STARTUP POLAND

DIGITAL HEALTH

2020
# TABLE OF CONTENTS

## Introduction
The modern healthcare compass is pointing towards a digital Top ten research findings

## Chapter 1
What is digital health?

## Chapter 2
Who and where?

## Chapter 3
The scientific aspect of the digital health sector

## Chapter 4
Technology and innovation

## Chapter 5
Cooperation with partners

## Chapter 6
Financing and the economic environment

## Chapter 7
Barriers to the development of the sector

Startup Poland recommendations for the development of digital health in Poland
Today, digital health is proving to have an ever-increasing impact on medical treatment and patient care. These solutions improve the quality of life of patients, help them overcome various barriers, and provide broader access to healthcare. The year 2020 is the right moment to reflect on nearly twenty years of digital development in the field of e-health, while looking at the new challenges - including the recent COVID-19 pandemic.

We are very pleased to present you with the report on Digital Health, prepared in collaboration between the Startup Poland Foundation and Roche. This document has been produced following an in-depth analysis of data gathered from innovative startup companies operating on the Polish market to offer insight into the current state of high-tech companies in the field of medicine. It fosters a better understanding of the environment, barriers and opportunities for companies focusing on digital health. Like a compass, this report helps to map how digital solutions created to support patients and physicians could evolve, it presents the digitalization of the healthcare system from various perspectives – from the technological aspects, through barriers to entry, to potential opportunities and benefits. Its primary purpose is to explain how each branch of patient care improves as technology advances. The future of modern healthcare is hard to imagine without information technology.

Faster and more adequate therapeutic decision-making, based on information from distributed big data sets, real-time monitoring of the patient’s condition, monitoring adherence to prescribed therapy, regulated and responsible sharing of data with authorized entities for the patient’s benefit, and use of digital biomarkers, platforms and remote communication tools – these are just a few of the opportunities that digital health technologies can bring to the future of healthcare. Developing countries with great potential, expertise and vast capabilities in technology, such as Poland, cannot afford to miss the opportunity posed by evolutions in digital health. By publishing the English version of the report, we intend to raise interest in the devel-
opment of these technologies across the region, as well as to connect investors with talent and innovation not only in Poland, but other countries as well.

We dedicate this report to the broadest possible audience in the healthcare ecosystem, as we believe it plays an important role in fostering dialogue and fruitful cooperation. We trust that the analysis provided below and our conclusions will encourage technology companies, investors and representatives of the scientific community to seek and form partnerships between science and business to create innovative digital health solutions. We aim to increase the level of attention and funding from investors, both private and public, in this domain. We would also welcome a discussion to identify the main barriers, draw up recommendations for overcoming these limitations, and invigorate the digital health market - with the ultimate goal of achieving greater benefits for patients.

At Roche, at our Global IT Solution Centres located in Warsaw, Poznań, Malaysia and Canada, we are implementing a broad range of international IT projects. We are working with others to create digital solutions used by patients and healthcare professionals all over the world every day. We partner widely with universities and scientists as well as with innovative and rapidly developing business. Through our work, we see the needs of patients and doctors on one side and the rapidly increasing capabilities of modern technology on the other. We are confident that digital health has great transformative potential in healthcare. In this document, we would like to raise awareness of this potential and demonstrate its context and advantages in many areas.

To deliver this report, we needed a reliable and committed partner with whom we could combine our know-how and experience. We were looking for a partner with a similar mission and who shared our vision for patients, and the healthcare and medical community. Startup Poland fits this profile perfectly. The Foundation knows and understands the Polish start-up community inside out. It empowers the development of entrepreneurship and innovative business by building awareness of start-up potential among officials in public authorities and supporting the Polish start-up community in shaping legislative processes. In short, Startup Poland is an exemplary think tank. On the other hand, we at Roche combine patient needs, medicine and modern technologies, and we have the know–how and hands-on experience in creating digital health solutions. From the very beginning, we found a common language and shared the perspective of how to connect the needs of start-ups and corporations, with respect and support for their collaboration, integrity and mutual growth. We encourage all members of the healthcare ecosystem to actively collaborate and promote the digital transformation in the industry. We look forward to seeing the more rapid development of digital health in Poland and in the region in the coming years, as this will undoubtedly bring tremendous benefits to patients.

We hope you enjoy reading the report.
TOP TEN RESEARCH FINDINGS
As many as 84 percent of startups plan to expand their operations into new international markets within the coming 12 months.

Primary barriers to cooperation with government institutions include bureaucracy and extensive legislative processes.

Key scopes of cooperation with business partners include marketing support and validation of business assumptions.

Startups are more willing to work directly with scientists than with universities. Nearly half of all MedTech companies work with individual scientists who support their research and development efforts.

Half of the startups do not own any patents and they are not in the process of obtaining any.

Startups use a broad range of financing options, more than half of them reach out for NCBR resources.

The medical specialization of MedTech startups varies. The main field is cardiology (31%), and psychology comes second (23%).

The IT solutions used by Polish MedTech companies include mostly remote technologies: telemedicine, mobile applications (mhealth), and web applications.

Target groups which the digital health solutions are aimed at are also differentiated, with a dominant position occupied by healthcare services, hospitals, and doctors.

Most of the study participants who manage digital health startups (66%) have a Master’s degree, engineering degree, or a Bachelor’s diploma, more than 1/4 of them hold at least a Ph.D., less than 1/4 have studied medicine.
WHAT IS DIGITAL HEALTH?
What does the future of digital health look like?

Digital health represents a cultural transformation of care. While technologies are certainly fueling the changes behind this transformation, perhaps even more important than which microchip comes out next year is how the traditional hierarchy of the doctor-patient relationship is transforming into an equal level partnership, how the passive role of patients is shifting towards a proactive, empowered attitude.

The ivory tower of medicine is breaking down, giving patients access to data and technologies like never before. Patients are becoming the point-of-care, receiving diagnostics and treatment wherever they are. This is the vision digital health technologies provide if we all embrace the cultural components of these changes.

Moreover, the COVID-19 pandemic has strained our already overwhelmed healthcare systems and billions of people have had to stay at home to practice social distancing. The most critical change is the rise in telemedicine, providing care from a distance. This not only protects healthcare professionals but also patients from exposure to infections. In monitoring chronic conditions, telemedicine has already been in use for years, but the pandemic has shed light on the importance of making it the new norm. This could help fill the gap caused by global shortages of physicians and save time by avoiding unnecessary visits to medical professionals.
A shift in the point-of-care is also supported by recently developed technologies.

The importance of digital health solutions has been made abundantly clear during these challenging times. They are ready-made options to bring healthcare to patients, rather than the other way round. Besides health apps helping people during the pandemic, devices like digital stethoscopes, portable ECG monitors, and digital otoscopes can be used at home and the results shared remotely with physicians. These eliminate doctor-patient visits whenever avoidable and also help reduce the risk of cross-contamination. Such devices should become commonplace, shifting the point-of-care to the patient.

Every organization, government, or company should keep two things in mind when focusing on the future of care:

- to develop technologies, processes, and products that make patients the point-of-care; and

- to address the cultural aspect of technologies to ensure that the core values of care remain with us forever, even when advanced, seamless and invisible technologies surround us.

**Dr Bertalan Mesko**
Director of The Medical Futurist Institute and Professor at Semmelweis University, Department of Behavioural Sciences
Sources of innovation that can drive the development of Digital Healthcare

When we look at digital healthcare services, we can identify two directions that have a significant impact on the development of new solutions. The first stems from academia or healthcare industry experts, while the second is more technology-driven.

The first builds on a deep knowledge of challenges that today’s healthcare services must tackle, looking for new ways to solve them. New opportunities in the technological sphere allow for new approaches to finding new therapies based on drugs and diagnostics (like the ability to process large volumes of genome data). Personalized healthcare is just such an example - an unprecedented convergence of medical knowledge, technology, and data science is revolutionizing patient care and is one of the pillars of Roche’s strategy.

As for the second approach, we can observe it when technology develops beyond its original domain. This usually happens when a given technology proves its value and becomes mature. As a result, there are more skilled experts on the market and entrepreneurs are looking for new areas to expand their business. One such example would be blockchain, originating in financial markets where it was invented to support distributed money exchange processes. Today, it may find new uses in many other areas, including healthcare. Helping to manage patient data and consent for its use in clinical trials or securing the supply chain to prevent counterfeit medicine are just a few examples of its potential uses.

