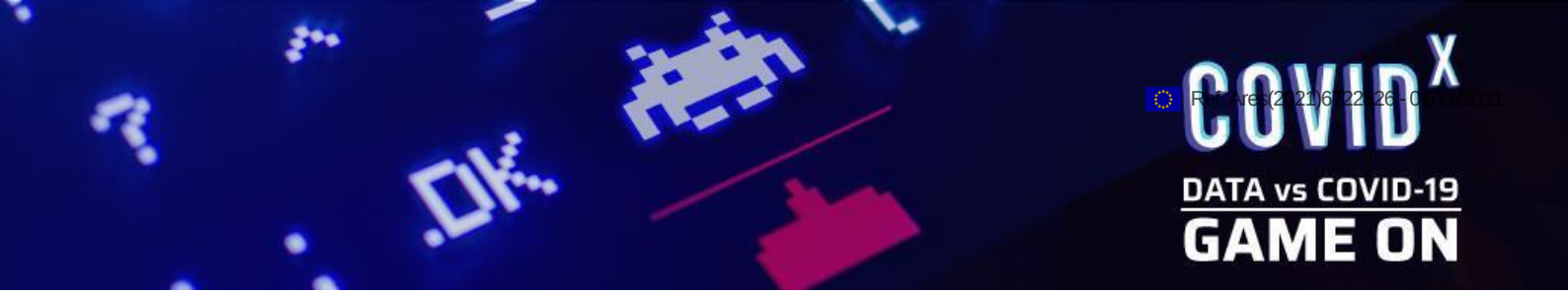

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COVID eXPONENTIAL PROGRAMME

GRANT AGREEMENT ID: 101016065

D1.4 – Recommendation to health authorities and systems

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Authors	Ronalds Strauhs (CIVITTA)

Abstract	This deliverable presents an overview of the legal challenges associated with the medical device industry and the proposed recommendations for policymakers to tackle them.
Keywords	MDR, Notified Bodies, Medical Regulatory framework, digital health, HTA

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EXECUTIVE SUMMARY

The objective of Deliverable D1.4 “Recommendation to health authorities and systems” is to outline the key legal and ethical issues hindering a faster uptake of digital healthcare solutions and provide recommendations and points of consideration for health authorities and other stakeholders. The insights presented in this document have been derived within close collaboration with the teams involved in the Covid-X project as well as industry experts; relevant literature has been used to highlight the issues at hand and to offer a look at the current status quo.

This deliverable serves as a reference point and action plan for policymakers on a national as well as European level and advises on future steps that ought to be taken to better facilitate the implementation of novel medical solutions; this is especially relevant for the healthcare industry that has had to transform and adapt in the last 2 years due to the Covid-19 pandemic and is looking for ways to use the newest technology to improve the current processes.

The document is organized in 2 closely related sections – one that explains the current situation on uptake of digital solutions in healthcare and outlines existing barriers for entry based on literature, involved experts and teams participating in the Covid-x Project; and the other that aims to offer potential solutions also derived from literature, involved experts and teams.

The key challenges that were identified in the regulatory domain were associated with the understanding and interpretation of the Medical Device Regulation, the shortage of Notified Bodies as well as the fragmentation of the local regulations in terms of Health Technology Assessment and reimbursement paths.

The identified challenges are in turn hindering a fast uptake of digital solutions, are causing disparities in the overall uptake of novel solutions between the member states and is putting SMEs at a disadvantage compared to large enterprises in terms of quickly bringing novel solutions to market.

To solve this, we are recommending the EC to extend their efforts in explaining the MDR to healthcare newcomers via novel information tools and services, to mobilise and optimise the current notified body network via restructuring and establishment of coordinating agencies and continuing and further intensifying the current efforts towards the harmonisation of health technology assessments and reimbursements.

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Introduction

The use as well as the need for digital solutions in healthcare was prevalent long before the pandemic started. However, it was arguably the pandemic that might have given the final push that was needed for the **healthcare industry to adopt digital solutions** more widely - namely to apply these solutions not only for the overall organisation of the system but also as means of prognosis, diagnosis, to provide treatment and after-care monitoring.

However, the particular nature of the medical industry has made it **increasingly hard** and **time-consuming to onboard and implement novel solutions into our everyday care.** Innovators need to think more about legal and bureaucratic requirements than they have the time to think about and improve their actual solutions. On top of that, **the process is rather expensive** and **requires a lot of resources** and **specific know-how**. These aspects are problematic to all medical device producers, but especially so to the health industry newcomers which in most cases are providers of digital or otherwise tech-heavy solutions that have previously not been applied in healthcare and have the potential to disrupt and significantly improve the existing processes.

Tharman Shanmugaratnam, Senior Minister of Singapore, and the co-chair of an expert panel established by G20 said in his address to the WHO in August 2021 that COVID-19 is not a "one-off disaster" and that "we are consequently vulnerable to a prolonged COVID-19 pandemic, with repeated waves affecting all countries, and **we are also vulnerable to future pandemics**."[1]

Meanwhile, in an event recently held by the Centre for Global development, experts, after careful modelling, agreed that there is a **47% to 57% chance of another pandemic** on the scale of Covid-19 **happening in the next 25 years alone**[2] which more than anything highlights the importance of better prepared health systems - driven by the newest technology.

After reviewing the existing literature and views towards the current state of the MedTech industry and coupling it with the experience from 16 data-driven healthcare start-ups participating in the Covid-X programme, **we have identified a set of alarming issues that are hindering an uptake of novel and especially digital and data-driven solutions**. Based on these findings, we hypothesise that the inability of start-ups and other small businesses to bring their solutions to market (due to the many existing barriers related to the lack of funds, time, resources, and industry know-how) is creating **an innovation divide in which new ideas and new technology from smaller companies is not brought to market successfully or in time**, thus limiting the EU's ability to use the most advanced tools to tackle health emergencies. We also argue that other regulatory constraints and the difference in local regulations are causing smaller producers to focus their efforts and commercialization of solutions in countries where the local regulation is more relaxed or where the potential market is bigger and offers more opportunity for growth as opposed to implementing solutions all over EU, thus **creating** even more **inequalities between national healthcare systems** and **limiting the share of the population that has access to** the newest technologies and **improved health outcomes**.

[1] Coming months critical for future pandemic preparedness, United Nations, 2021.
[2] The Next Pandemic could come soon and be deadlier, Centre for Global Development, 2021.

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We recognise both of these issues as alarming and in direct contradiction to the goals and vision of the EU, both in terms of digital solutions driving the overall development of the EU as well as EU ensuring equal opportunities and access to services across the member states. And thus, we attempt to **identify the most critical steps and actions that need to be taken by the policymakers** in an effort to solve these issues and to **better facilitate a fast uptake of digital solutions in healthcare**: from large as well as small enterprises and in mature as well as less developed markets.

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To **tackle the ongoing Covid-19 Pandemic** and to **better prepare the member states for any upcoming pandemics** or **health emergencies**, EC launched a variety of programs that aim to improve the overall state of health care systems in the EU. One of the key enablers of better prepared healthcare systems is the successful use and application of innovative solutions and breakthrough technologies. In the times when Europe has the development of digital tools as one of its core priorities, it is important to deploy these tools across all industries - healthcare among them.

One of such programs is **COVID-X** (funded under the grant agreement Nr. 101016065), the goal of which is to narrow down the divide between technology breakthroughs and the healthcare system to **fully exploit the power of data**. COVID-X aims to bridge the gap between the European digital sector and healthcare providers. Over a period of 2 years, the project is **accelerating 30 data-driven technology solutions** that have reached the TRL7 and are in the process of obtaining a CE mark. The teams are working together with health care providers of their choice or from the project consortia to facilitate the testing and later on the adoption of their solutions. During the program teams have access to a shared Covid-X Sandbox through which they are able to obtain data required to test their solutions. On top of that, the start-ups receive both technical and business mentoring to support them in improving their solution

This policy brief is thus created taking into consideration the **experiences of the first set of 16 teams** (digital solution providers) taking part in the Covid-X programme. These insights have been coupled with the existing literature and information on the topic and thus we believe that these **can be generalised to all providers of digital solutions** and not only in relation to solutions tackling Covid per se.

