in medical imagery analysis software, considering that Siemens Healthineers, General Electric and Philips continue to dominate the market for diagnostic imaging[49].

High investments from the European market leaders are planned by 2024: Philips, Siemens and Medtronic Ireland are all planning to maintain their spending on R&D (CAGR +3%), although to a lower extent than the average top 20 global MedTech companies (CAGR +4.5%)[50]. In 2019, 40% of MedTech patent applications were filed from European countries[51].

Strength: high requirements for safe and ethical technology

European legislation ensures the safety and efficacy of medical devices and the new EU MDR and IVDR took further steps towards transparency and security. The 'White Paper on Artificial Intelligence' emphasises that it is vital that European AI is grounded in European values and fundamental rights such as human dignity and privacy protection. In 2019 the High-Level Expert Group on AI presented its 'Ethics Guidelines for Trustworthy Artificial Intelligence'[52] and set out the ethical foundations by laying out a fundamental rights-based approach. It identifies and describes the ethical principles that must be adhered to in order to ensure ethical and robust AI, which are also very relevant in the medical devices industry.

Opportunity: Acceleration of VC investment

There are a lot of opportunities on the global market for EU companies in AI/ML-based SaMD. In Europe, venture capital invested in AI companies in healthcare has grown significantly since 2015: the amount has multiplied in size by 22, and €800 m were invested in 2019[53]. European VC funding is at a high level and startups can tap into a growing fundraising environment, which will ensure growth capital for next-generation AI-based medical devices, as highlighted in interviews. VC investors are especially interested in the potential of AI to help impact broader health system inefficiencies[54]. AI/ML-based software can be used for disease prevention, support for patient monitoring and in the care for chronic illnesses.

As a recent survey found[55], startup executives were confident about the prospects of the European market, seeing it on a par with the US, while investors saw the US dominating, with China as a growing new market.

It has to be noted that as an alternative to venture capital investment, cooperation with established players may provide the necessary kick-start for startups. Business for startups can come from selling to large firms and established medical devices companies, which may in turn provide financing as an alternative to a venture capital fund.

[46] MedTech Europe, 2019
[47] Evaluate Ltd, 2018
[48] Clairfield International, 2018
[49] Technavio, 2020
[50] Evaluate Ltd, 2018
[51] MedTech Europe, 2020
[52] https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai
[53] EIT Health and McKinsey, 2020
[54] KPMG, 2018
[55] Clairfield, 2018

Opportunity: EU support

According to the interviewees, Europe is lagging behind less and less in the Artificial Intelligence race, thanks to more initiatives at the EU level to support AI and the increased grant opportunities made available for startups and young firms.

The EU has taken the AI future of Europe seriously and identified how to foster the excellence of European companies in the field by supporting SMEs and partnering with the private sector[56]. There are opportunities to help the introduction of AI in healthcare through EU support[57]:

- Defining AI priorities and supporting these through (public and private) funding to help EU companies become fast movers in the market
- Clarifying data management rules to grow trust in AI-based systems
- Clarifying regulations on AI-based software to create a level playing field and lift barriers to adoption
- Create talent concentration to foster innovation and develop talent through supporting the creation of centres of excellence for AI in healthcare.

Moreover, the European Commission and EU Member States have developed a coordinated plan on AI: "*The aim is to foster cross-border cooperation and mobilise all players to increase public and private investments to at least €20 bn annually over the next decade. To do so, the Commission proposed, under the next programming period 2021-2027, that the Union allocates at least €1 bn per year in funding from the Horizon Europe and Digital Europe programmes to invest in AI*". The EU has launched networks of AI research-excellence and digital innovation hubs that will largely involve the stakeholders and focus on AI-related challenges and manufacturing[58].

Opportunity: Demand from healthcare professionals

Demand for AI in healthcare comes in two forms: on the one hand, care providers and healthcare professionals see more and more an opportunity in AI/ML-based SaMD; on the other hand, there is an increasing demand from patients to better manage their health from home.

Besides EU-wide support, the European healthcare systems can play an important role in catalysing AI in their ecosystems. AI can specifically support the healthcare-skilled workforce by redesigning clinical education processes and addressing the needs of both future healthcare and AI-focused professionals. Investment in upskilling frontline staff and designing lifelong-learning programmes is also crucial in this. Hospital administrators and staff have an appetite for solutions that can help reduce the time – and therefore the cost – spent on routine, repetitive administrative tasks[59]. Administrative workflow is perceived as an area where AI can help most. A 2018 study revealed that healthcare providers used AI tools most frequently for workflow assistance (14%)[60].

