

# Innovation in Medical Technologies

**Reflection Paper** 



### Innovation in Medical Technologies Reflection Paper

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### **Executive summary**

With this Reflection Paper, MedTech Europe aims to provide an overview of the current healthcare research and innovation (R&I) situation in Europe, shine some light on the healthcare ecosystem for European small and medium-sized enterprises (SMEs), outline some best practices from other regions and offer recommendations on how Europe can be a more attractive landscape for healthcare R&I. Namely, through:

- bringing a diverse set of stakeholders together, combining wide sets of expertise;
- building on specific EU advantages of greater safety and data protection standards, as well as universal healthcare;
- investing in healthcare innovation through Public Private Partnerships (PPP) and large EU funding initiatives; and
- establishing a more coordinated approach for EU regional innovation systems.

We would welcome the consideration of this document in future EU conversations on the strategic research agenda of Europe.

The medical technology sector is impacted by external conditions like regulation, healthcare systems sustainability, national health care organisation and financing, and fragmentation of health policies in the EU. While these conditions could slow down research and innovation, trends like digitalisation (including artificial intelligence), value and innovation-driven healthcare and a collaborative environment (e.g., through PPP) give it positive leverage.

The European medical technology landscape has a strong foundation to further drive innovation with its scientific excellence, numerous patent applications and issued patents, combined with a dynamic demography of startups supported by regional ecosystems. Innovation happens and develops there in different innovation pathways, where all stakeholders in the medical technology innovation arena play their role.

Europe is a breeding ground for innovation, but because of more limited funding, "a strict filter" applies and only very high-added-value ideas are selected. Innovating the delivery of care and advancing to value based healthcare systems, flexibility for startups and SMEs would certainly make the EU a first port of call for medical technology innovation (again).

The US has a mature research valorisation system (a system for utilisation of the results for more impact) where academics are highly focused on implementing and transferring ideas. It also has business angel networks and early-stage venture capitalists in place. Venturing is still quite new in the EU, valorisation systems are not as mature and early stage capital is limited. In Europe, however, high safety standards and the protection of personal data are clear advantages for developing innovative solutions, which could be enabled by a mix of public and private funding.

The EU has a long tradition of collaborative R&I in healthcare, associating academia, industry and the clinical community, and taking advantage of the wide diversity of organisations, disciplines, and cultures across the continent.

### Public private cooperation within alliances (like the Public Private Partnership for Health Innovation) is a major opportunity for the medtech industry.

**Digital transformation also creates opportunities in bringing innovative products and solutions to patients and healthcare systems**. The EU has an important card to play with its high standards on data protection (GDPR) and ethics, which make initiatives like the EU Health Data Space a strategic asset.

Due to the multicultural nature of the EU, there has been an emergence of **competing regional innovation ecosystems. A more coordinated approach would attract investment in ecosystems bringing together a wide set of expertise**, stakeholders, buyers and investors to support timely access of innovative solutions and overcome obstacles that can impede the journey from R&I to patients.

We should learn from the recent COVID-19 crisis how an urgent set of circumstances has broken down traditional barriers and may lead to unprecedented collaborations, regulatory changes and new ways of working and accelerating innovation.

### Introduction

The medical technology (medtech) industry is a dynamic and innovative sector working to save and improve lives. With more than 500,000 products and services on the market, companies in this sector are improving patient outcomes and helping to make health systems more sustainable.

### It is a major contributor to the EU economy, with 730,000 direct jobs and an €11.7 billion trade surplus in 2018.

Europe is an established leader in medtech research and innovation (R&I), delivering major advances in areas including cardiac pacemakers, deep brain stimulation, intravascular ultrasound, next generation sequencing, point of care diagnostic testing, home dialysis care. The high number of patents filed by medtech companies and the data on trade flows and employment statistics reflect the innovative nature of the sector.

By turning scientific ideas into solutions for patients, health professionals and health systems, industry has contributed to better outcomes and greater efficiency in healthcare. In the process, Europe's medtech companies have helped the region to be a world leader in a highly competitive sector.

To understand how innovation works – what makes innovation thrive – we need to look closely at the different actors involved. From this analysis, we can learn **how to improve Europe's innovation landscape**. To that end, MedTech Europe has teamed up with its Associate Partners NLC<sup>1</sup> (The European Healthtech Venture Builder) on this Reflection Paper on Innovation to deliver an updated and accessible picture of medtech innovation in Europe.

This Reflection Paper is based on a literature review, combined with 31 interviews with industry leaders, research institutes, regional authorities, clusters and investors. In Chapter 1, we examine the economic and societal reach of the medtech sector in numbers and discuss the factors that influence medtech innovation. Chapter 2 sets out the innovation landscape of Europe, followed by a comparison of EU and US R&I data in Chapter 3. In Chapter 4, we describe opportunities for medtech innovation in Europe and recommend how to make the most of them. Finally, Chapter 5 highlights why it is important for Europe to take advantage of its uniqueness to attract medtech innovation investment back to our shores.

# The European medical technology landscape



### 1 The European medical technology landscape

The constant evolution of the medtech sector is impacted by external trends like regulation, healthcare systems sustainability and fragmentation of health policies in the EU. These are imposed and could slow down research and innovation. On the other hand, some other trends are leveraging innovation in a positive way:

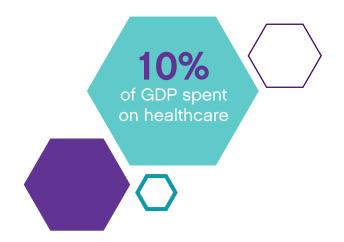
- Digitalisation, which helps service-oriented models and decentralised healthcare to cut healthcare costs
- The value-based approach in healthcare is aiming to optimize the cost of care and not only to consider the price of goods, helping the efficiency of healthcare systems and the sustainability of companies' innovation capacity
- Collaborative management of innovation and better use of EU ecosystems through Public Private Partnerships (PPP)

### **1.1** The European medical technology market in numbers

The European medtech industry directly **employs more than 730,000 people**. Germany has the highest absolute number of people employed in this sector, while the number of medtech employees per capita is the highest in Ireland and Switzerland. In comparison, the European pharmaceutical industry employs around 765,000 people. Jobs created by the medtech industry account for around 0.3% of total employment in Europe. These jobs are also highly productive, as the value added per employee is estimated to reach €160,000 per employee. These indicators show that the industry has an important economic and societal impact in Europe.



In Europe, an average of approximately **10%** of gross domestic product (GDP) is spent on healthcare. Of this figure, around 7.4% is attributed to medical technologies, i.e., less than 1% of GDP. Spending on medical technologies is estimated to vary significantly across European countries, ranging from around 5% to 12% of the total healthcare expenditure. Annual per capita expenditure on medical technologies in Europe is about €225 (weighted average). There are more than 32,000 medical technology companies in Europe. Most are based in Germany, followed by Italy, the UK, France and Switzerland. Small and medium-sized enterprises (SMEs) make up around 95% of the medical technology industry, the majority of which employ fewer than 50 people.