Looking at the report, we can see academia and healthcare industry partnership examples in the questions about R&D and business collaboration. Scientists, academia, and scientific institutes are shown as the most important partners to help with research and the development of new solutions. Similarly, the main theme for collaboration with businesses (apart from marketing support) is the verification of business cases and industry-specific expertise.
This is specifically important for Roche, where we see partnering as one of the key sources of new drugs to develop. Merging ingenuity, experience and the mutual support of many teams can lead to breakthrough therapies that will improve human lives, often through personalized medicines. Startups are an important part of this ecosystem with their dynamics and focus. They can develop and scale, taking advantage of their domain knowledge and available experience.

A technological perspective can also lead us to interesting conclusions. When we look at the technologies behind the solutions developed by the report participants, we can see some that are related to healthcare - neurofeedback, bioprinting, medical sensors, or telemedicine. We can also see technologies that first found uses in other industries now have a broader applicability, such as web and mobile applications, data visualization, robotics, or wearables. These can be examples of the second approach mentioned above. The variety of uses of these technologies can vary from medical devices, through healthcare providers supporting systems to lifestyle apps that help you to live a healthy life. The entry barrier can be perceived as high, however, with the need for certification or clinical trials, but the examples of MedApp, StethoMe, or Consonance show that it can be done.

The shift in the healthcare industry that is driven by digitalization has just started. We can see that the biggest disruption can be caused by the convergence of these two directions - innovations originating from deep medical knowledge and an openness to new approaches with groundbreaking technologies that cross industry boundaries. This shift, however, has a much bigger impact than on one industry. Putting the patient in the center and focusing the will and passion of the smartest minds around the world will have an impact on patient lives. This spotlight will lead to new breakthroughs comparable to the invention of antibiotics, with the potential to save and improve millions of lives around the world.

Imagine a therapy that is created for one specific patient by comparing their genome to millions of others to find this specific combination of compounds that will save their life, produced solely for them and sent directly to them via a smart device. It will administer the drug automatically according to their personal schedule, accompanied by an application that will monitor drug effectiveness, disease symptoms and motivate the patient to lead a healthier life - it is already possible. There is a lot more on the horizon, however, and we haven’t seen the best of it yet.

Łukasz Borycki
Head of IT Research & Development, Roche
A large group of startups uses laboratories to conduct R&D activities, with 27 percent having access to their own facilities, while another 17 percent cooperate with an external, accredited research and development lab. Aside from the above, 8 percent of participants in our study use the infrastructure of technology parks, i.e. business locations where companies of a given industry gather along with cooperating research and development units. This solution is increasingly common in Poland. This type of location can be found in every Polish voivodeship, and Silesia is clearly top of the podium, with a record number of technology parks (16 of them).

Along with technology parks, we also have a number of Technology Transfer Centers. These units are organized by universities or scientific institutes with the purpose of selling the results of research and development originating from the given institution or arranging its unpaid transfer. 4 percent of our study participants take advantage of this form of support. Another 2 percent indicated Business Incubators, and the same proportion mentioned Centers of Excellence, where scientists actively cooperating with different industries share their knowledge. All those entities have the purpose of increasing the significance of the role of science and research as a factor boosting the competitiveness of the Polish economy, which is significant to such an innovative sector as digital health.
WHO AND WHERE?
Among the startup representatives operating in the digital health industry surveyed for the purpose of this report, the vast majority - over 80 percent - are managers of such companies. Eight out of ten of them occupy the position of CEO, chairman, or board member.

The startup representatives who took part in the study are well educated. Only 6 percent of them do not hold a master’s degree - including 4 percent who are currently studying for their bachelor’s, master’s, or engineer’s title. Another 2 percent are alumni of vocational schools. Precisely the same number are currently working on a Ph.D. More than one in four (26 percent) already hold a doctorate or a higher scientific degree. Two-thirds of the study participants indicated that they have completed a master’s, bachelor’s, or engineering degree (66 percent).

Only 6% of respondents do not have a master’s degree, with over ¼ holding at least a Ph.D.

At what stage of education are you currently?

- I have completed my studies (master’s, engineering, bachelor’s) 66%
- I have a Ph.D. or a higher degree 26%
- I am currently studying (master’s, engineering, bachelor’s) 4%
- I am studying for a Ph.D. 2%
- I have a vocational school diploma 2%
It’s interesting to note that employees or managers of the startups which operate in the digital health sector are not necessarily alumni of medical studies. Less than a quarter of the study participants have medical degrees (23 percent). More than half of them (52 percent) have graduated or are currently studying humanities or social studies, including economics, management, sociology, law, history, and philosophy. A smaller percentage indicated technical studies, natural studies, computer science, maths, chemistry, or biology.

Also worthy of note is the fact that fewer than ¼ of study participants study medicine.

What field is your degree in?

- Humanities / social studies (e.g. economics, management, sociology, law, history, philosophy) 52%
- Technical studies/natural studies (e.g. computer science, maths, chemistry, biology) 46%
- Medical studies 23%

What is the current level of professional experience of the study participants? Nearly half of them have previously obtained business experience working as entrepreneurs (46 percent). Every third respondent has previously run a startup (33 percent).

One-fifth have previous experience in academia (21 percent) and an almost identical percentage in conducting scientific research (19 percent). Creating an effective solution in the MedTech sector requires both specialized scientific knowledge and significant business experience. Hence a combination of scientific and business communities seems an optimal solution for creating startups. Mixing modern technologies with the methods which are currently used in medicine also seems necessary.
Artificial intelligence in the service of healthcare

The medical industry is rapidly developing these days but many patients do not have access to the proper care at the right time. According to WHO studies, 50 percent of people in the world do not have access to basic medical services, and in 2030 we will have a gap of 14 million vacancies in healthcare. In addition, our current healthcare systems are often ineffective and if patients were immediately referred to a proper kind of treatment, it could generate significant savings. At Infermedica we have decided to confront global challenges by setting out a goal to create more accessible healthcare and digitizing healthcare systems. We have created a platform based on artificial intelligence to perform the so-called medical triage of patients.

The platform is available with the use of different interfaces, including API, the Symptom Checker application, and telemedical solutions – Triage Call Center.

How did we come up with the idea? It all started in 2011. We had this popular game back then called Akinator – a computerized version of 20 questions, which asked the player questions and discovered which fictional or real character they were thinking
It is surprising that only 27 percent of the owners in this segment of the startup market have any previous experience with the medical industry - 19 percent of them were medical doctors, and 8 percent of them have other professional experience in healthcare gathered in non-medical positions.

Medical practice allows people to recognize problems and ineffective processes within hospitals and clinics. Some physicians decide to move away from full-time work in healthcare for many different reasons. For these individuals working for a startup company can be an interesting further step in their careers.

Particularly worth mentioning is that 13 percent of study participants declared that they draw from their experiences in healthcare in their startup work, but rather those that they have gained from the perspective of a patient, not the employee. This type of experience may be very important in designing solutions that are needed in the market and match the requirements of patients. This phenomenon is a solid starting point that defines the actual demand and allows one to realize a business need.

We set off as a team of three engineers, eight years later we’re still a part of the company. In 2012 with the help of two medical doctors and one designer we have launched a prototype of our application called Doktor Medi, which quickly became one of the most popular tools used for checking symptoms in Google Play. This allowed us to raise the first round of financing, which came from Innovation Nest and EIT+. With the support of our investors, we developed both our product and the business model.

Today, Infermedica is a team of over 100 people: data analysts, software developers, physicians, and other experts. So far, our tool has been used over 7 million times worldwide, in 17 different languages. Our medical team has devoted almost 40,000 hours to creating and validating our medical database.

To date, we have established partnerships with nearly 60 B2B partners, including Microsoft, Allianz Partners, and PZU Zdrowie.
THE SCIENTIFIC ASPECT OF THE DIGITAL HEALTH SECTOR
THE SCIENTIFIC ASPECT OF THE DIGITAL HEALTH SECTOR
Creators of technological startups that operate in the digital health sector don’t always come from medical or scientific backgrounds. Their activity in a startup and the business idea may come as a result of experiences gathered in the role of the patient, and it may be an attempt to fill a particular gap in the healthcare system and offer an alternative (which can convert into a business with great potential if accurate). Another key factor of commercial success, as research shows, is the previous career path of the creators and managers of such companies.