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1. Problem Definition

Digitalisation is one of the political **priorities** of the current European Commission. An entirely new funding programme is being devoted to this priority: the Digital Europe Programme (DEP) that focuses on strengthening the strategic autonomy of Europe and supporting companies, citizens, and public administrations throughout their digital transformation. The programme is mainly centred on upcoming and emerging technologies like high-performing computing, artificial intelligence, cyber security as well as the digital skills that accompany digital transformation. In the health domain, the DEP offers opportunities around data spaces and the training of AI algorithms for clinical decision support, which can help with the collection and use of quality data.[3]

The field of digital health has evolved rapidly over the last 20 years and even more so during the last two.[4] Healthcare has undergone a rapid digital progression in 2020 and while the unforeseen **COVID-19 pandemic has** disrupted it and caused radical shifts in delivery models, it has also **accelerated the pace of innovation**, and digitalisation especially, by at least a decade.[5] The pandemic has forced primary care providers to instigate telehealth in a remarkably short period of time, while acute providers have become even more aware of the need for integration and interoperability to function efficiently in difficult circumstances. Large volumes of data associated with Covid have been made available and have allowed the global community of innovators to exploit them in efforts to help healthcare providers make more accurate decisions and provide better and more personalised treatment. This **digital transformation will be pivotal in shaping the future of healthcare**.

Emerging solutions offer tremendous potential to positively transform the healthcare sector, much of which is still unlocked and yet to be explored. As such, thousands of digital health solutions are on the market and thousands more are being developed, **mostly by start-ups and tech companies entering the sector for the first time** rather than traditional healthcare companies. Unfortunately, these start-ups are soon learning that **the industry is much more complex** than what they have been previously exposed to.

Due to the share size of the industry, many of the start-ups have set their sights on big rewards but are quickly realising that these rewards can be hard to realize, particularly when it comes to securing payment for a solution.[6] Further, the **evolution of methodologies to perform timely, cost-effective, and robust evaluations have not kept pace** and it remains an industry-wide challenge to provide credible evidence, therefore, hindering wider adoption of novel and untraditional solutions.

Moreover, Healthtech start-ups providing a wide range of innovative products and solutions **must navigate an ever more complicated regulatory and legal framework**. Key areas include rules of general application such as data protection and privacy, cyber security, intellectual property, international data transfer, as well as **sectoral rules such as those governing medical devices (including software)**, patient care and confidentiality, clinical trials, governance, labelling, advertising,

[3] Future priorities and opportunities for digital health, Digital Health Europe, 2021.
[4] Challenges for the evaluation of digital health solutions, Digital Medicine, 2020.
[5] Accelerating Digital Healthcare, UK Public Policy Institute, 2020.
[6] Europe's start-up ecosystem: heating up but still facing challenges, McKinsey and Company, 2020

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public procurement, and product liability. Navigating the policy environment can be complicated and, due to lacking resources, is not always a priority for entrepreneurs.

For the goal of **the EU is to advance the healthcare industry and facilitate its digitization**, the policymakers ought to recognize and pay attention to the existing barriers hindering the desired uptake. As such, there is a **need to investigate the various challenges** on a deeper level in order to solve them at their root cause.

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2. Current situation

2.1 MedTech Landscape

The European Patent Office (EPO) data for 2020 shows that the **medical technology sector made the highest number of applications – 14,295** to be precise – representing a 2.6% growth in patent applications compared to the previous year. The medical technology field accounts for 8% of the total number of applications, putting it ahead of digital communication, electrical machinery, energy, transport, pharmaceuticals, and others[7].

According to MedTech Europe, there are **more than 33,000 medical technology companies in Europe** in 2021. The highest number of them are based in Germany, followed by Italy, the UK, France, and Switzerland. Small and medium-sized companies (SMEs) make up around 95% of the medical technology industry, the majority of which employ less than 50 people (small and micro-sized companies).[8]

In Europe, an average of approximately 11% of gross domestic product (GDP) is spent on healthcare. Of this figure, around **7.6% is attributed to medical technologies**, i.e., less than 1% of GDP. The spending on medical technology is estimated to vary significantly across European countries, ranging from around 5% to 12% of the total healthcare expenditure. Expenditure on medical technology per capita in Europe is at around €265 (weighted average).

The European medical technology market is estimated at roughly €140 billion in 2020. The **biggest medical device markets in Europe are Germany, France, the United Kingdom, Italy, and Spain**. Based upon manufacturer prices the European medical device market is estimated to make up 27.6% of the world market. It is the second largest medical device market after the US (41.6%).

The European **medical device market has been growing on average by 2% per year** over the past 10 years. Demand fell in 2009 due to the economic crisis, resulting in a growth rate of only 1% (lowest in 12 years). The market regained its pace in 2010, and since then the annual growth rate has varied between 2.6% (2013) and 9.3% (2015), being 8.5% in 2020.

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

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

[7] Statistics and Indicators, European Patent Office, 2020.
[8] The European Medical Technology Industry in figures 2021, MedTech Europe, 2021.

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And while **the overall statistics and growth in the industry are admirable**, there is more to the story than meets the eye. It is hard to say exactly how many MedTech start-ups fail and never make it as far as to implement their solutions in our health systems, but the estimates by experts are quite discouraging, to say the least. Especially concerning is the view of Dave Chase a Digital Health expert, who states that the common census is that **nearly 98% of digital health start-ups are the walking dead right now**, meaning that even those that were able to secure funding or pass a certain level of validation are now out of business.[9] The reasons for this are plenty and are of course unique for each solution, however, there are common themes and trends across the industry that are briefly discussed in the next section.

2.2 Current overall challenges

The increasingly challenging environment for healthcare innovators and the reasons why MedTech start-ups fail in the EU and elsewhere has been previously discussed by many[10]. The past reports on the topic have recognised the complex nature of the regulations around medical devices, the flawed assumptions and estimates about the market potential, the lack of resources both for start-ups as well as the health providers that are supposed to implement the solutions and many more. We briefly discuss the challenges below as many of them have also been relevant to the Covid-X teams, however, in this document we primarily focus on the regulatory aspects in particular as we believe that these challenges are the ones in direct control of the policymakers.

THE INABILITY TO SECURE FUNDING | The challenge of access to funds is not limited to healthcare start-ups. However, due to the nature and long life cycle of business decisions in healthcare, MedTech start-ups have to burn through their cash reserves with much more precaution as their journey to market **will likely require much more time and resources than it would in other industries**. Unfortunately, investors see the healthcare space for what it is - complex and high risk. Thus the healthcare start-ups face fundraising challenges for the space they are in, as well as unnecessary additional hurdles from the home institutions, increasing the likelihood of scaring away already skittish investors.[11] Additionally, a lot of the MedTech start-ups are stemming from technical backgrounds and as such their initial plans and strategies for implementation **fail to consider the differences between the technology sector and the healthcare industry**, causing them to heavily underestimate the required funding and fall short before getting to market.[12]

EXHAUSTIVE PILOT PROGRAMS | Start-ups are often **completely dependent on partnerships or deals with larger healthcare organizations in order to grow and survive**. These deals often start with a pilot. Unfortunately, the dynamic between giant healthcare institutions and tiny idealistic start-ups for pilots is not actually set up to be mutually beneficial. In this scenario, healthcare systems have nothing to lose, orders of magnitude more resources and seemingly infinite amounts of time. Their incentive is to differentiate and "own" unique technologies so their competitors cannot get their hands on them. This is where start-ups often and understandably can make a big mistake — they believe the partner brings

[9] "Why 98% of digital health start-ups are zombies and what can they do about it?", Forbes, 2016.
[10] "10 reasons why healthcare start-ups fail", Stat, 2020.
[11] "Healthcare start-ups struggle to navigate a business world that's set up for them to fail", Tech Crunch, 2019.
[12] Why healthcare start-ups struggle and fail, Tech Tic, 2021.