### **1.2** Trends and factors impacting the medical technology sector

Corporate R&I in medical technology is influenced by internal strategy and external trends, like:



Collaboration in the form of PPP is also an emerging trend that seeks to make the best use of the EU health ecosystem.

### **1.2.1** Challenges and possibilities ahead of the digital transformation of healthcare systems

Digital transformation is a major trend affecting the healthcare industry. It refers not only to the growing footprint of global digital companies collecting healthcare data from citizens and patients, but also to the increase in digital products with medical purposes. In healthcare, the digitalisation trend increasingly covers:

- the possibility to exchange data through electronic health records (EHRs);
- the possibility to connect medical devices with information systems (e.g., the Internet of Things (IoT) or wireless technologies);
- the ability to utilise large amounts of data generated by these devices (e.g., through artificial intelligence (AI)); and
- the emergence of new digital methods for providing care (eHealth).

The COVID-19 outbreak has revealed the practical benefits and impact of telemedicine and digital technologies. It has gone beyond the virtualisation of medical appointments and has accelerated perceptions about the critical nature of emerging digital technologies like AI to process huge amounts of data extremely fast, beyond human capacity. Another lesson from the COVID-19 crisis was the sudden sharing of data to speed up the implementation of contingency measures and/or to expedite research on new tests or treatments. This happened not only in academia but also within industry. It has resulted in an acceleration of cooperation and time savings in R&I.

The trend towards increasing digitalisation and collection of more data by medtech also includes early development of blockchain applications to secure healthcare data transactions and the rapid spread of mobile apps. More personal health data are collected from patient and healthcare systems, in real time, that enables the merging of data for AI healthcare solutions. The rising use of personal and clinical data is positive for innovation, enlightening some hidden and unknown processes and providing insights into disease mechanisms to improve personalised medicine. A major challenge to using AI in healthcare is the absolute necessity to protect data. Proper use of healthcare data assumes the protection of personal data. **Thus, it is important to strike the right balance between the EU General Data Protection Regulation (GDPR) requirements and access to data-driven innovation**. The ownership of data is sometimes perceived as unclear between the patient, the hospitals and industry, decreasing the pace at which data-driven solutions are being developed and implemented.

### 1.2.2 Regulation

Medical technology is a highly regulated sector, which is currently transitioning to two new EU regulations: The Medical Devices Regulation 2017/745 (MDR) and the in vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR). These regulations significantly strengthen the current regulatory framework from the 1990s. All medtech companies are impacted by the MDR or IVDR, and due to the significant resources needed for compliance with these regulations, smaller companies may struggle the most to transition to the new regime. **The medtech industry supports the goals of the new regulations but has always stressed that a workable implementation must be ensured, without adversely affecting time to market (and thus patient access)**.

### **1.2.3 Value and innovation-driven healthcare**

A profound trend impacting medtech is the move from an increasing focus on a price-volume driven healthcare payment scheme towards a value-driven model and incorporating value into decision making. A value-based approach focuses on the patient, with much greater emphasis on the medtech sector demonstrating the outcome and the associated cost of care consequences of a product/service.

Although this shift is gaining traction, reimbursement models are slow to adapt and government policies are increasing demands (e.g., ecological, outcomes evidence) while still seeking priceonly driven awarding. This, in addition to the increased development and regulatory compliance costs and a lack of innovation access and funding programmes, poses a major challenge for the medtech sector, especially SMEs.

The medtech industry supports a value-based approach. Adopting universal methods for defining, evaluating and rewarding the value created by innovation(like value-based agreements and funding mechanisms) would offer more certainty and provide a level playing field for medtech companies.

### **1.2.4** Complementarity between centralised and decentralised care

Healthcare systems – networks of care providers – are changing. On the one side, industrialisation of healthcare drives consolidation and centralisation, as reflected in "hub and spoke" models, for instance. On the other side, we see the movement from centralised care at hospitals to decentralized, integrated and community care with both therapies and diagnostics delivered outside the hospital, to outpatients, patients' homes or nursing homes. Consumerism may be a factor that further drives this development.

This provides an opportunity and a challenge for the medtech sector as data about the patients becomes increasingly scattered amongst different care providers. The question is how to move towards a system in which the data from the different care providers is collected in one place and accessible to all care providers.

To grasp this opportunity, the system will require connections between decentralised devices to a central location to share information and use IoT to collect data. The continuum of care along the patient's journey should be taken in consideration, to avoid complications, with patient profiling. This also implies proper security and privacy frameworks that are critical for a safe roll-up of remote healthcare.

### **1.2.5 Patient-centric service**

Healthcare is moving towards patient centricity together with personalised care. The trend towards patient centricity refers to the situation where patients become more proactive, their own decision maker, etc. while personalised care refers to specific treatment based on patient data.

As patients shift to managing their own health, they will increasingly ask for individualised, personalised products. As a result, medical technologies are changing from an industrial sector to a hybrid industrial/service sector where companies do not only deliver products, but also services and solutions.

### **1.2.6 Collaborative innovation management & PPP**

The EU has a long tradition of collaborative R&I in healthcare, linking up academia, industry and the clinical community to harness the diversity of organisations, disciplines and cultures across the continent. There is an ongoing willingness of healthcare stakeholders to discuss multistakeholder partnerships in a non-competitive way, with a view to better coordinating national and EU efforts and overcoming fragmentation issues. For example, **collaborations like the Public Private Partnership for Health Innovation are major opportunities for the EU medtech industry. Other types of collaborations that show great potential are public procurement of innovative solutions (PPI) and pre-commercial procurement (PCP) initiatives** (described further in Chapter 4).

### Innovation in medical technologies



### 2 Innovation in medical technologies

Europe has a strong capacity for innovation with its scientific excellence and numerous patents, combined with a significant innovation capacity by startups established in R&I regional ecosystems. Innovation happens and develops in different innovation pathways.

Factors that stimulate innovation differ depending on the stage of the innovation. Stakeholders in medical technology innovation each provide certain drivers for, or barriers to, innovation and therefore each play "their" role in the innovation pathways.

### 2.1 The European innovation landscape in numbers

Medical technology is characterised by a constant flow of innovations, which result from a high level of research and development within the industry, and close co-operation with users. The average worldwide R&I investment rate (R&I spending as a percentage of sales) is estimated to be around 8% in the medtech sector with some great variations between medical devices and diagnostics, smaller than the pharma or semiconductor sectors.

Nevertheless, the R&I investment rate (intensity) is probably not the best indicator for monitoring the power and impact of medical technology R&I because large medical technology companies have historically bought proven technologies developed by other sectors (automotive, aeronautics) and/or smaller enterprises (startups). **Transformative and disruptive innovation in medical technologies is changing the delivery of care**. In addition, incremental innovation by multiple companies ensures a broad offering of technology, up to now due to an innovation friendly regulatory system. However, while regulation is increasingly challenging, health systems are becoming more conservative and under major budget pressures. Products typically have a lifecycle of 18-24 months before an improved product becomes available.