Interviewees pointed out that AI/ML-based SaMD will also open opportunities in the job market, offering highly qualified roles in R&D. Such roles can include designers specialising in human-machine interactions about clinical decision-making and specialists who will help create new workflows necessary for the integration of AI. Data architects will be critical in defining how to record, store and structure clinical data so that algorithms can deliver insights, while leaders in data governance and data ethics will also play vital roles. In other data-rich areas, such as genomics, new professionals will include 'hybrid' roles, such as clinical bioinformaticians, specialists in genomic medicine and genomic counsellors.

3.2 Key risks and challenges

European startups developing AI for healthcare generally face three challenges (and also risks):

1. access to high-quality datasets to validate their solution
2. access to the market, which is often related to difficulties in entering hospital public procurement processes
3. integration of the solution in the clinical workflow.

[56] European Commission, 2020
[57] EIT Health and McKinsey, 2020
[58] European Commission, 2019
[59] Administrative tasks can take up to 70% of a healthcare practitioner's time (EIT Health & McKinsey, 2020).
[60] HIMSS Analytics, 2018

Challenge: Trustworthy and high-quality data and data governance

The key challenge, but also the key cornerstone, in making this product successful is the availability of and access to high-quality and trustworthy data. The emphasis is not on the quantity of data or large datasets – large amounts of data are already available – the issue is whether we can trust these data. Even if a smaller set of data was available, but it was well standardised and well cleaned, it would help AI/ML-based SaMD take-up in the EU.

How AI and machine learning is trained is very important. Such software needs to recognise the differences between people and help make decisions that work for each individual, not treat all as a homogenised composite which may only represent a subset of all individuals.

The main risk related to AI/ML-based SaMD is in the **handling of patients' data**. With the rise of AI-based software, legal and ethical concerns have started to multiply. AI technologies generate useful information from enormous volumes of data and help businesses make critical decisions. However, customers fear their personal data being collected and used by AI. Safeguarding this information is a challenge for enterprises. The EU has implemented the GDPR to protect citizens' privacy and avoid any misuse.

Nevertheless, it is unclear how GDPR will be applied in an environment of ever-changing AI software, which can quickly make regulatory requirements unclear and therefore burdensome for enterprises. If the regulatory requirements are too tight, this will impact the speed of innovation and the creation of new business models by companies, as warned by interviewees. This is especially relevant for companies from outside the medical devices industry, which often underestimate the special features of European standards and regulations. For example, automotive companies must demonstrate a special quality management system for medical technology. In addition, some software companies must classify their products as medical devices, which requires a conformity assessment and the CE label. This constitutes a barrier to market entry[61].

At the national level, there is not always a clear pathway on how to introduce the SaMD (documents, procedures) and most AI solutions are not reimbursed in most EU Member States (e.g. teleconsultation).

Interviewees pointed out that currently companies train their AI/ML systems using data from outside Europe. The AI White Paper references some possible countermeasures, to enable testing on EU data (i.e. creation of excellence and testing centres), but this is still a significant risk and challenge. Democratising data access will make the market friendlier for smaller players.

Addressing the access to high-quality, trustworthy and well-standardised data will ensure Europe will have a more thriving ecosystem than the US, where startups are quickly acquired by the largest players (Google, Amazon, etc.), as highlighted during the interviews.

Challenge: Matching AI tech with clinicians

AI researchers still work at too far a remove from medical practitioners to understand their problems. The real-world applications are very specific, and doctors do not have time to engage.

A major challenge for EU companies that want to put an AI-based SaMD on the market relates to the specific IT know-how. AI knowledge and understanding is relevant both for the end users (hospitals and patients) and for the technology workforce. In the first case, it is a matter of technology adoption. In the second, it is a matter of technology production.

Regarding end users, convincing the health system to take a turn toward the digital means making sure health professionals understand the usefulness of AI-powered software (e.g. gain time for quality time with patients) and how to interact with it. IT know-how is closely related to training of staff. Nevertheless, national health systems will need to financially support and heavily invest in these trainings at a time when most countries face serious financial difficulties and healthcare budget pressures. The time spent on digital training is expected to double for the caregiver profession by 2030 (+124%). This is a primary need, and it will have to be accompanied by continuous training to remain relevant thereafter. Besides the costs, it will require new roles in training, designing new workflows and communicating the benefits of AI[62].