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more value to the table than they do. For example, just having a pilot, even if it's unpaid, with a major institution seems like it could help win over investors or additional customers. This leads to a spiral of events that frequently ends in sending start-ups into a trajectory toward failure (aka death by pilots).[13]

FINDING THE APPROPRIATE BUSINESS MODEL | Due to the many stakeholders and evolving systems of caregiving, the providers of medical solutions have a hard time assessing as to whom exactly their product should be sold, who will be the end-consumer and who in the stream of actors is willing to pay for this. The development of digital solutions and global access to digital tools has especially caused the innovators to **directly target consumers without considering the other involved stakeholders** who in reality, are the significant gatekeepers for the marketing and sales channels of their products.

Many health care start-ups develop a strategy that will let them sell straight to consumers so they can skip regulatory approval, which can be time-consuming, labour intensive, and expensive. Angel investors with small pockets tend to favour this strategy. The problem is that this relies on the **often-flawed assumption that consumers are willing to pay out of pocket** for health-related products and services.

It is crucial for healthcare start-ups to learn more about the payer of the product, especially so when reimbursement is the desired path. **Misunderstanding** the details of the economics of payment impacts the healthcare business severely and **may result in its downfall**. Producers often do not consider the reimbursement payment will not be able to cover all the incurred costs. Therefore, pricing any of the products without profoundly understanding the cost of goods, the reimbursement, and the payment dynamic will doom a healthcare start-up to failure.

DEFINING A CLEAR VALUE PROPOSITION | The value proposition is the fresh medium to marketing and sales. Most of the start-ups in health care pitch themselves as "more enhanced, Swiffer, and cost-effective" than what's already on the marketplace, and their business approach ends there. Yet they **fail to explain how and why their solution is performing better**, how much Swiffer it is and how much more cost-effective than the benchmark of existing care. Start-ups often fail to form a unique value proposition and struggle to decide what value to propose in front of diverse stakeholders.

FLAWED-ASSUMPTIONS ABOUT CUSTOMER NEEDS AND HABITS| Doing comprehensive market research and then developing the product based on what precisely is required in the marketplaces has a healthier likelihood of being in demand. However, many tech innovators are often tempted to avoid this process as it is painstaking for them to understand and address the stakeholder requests genuinely. This is why they **jump quickly into product development without any need-collection**. And therefore, fail to answer the most crucial question before commencing a company of whether there is an explicit requirement for the product they are about to provide.

Most healthcare products are innovative, but they **do not blend effectively into the existing workflows**, current schedules, and the daily lives of the audiences they are targeting. It is not merely substantial that producers prove to have an Integrable solution if it is not friendly with the existing healthcare facility's IT software or systems.

[13] Healthcare start-ups struggle to navigate a business world that's set up for them to fail, Tech Crunch, 2019.

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Furthermore, it is not acceptable if it puts an additional management burden on the present employees or needs them to place an added mile and get further digitally educated to use the solution.

NAVIGATING REGULATORY REQUIREMENTS | The medical devices might take years to reach the final market due to the jumping required through complicated clinical and regulatory hoops. And it cannot always quickly be iterated once done. To attain the key milestones such as regulatory clearance, obtaining insurance reimbursement, or raising capital, the health care start-ups must gather certain specific evidence and clinical data. This evidence generation is falsely believed to be of linear manner. This is a common and costly mistake that can pointedly delay the amount of time required for revenue accomplishment. Although some digital healthcare start-ups prevail with regards to accomplishing the achievement, they come up short on financing before creating explicit proof to persuade customers to purchase from them. Lack of knowledge about what product is being worked on in the context of appropriate regulations also does not allow for rational planning of its development path. Without this, it is **not possible to reasonably estimate the necessary financial resources**, timetable or to identify and manage risks.

Lastly, **healthcare is not the space to transform things quickly and hurry with innovations**. It has several stakeholders, guidelines, regulations, and interests to follow precisely. The industry is disinclined to alter rapidly, and thus acceptance is relatively slow, which is a big challenge for most start-ups.

2.3 Current legal challenges

While the legal challenges are not the only ones hindering the successful uptake of digital solutions, it is clear that the regulatory requirements are the ones that often hinder a faster uptake of those solutions that are eventually going to make it to the market and make the lives of many patients around the world better. In the following two sections we briefly introduce the current legal framework in the EU and later describe what are the main challenges and why it is so difficult for start-ups, SMEs, and in many cases even larger enterprises to bring their products to the market.

2.3.1 Current Legal Framework

Before a medical technology can be legally placed on the EU market, a manufacturer must comply with the requirements of all applicable EU legislation and affix a CE mark to their device. Medical technology itself 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[14].

[14] Innovation in medical technologies reflection paper, MedTech Europe, 2020.

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On top of the EU-wide regulations, **each country can have additional regulatory requirements** in place that the devices have to comply with before they can be sold in the desired market. This adds yet another layer of a legal framework, as much of the regulations are not harmonised between the various countries thus making it increasingly hard, costly, and timely to scale solutions across Europe. This is further coupled with the different healthcare systems, compensation models and reimbursement paths that also have to be taken into consideration when considering a viable business model.

2.3.2 Industry challenges arising from the current legal framework

The **MDR** became fully applicable in May 2021 and **has already received a fair share of criticism and worry.** For example, Jeffrey Jump (CEO of Med Alliance Swiss Medical Technology) feared that the pace of innovation in Europe will be diminished, suggesting "CE mark lead approval time will at least double (6–12 months)", and claimed, "the number of **innovative medical devices receiving CE mark will drop down by** an estimated **30%**." Gido Karges of Straub Medical AG explained the ramifications: "Expenditures associated with MDR compliance are enormous. German and Swiss health authorities predict the extinction of 30% of all medical device manufacturers. They also expect that **50% of all medical devices will be discontinued** or fail to meet the requirements."[15]

Meanwhile, Julia Steckler (CEO – Medical Mountains GmbH) said that "it feels like the wording 'patient safety' is not only weighted as one of the most important goals of every MedTech actor but is sometimes misused as a defence against considerations towards improving the functioning of the European internal market.

> If **the balance between safety and the functioning of the internal market** keeps tipping, it will have a severe impact on European healthcare and patients. As a consequence, whole R&D departments are relocated to other countries. In the worst-case scenario, **significantly fewer innovative products will reach European patients**."[16]

Another worrisome issue has been raised by BV Med CEO Dr. Meinrad Lugan who highlighted the **effects the new regulation will have on SMEs as compared to larger enterprises**. "If small and medium-sized companies, in particular, are forced to shift all their development resources to regulatory, at the expense of innovation, then this shows that MDR has apparently overshot the mark." This is also supported by a case Study from the Czech Republic (2021) which shows that **the larger the company the lower the percentage change in increased costs caused by the MDR** new requirements. It was also apparent that, in general, micro-cap companies are specialized in the production of a few MDs in higher safety classes. Therefore, they will be disproportionately affected by new regulations, estimates of increases in certification costs as % of revenues are high. Larger companies focus on the large-scale production of class I MD's where it is harder to compete with small companies due to the economies of scale. That leads to specialization on MD's in more demanding safety classes, which will, unfortunately, be harder hit by increases to certification costs. Some SMEs may be forced to diversify

[15] "Europe braces for harder times in medical device innovation while US FDA eases regulations", Vascular News, 2018.

[16] "Is medical technology innovation leaving Europe?", MedTech Views, 2021.

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to “non-medical” products, with the inevitable **loss of innovative MDs being made available to patients** and healthcare providers.

At the same time, **MDR is forcing larger companies to put the innovative technology on hold** and concentrate on MDR certification of existing products as they have a wide range of medical devices. On top of that, firms are evaluating the product portfolio carefully (estimating how much it would cost to update each file for MDR compliance and then comparing it to both current and anticipated business) to assure that they only spend valuable time and resources updating technical files to meet the MDR regulations if doing so makes good business sense.