The key role in this scope is played by academics. A large proportion of the study participants have previous experience in academia - more often than in medicine. One in five of the study participants (21 percent) was a scientist before they’ve set up their business. A similar proportion mention research work on their resume. Thus they have both, deep knowledge in a particular scientific area, which gives their startup a chance for stable development, but also other skills, as it can be observed in businesses managed by practicing physicians, or entrepreneurs, who don’t have any academic experiences.

Their advantage is their network of peers at universities and the fact that they know how to optimally divide their time between business and academia. More than eight in ten startups (85 percent) conduct R&D operations. Good relations with universities and scientists are a very significant element of their work. On the other hand, thanks to working with startups, scientists can become involved in new, interesting, and innovative projects, and watch how their scientific knowledge transforms into business practices.
What was your background prior to founding this start up?

- I was an entrepreneur: 46%
- I managed my own startup: 33%
- I worked in academia: 21%
- I was a researcher: 19%
- I was a physician: 19%
- I was a patient: 13%
- I worked in healthcare (but not as a medical doctor): 8%
- Other: 10%
- None of the above: 12%

Startup managers mostly have business experience.

Where do Polish startups look for partnerships in their research and development activity, if they decide to take this step? Nearly half of our study participants pointed to direct cooperation with particular scientists and this was the most common answer to this question (48 percent). Fewer companies decide to cooperate with an institution of higher education (38 percent). Among all of the subjects, 15 percent conduct R&D activities with the help of scientific institutions other than universities.

The Polish Academy of Sciences is a good example. 15 percent of respondents indicated PAN as their partner. So, why is it that the model of individual cooperation with scientists and researchers is more common?

It turns out some people argue that a large proportion of universities and research and development institutes in Poland are not properly adapted to cooperation with startups. They lack proper procedures, a suitable legal form, or experience. The regulations of these institutions often state that they will take control of the technology being developed, something which is often an impassable obstacle for startup owners. The only thing they can do in this situation is to pay for research as a service, which is an external cost and often perceived as unqualified.

15% of startups do not conduct any research and development activity.
In the scope of our R&D activities we cooperate with:

- Individually with an academic researcher: 48%
- University: 38%
- We have our own research lab: 27%
- Accredited research lab: 17%
- Scientific institution other than a university (e.g. PAN): 15%
- Science or technology park: 8%
- Other: 4%
- Technology Transfer Center: 4%
- Business incubator: 2%
- Excellence center: 2%
- We do not conduct any R&D activity: 15%
What is digital healthcare?

A transformation of the healthcare industry

The healthcare service is currently undergoing a massive digital transformation. It encompasses multiple areas, from digitally-enabled tools for diagnosis through telemedicine and continuous monitoring, to personalized treatments. Digital tools provide a more holistic view of patient health and promise an improvement in medical outcomes and enhanced efficiency. They become essential in the development of truly personalized healthcare services. More specifically, their benefits include:

- **360° patient profile for clinical decision support**, leading to faster and more informed decisions
- **Increased patient engagement** thanks to actionable insights provided by tools organizing patient’s data into user-friendly profiles
- **Consumer engagement** by making smarter decisions about health, wellness, and fitness
- **Improved treatments** thanks to tools extracting the most relevant information from vast volumes of reports, publications, and data
- **Artificial intelligence** that will fuel self-learning healthcare products

Digital Health addresses the issue of ever-increasing complexity in healthcare fueled by advances in science and technology. Managing this complexity, connecting the dots by combining data and cooperation to unlock the potential of digitalization is the key to creating life-changing leaps in patient care, which is in line with the themes identified by World Economic Forum (WEF).

According to the WEF report entitled “Building the healthcare system of the future”, the healthcare system after the digital transformation will look very different compared to what we have today. Location and type of care are two areas ripe for the largest disruption - moving care closer to home (an outpatient setting) and complementing treatment with prevention and management are going to dramatically change the landscape of the industry.

The potential for this transformation has not yet materialized, a claim that many experts also make. They point out that the barriers are often non-technological - Healthcare Information and Management Systems Society (HIMSS) president Harold F. Wolf considers a change of culture to be the biggest obstacle in the industry’s transformation. The most obvious driver for change is the current COVID-19 epidemic. It has enforced the broad adoption of technologies like telemedicine that have been waiting on our doorstep for many years.

On the other hand, the numbers already indicate that a change of mindset has already started. The landscape of Digital Health solutions is growing rapidly, with hundreds being created daily and hundreds of thousands already in place, chasing the Holy Grail of creating personalized care for patients all around the world.
What is digital healthcare technology?

The digital transformation in healthcare covers a vast area with often unclear borders. At the heart of digital healthcare are solutions with a direct influence on health, healthcare, or patient-doctor interactions.

These are often digital treatments with clear and proven benefits supported by either industry-standard evidence or certification as a medical device. However, the ecosystem is much wider and contains tools and solutions that do not have to meet these stringent requirements (e.g. appointment booking or doctor rating services).

Let’s consider specific examples. There are indeed hundreds of scientific publications listing the various health benefits of meditation.

A smartphone meditation app might indeed help in meditation practice, but is not itself a digital treatment, because a specific procedure of conducting meditation has not been independently assessed as providing substantial benefits over a placebo (that would be just sitting quietly for the same amount of time).

This does not rule out the fact there is space for meditation apps in the digital healthcare landscape, because there is room there for prevention and creation of positive changes in patient lifestyles.

To give just another example, video games might not often be considered a healthcare technology, yet a video game devised by Akili Interactive Labs received FDA approval for the treatment of children with ADHD earlier this year. Here, a particular technology became a digital treatment.

Decomposing digital healthcare

Digital healthcare can be viewed via multiple lenses. From the technology perspective, the key elements of the ongoing transformation are:

- wireless devices (including mobile networks),
- hardware sensors (including integrated circuits),
- software sensing technologies (ML/AI, including digital biomarkers),
- health information technology (including integrations between sensor data and medical records)
- high-throughput technologies, especially various “omics” (genomics, proteomics, metabolomics, metagenomics, etc.)

From the perspective of domains spanning digital healthcare, we can list at least the following:

- clinical decision support (diagnosis, analysis, and interpretation of patient data)
- disease management & therapeutics
- assistive technologies & specialty care (including rehabilitation robotics, virtual reality, and visual games)
- communication aids (speech recognition, natural language processing)
- remote care (telehealth, telemedicine, telerehabilitation)
- drug discovery
- clinical trials and real-world evidence.
These two dimensions, while not very extensive, provide a useful way for the rapid classification of existing tools. They can also serve as a simple map, where we forecast the medical areas which will be the sources of the greatest need for digital healthcare solutions in the coming years.

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Using this as an outline, we can also refer to some real-life examples to see how it works in practice. As early and accurate diagnosis can be crucial in efficient patient care, newly developed digital methods for tracking eye movement or voice disturbances accompanied by complimentary machine
learning algorithms – so both CDSS and hardware sensors – can enable an early Alzheimer’s diagnosis. Given that no drug able to reverse the physiological changes related to this disease exists, its early diagnosis is of vital importance. Delaying the onset of symptoms by means of lifestyle modifications and the introduction of certain drugs is currently the best strategy for Alzheimer’s management.

This is just one example of how digital healthcare can, and most certainly will, continue to change the world for the better.

Agnieszka Kościuszko-Wyrwał  
IT Expert, Roche

Paweł Szczęsny  
IT Expert, Roche
Scientific knowledge and business experience are the keys to creating effective solutions

The biotech industry is currently undergoing a genuine boom. Crises such as the COVID-19 pandemic are testament to the fact that this is not a flash in the pan but a long term trend.

Innovation in medicine, pharmacology, biotechnology, etc. responds to the key social issues related to maintaining and improving human health. The SARS-CoV-2 virus has allowed scientists, entrepreneurs, investors, institutions, and consumers to realize that effective medical solutions secure the most basic, biological, and physiological needs from the perspective of Maslov’s pyramid, as well as the need for safety.