A cultural change needs to happen among clinicians, who will increasingly revise their first diagnosis by using an algorithm. With an open mind, physicians will have to understand the basics of the software, and its limitations. Training physicians to comprehend the system is also a way to reassure them that

[61] Clairfield International, 2018
[62] EIT Health and McKinsey, 2020

AI solutions will not replace doctors. Besides, it can help them prevent any overconfidence in AI systems from patients. A study commissioned by the US government, on the use of learning computer systems in the diagnosis of breast cancer using MRI scans, showed in 2016 that whilst the error rate of the best physicians was 3.5%, even the most capable AI systems achieved only 7.5%[63].

The second challenge for EU companies is to attract the right talent. In a sector where the demand for AI talent exceeds the supply, MedTech professionals are confronted with many challenges in making this happen[64]:

- Competing with the allure of other sectors for a limited supply of AI talent
- The highly regulated environment and longer time-to-market may make the overall healthcare industry less attractive to AI experts, as more stands between the mandate of an AI expert's work and the final product
- The slowness of the sector's hiring processes
- The need for an "AI star". AI leaders in MedTech have observed the importance of their existing team in the ability to attract additional talent.

Risk: Global competition

Currently, the largest tech companies are overwhelmingly based in the US, where startups benefit from a culture of VC funding unmatched in Europe. The US accounted for 221 VC deals in AI in healthcare from the start of 2010 to the end of 2019, while there were only 108 in Europe and 76 in Asia[65].

International competition does not only come from the US. China has moved up the value chain of medical devices significantly. For example, in the first decade of the 2000s, foreign investments in China's medical device sector were primarily directed towards manufacturing — the lowest value-added segment of the value chain. Chinese exports were at that time predominantly composed of low-technology (tech) devices. However, during 2010–17, a shift occurred in the composition of FDI, which went into high-value-added activities. These are research and development, sales, and post-sales services. At the same time, China's medical device exports transitioned into mostly medium-to-high-tech categories[66].

Risk: Access to market

Interviewees have underlined that as a region Europe has natural barriers and the market is fragmented compared to other large countries. Overall, the United States currently leads in AI, with China rapidly catching up. On the global market, the European Union has the talent to compete with the United States and China. Indeed, it has more AI researchers than its peers and typically produces the most research as well. However, it is lagging behind in terms of commercial AI adoption and funding[67].

Facing this fierce competition, the EU has to cater for the specific needs of its SMEs and young companies[68]:

- Startups need to rely on venture capital investors in order to secure their first investments. The number of investors in this area is still manageable. Companies have already been established in the software, wearables and diagnostics sectors.
- Medium sized companies must review their business models in order to be prepared for continuing price decline and increasing digitalisation. The development of new technologies and business models can often only be realised through new investors or mergers.

Risk: Cybersecurity

It is clear that European companies need to integrate digitalisation into their business models in order to succeed in the long term. Thus, there is a strong need for specific data protection and data security requirements[69]. With companies from outside the industry increasingly entering the medical technology market, especially from the automotive and IT sectors, the EU approval procedures and the associated requirements in distribution and monitoring must be observed.

[63] Clairfield International, 2018
[64] Bajwa & Flören, 2019
[65] EIT Health and McKinsey, 2020
[66] Torsekar, 2018
[67] Castro, McLaughlin, & Chivot, 2019
[68] Clairfied International, 2018
[69] Clairfield International, 2018