The regulation has also been criticized for its **lack of consideration of the quickly developing technologies** that are quickly entering the MedTech market. While the regulation distinguishes medical software as a critical part of the MedTech industry, the regulation has not captured the most important features and characteristics of software development, i.e., the training of an algorithm might over time increase its accuracy which is desirable, however, any change in the algorithm is considered a significant change to the product and in practice means that the product will have to be recertified, thus limiting the time in which improved products can be brought to market.

2.4 Challenges faced by Covid-X teams

Having looked at the overarching challenges in the industry, the particularly challenging aspects need to be inspected more closely. To do this, **insights** were derived from the experience of **teams participating in the Covid-X project** using a combination of methods. First, the partners were tasked to note down any legal or ethical issues that were raised by the teams during the project - where possible, these issues were resolved on a project level, e.g., by issuing relevant guidelines, or on an individual level, if the challenge was only relevant for a specific team; other more systematic issues that could not be solved within the consortia have been included in the following section. The second method for insight collection came from the business mentoring module that was focused on healthcare regulation; a healthcare regulation expert was invited to give the teams a general webinar on the newly adapted Medical Device Regulation, to introduce other legal considerations for local markets as well as to discuss in detail the most common and confusing aspects of the said regulations. After the general webinar, the teams had the opportunity to ask any questions in the following “Ask me anything” sessions - the questions as well as the confusion around them was captured and they have also been included and discussed in more detail in the following section. Lastly, a survey was sent to the teams designed to identify the particular pain points - the teams were able to freely share their unique experiences.

Not surprisingly the challenges faced by the Covid-X team resembled those that had been previously discussed and outlined in the literature and relevant industry experts. However, the studying of Covid-X teams gave us an even **deeper insight into the challenges start-ups and first-time innovators face** when they have to navigate the healthcare regulations for the first time as compared to more experienced and established SMEs and larger MedTech companies. On top of that, we were able to observe **the challenges and different barriers when onboarding new solutions with healthcare**

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providers which goes a step further than the existing literature that is mostly focused on the general challenges for market access.

When teams were first asked about the aspects or steps, they found to be the most challenging or time and resource-consuming in the overall process of bringing their solutions to the market, a variety of issues were raised among which the most common was the already mentioned regulatory framework, however, other aspects were mentioned too, all of which have been detailed below.

ETHICAL APPROVAL | Half of the teams mentioned the ethical approval process and described it as complex and time-consuming, with a few teams implying that the respective ethical committees were **not used to evaluating the ethical use of software** and other data-driven tools as opposed to more traditional medical devices or drugs. On top of that the committees seem to meet ever so often thus it takes a lot of time for the teams to be able to go through the ethical approval process, especially so when more than one intervention or action of the committee is required. The **onboarding of a solution cannot start without the approval of the ethical committee**, so this is a critical step that the teams and other innovators have to go through to be able to test their solutions in real life thus indicating its overall importance in the product to market journey.

DOCTOR ENGAGEMENT | The commitment and engagement of healthcare professionals also seem to be an issue as it does not meet the enthusiasm and expectations of the innovating teams - it is also outlined that this is not always due to a lack of interest but rather lack of resources and time that the providers are able to allocate to engage with the onboarding of these solutions. Nonetheless, the **unwillingness to change** or the **long lifecycle of business development** in health care has also been mentioned thus indicating a wider problem in receptiveness to new technology, and digital and AI-driven solutions specifically. It has also been previously mentioned in the literature that the health providers have in the past and continue to be in general quite hesitant to new solutions as onboarding them requires investment and the precious time of doctors (that are already busy) to be able to integrate them in their routine. It is also possible that some solutions just do not offer as much of direct benefits to the healthcare professional and instead requires them to make more interventions than the existing solution or system in place does - this false sense of demand or misjudgement of the needs can often lead to failure and is one of the challenges commonly referred to in the literature when stressing the importance of the value proposition. For an innovation to be onboarded it has to offer value to a user group, one that can be easily perceived.

USE OF DATA | The goal of the Covid-X programme was to exploit the power of data, as such a significant component of the programme is the Covid-X Sandbox through which the participating teams are able to access data from healthcare providers that could help them test and validate their solutions. The purpose of the Sandbox was to couple multiple data points from various health actors in an attempt to provide innovators with more reliable data while avoiding the time and bureaucracy it takes to otherwise get access to this kind of data. One of the issues arising from this initiative was the interpretation of GDPR as well as the implementation of complete anonymisation. Teams had trouble navigating how the “right to delete my data” would apply and in what cases can the data still be used after the withdrawal and when can it not. Other challenges included the use of pseudonymised data and how can that be safely anonymised – the healthcare providers are also essential in this step; thus, it takes time and a lot of precaution before it can be successfully implemented. Finally, it is worth

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mentioning that not all health providers have successfully transitioned to digital data collection, thus hindering the potential of digital solution testing and adoption.

2.4.1 Medical Device Regulation

Further, teams were asked about the particular legal challenges they had faced so far and the answers without a surprise were centred around the MDR, for which there are many associated issues and concerns.

UNDERSTANDING THE MDR | As for any regulation, a common problem is the ability of a given individual or team to be able to understand and interpret it in relation to their solution. This is of course especially **relevant for start-ups and tech-savvy teams** that are mostly composed of individuals focusing on the technological development and improvement of the solution rather than on understanding the array of legal requirements and procedures. That is not to say that teams have no consideration of the legal requirements or that the products would not be able to comply with the regulations - it is to say that teams have **trouble navigating and fully comprehending the steps that need to be taken** to make their solution compliant and place it on the market. Nor do they have a good sense of how long, expensive or resource consuming the process is going to be and at which stage should certain steps be taken to make the process as quick as possible - which is, of course, crucial when the goal is to develop a solution for a problem as urgent as Covid-19. It is also worth mentioning that this general confusion can still be associated with the recency of the document and that experienced manufacturers were struggling to navigate the new document as much as the newcomers were.

TIME AND RESOURCES | Another aspect that troubles the teams in relation to MDR as we will also see outlined further down is that it takes an incredibly long time and a lot of resources, both of which are usually lacking for start-ups of any kind, but especially so the healthcare ones that are not able to make any money before they have brought their product to market, and thus have to sustain themselves from external capital only up until then. The teams went on to say that the to go through all of the certifications and **getting approval takes on average 1 to 2 years** for any medical device, add that to the time it takes to come up, develop, and test a solution and it is simply too long to tackle a pandemic, even one that seems to be going on forever.

> The main bottleneck of the process according to many is the **long assessment time with a notified body**. On top of that, the **start-ups often lack the human resources** to take on the process altogether.

In a survey done by Climedo two thirds of companies surveyed said they planned to **hire at least one new employee specifically to manage EU MDR compliance**[17] - a luxury that many start-ups cannot afford. The MDR also states that an organisation applying for certification will have to identify at least one person within that organisation that is ultimately responsible for all aspects of MDR compliance.

[17] Survey: One Year after the EU MDR Delay – Lack of Clarity, Manual Processes and High Costs for Manufacturers Persist, Climedo Health, 2021.

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The requirement also stipulates that the qualifications of this individual have to be documented as they pertain to the required tasks, thus restraining smaller companies even more.

CLASSIFICATION | The classification of a device is one of the first steps in the regulatory process and requires specific attention as it defines further legal actions to be taken. The classification of a device is essentially an assessment of the overall risk associated with the medical device; thus, the device can belong to either one of the 3 categories which represent low, moderate, or high associated risk. Devices belonging to Class I, for example, have the lowest perceived risk, which is why devices in this category, unless sterile or serving a measuring function, can suffice with a self-certification and written statement that confirms the compliance with MDR, in this case, no other interventions are required. Other **devices, belonging to class II and class III,** as well as those belonging to class I that are sterile or serve a measuring function, **will have to receive an assessment from a notified body**. The category to which the device belongs should also be in line with its intended purpose - when deciding on the risk category, one should always go back to the intended purpose and see that the assessed class and purpose are not in conflict and represent the same use case.