This phenomenon is also a unanimous signal for the market: there is and there will be more demand for new solutions in biotechnology. Even the study participants who do not come directly from the healthcare sector or the scientific community are aware of this fact. They are discovering gaps in the market for medical products and services by... becoming patients. This is a solid starting point, one which defines actual demand and allows us to acknowledge a genuine business need.

The commercialization of projects in the medical and technology sectors is particularly difficult because the process of creating an effective solution requires both specialized scientific knowledge and substantial business experience.

We have many outstanding scientists, institutes, and research teams at Polish universities. While leveraging their pioneering work into practical applications is surely tempting, it is also difficult and it requires some hermetic knowledge and confronting some complicated, expensive, and time-consuming procedures. The entry barrier to the biotechnological sector is much higher than in the case of typical seed-stage projects such as IT, for example. Creating a biotechnological product is incomparably more expensive than developing new software applications.

Investing in biotechnological projects, especially at the early stage of development, not only requires specialized knowledge but also a visionary approach to business. It is necessary to understand both the need in the market and the significance of the
solution on offer, as well as the process of commercialization and raising funding. This is a sector for the patient (!), and that patience can be rewarded with a particularly favorable rate of return.

*Case study: Biotechnology is a sector where it is worth looking for a niche. One of the more interesting examples is veterinary biotechnology, which is particularly favorable in terms of the returns to gains ration and potential risks. A good example here is the Wrocław-based Bioceltix veterinary startup. Its visionary and founder, Łukasz Bzdzion, is fascinated with innovative treatments for animal diseases, and he has convinced investors to believe in his vision, building a strong, diversified team, and successfully developing medicine for animals based on stem cells.

A combination of his scientific vision and the business experience of the other partners in the company has resulted in the creation of a pioneering organization with tremendous potential in the budding market for biological treatments for dogs, cats, and horses. What initially seemed a niche has gradually allowed them to assume a strong position in an interesting segment of the biotechnological market.

While not every startup in the digital health sector gets engaged in research and development activities, embarking on cooperation with universities, scientists, researchers, or other entities which allow them to take advantage of scientific knowledge and support, if they want to function in the market they usually have to work with commercial partners. Of the startups which participated in the study, this relates mostly to working with partners providing marketing support - four in ten companies declared they enjoyed such a form of cooperation. We can safely assume that they use the services of marketing agencies or other experts in communication and in conducting advertising activities.

In the second place, we found ex aequo the entities dealing with validating business assumptions and those which provide expert support in the given area of medicine or diagnostics (36% each). The first category includes e.g. consulting companies providing advisory and auditing services, the second includes entities with expertise in areas that are key to the development of a medical startup. Most probably this type of cooperation largely relates to startups managed by founders with no medical education or specialized in a different field. In addition, some of
the study participants indicated that they take advantage of the support provided by experts who have competencies that are missing within the company’s founding team (21 percent).

A separate category includes cooperation in terms of raising financing - 29 percent of the studied companies hire external experts in the field of obtaining sources of financing. On one hand, this may comprise the search for external investors, on the other, it may relate to obtaining financing in the form of grants, or EU funding.

One in four companies have sought the support of a business partner in managing processes, technology, obtaining a proof of concept (PoC), consulting or technological research (24 percent), and one in five (21 percent) require legal assistance related to the results of R&D activities, including e.g. licensing, selling rights to the results of their studies or incorporation. One in nine startups (12 percent) conduct training courses in the sphere of protecting intellectual property in cooperation with an external partner.

The most common form of external support sought by startup owners is marketing support.

In what scope do you currently cooperate with your business partners?

Marketing support 40%
Validation of business assumptions 36%
Support of experts in the given field of medicine or diagnostics 36%
Providing the possibility to carry out clinical trials or tests on a group of patients 31%
Expert support in the scope of competencies unavailable within the team 29%
Support in obtaining external sources of funding 29%
A business partnership providing support in the scope of processes/technologies/skills/proof of concept/consulting/technological research etc., as part of ongoing cooperation 24%
Access to laboratories and equipment e.g. located outside of the business unit 21%
Legal support regarding selling the results of R&D studies (licensing, selling rights to study results, incorporation, selling know-how) 21%
Training/courses regarding intellectual property rights 12%
Other 10%
TECHNOLOGY AND INNOVATION
SaMD, which stands for software as a medical device, is a type of software used in medical applications which does not constitute any part of the medical hardware. Regulatory bodies worldwide recognize the need to draw up common frameworks and regulations for medical device software. The purpose of this regulation is to better protect patients. The International Medical Device Regulators Forum (IMDRF) argues that some types of devices, just like pharmaceuticals, significantly influence patients and public health. As such, they require regulation to ensure their safety, effectiveness, and efficiency, with the result that the process is subject to certification. It is worth noting that a SaMD product that is being introduced into the market can be positioned in a much more favorable light for the client and potential business partners. Nonetheless, the results of the study conducted for the purpose of compiling this report suggest that two out of three startups do not have SaMD certification for their solutions, nor plan to apply for it in the future.

2/3 of the respondents do not plan to apply for SaMD certification.

Have you obtained or do you plan do obtain SaMD certification for your solution?

- Yes: 33%
- No: 67%
Completing the certification process gives a company a greater chance of surviving in the market

Clearly, the use of advanced algorithms and the available data to support physicians in decision-making, and involve patients in their treatment management, is of great benefit to the latter and will change the future of healthcare.

Nonetheless, for this transformation to be mutually beneficial, software manufacturers must make every possible effort to ensure that eHealth technology is monitored and bears no risks to patients. With patient well-being in mind, Roche has been improving personalized healthcare for many years, while investing in the development of technology and processes to produce digital health tools.

The benefit-risk ratio should be assessed whenever a company is about to produce a digital health solution. While it is obvious that a benefit analysis is needed (to assess the possible return on investment), risk analysis is often overlooked.

Moreover, disease diagnosis solutions or clinical decision-making support tools pose a risk to the users. This risk should determine how the solution manufacturer plans, develop and maintains its product based on the evaluated risk.

The risk analysis carried out at the planning stage enables us to determine to what extent our solution can be qualified as a
general lifestyle tool suited to digital health in the broad sense (i.e. well-being services, wearables) and to what extent it might interfere with patients' lives. Certification of the solution would demonstrate compliance with local regulations. CE certification may help our solutions stand out from those of our competitors and will certainly be a reason for our users (patients or medical doctors) to trust our software.

While the certification process will delay the launch of the solution, it will also surely mean that a company is better prepared to manage a full portfolio of certified products. It will also force the whole organization to change: the company will have to build a quality management system and hire a person responsible for compliance.

Small and medium-sized enterprises will be exempt from the second requirement. This creates a great opportunity for this kind of specialist on the market, but unfortunately there are few of them. This may turn out to be the bottleneck in the certification process for start-ups.

The above follows from a new regulation, Regulation 2017/745 on medical devices, which will come into force on May 26, 2021, and another regulation, Regulation 2017/746 on in-vitro diagnostic medical devices. Both of these regulations provide for a highly stringent approach to classification in terms of patient risk.

This may mean that a solution that has not currently been classified as software as a medical device (SaMD) will have to be re-developed to meet the new requirements. Due to this upcoming challenge, knowledgeable digital health software vendors need to begin analyzing their solutions now in view of the new requirements, to create truly groundbreaking solutions that will significantly improve patient care and treatment.

Justyna Ochal
Regulatory Partnering Leader, Roche
Cooperation between startups, medical doctors, and hospitals should become the foundation

One of the greater challenges in healthcare today, especially in oncology, is making the most informed clinical decisions based on structured knowledge regarding the biological and physiological processes taking place at different levels in our bodies, cross referenced with the available methods of diagnosis and available treatments. We are living in times where a new diagnostic device is created before we manage to learn how to interpret and understand the data produced by existing tools.

On top of that, there is a justified belief among the medical community that optimal decisions are the result of obtaining information from many different sources.

Therefore, it seems that one of the key drivers of innovation in the area of digital health should be software that combines multiple sources of information and supports clinical decision making; physicians themselves attempt to develop such methods.

Considering the situation, the fact that 33 percent of the studied startups have gained or plan to obtain SaMD certification for their solution is disappointing in my opinion – especially given that the startups which took part in the study declare that their products are mostly designed to facilitate or improve the process of diagnosis, provide personalized medical care or support decision making.