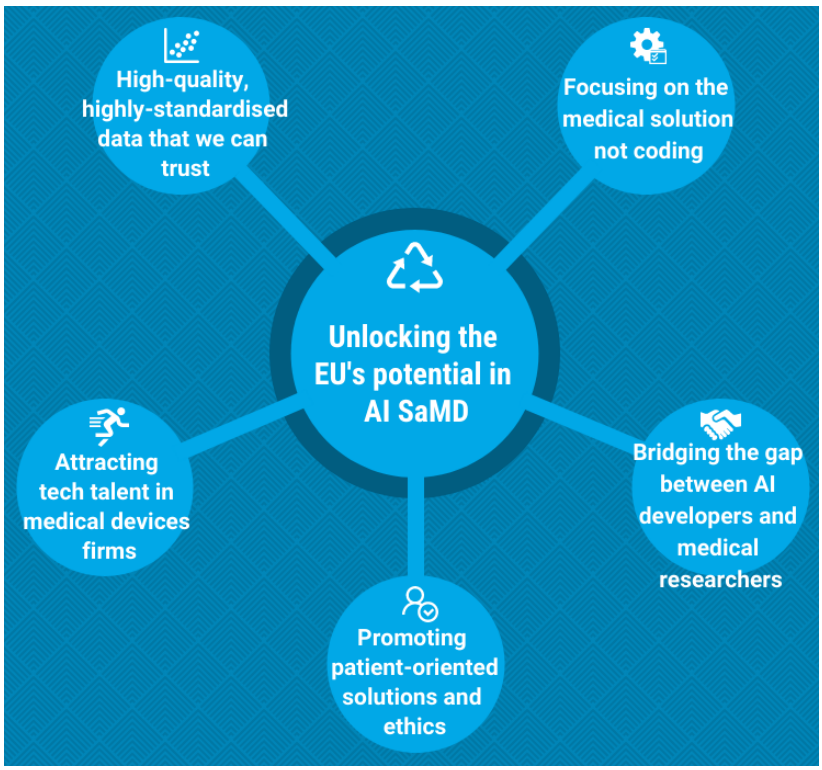
Section 4

4. Conclusions

4.1 Conclusions

AI/ML-based SaMD has a significant potential for many applications in healthcare. Expectations are high regarding the potential of this new technology to solve the "iron triangle" in healthcare: the necessary trade-offs between access, affordability and effectiveness. In particular, hopes are high in the areas of diagnostics and monitoring of diseases, and regarding the potential to make healthcare institutions more efficient. Nevertheless, the uptake of AI/ML-based SaMD faces several challenges and the EU has a range of opportunities to unlock the potential in this area for the benefit of its citizens.

Figure 6: EU's potential in AI SaMD – summary conclusions



Source: Technopolis Group, 2020

Access to high-quality data that we can trust

Data is a key factor that enables the development of new AI/ML-based SaMD products. Nevertheless, beyond the great promises of AI as a medical device, it is currently very hard to find high-quality and trustworthy health data on which AI can be trained. In various cases, data has turned out to be wrong or biased, which has had a negative consequence on diagnoses. All these incidents are wake-up calls that the focus should be put on the quality and trustworthiness of data instead of volume. In this respect, Europe's potential lies in enabling the development of secure, highly standardised and interoperable datasets. This also has further implications for data governance.

Finding the European way between AI powerhouses

While Europe has a strong industry in medical devices, and startups in medical technologies are numerous, the continent lacks big players in tech and IT. US companies have exploited their established market position in IT and AI and have already entered the healthcare field. They have done so either by partnering with renowned health companies or by developing their own expertise. The main upcoming player, based on its large internal market, extensive investment efforts and loose regulation is China. Between these two powerhouses it is key that European companies find their competitive advantage. EU regulations are a strength in general but there is a weakness in that the current unclear regulations regarding AI still hinder its potential being fully realised.

Putting the focus on the solution and not on coding

While the EU is carefully watching its US and Chinese counterparts, companies and healthcare institutions operate in a totally different environment, and this needs to be taken into account. AI trained on US data cannot necessarily be used in EU settings. To win the AI medical-device race the EU should not copy the US or Chinese approach, or fear US software technology, but put more emphasis on the specific European solutions developed in specialised health- and medical-technology ecosystems using high-quality datasets.

Europe does not need to follow the US technology-driven perspective that is prevailing at the moment but should adopt a solution-oriented and patient-centred strategy. The emphasis should be put on the medical solution not on coding.

AI tools might become commodities – like programming languages – in the future and "domain know-how" will decide the winners, notably what quality data is available and for what specific medical purpose. AI/ML-based SaMD is not only about data and AI algorithms, but is about how AI fits into the medical device and supports a better medical outcome. In this respect, putting the focus back on the know-how of medical device manufacturers should be better leveraged in Europe.

Bridging the gap between AI developers and medical researchers

AI researchers are often working at too far a remove from medical practitioners to understand the real-world problems in question, which can hinder the use and uptake of AI-based medical solutions. The actual applications of AI-enhanced medical devices can be very specific and sometimes represent niche areas. It is often an issue that clinicians and doctors do not have time to test and co-develop the algorithms with tech firms or medical device manufacturers that set the rules for AI. Regional and local healthcare and medical technology ecosystems can provide the required setting, where healthcare professionals, technology firms, medical universities and research organisations can work more closely together. Support to such local environments will be crucial to unlock the potential in AI-based products in healthcare.