One of the problems associated with the classification process is of course the assessment itself - because the evaluation of risk can differ, and in the case of Covid-X, digital solutions and software can have a particularly difficult time assessing the potential risk of their device. As explained in the AMA sessions, **even the slightest alterations in the way output of software is presented could sway the software for higher risk classification**. The teams then have to decide between a trade-off where one option is increased functionality of software that will require the NB assessment or rather limited functionality that would allow the software to remain in the realm of self-certification and low associated risk. Even though **guidelines and infographics** have been prepared on the classification of a device, many teams admit that these **do not properly consider the varying nature of digital solutions** - and that in most cases it requires consultation of an expert to determine to which class the device belongs.

2.4.2 Notified Bodies

Notifies Body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required - this is of course done to make sure that the products placed on the market are tested and certified by the same standards. As mentioned, **getting a certification from an NB is also crucial for most medical devices** - the obvious problem associated with this is again the amount of time and resources it takes to get this certification. While the process itself is long enough, there is **additional wait time added to that due to the lack of NBs available**.

According to The NANDO database, **the current number of NBs** that are available to issue certificates for **MDR compliance is 24** (23 of which are able to certify medical software) and the amount for **IVDR is 6**. Which is more than a 50% reduction from the 50 and 24 notified bodies that were able to certify medical devices and In-vitro devices under the preceding directives.

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The number might increase eventually, however, claims have been made that some notified bodies are dropping out themselves because the MDR is more complex and more expensive to carry out - NBs also have to apply to be designated for the ability to carry out MDR evaluations, the designation process can take up to 12 months.[18]

The **shortage of notified bodies** has been stressed on multiple occasions by the experts as well as the Covid-X teams; the problem has escalated even more in the transition period (existing devices had to be recertified by 2021). However, according to MedTech Europe, it seems that the problem was prevalent even before the transition period and will continue to be pressing in the future unless more bodies are able to get the required recognition from the EU and offer their certification services to medical device manufacturers[19].

In a 2019 survey of 230 companies, a staggering **43% of both large and small medical device producers said they would discontinue their presence in the EU market** due to the new regulations[20] and the difficult process that comes with it, re-certification with a notified body being one of them. On top of that, **more than half** of the 230 respondents said they **plan new product launches outside of Europe** because of the stricter new rules.

The exact amount of time it takes from the first point of contact to a full certification from NB varies but is cited to be anywhere from 3 to 9 months and depends on a variety of aspects that are often out of the applicant's control. The first aspect being the initial response time that in some cases happens to be as low as a few days and in others takes up to a few weeks or lacks a response at all. The expected waiting times of different notified bodies can occasionally be found on their respective websites; however, it is not a common practice as of yet. Moreover, the **NBs are private companies in a competitive market** and are **not regulated either by the EU or their respective governments** in terms of pricing, thus the applicants are encouraged to ask for a bid at more NBs to be able to secure one that fits their budget and time constraints. The **uncertainty of waiting times and the expected fees** means that companies seeking a certification have to spend a lot of time and resources contacting and inquiring about these aspects to multiple NBs, which again is an even bigger burden on start-ups.

In May 2020, the EC conducted a survey to assess the average capacity and waiting times of NBs across Europe for certifying medical devices related to Covid-19. Of the 55 bodies available at the time, only 37 replied to the survey.

The responses indicated that **only 36% of the NBs would be able to initiate the process for new applicants in less than 15 days**, while 16% said it would take more than a month for them to start the process. Another 16% said they were not taking any new applications at the time of the survey.

When asked about the time to process the overall procedure for new applicants, the times differ based on the device classification, however, less than 50% of the applicants said it would take 3 to 6 months

[18] Factsheet for manufacturers of Medical Devices, European Commission, 2020.

[19] Implementing the new IVD and Medical Devices Regulations - Early availability & capacity of notified bodies, MedTech Europe, 2017.

[20] Disruption of the Year: EU MDR notified bodies shortage, MedTech Dive, 2019.

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in a best-case scenario, while others said it would take more than that.[21] The expected wait times and overall processing times are shorter for existing clients of the NBs, indicating that **new applicants and start-ups are again at a disadvantage**.

Lastly, it is worth mentioning that the NBs only serve the role of certifying the device and are not required to provide any consultations or advice to the applicant if the certification is not granted. Meaning that in most cases the organisations will need to hire external support to be able to work out the problematic aspects and re-apply. This also hints towards a more general problem where other **companies are building a business model based on the difficult nature of MDR and are charging premiums** to guide the newcomers through the process, which is again another costly service that start-ups have a hard time affording.

2.4.3 Local requirements

On top of the EU-wide regulations that the producers of medical devices have to comply with in order to even be able to put their product on the market, they also have to comply with the local regulations of each individual country. What this means in practice is that **receiving the CE mark and certification from a notified body does not automatically grant you the opportunity to sell your device in each member state**. The first and less difficult part of the local compliance is concerned with the language requirements - to be able to place the product on market in the desired country the product must include information in the **local language**, e.g., manuals, labels, brochures, interface, etc. Moreover, there are different regulations regarding the **advertising and promotion of devices**, so an organisation must do their due diligence to make sure they are compliant in their desired country - what is legal in one country can be a violation in another.

A more difficult aspect of the local regulations is the **healthcare technology assessment (HTA)** which is particularly important for solutions hoping to apply for reimbursement. HTA is a multidisciplinary process that summarises information about the medical, social, economic, and ethical issues related to the use of health technology in a systematic, transparent, unbiased, and robust manner. These assessments are **done on a national level** and in essence evaluate if the medical technology that is being assessed adds value to the patients and public in general, whether it has the potential to cause any harm on the patient or society, whether it performs better than existing solutions, whether it saves money, resources or is in any other way superior to other solutions, etc. The HTA assessment is crucial in driving well-informed policy decisions and is also essential for the reimbursement process - since only solutions that add value, perform better or are more efficient than the currently existing ones will be reimbursed.

The current issue with the HTA and the reimbursement process is that it is **not harmonised across Europe and has to be done individually in each country**. This again takes time and resources as the process for medical devices is lengthy (e.g., up to 365 days in the Netherlands), difficult and quite expensive. On top of that, HTA is not an inexpensive institution for a country to run as it requires a lot of experts and professionals in the fields - which some smaller countries do not have a lot of, thus limiting the capacity of their local HTA body. A mapping of THE bodies in 2018 showed that HTA bodies

[21] Availability and capacity of notified bodies to carry out conformity assessments for COVID-19 related medical devices and in vitro diagnostic medical devices, European Commission, 2020.

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in 25 EU countries occasionally use HTA information from other jurisdictions[22], however, it is unclear as to when an HTA body might do so and whether this would be sufficient to enter multiple markets based on a single HTA assessment. Thus, manufacturers willing to scale their products across all of Europe will have to spend a lot of time applying for HTA in various countries. While some national markets are big enough and can facilitate a reasonable growth opportunity for a start-up, not all of them are, thus the ability to bring solutions to more than one market at a time is highly important for the start-up's survival. In the case that the start-up cannot apply for HTA assessment in multiple countries, they **will likely target bigger markets with opportunities for scaling and growth**.

On top of that, **reimbursement pathways for digital health solutions are evolving at different speeds in different European markets**. Germany, Sweden, and the United Kingdom are relatively mature markets where governments are promoting the digitization of care and have standardized reimbursement pathways.[23] Elsewhere, pathways are either not yet established or far from clear. Spain, for example, has many highly autonomous regional payers, so the pathways and evidence requirements vary. It is thus a hard market to tackle. Even in less fragmented markets, the structure of public healthcare systems means that reimbursement mechanisms are likely to be complex. Take Germany, where there are multiple different reimbursement pathways, depending, for example, on whether a solution is for in- or outpatient hospital care, for preventative care, or for care that qualifies for reimbursement by the country's innovation fund, set up to promote new forms of care that improve on current standards.