However, it is encouraging to see that 85% of startups are actively involved in research and development and the vast majority of them use artificial intelligence methods, which may lead to the need for SaMD certification at some stage. Even so, the lack of cooperation with doctors or hospitals in this aspect is worrying.
All ideas in this sector should be consulted with them during the early stages of development because they should be confronted with the reality as early as possible.

All ideas should be consulted at an early stage, as it is crucial to quickly confront ideas with reality. I often observe ideas that are actively developed by various groups that do not really have a chance to succeed because of the reality of the medical market. This is especially the case with startups that focus on the accumulation and analysis of real-world data and evidence - the clue here is to know how hospitals function and how doctors generate and collect data.

A lack of understanding of the healthcare sector often leads to situations in which a startup encounters barriers that hinder the broader introduction of their solution into medical practice. More than 50% of the surveyed startups responded that the lack of understanding of the technology and how to use its potential by the government (Ministry of Health, National Health Fund, Center of Health Information Systems) is a barrier.

In my opinion, this is far from being true, and the problem actually lies with the startups, which often can’t present direct measurable benefits of their solutions in a simple and convincing way. We should bear in mind that the implementation of such a solution on a broad scale is a very complex and costly process (decision makers must always take into account cost and efficiency analyses).

To summarize, I feel that the current startup market in the digital health area is not sufficiently connected with the sector or the healthcare market and this is its biggest weakness. It is demonstrated by the fact that, despite significant health service problems during the pandemic, more than 40% of the startups responded that the presence of COVID-19 did not affect their activities, and 15% do not have an opinion on this aspect.

Dr Jan Poleszczuk
Professor at Maciej Nałęcz Biocybernetics and Biomedical Engineering Institute of the Polish Academy of Sciences, Director of the Chair of Oncological Mathematics at the Maria Skłodowska-Curie National Institute of Oncology - National Research Institute.

In order to operate effectively, technology start-ups require an appropriate infrastructure. This is no different in the case of startup companies providing solutions for the digital health sector. It turns out that the most popular model of infrastructure acquisition used in the construction of those tools is taking advantage of popular cloud computing services, such as AWS, GCP, Azure, etc. They appeared in the responses of almost four out of ten respondents (38%).

On the other hand, one startup in four (25 percent) does not limit their activity to one such resource - they apply a combination of several methods of obtaining infrastructure. Computing clouds are more popular than buying their own servers and other required infrastructure (that is preferred by 23 percent of startups). 10% fewer companies chose to host their servers and infrastructure in the local IT market (13 percent).
The infrastructure solutions used by startups in the sector include the most popular cloud solutions, with nearly a quarter of the companies planning to purchase their own servers and tools.

What model of obtaining infrastructure do you use in constructing your tools?

- Popular cloud computing solutions (AWS, GCP, Azure, etc.) - 38%
- Combination of several methods of obtaining infrastructure - 25%
- Purchase of own servers and the necessary infrastructure - 23%
- None of the above - 13%
- Hosting servers and the necessary infrastructure in the local IT services market - 13%
- Other - 6%
- I don’t know/I have no opinion - 6%

Digital Health is a capacious term and companies operating in this sector apply different IT solutions. When asked which is the dominating character of these tools, they most often mentioned telemedicine (43 percent) and mobile applications, i.e. the so-called mHealth (41 percent). Web applications were also listed among the leading solutions (39 percent).

Telemedicine and solutions for diagnostics or healing patients remotely are especially significant during the COVID-19 pandemic, when both patients and medical staff are particularly susceptible to infection, and this, in turn, significantly influences the healthcare system.
The boom in telemedicine was certainly not started by the 2020 pandemic. As the report shows, all the startups building telemedicine solutions were founded in 2019 or before. However, it seems that telemedicine is currently “the thing”, being a common theme for startups of different ages, business maturity levels, and sizes.

So what is telemedicine exactly? The basic definition of “the remote diagnosis and treatment of patients” which, incidentally, is a perfect fit to pandemic times. So, unsurprisingly, out of questioned startups which reported positive revenues increase due to the current pandemic 85% are interested in telemedicine. For those with a high increase in the customer base, it is 60%. For comparison, at the same time, 23% of startups declared experiencing a negative impact of the COVID-19 pandemic on their revenues.

**Where does the true value of telemedicine lie?**

Telemedicine seems to be closely related to mobile and web applications. These are convenient interfaces for connecting to end users no matter the primary purpose of the product. Mobile and web apps are tools for immersive patient engagement. As such, they are an important synergic element in the value creation chain for patients and practitioners, alongside, for example, data or analytics.

Data visualization and marketplaces are intrinsically linked to telemedicine as well. They are relatively common among bigger companies that have a mature product.

As a general conclusion, we might anticipate that telemedicine will most likely continue to grow as a result of the pandemic. Enabling efficient remote diagnosis and treatment supported by advanced technologies is of indisputable value to the patient and as such is very much anticipated.

**Common research areas**

Of the companies focused on research, younger startups gravitate towards sensors and robotics. Constant advancements in microchip technologies and molecular chemistry makes detecting chemical and biological signals through sensors more accurate and efficient. This technology can be successfully applied to supporting diagnosis and patient self-monitoring. Robotics comes with support in precise operations and, in addition, it targets administrative or monotonous tasks that could save time for medical professionals with a clear benefit to patients.

The startups built on sensors were founded mostly in 2017 or later (60%). Similar figures can be found for robotics, with the latter also being smaller companies (up to 10 employees). From this perspective, it is worth keeping an eye on whether sensors and robotics become a new trend among Polish startups.

On the other hand, older startups focused on research are into 3D printing and
bioprinting, as well as neurofeedback. 50% of all those interested in 3D printing were founded in 2016 or even earlier when it comes to bioprinting and neurofeedback.

3D and bioprinting is a broad area with various possible applications like surgical tools, patient-specific surgical models, prosthetics or even creating artificial tissues and organs. The fact that older startups declare that they are still working in development phases might mean that these technologies are difficult or time-consuming to make them productive. Possible reasons for this complexity could stem from usage patterns, manufacturing, or a need for extensive certification.

Startups move towards the cloud

Startups are also following the trend of moving to the cloud for cheap and flexible computing power, operational convenience as well as remote-work accessibility. The majority of startups either use popular cloud computing providers (38%) or a combination of different ways of infrastructure provisioning (25%). Clouds are popular across all maturity levels since they offer flexible pricing and fast provisioning for product shaping and development. For mature products, they represent an easy scale-up option and cost management. Cloud infrastructure enables agility and could shorten the time patients need to wait for modern Digital Health products.

It's interesting to see that there is a fairly high fraction of startups that use on-premise infrastructure for their solutions (23%). The more mature and older the startup, the more often it has invested in its own infrastructure. On-premise infrastructure gives both absolute control and responsibility to a company on where and how the data is stored and protected. At Roche, we believe this control could be necessary to assure proper data security which should be treated both as an obligation, as well as a great privilege.

Younger startups rarely make on-premise investments and have definitely turned to flexible cloud infrastructure offerings.

The minority subscribing to server hosting services on the local Polish market might indicate either the limited capabilities of local Polish hosting providers or a lack of the cost-effectiveness of a regular hosting model.

Focusing on cloud infrastructure is a common trend not only for startups. Big companies apply the “cloud-first” strategy for their research more often, as it allows the quick deployment of proofs-of-concept or simply lowers costs fast and effectively.

Polish startups bet on AI

Only 22% of interviewed companies replied that the solutions they build do not contain any elements of Artificial Intelligence, meaning that AI is a primary driver for Polish startups.

Advanced analytics (46%) is the most common focus for startups, irrespective of their age, and maturity. Analyzing datasets is a foundation of decision support systems and applying ethical machine learning in a diagnosis is more often a focus of startups around the world. To make a successful analytical product, a company needs a certain level of resources to deal with the complexity coming from data volumes and computation.

Image recognition and computer vision (26%) could be bound with telemedicine and possibly remote diagnostics services. This is especially true given that none of these startups declared a negative impact of the pandemic and 31% declared a positive influence on their revenues. Applying huge processing resources to analyze medical images in an automated way is desired in many fields of medicine, from oncology to ophthalmology, and could greatly improve rapid and accurate diagnoses.
Natural language processing (14%) is significantly less popular, with it tending to feature in the case of mature and bigger companies: NLP is a fairly complex technology and might require more resources to make a solution productive. NLP technologies can support patients in a whole range of applications, like pre-screening chatbots, medical documentation digitalization, search engines, or symptoms coding.