Attracting tech talent to medical device manufacturers

The AI industry is particularly fast moving and calls for highly innovative solutions. To be innovative, companies need to harvest talent, but the demand exceeds the supply, with too few professionals combining AI and health competences. Beyond internal competition for AI engineers there is competition from other, potentially more attractive sectors with more established AI industries.

Ethical behaviour is a strength that should not be compromised

The EU demonstrates a robust research sector, a collaborative culture and a willingness to tackle data privacy issues, and these factors may become Europe's selling points. The future increased use of AI applications in healthcare raises multiple ethical, legal and regulatory issues, especially around the impact on people's autonomy and privacy, and over the use and ownership of data.

In addition, several experts caution against the negative consequences of the use of AI in healthcare and call attention to the importance of patient safety throughout the medical procedure. The World Economic Forum also pointed out the dehumanising impact of using AI in patient care through chatbots and robotic medical devices[70]. The positive and negative effects of trusting patient care to AI algorithms must be carefully assessed in each case. AI should not be promoted just for the sake of AI, or proliferate unnecessary interventions, but should be used when the positive patient outcome is evident.

4.2 Outlook

AI is a technology that is profoundly transforming the medical devices industry, where the market is increasingly characterised by the convergence of healthcare and IT. The ageing population, chronic

[70] https://www.weforum.org/agenda/2019/11/care-robots-ai-4ir-elderly-social/

disease, and cost pressures on the healthcare system all drive the development of AI-based SaMD solutions that can increase efficiency of treatments in hospitals and provide support to patients' own health management beyond healthcare institutions. Not only medical devices companies, but IT and electronics firms see an opportunity in automating the process of how patients receive medication.

In the future, industry representatives expect even more convergence among technologies. Interviewees pointed out the following particular opportunities:

- The **integration of AI and IoT** is expected to witness even more growth, and new innovations are expected to diversify the medical-devices product landscape.
- **Medical devices will couple AI and augmented/virtual reality,** which is expected to revolutionise the MedTech industry through new treatment and diagnosis possibilities, benefitting patients and healthcare providers.
- The **convergence of AI and consumer technologies** is expected to enable the development of more personalised health monitoring and health management.

4.3 COVID-19 – impact on AI-based medical devices

COVID-19 will have a long-lasting impact on the medical devices industry, and hence also on the future potential of AI-based SaMD. With limitations to travel and mobility, not only will testing and clinical trials become more difficult, but patients will need more home monitoring and may request more home medication. These changes are likely to create new demand for AI-based solutions.

AI software is well placed to alleviate the strain on the healthcare sector, which is under high pressure. Some of their positive potential impacts are the following:

- **Detection and diagnosis**: AI can analyse patient health and help support healthcare personnel when diagnosing patients with COVID-19-like symptoms in order to avoid underestimating or overestimating the seriousness of the case. Not just accuracy but timeliness is also crucial and AI-based algorithms can help doctors analyse symptoms fast and avoid patient deaths.
- **Treatment**: AI software can be integrated into chest X-ray technology or medical devices that treat multiple organ failure. They can also categorise and quantify lesions from pneumonia, which helps identify suitable treatment.
- **Telemedicine**: Artificial Intelligence can also support home monitoring through a chatbot application that asks questions about symptoms over the internet or on the phone. Protocols may have to change to allow for more at-home visits and telemedicine, which will again increase the use of AI-IoT integrated medical devices.

5. Annexes

5.1 List of interviewees

Interviewee	Company	Country
Hans-Peter Bursig	Managing Director Medical Engineering Division ZVEI	DE
Fabrice Ruiz	CEO of ClinSearch	FR
Matteo Melideo	Head of R&D unit "IT systems for health" at Engineering	IT
Giuseppe Recchia	Founder of daVinci Digital Therapeutics	IT
Vincent Keunen	Founder of Andaman7	BE
Danny Van Roijen	Director Digital Health at COCIR (European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries)	BE
Patrick Boisseau Michael Strübin	Director of Research and Innovation at MedTech Europe Director Digital Health at MedTech Europe	BE
Sergio Muñoz	Senior Advisor at FENIN, Spanish Federation of Health Technology Companies	ES

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The EU's industrial policy strategy promotes the creation of a competitive European industry. In order to properly support the implementation of policies and initiatives, a systematic monitoring of technological trends and reliable, up-to-date data on advanced technologies is needed. To this end, the Advanced Technologies for Industry (ATI) project has been set up. It provides policymakers, industry representatives and academia with:

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