This **lack of consistency** of what solutions would be considered reimbursable in different countries is again causing uncertainty to the innovators and **pushing digital solutions to first enter the digitally more mature markets** - thus accelerating the gap between more and less digitized health systems even more.

Even so, the **healthcare systems in the EU are dramatically different** and solutions that have been adapted to a specific healthcare system can be hard to scale elsewhere even after receiving positive assessments in the desired country. This was also the story for at the time one of Europe's most promising digital start-ups Min Doktor which after successfully being implemented in Sweden was later brought to Denmark, the UK and France, just for the founders to conclude that "healthcare differs from country to country and to create something huge and then to scale it is really hard if not impossible within healthcare, due to the local regulations and traditions."[24]

2.4.4 Additional regulatory frameworks

It is worth noting that the application of novel technological solutions in often cases mean that the solutions have pre-existed and are just now being applied to the medical field which is why they have to comply with either MDR or IVDR, however, some technological solutions will still belong to their respective product class outside the scope of medical regulation and will have to **comply with relevant regulations for that product class**, e.g., a wearable device would have to comply with the Radio Equipment Directive. This is also increasingly relevant for AI-drive solutions as the EU is now actively

[22] Mapping of HTA national organisations, programmes and processes in EU and Norway, European Commission, 2018.
[23] The European path to reimbursement for digital health solutions, McKinsey and Company, 2020.
[24] How one of Europe's most promising healthtech start-ups failed to scale, SiftEd, 2019.

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working on a horizontal AI regulation, meaning that even though deployed in the medical field, the solutions will also have to comply with the general AI guidelines and directives implemented by the EU.

2.5 Overview

2.5.1 Identified Challenges

This section provides an overview of the challenges identified within the literature in a combination with those retrieved from the Covid-X project. Thus, the main regulatory challenges faced by the industry as seen by the experts and the innovators themselves are the following:

- **Increased development costs** related to MDR certification, which will disproportionately affect the SMEs
- **Additional employees** or external experts are **required to ensure compliance with the MDR** which strains the already limited resources of SMEs.
- MDR is causing **lengthened and more difficult development trajectories** for device manufacturers seeking market approval in the EU, causing them to first launch their solutions in other markets instead or in some cases leaving the EU market altogether.
- There is an **extreme shortage of Notified Bodies**, especially for certification of new and innovative devices - the first-time applicants experience longer wait and processing times than existing medical device producers, the process and associated fees are also much more unclear to them and there is no particular support system to guide or help the innovators going through the process for the first time.
- The **HTA network as of now is still fragmented** causing duplication of efforts among the HTA bodies and limiting the number of national markets innovators are able to enter in a timely manner.
- The reimbursement process, which is also different in every country, is slow and the **reimbursement pathways for digital health solutions are evolving at different speeds** in different European markets causing inequality in access to the novel digital solutions across the EU.

The **general process for ensuring MDR compliance** and the **associated challenges at each stage** have been shown below (see figure 1). The first stage corresponds to the steps that should be taken before contacting a Notified Body, while the second stage describes the certification process with a NB as well as compliance with local regulations, e.g., individual HTA.

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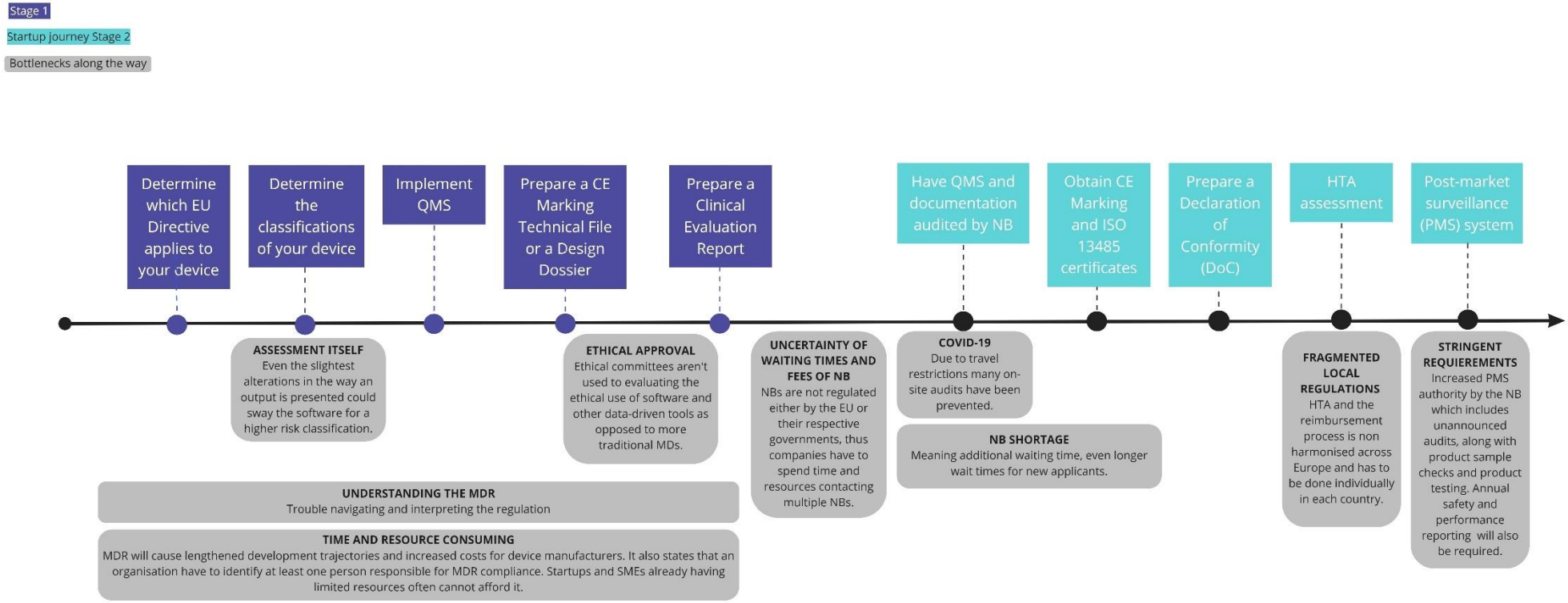

FIGURE 1: REGULATORY COMPLIANCE JOURNEY

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2.5.2 Ramifications

The identified challenges have contributed to 3 alarming outcomes: a slow overall uptake of novel digital solutions, the innovation divide between mature and less developed MedTech Markets, and the difference in ease of market access between SMEs and large enterprises.

SLOW UPTAKE OF NOVEL SOLUTIONS | The first set of 16 teams participating in the Covid-X project were onboarded in April 2021 and started their journey in June, which now counts to 5 months. In this time, they have individually worked towards integrating with the Covid-X data sandbox and onboarding their solutions with their chosen healthcare providers, they have had to acquire the ethical approvals from their chosen institutions and had to meet other internally set KPIs. Furthermore, they had to work on their regulatory compliance and market-entry strategy. Through this process, the teams had access to both business and technical support at all times - with additional interventions from external experts on various topics of importance, e.g., creation of value proposition, development of business models, fundamentals of Big Data, navigating healthcare regulations, etc.

The teams participating in the program were and continue to be on different stages of development and progress in relation to market entry and regulatory compliance. The solutions are also diverse in their intended purpose and technical specifications, which means that their regulatory journeys also differ. Some have to comply with MDR, others with IVDR, yet some have opted out of the medical realm altogether to not have to undergo the compliance procedures.

Of those having to comply with MDR or IVDR, there are some that were CE marked before the program and some that still have to go through the process. Those that are yet onboard on this journey admit that they **have struggled in the classification process** and have had to consult with experts both in and outside the scope of the project to correctly identify the product classification and if the product had to be certified under the new regulations at all. It is worth noting that even the solutions in the program belong to both class I as well as class II devices, thus highlighting the diversity of digital solutions and their respective regulatory journeys. Teams are also spending time to identify gaps in their current quality management systems, which they admit is also taking time and they have turned to external experts for this too.