VR / AR are a more common focus for younger startups and most of these are still in the phase of product shaping and development. It looks like we observe a niche that newcomers are trying to fill with their solutions. It will be very interesting to see the outcomes in the upcoming future.

This technology has extraordinary potential. For example, it could change the way a modern diagnostic laboratory operates by providing a remote support service - not even mentioning surgery planning or explaining complex medical conditions to the patients.

Medical data processing patterns

Digital health is closely related to medical data processing and GDPR has placed a lot of responsibility on companies when it comes to patient data protection. As a result, startups that work on patient data have a much more complex legal and technological ecosystem to deal with.

Patient data is undoubtedly both the biggest chance for making personalized healthcare come true and a great obligation to work with. Advanced analytics of medical datasets is used to reveal the mysteries of human biology. By sharing data, the patient contributes to scientific progress and ultimately benefits from better treatment. At the same time, the patient expects their data being handled responsibly and supporting transparent ethical and governance frameworks.

As expected, the majority of the questioned startups are processing (37%) or producing patient data (25%). At the same time, 25% of companies declared that they are not processing any patient or medical data at all. It is hard to say what is the nature of the latter types of digital health products - we can only suspect that they are probably younger initiatives at a lower maturity level.

Software as a Medical Device certification

There is a great responsibility that goes along with producing software that is going to be used in medicine and the manufacturers of such software should consider SaMD certification for their product. The vast majority of surveyed startups (67%) replied that they are not going to certify their product. This is very surprising, especially taking into consideration the fact that 62% of these companies are going to either process or create patient data. It becomes even more surprising when we look at the most common reported purposes of products: improving digital diagnostics, personalized medical care, or clinical decision support.

Possible reasons could come from the strong need for agility and the limited resources a startup can spend on research. Certification may increase the cost of a given development and slow down the launch, factors which are evidently not appreciated. On the other hand, it is worth stating that a posteriori certification (if it becomes necessary) may mean development from scratch. So, in some cases, planning certification from the outset might be considered a saving.

SaMD certification brings a lot of benefits to patients and medical professionals, as well as to the product itself. It allows the software be applied to serious processes like decision support and integrating with other certified medical software or instruments. Certification can help limit compliance risks after product launch and, if carried out in a proper way, is an investment of a reasonable size.
Intellectual property protection

Patents are an extremely popular and important way of protecting intellectual property globally and startups choose this form of protection willingly. 50% of startups declared that they already have a patent, or they are in the process of submitting one. The younger the startup, the higher the fraction of companies without patents. This could mean two things: either younger companies are still in an early research phase or they are operating in areas less commonly protected with patents, like services or software development.

Polish startups tackle nontrivial medical problems and try to solve issues building cutting-edge solutions on modern infrastructure. The focus on Artificial Intelligence is testament to their extraordinary ambition as it requires responsible and ethical data usage, extensive data protection, and certification effort. Overcoming this complexity will strengthen the position of Polish startups in the Digital Health space globally and, perhaps more importantly, significantly improve patients’ lives. ■

Krzysztof Bokiej
Lead IT Expert, Roche
Three startups out of ten (29 percent) use medical sensors, e.g. those which can monitor the current level of patient activity.

Devices which the patient can use themselves at home are effective because they allow the patient to remain under the control of the doctor, while the direct physical doctor-patient contact is limited.

One in four medical startups uses IT tools to create data visualizations which provide for better planning and carrying out complicated medical procedures. Every fifth company uses marketplaces or other types of online platforms to provide medical services (22 percent).

Using 3D printers is a crucial technological element of the activity of 16 percent of subjects of the study. Slightly less, that is 14 percent of startups, use robotic technologies. Every tenth company indicated neurofeedback, referring to IT technologies used to analyze and process EEG signals for real-time brainwave imaging purposes.

Further down on the list are solutions such as wearable devices (e.g. smartwatches), smart drug delivery devices, bioprint (used for creating 3D tissue models), and nanotechnologies – that is the use of particle-sized structures. All of the above-mentioned IT solutions were mentioned in 6% of responses.

Artificial Intelligence is the foundation of digital health startups. AI algorithms play a vital role in the analysis, diagnosis, and monitoring of progress in the healing process. According to most experts, the use of artificial intelligence in medicine will become increasingly popular – it is expected that in the coming years we will witness an AI revolution in the context of healthcare. The vast majority of startups are already using these types of solutions today (78 percent of respondents declared that they did so).
2020 was defined by telemedicine, with greater numbers of outpatient services than ever before being delivered remotely.

Due to the isolation caused by COVID-19, almost overnight we witnessed a change in the manner in which conditions are diagnosed, treated, and how patients are monitored.

More and more small and large companies responded to the market need by introducing products and services which are meant to facilitate the provision of medical services, also through remote teleconsultations.

What do service providers and their beneficiaries expect from such a product?

First and foremost, security and this is not just about the safety of the patient. Physicians have learned to select certified medical products because the CE mark stands for a lower risk of improper diagnosis. Honest performance in the medical trade is mostly about the careful selection of methods. There are many commonly available gadgets on the market which are of dubious value in terms of providing support in diagnosis. On the other hand, there are still relatively few medical products certified for home use.
The second thing they are looking for are documented benefits of using the given product or service. A doctor will not recommend an innovative solution if it doesn't result in obtaining reliable data, which will give solid grounds for a particular treatment. The doctor and the patient must understand the result of the service to be convinced that based on the information it provides the right decisions can be made.

Finally, they expect it will be easy to use at home. Many safe and effective tools won't become popular, because the patient's home would have to be significantly adapted to use them, they require support from third persons, or they require the use of complicated applications or the installation of super-accurate sensors in particular places on the patient's body.

Creators of products and providers of services must understand that expecting a patient to take a pill in the morning or measure their blood pressure once a week is already a lot. If they have to use the device every day to obtain crucial information about the patient's health, in both the morning and the evening, you might as well ask them to perform a ritual at sunrise depending on the phase of the moon.

Within a few weeks, we observed a breakthrough in medicine which we have been expecting for years. The common presence of telemedicine surprises even those who have been promoting remote diagnosis and treatment for years. One thing is certain: telemedicine has proved effective and is here to stay.

Dr Andrzej Caćko, M.D.
Head of the Department of Medical Informatics and Telemedicine, Rector’s Deputy for University Digitization, Advisor at the Center for Medical Simulations and Innovation at Warsaw Medical University
AI as an integral element of an increasing number of sectors and services

The success of every startup depends on an innovative idea, a well-matched team, supporting partners, suitable infrastructure and financing, all of which give the company the comfort of being able to focus on the project and, at the final stage, ensure the commercialization of the solution obtained.

Poland is a unique country where combining all of those conditions is not easy, and the way particular elements are selected in most cases leads to failure before the phase of obtaining revenue is reached.

Initiatives that utilize artificial intelligence are at the center of investors’ attention at the moment. This is mainly due to the fact that those projects deal with vast amounts of data, which has tremendous value in itself. The effects of their work allow for savings in time and money, facilitate or replace the tasks performed by many people, which in turn drives the value of an enterprise. In most countries in the world, software solutions cannot be subject to a patent as long as they are not enclosed within some sort of a device. Meanwhile, data and analyses of data are of greater value than patents, naturally, if we assume a reasonable business model that uses them.

The startups which intend to embark on the adventure with artificial intelligence do not have an easy task ahead of them. Most of all they need qualified and experienced data analysts and AI software developers. Powerful machines with great processing power, properly configured equipment and planning on how to train algorithms by people, and also - how to provide the system with access to vast amounts of data. Without this, it makes no sense to apply machine learning.

The problem of infrastructure can be solved with the help of MLaaS (Machine Learning as a Service) providers, but you have to meet a list of criteria in order to obtain “credits” to build your solution. Among the largest companies supporting the development of startups you can find Microsoft with its Microsoft for Startups program, offering USD 120k in a two-year acceleration program, or Amazon and Google Cloud AI.
Due to the unique nature of our project, we have decided to join Microsoft for Startups (Azure Machine Learning Service). The use of ready-made technologies facilitates the fast training of models and their implementation and each program additionally offers many benefits, such as the support of dedicated experts, the ability to take part in training courses, access to the global marketplace, or marketing support. There is one catch: in order to join these programs, you need an innovative business idea and a major investment fund on board to legitimize your activity. Unfortunately, this is not so simple to achieve for most startups at the stage of proving their concept.