Digitalisation and the shift towards service-rendered products may change this picture. The global digital health market was valued at USD106 billion in 2019 and is expected to witness approximately a 28.5% compound annual growth rate (CAGR) through 2026<sup>2</sup>.

#### In 2019, nearly 14,000 patent applications were filed, and 10,475 patents were granted by the European Patent Office (EPO) in the field of medical technology.

The number of patent applications shows a 0.9% growth, while the number of granted patents increased by 12% compared with the previous year. As a comparison, according to the latest available statistics 17,596 medical device patents were granted by the USPTO (US Patent and Trademark Office) in 2015.<sup>3</sup> In that year the EPO registered 5,959 granted patents.

In Europe, the medical technology field accounts for 7.7% of the total number of applications, the second highest among all sectors. Of all the medical technology patent applications, 39% were filed from EPO countries (including EU27, UK, Norway and Switzerland) and 61% were from other countries, out of which most applications came from the US (40%).

<sup>2)</sup> Global Market Insights, 2020, Digital Health Market Share Trends 2020-2026 Growth Report, <a href="https://www.gminsights.com/industry-analysis/digital-health-market?">https://www.gminsights.com/industry-analysis/digital-health-market?</a> 3) US Patent and Trademark Office, 2016, PTMT technologies profile reports on Medical Devices, <a href="https://www.USApto.gov/web/offices/ac/ido/oeip/taf/meddev.htm">https://www.gminsights.com/industry-analysis/digital-health-market?</a>



#### **Evolution of European patents by technical field**

When comparing sectors, the EPO received around 7,700 pharmaceutical applications and 6,800 biotechnology applications in 2019. While over the last decade the number of EPO filings in the field of medical technology has doubled, pharma and biotech patent applications were relatively stagnant.

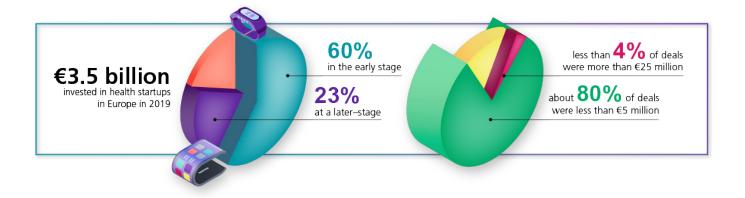
In Europe, patents are mainly filed by large enterprises (72% of applications). Universities and public research organisations file 10% of applications, while SMEs and individual inventors file 18%.

Innovation comes from different sources, including startups. The exact number of startups in Europe cannot be stated as definitions of "startup" differ and a uniform registration is lacking, but it is estimated that there are 80,000-200,000 across Europe in all sectors.<sup>4</sup> If we were to use the ratio of investment in startups in health (€3.8 billion) vs. total investment in startups (around €30 billion), we can estimate that the number of startups in healthcare is around 25,000 in Europe.

From an investment point of view, more than €3.5 billion was invested in health<sup>5</sup> startups in Europe in 2019<sup>6</sup>; this is the third largest sector after fintech and software, experiencing a year-over-year growth of about the 80%.

Overall, 2019 experienced the highest ever amount of capital invested in startups, reaching the peak of more than €30.5 billion in all sectors and a total count of more than 4,000 transactions.<sup>7</sup> Around 60% of European healthtech venture capital activity has been in the early stage, while 23% is related to later-stage<sup>8</sup>. Less than 4% of deals were more than €25 million; about 80% of deals were under €5 million.

- 4) GlassDollar, 2020, Estimating the number of startups in Europe, <u>https://medium.com/glassdollar/estimating-the-number-of-start-ups-in-europe-5d28286307f8</u> 5) Source: Dealroom.com data excluding biotech startups
- 6) State of European Tech, 2019, https://2019.stateofeuropeantech.com/chapter/state-european-tech-2019/article/word-orrick/
- 7) Crunchbase News, 2020, European Venture Report: VC Dollars Rise In 2019, <u>https://news.crunchbase.com/news/european-venture-report-vc-dollars-rise-in-2019/</u> 8) Pitchbook, 2019, Digital remedies: The tech future of European healthcare, <u>https://pitchbook.com/news/articles/digital-remedies-the-tech-future-of-european-healthcare</u>



Investments are coming not only from Europe but also from the US and Asia, shifting the percentage to more than 40% of total investments<sup>9</sup>. In particular, the greatest shift occurred between 2018 and 2019 where American and Asian investors invested 70% and 135% respectively over the previous year.

### 2.2 Innovation pathways in the medical technology sector

For an innovation to reach the patient it goes through various phases. The pathway – from the idea generation to a product or service that is sold and provided to a patient – is called the "innovation pathway". This can be divided into three phases (see diagram):

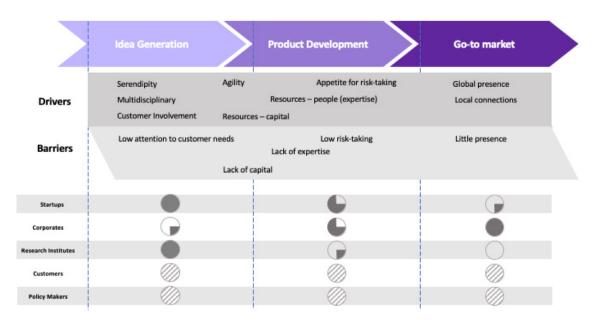
- 1. **Idea generation**. The first phase of the innovation pathway includes every step and activity related to the generation of an idea: a new concept for a product or service. Ideas are generated by various sources including corporates (R&I), research institutions (universities), healthcare providers (medical specialists), patients and patient representatives (patient associations).
- 2. **Product development**. During the second phase, the idea is developed into a product/ service that can be brought to market to be sold to customers. This includes everything from the development of a first prototype to testing the product/service in (clinical) trials and getting the required regulatory approvals.
- 3. **Go-to-market**. The third phase starts when the product or service is ready to be brought to market. It includes everything related to selling the product/service to the customers. This is usually the moment at which the business is rapidly scaling. This go-to-market generally faces two major hurdles: a) acceptance of disruptive, transformative innovation; and b) a progressive uptake and penetration/use to become a part of a standardised treatment/ care provision. By the time we reach this phase, there might be offerings from multiple companies and we have a competitive market dynamic given the open access model.

A more in-depth discussion of these pathways can be found in the next section.

<sup>9)</sup> European Trends in Healthcare Investments and Exits 2018, SVB; European Venture Capital Report (2019) Dealroom. Note that this data refers to VC rounds of all the sectors. It is not specifically related to health/healthtech.

### 2.2.1 Key drivers of and barriers to innovation

Innovation is driven by different factors, which differ for each innovation pathway. Factors that stimulate innovation in one phase can have an opposite effect in other phases of the pathway.