Those that need to comply with the **MDR** and have not started the process as of yet, indicate that they will do so only after the project ends as doing it **will require more time and resources than they currently have**. One of the teams has allocated a minimum of one year for the process, thus indicating that their solution, in the best-case scenario, will only go on the market in fall 2022. One team is delaying the transition process from MDD to MDR due to the current lack of NB capacity - which limits their ability to get the best deal for their certification procedure.

While the **solutions** have achieved great progress, it is clear that those that were not previously CE marked or present in the market already, **will likely not enter in a year's time** - which might not seem long in relation to the general life cycle of healthcare technology, but can be deemed **insufficient for quickly responding to an epidemic**.

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INNOVATION DIVIDE BETWEEN MEMBER STATES | The aforementioned issues with non-harmonised HTA networks are causing the SMEs to carefully consider the market in which to obtain their first HTA assessment and in many cases, this consideration favours the more mature markets. When given the choice, the producers are mostly targeting markets that offer them a substantial opportunity to scale, e.g., Germany, France, Italy, and are leaving smaller and less developed member states behind. This in turn creates **unequal access to the newest technology across Europe** and limits the innovative potential.

The phenomena of **unequal access** has been recognized by the EC in the 2018 "Proposal for a Regulation Of The European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU" in which as one of the 3 key problems with the current HTA system they recognize the **duplication of work** for national HTA bodies indicating that Clinical assessments of the same technologies are being conducted in parallel or within a similar time-frame by HTA bodies in different Member States, resulting in **inefficient use of resources**.[25] Furthermore, these assessments can result in different outcomes/conclusions, which **negatively affect business predictability** and contribute to delays and inequalities in patient access to the most innovative health technologies.

EASE OF MARKET ACCESS BETWEEN SMES AND LARGE ENTERPRISES | According to Serge Bernasconi, CEO of MedTech Europe "until these [mentioned above] challenges are resolved, roadblocks will continue to limit the sector's ability to seamlessly supply certified devices under the new rules. This is especially true for many small and medium enterprises (SMEs), who contribute a significant portion of Europe's medical device innovations.[26] The difference in access to resources between SMEs and large enterprises is evident in every industry, however, it is in healthcare where the knowledge gap between the two has so much weight that it **limits the ability of SMEs to equally compete with their more mature and resourceful counterparts**. The MDR requiring producers to have a dedicated person for MDR compliance with a certain set of qualifications is just one of the examples in which SMEs are at a disadvantage. This is not only discouraging for SMEs but also unfortunate for the patients as this might **delay the rate at which novel solutions from smaller players are able to make it to the market** - which is especially important in the case when a device is meant for a smaller user group suffering from, e.g., a rare disease, which due to its small market size makes it an unviable business for large enterprises.

[25] Regulation of the European Parliament and of the Council on Health Technology Assessment and Amending Directive 2011/24/EU, European Commission, 2018.
[26] "EU MDR has arrived - what challenges remain?", Med-Tech News, 2021.

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3. Policy recommendations

The recommendations in the following section come from a broad range of information sources; while much of it is based on the recommendations from experts as well as market players in the field, a layer of novelty is added based on the specific experiences and needs of teams involved in the Covid-X project. These recommendations thus focus **on how the policymakers could make life easier for early-stage MedTech start-ups** in relation to navigating, understanding, and ultimately complying with the applicable regulations and other related requirements. This section also acknowledges the current efforts by the policymakers and pins the most important and impactful measures for improving the current situation.

3.1 Understanding MDR

This section should be started off by saying that the **MDR** is not on its own a bad regulation, and despite its many critiques it does **offer significant improvements** in **fighting counterfeit devices**, puts a lot more focus on the **safety of the patients**, and enforces the adoption of **more clinically effective** devices. The EC has also been generous with the allocated time for transitions and has put in substantial effort in explaining and simplifying the otherwise hard to understand regulation. For example, the medical device coordination group (MDCG), which has been set up to provide advice to and assist the Commission and the Member States in ensuring a harmonised implementation of MDR has issued general interpretation guidelines, e.g., MDCG 2021-24 Guidance on classification of medical devices, or even more specified ones targeting specific product groups, e.g., MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.

However, these documents can still be incredibly difficult to decode for a first-time reader and medical device newcomers. For example, the Covid-X teams had the possibility to ask their questions to a relevant expert in the field and had a team of healthcare experts helping and guiding them through a lot of the necessary steps. However, even after that they still stated the **MDR remains a challenge** and that much more understanding and interpretation of the document needs to happen over time that cannot be supported with a single consultation and thus much more **help and advice from relevant experts are needed continuously** down the line. This is even a bigger problem for providers of digital solutions that have not had access to the tools and experts the Covid-X team did, meaning that most of the healthcare start-ups will at some point be struggling to ensure MDR compliance.

> This indicates that there is still a gap in access to information and **there is a place for new and improved information tools** and channels to be deployed in this domain.

CASE EXAMPLES | One of the key problems with understanding and interpreting the MDR is the diversity among the potential applicants and their respective devices, which makes it incredibly hard to generalise the overall process and give any estimates of the expected times and fees. One way to solve this and give future applicants a better insight as to what the process holds for them would be to create and diffuse a variety of case examples from different producers and their respective devices. The case examples could be in the form of **process diagrams, videos, infographics, or short text** but would essentially describe the overall MDR compliance journey for a given producer - this would **detail**

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all the steps taken down the road, **the time it took** for each step, the **number of employees** that were involved, the **costs they had to incur**, the setbacks they had or adjustments they had to make to their initial applications, etc. While the actual journey for every applicant will still be different, this could potentially help to break down the various steps and help the applicants better understand what to prepare for in each stage. This would also allow the newcomers to **better plan and allocate their resources** and avoid coming short in funds just before the regulatory milestone has been achieved. Having a variety of examples, e.g., devices from different classifications, experiences of SMEs and large companies, would also help different producers to identify the process that is most likely to resemble theirs and make the most accurate estimations.

CHECKLISTS | Another expansion on the preparedness could be readily available checklists which would allow the applicants to identify which of the required steps or documentation they have obtained as of now and what is still missing to start the process - this would help in avoiding sent-backs from the NBs for when a document is missing. The checklists could also be tied to the case examples detailing which kind of documentation and annexes were required for different kinds of solutions.

CONSULTATIONS | The insights from the Covid-X project have shown that the ability to talk face-to-face with an expert even for a small period of time can significantly help the innovators to validate their own assumptions about their required medical journey, e.g., the teams often suspected on their own to which class their solutions belonged, but **short feedback from an expert helped them to confirm that assumption** and move on with the process. It is of course unreasonable to propose that EC allocates free full-time consultations as there simply would not be enough time and resources to carry this out from a policy point of view, however, it would be reasonable to suggest that some form of regulatory consultations are available after meeting a set of qualifying criteria or stage of development, e.g., a certain amount of hours over a period of time for solutions that have reached a certain TRL or need validation from a healthcare provider.

3.2 Notified Body shortage

CERTIFYING MORE NBS | In the case when all of the EU's capabilities to bring medical devices to market is influenced by the lack of NB capacity, the EC should make it their number one priority that there are enough NBs available to carry out the task. Considering that there were twice, if not more, as many NBs certifying devices under the MDD, the **EC should approach those that have not yet been designated for MDR** (but were designated for MDD) and see how they can encourage and help them become certified yet again. For the medical device market is ever-growing and there are more and more innovative solutions, the capacity and number of NBs should be increased as much as possible. For those NBs that have decided to not undergo the MDR designation due to the many costs associated with it, the EC should consider a one-off funding scheme or support system that would alleviate the cost burden for the NB and would allow them to go back on the market and offer MDR and IVDR certification.