The sector of companies that base their activity on the mechanisms of artificial intelligence is still developing in Poland, but it seems that in the near future artificial intelligence will become an integral part of more and more sectors of the industry and the service marketplace.

Anna Rybka-Krysiak  
Chairwoman of the Board at Diagu.ai
Nearly half of the participants in the study (46 percent) take advantage of advanced analytics based on artificial intelligence, machine learning, and so-called deep learning, that is the process in which the algorithm learns to perform the tasks which are natural for the human mind, such as recognizing speech and images and using that information to create analyses and prognoses. Every fourth startup takes advantage of computer vision, a technology used to recognize images, where a computer converts an image into a digital description with the purpose of further processing and analysis.

NLP - Neuro-Linguistic Programming, i.e. the processing of natural language by artificial intelligence algorithms, is used by 14 percent of respondents to the study. 12 percent of them use VR (Virtual Reality) and AR (Augmented Reality). An example of that is the facilitation of surgeon training, who can safely prepare for complicated procedures using three-dimensional models of organs, which often significantly limits the potential for future mistakes.

One in ten startups in the study pointed to voice interfaces that allow for interactions with a computer thanks to a platform which can initiate an automated process and the carrying out of a particular activity. An identical proportion of respondents use chatbots for this purpose, which automate online conversations (either through a computer or a smartphone).

An important part of the activity of technology startups is the data provided by the users of their solutions. This is particularly important in the case of entities from the MedTech sector - they have access to medical data that are often sensitive and requires tight security and protection. However, it turns out that every fourth system used by Polish medical startups does not process any data from patients or medical institutions (25%).

37 percent of companies declare they have access to such data and process this information further (in an explicit or pseudo-anonymous form, that is in which the anonymity of the data can be reversed by using the appropriate key). A quarter of them not only process it but also generate new data referring to these patients or medical institutions.

The implementation of blockchain technology can play a significant role in the circulation of medical data and digital health solutions, as those types of IT systems require increased resistance to failures and cyberattacks.
We bring knowledge and capital to the table

Startups that are developing innovative ideas in the health sector constitute about 10 percent of the “population”. The authors of this report have revealed that nearly half of them are seeking venture capital financing.

Two projects which are outstanding in the domestic market are DocPlanner and Infermedica, which raised significant rounds of financing and are carrying out international expansion. Both these companies were founded nearly a decade ago and there is a lot of fresh blood in the market. While we were observing a growing number of innovations in the scope of health improvement, in 2019, we made the decision to launch the BioMed Academy - a project dedicated to startups, which were at the stage where they had a prototype or a working solution or service.

We invited 20 projects to join our educational program (15 in the area of Medtech and 5 in biotech) and 5 venture capital funds. A two-week marathon of training sessions and workshops between Warsaw and Nottingham ended in a demo day in front of investors. We are particularly glad that it didn’t turn out to be a simple test of presentation skills, but a closed deal for a PLN 7 million round of investment between Montis Capital and Biotts.

It’s not the only example of how we support the healthcare segment. PDF Groups provided financing to more than 30 startups in the sector, which translates into 10 percent of our entire portfolio. Considering the fact that the healthcare industry is listed as one of the target segments within the investment strategies of new funds, we can expect that their involvement will increase in the coming years.

Top 10 Healthcare startups
1. DocPlanner
2. Infermedica
3. StethoMe
4. Biotts
5. Genomtec
6. Telemedi
7. Aether Biomedical
8. Jutro Medical
9. Holo Surgical
10. Molecule One

Eliza Kruczkowska
Director in the Department of Innovation, Polish Development Fund

Rozalia Urbanek
Investment Director at PFR Ventures
Guaranteed exclusivity is a very significant issue in the case of developing innovative solutions. Patents that protect intellectual property and limit the risk of ideas being copied by competing entities may be the foundation for rapid business development, but it’s not always possible to obtain this level of protection. It is worth noting that, according to the provisions of patent law, software cannot be protected by patents and so software solutions are excluded from this type of protection altogether (and this refers to a share of the activities of some technological startups).

However, this is a complicated issue as it requires a distinction to be made between software as such, and solutions that are perceived as technological tools that use the software. The exclusion from patent protection refers to only the first category. In reality, it turns out that every second startup asked this question does not have its own patent and is not in the process of obtaining one.

Software solutions that are not an element of particular hardware cannot be patented Not only in Poland but in most countries in the world. But it’s the data and results of data analyses which constitute a greater value than patents, naturally if we assume that there is a reasonable business model in place which allows for using this information. Business initiatives that apply artificial intelligence are raising significant interest among investors these days. This stems from the fact that these projects process vast amounts of data, which is a value in itself.

Among those which took this path, the majority holds patents that are registered in Poland – this is the response we got from four in ten of the study participants (40 percent). One-fifth of them hold patents registered in other countries of the European Union (19 percent), and another 17 percent have registered patents in the United States. An additional 6 percent indicated that they hold patent rights in countries other than the US or EU member states.

50 percent of startups do not hold any own patents and are not in the process of obtaining any such protection.

**Does your company hold any patents, or is it in the process of obtaining one?**

- Yes, outside of Poland or the EU 6%
- Yes – in the EU 19%
- Yes – in the US 17%
- Yes – in Poland 40%
- No 50%
COOPERATION WITH PARTNERS
Cooperation with partners

In chapter three, we report on the scope of cooperation between the Polish digital health startups and their business partners. Among the responses gathered, the dominating field of cooperation mentioned by respondents was marketing activity, validation of business assumptions, and expert assistance in different fields of medicine and diagnostics. When asked about their expectations, there are a few differences between what they are looking for and what they get. It seems as if their needs in this scope are largely fulfilled.

When asked about what type of cooperation they expect to seek, most study participants mention marketing support - this type of response was given by more than half of the respondents. Nearly one in two of them require the support of experts with competencies that are absent among their teams, and specialists in the given field of medicine or diagnostics. The issues related directly to the required support in the field of medicine include the possibility to conduct clinical research or testing or a larger group of patients (35 percent) as well as access to laboratories and devices which are not available within the given business unit (28 percent).

Another high ranking type of support is help in validating business assumptions - this was the response of 40 percent of respondents, and 35 percent of them expect support in obtaining external sources of funding. Exactly one-third of startups (33 percent) need legal assistance in selling R&D results - licensing, selling rights to results of studies, commercialization of knowledge and know-how, etc. 28 of those surveyed seek ongoing business cooperation in the form of process and technology consulting, conducting proof of concept or technological research. One in nine listed training and courses on protecting intellectual property.

An analysis of results reveals an interesting phenomenon - Polish startups in the digital health sector more frequently turn to corporations (63 percent) when seeking support in tackling the above-mentioned challenges than to universities (55 percent). Nearly one in five (17 percent) indicates that they have reached out to an R&D Center.
Universities can and should become incubators for scientists looking to become autonomous in business. In fact, it should be the place where they first hear of such a career path, a place where ambitious researchers who are not afraid of risk can make the decision to become self-sufficient in a business and scientific sense, with complete awareness of potential risks and benefits of taking such a path.

Of course, it is optimal if the university is attractive for its employees both as a scientific institution and as a business incubator, so that regardless of the decision they make with regards to their career path the outcome is positive, conscious, and not just a choice of the lesser evil.

Moreover, just by creating a favorable environment for creating startups at universities, including medical schools, they should positively encourage not only future scientist-businessmen but also the entire scientific community gathered around such academic institutions.

Why? Because this type of environment forces people to move away from their routines, it begins to encourage them to boldly combine theory with practice and, what’s even more important, it creates a habit of approaching scientific issues suggested by their imagination and the surrounding reality with the right amount of courage.

In medicine, there are at least a few areas for natural cooperation between startups and universities. One traditional and highly explored field of cooperation is the creation of different medical devices with the help of talented scientists gifted with great creativity.
and empathy. This has led to the creation of hundreds and thousands of prostheses, implants, stimulators, monitors, surgical cameras and tools, etc.