### - Innovation pathway – idea generation

Idea generation thrives in an environment with the following elements:

- **Serendipity**. The best ideas are often generated by accident. Local policies try to increase the chance of serendipity by bringing stakeholders closer together, thinking of local innovation hubs and campuses where universities, hospitals, entrepreneurs, startups, incubators and larger companies share office space. This also stimulates cross-over effects from innovations in other industries to the medical technology industry (and vice versa).
- **Multidisciplinary**. Ideas are best generated in an environment where multiple stakeholders interact. Different stakeholders offer different perspectives, enabling them to co-develop ideas that are feasible for each of the stakeholders and/or kill ideas that are not feasible fast.
- **Customer (patient) involvement**. End-users and patients are essential for innovation: they raise awareness on specific needs and are, in the end, the customers that would buy the product or service. Meaningful innovation should bring value to the customer.

### Innovation pathway – product development

This process is best served by a system that involves the following factors:

• Agility. The development of a concept into a product and service is not a "first-time-right" activity. It involves constantly changing the strategy, the concept itself and the product and service. This is best done in an agile environment that allows for flexibility and fast changes. Once the prototype is finalised, a phase of clinical trials for the regulatory approvals follow. This requires a stable environment as procedures need to be strictly followed.

- An entrepreneurial mindset. It takes motivation and willpower to pick up an idea and start development even though there are many risks associated with it. It is a challenging, uncertain process. Therefore, it requires an environment where risk-taking is stimulated; involvement of entrepreneurial people (people open to risk-taking) and a system where risk-taking is rewarded (and not punished).
- **Resources capital**. At the beginning of the product development phase, capital is often the biggest constraint on progress. The first round of funding is relatively the most difficult. Even though it is the smallest round in terms of capital, the effort it takes to raise the required funding is relatively high. This is especially the case in Europe, which has a low number of angel investors and venture capitalists (VCs) that seem to move towards less risky investments resulting in a "funding gap" in the early-stage (pre-seed and seed) funding landscape.
- **Resources people (expertise)**. The different development phases of a product or service require people with certain competencies and expertise. At the beginning of development, people with an entrepreneurial mindset and competencies are required to push the idea towards a working prototype. Later in the development cycle, specific expertise (e.g., on clinical trials, regulatory approvals, etc.) is required to drive the progress.

# Innovation pathway – go-to-market

This process works best within a system that incorporates the following:

- **Global established networks**. Having a global presence and existing distribution networks in place enables a business to distribute and provide its product/service in a rapid and cost-efficient way.
- Local presence. Local presence enables better understanding of each individual market and its local stakeholders needs and regulations. This helps the development of multi-stakeholder alliances that will consequently promote innovative solutions to support a sustainable healthcare ecosystem.

### 2.2.2 A multi-stakeholder ecosystem

In the medical technology sector multiple stakeholders are involved in innovation. Each possesses the attributes needed to drive innovation. Stakeholders are involved in every phase of the innovation pathway, but it could be argued that each of the stakeholders has an "optimal" environment.

The main stakeholders involved in the innovation pathway are:

- **Startups**. Startups are a perfect "vehicle" for early-stage product development as they offer an agile environment that allows for the required flexibility to quickly change strategy or direction. At the same time, startups suffer from a lack of resources. Especially at the beginning, raising capital puts a big constraint on progress. Later, the lack of regulatory expertise poses a barrier to progress. Moreover, increasingly complex clinical equivalence requirements contribute to longer timelines and elevated trial costs.
- **Corporates**. Corporates offer a stable environment, global presence and resources, and thus a perfect vehicle for later-stage product development and commercialisation of products/ services. Corporates have established connections on a global scale, enabling them to quickly

scale up distribution. They often lack agility due to their size and complexity and are therefore a less favourable environment for product development. As such, they tend to experiment with corporate venturing and investing in/acquiring startups once products/services are developed. Moreover, corporates require involvement of customers and stakeholders for generating ideas for innovation. The more disruptive, the more challenging it gets to do this in-house R&I. Corporates also use scouts to identify promising innovations in focus areas. They collaborate with researchers, customers, startups and participate in innovation hubs or respective networks to access, foster or cocreate disruptive innovation.

- **Research institutes**. Research institutes are a breeding ground for idea generation. They provide a continuous flow of ideas. However, they often lack the competencies and resources to transform ideas into products themselves and therefore collaborate with other stakeholders mostly corporates to do this (valorisation).
- **Customers**. The "customer" in the medical technology sector is less straightforward than in other sectors. In the end the patient is the customer of the products and services, but often the products or services are used/provided by other stakeholders, namely care providers, which therefore can be seen as the primary customer. Involving the customer in idea generation and product development is crucial for a successful product/service and during go-to-market for adoption of the innovation, but within the medical technology sector it needs to be thoughtfully determined who should represent the customer.
- **Regulatory/policy makers**. Regulation can be seen as a driver of or a barrier to innovation, but it is best described as a factor that sets the scene: it defines the environment. Regulation is often thought to slow down innovation, because requiring regulatory approvals can be a difficult and costly, complex process that is open to interpretation. But it is also fair to say that it enables innovation, as regulation also organises, for example, fund raising and grants. Healthcare in Europe is often seen as being highly regulated; this is, however, the result of the mindset that healthcare is a human right that should be protected and provided in accordance with quality standards.
- "Indirect" players. There are a lot of stakeholders that play a role in medical technology innovation, but some play more of an indirect role. In other words, they support the process rather than steer it. These players include, for example: investors in startups, care providers, suppliers and manufacturers.

Innovation can be further stimulated when each of the stakeholders focuses on contributing their competencies. A couple of examples of this are presented below.

### **2.3 Best practices for innovation pathways in Europe**

Collaboration between stakeholders is a driver for innovation. **All stakeholders can add value to products and solutions, but it requires experience in open innovation and a long-standing knowledge of market and market trends to come up with working ideas**. This entails assembling a broad base team of expertise: patients, key opinion leaders, reimbursement systems, engineering, governmental policies, administration of hospitals, translational parts from a range of different stakeholders including medical technology companies, startups, financiers (VCs), big tech and pharma companies.

### Where does innovation happen?

Co-creation happens in sessions where all these different perspectives and stakeholders are brought together to share and test ideas from the starting point of healthcare needs. Without proper organisation, however, too many inputs can slow down the process. **So, there is a need to orchestrate a large network of partners and use this network efficiently**. Open innovation platforms, (online) systems where multiple stakeholders are connected, enable collaboration between all the different stakeholders. **Technology research institutes are strong drivers of idea generation in Europe and are known for their high qualification**. They form a starting point for innovation and can establish spin-offs in startups/corporates. This can be enabled and stimulated by setting up networks of stakeholders and directly supporting startups – incubators, accelerators and living labs.