SATELLITE NETWORK | It seems that one of the key problems with the NBs is that as privately owned companies they function very independently from one another and there are no collaboration efforts taking place. As of now, there is no information source that would compile the availability and capacity of the NBs in one place, this means that the applicants are spending a lot of time browsing, individually

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contacting, and selecting the NB, which is losing them a lot of precious time. The processing and waiting times differ from one NB to another, causing **disparities in the quality of a service that is critically essential for the MedTech industry** and the overall healthcare systems as a consequence of that. A possible option for the EC to facilitate a faster uptake of novel medical solutions would be to establish a partially centralized satellite network for the NBs. The **goal** of which **is to better manage the flow of information** and to ensure that the **procedure and quality of service is more homogenous** among the various NBs. In practice, this would mean establishing a number of contracting agencies that are situated across the EU and would oversee a set of NBs within their respective region or area of expertise. This would allow the applicants to contact one agency instead of multiple NBs, and the agency would be able to match the applicant with the NB in the best position to attend to the applicant's needs and solution based on the current capacity and experience of NBs. This would replace the otherwise inefficient process taking place now and would substantially save the time and resources of the applicants. These agencies could also manage the support efforts mentioned before, e.g., consultations, revisions of checklists, etc. The network system would also allow the EC to ensure better service quality and equal opportunities for all innovators.

FAST-TRACK FOR PRIORITY SOLUTIONS | Despite the many efforts and preparations before it, the Covid-19 pandemic still took Europe and all of the world by surprise - a lot of things had to be temporarily put to a halt or shut down until the situation could be properly controlled and managed, and even now, one and a half years later, our lives are still tampered with by the virus. In cases like these, it is important to find solutions and possibilities for improvements in the system as quickly as possible, thus one could argue that in times like these there should be a fast-track option for solutions that are specifically targeting or solving the key health emergency at stake. As such, there is good basis for suggesting that the **EU should establish and frequently update a priority list of desired treatment areas**, that would allow certain solutions move through the process more quickly than they usually would have had they not been given the fast-track access. In practice, this would not mean that the process of other solutions is significantly prolonged or that their applications for certification are not being attended to. The suggestion could be to **select a portion of the NBs that for the time being are mostly focused on certifying the priority solutions**, e.g., solutions tackling Covid-19. Choosing just a group of the NBs would allow the selected NBs to become more specialised on these solutions - after having assessed one novel solution tackling Covid, it is easier to build on that experience and make the process for other solutions even faster, in this way the experience is used as a valuable asset that can significantly improve the efficiency of the NBs. This approach could later on also work for other priority areas other than Covid, e.g., priority is given to solutions that are in line with the EU's key research areas - Antimicrobial drug resistance (AMR), Brain research, Cancer, Cardiovascular diseases, Chronic diseases, Diabetes, Ebola, Emerging and remerging infectious diseases, HIV/AIDS, Human development and ageing, Malaria, Public health research, Rare diseases, Tuberculosis, Zika.[27] Another possibility is to over time, designate **NBs that are focused and more experienced on certain types of solutions by treatment area or deployed technology**, e.g., designated NBs for certifying AI-driven medical devices. This would again deploy the experience as a key asset for driving efficiency at NBs.

[27] Health research and innovation, European Commission, 2021.

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The fast-track for priority solutions could also include potential financial support at this stage, coming directly from the EC. A suggestion would be to have an **EC funding pool for innovative solutions in the priority domain which are to be used particularly for the MDR or IVDR certification process**, and only when the solution has already been proven to be beneficial for a healthcare provider or in clinical practice. This way the funds would go directly towards **accelerating the pace at which novel solutions are being implemented,** thus tackling the problem of slow solution uptake.

REMOTE AUDITS | Another recommendation is to exploit the lessons we have learned during the pandemic and embrace the digital capabilities by implementing remote audits more widely. The European Union temporarily allowed remote audits of medical devices and in vitro diagnostics under the new regulations (MDR IVDR) due to the COVID-19 pandemic and travel restrictions that made in-person audits at manufacturers' facilities difficult if not impossible. Remote audits appear "to demonstrate an adequate level of safety and not to compromise the overall reliability of such assessments". Even so, the Commission is putting constraints on the use of remote audits. Notified bodies will need to show there are "concrete obstacles" that prevent a safe on-site audit that is needed to ensure the continued supply of devices. The Commission has asked the Member States to let it know about notified bodies that perform remote audits and the information they use to justify their actions. We strongly **encourage wider adoption of remote audits**, especially when considering digital solutions, where physical presence is not required on the same scale as for other more tangible solutions.

3.3 Time and resources

The time and resource challenge are of course not unique to the healthcare industry and the problem of access to funding for innovative solutions has to be tackled on a wider and much more global scale, however, the healthcare industry is rather unique in a sense that the success or the failure of these solutions will have a direct impact on our lives, thus it is arguable that healthcare start-ups should be allocated, if not additional funds, then other means of additional support. To ensure that these solutions are actually brought to market and implemented where we need them the most, **additional support** should be allocated to facilitate **direct partnerships** and **pilot programs between innovative SMEs and health care providers**, thus enabling faster technology transfer and adoption. Attention should also be drawn to **allocating the support to the hospitals and other healthcare providers**, as much of the time, they simply do not have the resources or skills and knowledge to successfully onboard them. The lack of resources on both ends of the partnership is causing a lot of them to fail in meeting the desired outcomes. There is also a lot of value to be gained from experience, e.g., one successful onboarding of a solution, could significantly accelerate the hospital's possibility to successfully onboard other solutions. Thus, more projects and funding should be focused on **initiatives that involve and at the same time fund** both **the entrepreneurs** as well as the **healthcare providers**.

3.4 Fragmented HTA

Up until now, the EU has implemented 3 EUnetHTA joint actions in an attempt to improve the work and cooperation between national HTA bodies. The 3rd joint Action was running from 2016 to 2021 and was able to achieve substantial progress, however much of these efforts were concentrated on

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the harmonisation of HTA assessments for pharmaceuticals while **the assessment of medical devices faded in the background**. The joint actions have been running continuously for 15 years and since there is more progress and a higher level of cooperation to be achieved, it is expected that a new joint action plan will be revised and put into place soon. When designing this it is important to consider the importance of HTAs in the EU's overall ability to quickly and homogeneously uptake digital solutions in healthcare. The goal of these efforts should be to **develop a cooperation model which would allow the manufacturers to go through the assessment process once and have it recognised in all of the member states**. Thus, eliminating the duplication of efforts, relieving the burden on individual HTAs, and enabling the adoption of innovative solutions simultaneously across the EU. This is of critical importance not only to save the already limited HTA resources but to also from a business point of view - the harmonisation of HTAs would essentially enable the applicants to scale more quickly and deliver their solutions to more countries, this would also allow for more feedback loops, experience, and proper effectiveness testing, which would in turn drive the overall quality of the solutions and the health care systems as a consequence. There is no doubt that such harmonisation on an EU-wide level will take time, but even regional cooperation would significantly boost the adoption of solutions.

The HTA is also part of the reimbursement journey, which is also rather fragmented in relation to what kind of solutions are accepted for reimbursement in different countries. Those countries that are more experienced with **the adoption and reimbursement of digital solutions** should share their practice with others to enable simultaneous digitization of healthcare across the member states. In practice, this would mean building on the HTA network and recognizing not only the assessments themselves but also the reimbursement decisions. This, of course, can be difficult as the health systems differ from country to country and some solutions simply cannot be implemented or reimbursed elsewhere, but the harmonisation of reimbursements should be desired in most cases.

A practical example of implementation could be drawn from the "seal of excellence" initiative - in the cases when EC is not able to support a research or innovation project due to budgetary constraints but believes that the project has the potential to deliver impactful results, the EC will issue a *seal of excellence* to notify other funding schemes that the project is of good quality.[28] In the case of HTA, the decision of reimbursement in each country is based on the country's individual capabilities and budgetary constraints - as such, the countries could issue an equivalent document to the *seal of excellence* which would to other countries indicate, that had the budget been bigger for them, they would have reimbursed the solution and other countries should too, if their constraints allow them to.

[28] "What is the Seal of Excellence?", European Commission, 2021.

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