Example: Local innovation hubs where research institutes, care providers, startups, incubators, and accelerators are closely situated provide the ideal characteristics for idea generation. The successful Eindhoven innovation hub is known for its close collaboration between the Dutch government, corporates and research institutes resulting in many high-quality inventions. The Brightlands Health Campus in Maastricht is another example of strong support to early innovation with acceleration services.

#### How are ideas generated?

Each country in the EU has its own system for regulatory approvals, market access, reimbursement, health care delivery, etc. This fragmentation is primarily seen as a disadvantage by startups, especially when it comes to commercialisation of products/services.

But in the context of idea generation, fragmentation is an advantage because it leads to multiple stakeholders brainstorming about new ideas, independently from each other in parallel. This stimulates competition among the various sources, increasing the volume and quality of ideas.

Innovation happens in places where entrepreneurship and agility are available in a smallscale environment, like startups. But once a startup has developed a commercial product, it needs a bigger corporation to distribute and sell the product. This is a tricky collaboration as startups often feel that working together with corporates in early-stage product development may compromise their leverage in future negotiations. But, at the same time, setting up a collaboration with a corporate takes time and startups are often in competition.

Example: NLC scouts promising technologies and then sets up a startup to develop the technologies into a ready-to-be commercialised product. This approach provides the ideal environment to transform technologies into a new product: the startup environment. Once the product is ready to be commercialised, the venture (the product) is transferred to a corporate, so the product can be brought to market using established distribution networks and local connections.

### What can stimulate innovation?

Innovation makes great strides when there is sense of urgency, or a so-called burning platform. It requires **breaking with traditional systems and ways of working, and a burning platform creates an enormous push to do so**.

Example: The COVID-19 crisis created a burning platform resulting in the breaking down of traditional barriers and ways of working. Sharing of data across nations, previously not seen as a priority, suddenly became a necessity. Regulation was reformulated and systems were put in place to enable rapid data sharing. In addition, ideas on treatment solutions for COVID-19 were collected and prioritised, enabling faster development of solutions in a collaborative way.

### How is innovation brought to market, and ensured to be valued?

To successfully bring innovation to market it is critical to understand what is valued and for what there is a willingness to pay taking multiple perspectives. There are existing instruments like PPI (Public Procurement of Innovation) and PCP (pre-commercial procurement), but the benefits of innovation procurement should be better highlighted, as well as other instruments like European Investment Bank loans to enable innovation. An early value analysis including an understanding of the economic value is becoming of increasing relevance to ensure a return on investment.

Example: Some regional health authorities like Wales and Catalonia have dedicated health innovation officers or structural set-up to use innovation and partnership to address local health care challenges. These are early-stage developments and quite forward-thinking local initiatives to consider innovation to drive health system transformation policy.

## Comparing the innovation ecosystems in Europe and the US



### **3** Comparing the innovation ecosystems in Europe and the US

To understand the pros and cons of investing in the EU vs. the US, it is helpful to compare their innovation ecosystems. The table below gives a snapshot of the two markets.

	US	EU
Capital market	Mature, with systems in place for early- stage funding by angel networks and early-stage VCs.	Less mature, especially for early-stage innovation. Limited number of early stage VCs. Angel investors are scattered, no structures in place. High number of public grants.
Innovation	Innovators produce many ideas and pursue more ideas, but this can open the door to some relatively lower quality innovations, especially on incremental changes.	The EU is a breeding ground for high-quality ideas. Because of limited funding, there is "a strict filter" on innovations and only the ones that truly add value are selected.
Valorisation (utilisation of results for more impact)	Mature system – research institutions are highly driven to add value to ideas. They have put in place systems to stimulate and support valorisation and have been building up competency for years.	This is on the rise, but most research institutions still focus primarily on licensing out their tech/IP to corporates instead of considering other ways of valorisation (e.g. venturing).
Access	Despite market access being more straightforward, patients were accessing disruptive, breakthrough innovation later than in the EU. New regulatory and payer initiatives seek to have innovation accessible first in US.	Notwithstanding apparent and long-standing weaknesses (risk-averse attitude, low capital investment) patients until recently have gotten quick access to innovation due to less limited policies on new products/services.

A mix of more public and private funding could enable the development of innovative solutions taking advantage of the high safety standards and protection of personal data in Europe. Moreover, harmonisation of regulation, market aces conditions, specific innovation funding programs and flexibility for startups and SMEs would certainly make the EU a first port of call for medical technology innovation (again).

### 3.1 Benchmark data

There is extensive research dealing with the deficit in Europe's overall R&I intensity compared with that of competing economies, with a special focus placed on the US. Based on OECD data, in 2018 GERD (gross domestic expenditure on R&I, defined as the total expenditure on R&I carried out by all resident companies, research institutes, university and government laboratories) reached only 2.025% in the EU compared with 2.826 % in the US.<sup>10</sup>

More specifically, around two-thirds of GERD is performed by the business enterprise sector. Thus, **companies in the private sector play a crucial role in improving Europe's competitiveness and its transition towards a more knowledge-based economy.** 

<sup>10)</sup> OECD, 2020, Gross domestic spending on R&D&I, https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm

A recent article<sup>11</sup> goes one step further and analyses the differences between the EU and the US by identifying the sectors that are more accountable for the aggregate R&I intensity performance of these two economies. The paper concludes that the EU holds a much lower number of both larger and smaller R&I investors than the US in the four high-tech sectors that account for the bulk of the negative EU structural R&I intensity gap – interestingly, one of these sectors is Health Care Equipment & Services. When analysing the general reasons behind the R&I intensity gap, the theoretical framework suggests that one of the key elements is the structure of the economy together with socio-economic and policy framework conditions.

With regards to the global R&I investment funded by medical technologies, the 2019 EU Industrial R&D Investment Scoreboard reports 86<sup>12</sup> companies under the Health Care Equipment & Services industry which belong to the top 2,500 companies investing the largest sums in R&I in the world in 2018.<sup>13</sup> These **medical technology companies invested a total sum of** €16.6 billion in R&I, which accounts for nearly 2% of the world's business-funded R&I.

Among these mostly innovative medtech corporates, **22 are headquartered in Europe**, **accounting for around 33% of global Health Care Equipment & Services R&I investment**. This is compared with 48 companies registered in the US, which account for more than half of the global Health Care Equipment & Services R&I investment.

Having said that, studies like the EU Industrial R&D Investment Scoreboard which compare R&I intensity among different regions are limited in their methodology as they are able to attribute each company's total R&I investment to the country in which the company has its registered office and not necessarily where R&I is actually performed. **To better shape the EU R&I framework and incentive system, we need to accurately analyse and benchmark the innovation capacity of the European medical technology ecosystem**. Thus, there is an increasing need to collect and analyse data on R&I performed in different geographical territories. For this purpose, we encourage all medical technology companies to regularly collect and provide accurate R&I investment data with a regional breakdown to support a data-driven and evidence-based R&I agenda in the EU.

### **3.2 Differences in ecosystems**

### 3.2.1 Access to funding for innovation

The key issue in Europe is that **there is less capital available and the capital that is available is focused on late-stage investment opportunities**. Too many traditional European VC funds do not invest in the pre-seed and seed phase. European healthtech startups may thus rely too heavily on (semi-) public grants and loan facilities (which are too often also shifting towards later-stage innovation support) and angel investors/family offices. Since there is not enough capital from angel investors/family offices available, the European early-stage healthtech landscape faces a funding gap between the very early stage (pre-seed and seed) and Series-A/B.

<sup>11)</sup> JRC, 2020, The EU vs USA corporate R&D&I intensity gap: Investigating key sectors and firms, <a href="https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/eu-vs-USA-corporate-rd-intensity-gap-investigating-key-sectors-and-firms">https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/eu-vs-USA-corporate-rd-intensity-gap-investigating-key-sectors-and-firms</a>

<sup>12)</sup> Please note that some companies providing medical technology solutions are categorised solely as Pharmaceutical & Biotechnology Industry in the JRC Score board and thus we are not able to include their medical technology specific R&D&I investment. (e.g., Abbott, Johnson & Johnson, Roche)

<sup>13)</sup> JRC, 2020, The 2019 EU Industrial R&D&I Investment Scoreboard, <u>https://iri.jrc.ec.europa.eu/sites/default/files/2020-04/EU%20RD%20Scoreboard%202019%20</u> <u>FINAL%20online.pdf</u>

**Traditional European VC funds, generally speaking, do not focus on the pre-seed and seed phase** for three reasons: (i) they lack the knowledge/network to properly assess an investment opportunity with a lot of unknowns; (ii) they cannot afford to spend money and time on investment opportunities of less than €500k; and (iii) there are apparently still too many good late(r)-stage opportunities available that they can afford to wait for.

### Pros and cons of EU & US funding mechanisms

In the EU, investments are mostly grants and institutional funding, which are more accessible than those in the US. While grants at the US Defense Advanced Research Projects Agency (DARPA) or the US Department of Defense (DoD) are certainly bigger, auditing of funded projects is more cumbersome.

Compared to the US, Europe offers a decent level of (semi-)public grants/loan facilities, but quite a bit of these still focus on existing companies with (close to) proven products/services, hence too many of these public schemes are too late-stage (i.e., not early-stage enough). Furthermore, in Europe we encounter another level of fragmentation, with local/regional/national funding agencies looking for returns on their territory first.

To accelerate EU medtech innovation, we need to work towards a mature early stage capital market with more (semi-)public grants, private investment and loan facilities focusing on the very early stage. Harmonised tax credit facilities for angel investors and family offices (like the Seed Enterprise Investment Scheme (SEIS) in the UK) as well as tax reduction for individuals investing in SMEs (e.g., the French tax system or the UK SEIS system) would incentivise private investment.

The value of VC deals in the US is approximately four times greater than that of Europe – in 2019 healthtech VC deals were valued at USD1.440 million in Europe vs. USD6.073 million in the US<sup>14</sup>.

### 3.2.2 Access of innovation to the market

There is a major cultural difference between the EU and the US regarding the subsidisation of product development. Product development is a science in the US alongside health economics being recognised and funded, unlike in the EU. We see US companies seeking to enter Japan first and then the EU market once the development is achieved. **The EU was originally the first stop for innovation, but now it ranks second or third**. European SMEs are well known for their innovative mindset, thinking about market access from the early stage. They look first to their national market, but new regulatory burdens and market opportunities are leading them to the US. This raises an important question: **Is the EU doing enough to attract companies launching their innovative products to make it the first market of choice?** 

If the EU and Member States were to propose creative incentives, more SMEs would stay. This goes hand-in-hand with bringing and keeping R&I in the EU through appropriate funding measures, a suitable regulatory framework and attractive tax incentives.

The recent COVID crisis has highlighted the threat on access to innovative medical technologies or pharma products developed by EU medical technology companies established abroad: those produced in US stay in the US.

<sup>14)</sup> Silicon Valley Bank, 2020 Annual Report, Healthcare Investments and Exits, <a href="https://www.svb.com/globalassets/library/uploadedfiles/reports/healthcare-re\_port-2020-annual\_full.pdf">https://www.svb.com/globalassets/library/uploadedfiles/reports/healthcare-re\_port-2020-annual\_full.pdf</a>

### 3.2.3 Attitude towards innovation

In the US there is a greater willingness to invest and take risk because the mentality is different:

### "If you fail in the EU, you fail; if you fail in the US, you learn."

The landscape for innovation is different but it is hard to say whether one is better than the other. Historically, the EU was the first market for innovation. The number of patents is lower in the US but bigger investment in US makes a difference when it comes to development.

The EU is as creative and as innovative as the US, with EU basic science in universities and academia being very strong. **The scientific output and reputation of the EU is very good**, **but it is not reflected in the market uptake**, which is lower. At the early stage of innovation, there is no significant difference between the EU and the US, with ideas and innovative projects in abundance.

The big difference comes at the next steps, when turning innovation into a viable product. The consequence is that innovation happens at different speeds in the EU and the US. Translation of innovative concepts from research and technology organisations to spin-offs and/or large companies is much faster in the US. Allocation of funding at early stage is mostly dedicated to maturation in US whereas EU investors give preference to investment at a later stage, when technologies, products and services are validated and de-risked.

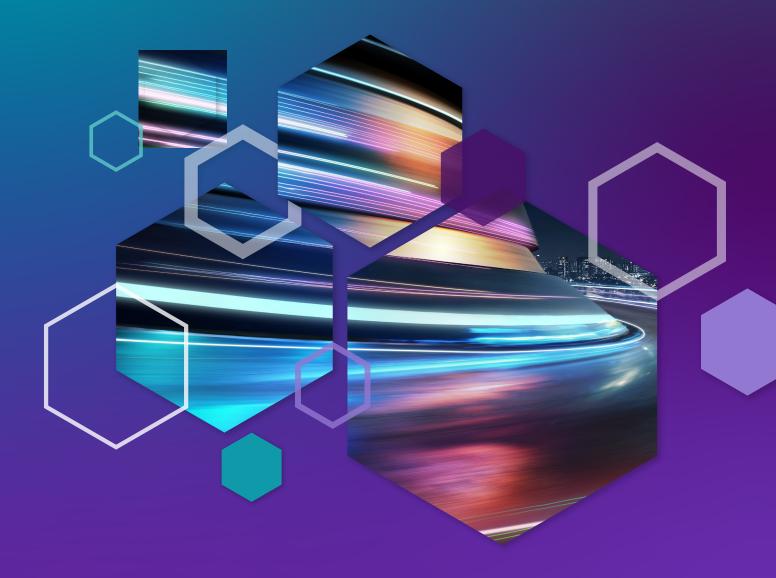
Even though the US has the privilege of first access to innovation, US patients were accessing disruptive innovation three to five years later given the differences in clinical evidence requirements. The FDA is now committed to pave the way for innovation to appear first in US. They have adapted the regulatory requirements, shifting clinical evidence into the post-market approval phase. Comparatively, the EU excels at bringing innovation to healthcare delivery. The EU focuses on **healthcare as a universal right**, with a more pragmatic approach, which in the long run improves "bench to bedside" translation (the process by which the results of research done in the laboratory are directly used to develop new ways to treat patients). Interestingly, the EU's solid foundation for innovation is partly due to its fragmentation.

#### **3.2.4** Improving the translation of innovation to market and healthcare systems

The EU could be more positive and courageous about the capacity of EU companies and entrepreneurs to bring innovation to the healthcare market. The European Commission could have more central roles and responsibilities, as drafted in the EU4Health programme. More cooperation between industry and the public sector with, for instance, an increased business participation in PPP would correct the remaining cultural gap in the EU between academia and companies, and investment could be done on the preparedness and availability of entrepreneurs from technical solutions, getting their solution to the market.

Technical universities and research and technology organisations (RTOs) that work closely with clinical partners to develop prototypes ready for scale-up could provide the needed intermediate step to compensate the poor translation capacity observed in EU due to the gap between academia's objectives and companies' needs and objectives.

# Opportunities for Europe



### **4 Opportunities for Europe**

As mentioned earlier, the EU PPP for Health Innovation is a significant opportunity for the medical technology industry. It will become **one of the largest PPP in healthcare in the world, and will increase EU attractiveness for healthcare R&I**.

Digital transformation will also create new opportunities for the medtech industry in bringing innovative products and solutions to patients and healthcare systems. **The EU is unique with its high standards on data protection (GDPR) and ethics, making initiatives like the EU Health Data Space a strategic asset**.

**Risk taking and risk sharing** from research to market access should be incentivised, as well as the desire to develop an **early-stage investment landscape** for angel investors and small family offices. At the same time, governments should invest in the long term by **offering large companies tax breaks or tax incentives** for R&I.

The multicultural nature of the EU is behind the emergence of competing regional innovation ecosystems, but with only a few being world class. **A rational and coordinated approach will attract investment in place bringing together a wide set of expertise**, stakeholders, buyers and investors to support more timely access of innovative solutions.

### 4.1 Build public and private partnerships in health research

A positive perception exists towards increased collaboration with universities, technologies research institutes and hospitals in the framework of PPP, considered as more agile to perform result-oriented projects. EU stakeholders in healthcare are ready for an open platform to discuss needs, innovation potential and partnerships (that include patients) in a non-competitive way. This is the objective of the future PPP for Health Innovation being prepared under Horizon Europe, the EC's ambitious R&I programme to succeed Horizon 2020<sup>15</sup>.

It will be another effort where medtech companies will stand close to customers and end users to understand their needs, what is valued and for what there is a willingness to pay and mutually develop sustainable solutions – a place for co-conception involving all stakeholders and final users (nurses, physicists, citizens, patients). This PPP will accelerate innovation and better coordinate national and EU initiatives, bypassing the fragmentation of national R&I support systems.

#### This type of public private cooperation must be reinforced and be cross sectoral to desilo domains, disciplines and sectors.

Other public private projects are the EU PPI/PCP initiatives where applying a value-based approach will enable the introduction of innovative solutions with supportive EU financing (still limited use and preparedness throughout Europe). Nationally, we see this beginning to take hold in some regions that have dedicated officers who are responsible for transforming and innovating the delivery of care by introducing innovation, for example, through innovation procurement and longer term value based partnership agreements.

### A stronger dialogue among stakeholders on needs must be initiated at EU level to collect feedback from patients and healthcare professionals in innovation processes.

Connecting payers and regional health authorities to industry will also accelerate the translation of innovation and adoption, use of the innovation. Better communication and transparency with hospitals will help adjust innovation to the needs of healthcare professionals and provide a greater understanding of their problem: shortcomings in the systems, and innovation gaps in care delivery. More interaction with research organisations, SMEs, health economy researchers, hospital administration and procurers will facilitate a broader implementation of value-based healthcare.

Companies alone cannot drive these initiatives. **Together with their trade associations they need to create trust and confidence in the pre-competitive space**. The role of medtech companies in this partnership will not only be to provide resources and funding, but also to contribute to the consulting phase, mobilising their networks and gathering SMEs, hospitals, investors and payers.

Industry should organise this cross-sectoral cooperation and be an active member of the medtech innovation ecosystem. The success of such partnerships relies on attracting more medtech companies for performing pre-competitive research, in a secured intellectual property and confidentiality framework. Opening to and cooperation with other healthcare sectors like pharma, biotech and digital will reflect the patient's journey along the continuum of care and provide integrated and consistent tools and solutions.

### **4.2 Take advantage of digital technologies in medical technologies**

Digital is everywhere and the medical technology sector is no exception. Data collected from clinical trials or from real-world evidence are there to help industry conceive innovative and personalised health solutions. Healthcare is moving towards a real-world data value driven model.

A lot more data is available but how do we transform it into information to diagnose, treat and cure? What are the business models and the value associated with information generation?

The emergence of AI and machine learning is enabling the processing of huge amounts of data. All major medtech companies will need an AI backbone very soon due to its transformational power. The consequence is that data is becoming essential and it requires a large infrastructure to handle data and data lakes. The availability and accessibility of data is key for the development of new products.

The EU is falling behind the US in digital technology and it is highly dependent on the US or China for key technologies. Most European medical technology companies have not yet cooperated at a significant scale with the US-based "big five" data companies (GAFAM).

In order to take advantage of the huge healthcare market and patient population in Europe, the EU is taking ambitious initiatives like the European Health Data Space to overcome the fragmentation of national initiatives and support the EU strategy on healthcare AI, with high-level requirements in ethics, privacy and security on data and data treatment.

While these requirements offer a great potential ahead of the harmonisation and high standards of the market, they also hold a risk of slowing down digital development at the moment, as regulation might often offer uncertainties for business and vary in its interpretation across EU member states. Reducing those uncertainties can stimulate digital development.

Medical technology companies are open to a stronger collaboration with healthcare providers that hold data, with technology developers that are not only startups, and more willing to share risks with EU digital companies.

### 4.3 New ways of funding and financing

Medical technology innovation and early-stage development are predominantly taking place in startups and SMEs. Sometimes medtech companies prefer to pay for a product or service that can be put on the market tomorrow, rather than valorising these innovative ideas in their own corporates.

Small companies require seed funding or development funding. Easier access to money, access to funding of R&I projects, less bureaucracy and more attractive funding dedicated to R&I would improve innovation and the development of innovative solutions by startups. Creative ways to support proof of concepts in medical technologies (public support, angels, small family, outside) would positively impact the development of early stage concepts.

Beyond the encouragement of entrepreneurship in university curricula and intrapreneurship within companies, risk taking and risk sharing from research to market access should be incentivised, as well as the desire to develop an early-stage investment landscape for angel investors and small family offices.

At the same time, governments should invest in the long term by offering large companies tax breaks or tax incentives for R&I.

The EU and Member States should seek more investment from outside the EU – even from the US and Asia – by marketing the fact that EU healthcare systems are more stable and sustainable in the long run.

### 4.4 Invest and get return from regional innovation ecosystems

Innovation in medical technology requires the cooperation of multiple partners for funding, technologies development, scale up, validation and approval. **Medical technology SMEs are numerous in Europe, but they require an ecosystem around them to operate**. Several innovation ecosystems mostly supported by regional policies and local networks (clusters, RTOs, large companies) facilitate the interaction of partners to speed up the R&I of innovative solutions. Regional authorities act as catalysts to maintain excellent conditions to innovation: campuses and infrastructures, collaborative projects, entrepreneurship programmes, networking among startups, participation in venture funds, services to promote clinical trials locally (such as Helsinki-Uusimaa, Copenhagen Capital Region, Limburg, Baden Wurttemberg).

Beyond individual regional ecosystems, there is a critical lack of coordination among them. A better interconnection and financial support of these innovation ecosystems throughout EU would add value to their specificities, highlighting the "hotspots" in Europe.

#### To further strengthen regional innovation ecosystems, research institutes should be supported in developing their valorisation capability and skills to provide excellent services to corporates, whatever their size.

The medical technology industry is generally used to taking over proven technologies developed by small companies or startups. It could increase its capacity to invest jointly with public organisations for early stage R&I, taking advantage of the specific assets of these regional ecosystems with a longer-term vision. **Common labs, affiliate programmes, pilot lines allowing a common access to enabling technologies would enable scale gains as tentatively explored with the electronic components and systems industry under the ECSEL Joint Undertaking**. Co-investing in regional European ecosystems reinforces trust in the EU medical technology industry locally, including non-EU based companies.

#### **4.5 Demonstrate the value of innovative medical technology products and services**

Healthcare has recently, to address various pressures, been driven by volume and price only. More investment is needed in identifying, measuring, and monetising the value of medtech products and services. This requires an understanding of what is valued. Value should be put forward and incorporated in (investment) decision-making in healthcare.

To this end, **the EU will benefit from adopting innovation earlier in the innovation process**. Furthermore, **training future procurers and purchasers needs to be a priority** because they are future decision makers on purchasing and bringing innovative medical technology solutions into the healthcare systems.

## Conclusion: Take advantage of Europe's uniqueness



### **5 Conclusion: Take advantage of Europe's uniqueness**

In this Reflection Paper, we looked at the drivers of innovation and the stakeholders involved in its various pathways. By gaining a better understanding how current trends and factors impact medtech innovation in Europe and by looking at the US market, we were able to reflect on **steps that could be taken to put Europe back at the top of the list for investors in medtech innovation**.

The European research area is a unique context in which to perform R&I, with a long tradition of transnational collaborative projects, networks and infrastructures. The diversity of innovation sources is unparalleled (HCP, patients, institutes, universities, entrepreneurship programmes, incubators, etc.). These assets could highlight the attractiveness of EU for medtech innovation, but their diversity makes them difficult to identify. Nevertheless, the EU is well-placed to take advantage of positive trends such as digital transformation, use of innovation to transform health care delivery, applying a value-based approach in procurement and collaborative management of innovation.

When considering the EU's overall economic and R&I footprints, the European Commission is welcome to do more to support companies, which want to stay on board in the EU and be incentivized to innovate the care delivery, to improve efficiency and contribute to a heathy population, rather than going to other markets like the US. Most global medtech companies are present in Member States to access to their internal market, but do they want to take advantage of this innovative capacity to perform R&I in Europe?

Collaborative R&I can be improved in Europe by taking advantage of the wide diversity of stakeholders, the quality of research institutes, the different sources of funding and financing, the national specificities and specialisation. Above all, the spirit of cooperation can be further developed by enabling a more efficient alliance between large companies, startups, research and education organisations, built on their respective capacities and expertise at the different steps of development.

The regional ecosystems should make their work and mission clear, to facilitate faster access to their specific assets, expertise and infrastructures. The huge diversity of EU or national funding programmes for early-stage research should become more visible and accessible to maximise the investment by public agencies and companies, prevent duplication and avoid reinventing the wheel. The opportunities for collaborative frameworks, such as PPI/PCP projects, in Europe should be incentivised. Moreover, aligning national policies, especially regarding innovation funding and payment schemes schemes, would boost the speed of innovation significantly by enabling faster market access.

EU innovation ecosystems should better benchmark their competitors in the US and Asia and monitor the transformative ability (to market, to patient, to healthcare systems) of innovative projects and companies in the EU.

In the absence of collective efforts to make the EU more medtech innovation friendly, the EU will lose its ranking in accessing innovative medical technologies. This will result in later access to innovation and at higher costs for healthcare systems, due to not having patients in good health and not avoiding unnecessary spending. The recent COVID crisis has highlighted the critical role of R&I in healthcare and its impact on national or regional sovereignty. The EU can learn from this experience and translate it into a corresponding effort to improve the efficiency of the EU medtech innovation ecosystem, making the EU the leading market for innovative medical technologies and solutions (as it was in the past).

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### About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. MedTech Europe's mission is to make innovative medical technologies available to more people, while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations. It also promotes medical technologies' value for Europe focusing on innovation and stakeholder relations, using economic research and data, communications, industry events and training sessions.

### About NLC

NLC – the European Healthtech Venture Builder – advances health by building ventures. The gap between the early-stage nature of many healthtech ventures and the stage corporates can add value and are willing to be involved, is rapidly increasing. Therefore, many promising healthtech inventions never reach the patient. NLC bridges this gap by transforming promising healthtech inventions into new products. Following its unique 'entrepreneurship at scale' approach, NLC scouts the best early-stage technologies at renowned knowledge institutions and leading corporates and sets up ventures to transform these promising technologies into products. These ventures are actively supported. Once the technologies are de-risked, the venture is transferred to a corporate partner who can accelerate growth and distribute the technologies to patients all around the globe.

### **Abbreviations**

AI	Artificial Intelligence
DARPA	US Defense Advanced Research Projects Agency
DoD	US Department of Defense
EC	European Commission
ECSEL	Electronic Components and Systems for European Leadership
EU	European Union
GAFAM	Google, Amazon, Facebook, Apple and Microsoft
GDPR	General Data Protection Regulation
HCS	Health Care Systems
НСР	Health Care Professionals
HER	Health Electronic Records
HTA	Health Technology Assessment
IMI	Innovative Medicine Initiative
IoT	Internet of Things
MDR	Medical Device Regulation
IVDR	In Vitro Diagnostic Regulation
PPP	Public Private Partnership
R&I	Research and Innovation
RTO	Research and Technology Organisations
SME	Small and Medium sized Enterprises
TTO	Technology Transfer Office
US	United States of America
VBHC	Value Based Health Care
VC	Venture Capital or Venture Capitalist