These are devices which save patients’ lives and health, but also frequently bring profits to their creators. The field where we can see even more complementary roles of startups with potential and medical universities is bioinformatics and artificial intelligence. We can’t ignore the panache of those innovative 4.0 solutions created by startup creators gifted with unlimited imagination, but we should keep in mind that the uniqueness of AI solutions is directly proportional to the uniqueness and quality of the databases used to train those solutions.

And creating a complex database of clinical information, laboratory data or e.g. genomic data from thousands of patients is not an easy task for a startup and still remains within the domain of medical universities and cooperating clinical hospitals. For these reasons, among others, a mixture of the potential and complementary cooperation between a startup and university in the field of the so-called big data provides a change for creating truly original and clinically and socially useful bioinformatic solutions.

Prof. Marcin Moniuszko
Vice-Rector for Science and Development at the Medical University in Białystok

When asked about who they would like to cooperate with, the trend in preference to working with corporations proves even stronger. Three-quarters of respondents declare a willingness to establish business cooperation with a corporation. R&D Centers ranked second and were mentioned by 65 percent, while 49 percent would like to cooperate with a university.

**With what type of business partners would you like to cooperate with in solving the above-mentioned challenges?**

- A corporation: 76%
- An R&D Center: 65%
- A University: 49%
Most startups in the digital health sector cooperate with different types of medical institutions, yet 16 percent of them do not work with any entity in this field. In this case, similarly to R&D, the surveyed companies are most willing to cooperate with individual physicians or other medics. This is the response of more than every other startup (51 percent).

Clinics maintained by medical universities and focused on training medical doctors ranked second (47 percent). With regards to hospitals, the startups which participated in the study are evidently more willing to enter into cooperation with private institutions (40 percent) than public ones (33 percent). The further ranks are taken by diagnostics centers and walk-in clinics (both indicated in 28 percent of cases). Other health service institutions were indicated by nearly one in five survey participants (19 percent). A similar proportion (21 percent) conduct joint efforts with a pharmaceutical company.

Startups cooperate with different types of institutions in the healthcare sector, yet 16% of them do not work with any other institution in the industry.

What types of medical organizations do you cooperate with?

- Individually with doctors/medics: 51%
- Clinics: 47%
- Private hospitals: 40%
- Public hospitals: 33%
- Walk-in clinics: 28%
- Diagnostic centers: 28%
- Pharmaceutical companies: 21%
- Health service institutions: 19%
- Foundations and NGOs representing patients: 9%
- Government institutions (including the Ministry of Health): 7%
- Other: 9%
- We don't cooperate with any such institution: 16%
FINANCING AND THE ECONOMIC ENVIRONMENT
Medical startup business models

The target of digital health startups, i.e. the end-user of the solutions they offer, turns out to be differentiated, although evidently entities operating in the broadly understood healthcare system predominate. More than half of survey participants declared that they mostly address their services to healthcare institutions (54 percent), hospitals (52 percent), and individual physicians (52 percent). One in four solutions is meant for other employees of the healthcare service than doctors. There are also quite a few companies which do not target the employees or institutions of the healthcare service, but patients or individual customers directly (46 percent). Many startups provide services for corporations, offering them to companies as such and employees of those companies (42 percent). More than one in four startups (27 percent) cooperate with institutions of public administration and share their solutions with such entities as the National Health Fund or the Health Ministry. One in five survey participants have a product or service which is meant for insurance companies (21 percent).

The intended target audiences of startups is a diverse one, with the healthcare service, hospitals, and doctors in the leading positions.

To whom do you offer your solutions? Who is the end-user of your solution?

- Healthcare service units: 54%
- Hospitals: 52%
- Doctors: 52%
- Directly to patients/individual customers: 46%
- Corporations: 42%
- Institutions of Public Administration: 27%
- Other medical staff: 25%
- Insurance companies: 21%
- Other: 21%
Solutions for the digital health sector offered by Polish startups in nearly half of the cases have the intention of facilitating a medical diagnosis (48 percent). We turn to modern solutions in search of answers e.g. to the difficulties in reaching a certain medical specialist or for particular medical tests, where the waiting time is usually too long. Hence this is a field that requires improvement in Poland. On the other hand, improvement of the quality of digital diagnosis is the purpose of solutions offered by 44 percent of the surveyed companies.

An identical proportion of study participants declared that their products offer their clients personalized medical services. Four in ten startups indicated that the services they provide serve the purpose of supporting the decision-making process related to selecting proper treatment, and one in three is meant to increase patient engagement (33 percent).

One-fifth of the companies taking part in the study declared that their product or service has the purpose to gather and analyze real-world data or is meant for educational purposes (19 percent of responses in both cases). Another 15 percent define their purpose as a market access solution.

One in nine of the surveyed companies offer tools that facilitate following the recommended treatment and provide support to patient minders and disabled persons (12 percent). One startup in ten specializes in the rehabilitation of patients with disabilities (10 percent). In addition, the surveyed startups indicated that they intend to improve the process of electronic clinical outcome assessment (eCOA) – 6 percent, and genome profiling - 4 percent.
Coronavirus fever prevails

For the MedTech industry, as opposed to other industries – the pandemic outbreak became a catalyst for change. The processes which were taking place in the MedTech product market rapidly increased their pace. What was supposed to take years, now happens in a month, with yesterday’s gadgets becoming daily tools. Previously conservative sectors are opening up to new concepts.

A vast number of projects have arisen, many of which present technological excellence. Yet few of us are aware that when the pandemic dust falls, we will witness an oversupply of projects and products. The increasing expectations as to the demand for certain products will be painfully reduced. Those who have the best technologies and strongest commercial partners will prevail.

What conclusions should be drawn from the above? We must take advantage of these windows of opportunity. Whoever builds a healthy business model and strong partnerships at the right moment will successfully stand the test of time. Those who don’t manage to do so will find the window shut. All you can do then is knock, so that someone gives you a hand and lets you in, but this will cost. Many teams look at the market from the perspective of “here and now” and don’t see that the rapid dynamic which is now giving us tremendous opportunities is actually a sword of Damocles.

There’s no point working on products that can be introduced in 2022 because in the meantime others will take their place in the marketplace and you will have to knock at that window. There’s no point preparing for the scale measured at the peak of the “plague” if the future fixed cost anchor will pull us to the bottom. You have to be clever, find your place in a market which won’t evaporate, you must find customers who will keep buying your “post-plague products”.

In order to understand what is going on, we are trying to overlay some views of the past. Some processes should take this-and-this long to complete (vaccine), the dynamics should be such-and-such. We don’t take into account the fact that the pressure on decisions made today resulting from economic losses is unprecedented. Research expenses and pressure on decisions to speed up certain processes are huge. Because of that, you have to take your chances now or start looking for other ones.

Tomasz Gondek
CEO, SensDx
In the study, in addition to questions about the nature of services and products and the specifics of their customers, the survey also asked about revenues obtained by startups by selling their solutions. It turns out that during the last year, the average monthly income amounted to a maximum of PLN 10k.

This was the response of nearly one-third of our survey participants. 15% of the respondents achieve the average monthly income of PLN 10k-15k. Interestingly, the same percentage declared revenue amounts of PLN 100k-200k. Another 5 percent secured an average revenue of PLN 200k-500k, 8 percent generate between half a million and 1 million PLN. Revenues of one startup in ten exceed 1 million PLN per month.

What has your average monthly revenue been over the last 12 months?

- up to PLN 10k: 31%
- PLN 10k-50k: 15%
- PLN 50k-100k: 3%
- PLN 100k-200k: 15%
- PLN 200k-500k: 5%
- PLN 500k-1M: 8%
- Over PLN 1M: 10%
- I don’t know: 13%

The amounts of revenue are generated in the Polish market and in international markets in nearly equal proportions (on average 52 percent vs 48 percent).

What percentage of all revenues comes from the Polish market?

Average: 52%

The vast majority of Polish startups in the digital health industry (84 percent) are planning to expand their operations into a new international market in the coming 12 months, with Western Europe being the most common direction and in the crosshairs of 75 percent of study participants. Northern America ranks second at 42%, and the Middle East is indicated by 31% of responses. What’s interesting is that only 22 percent of startups intend to expand into a new market in our region in the near future. Perhaps in some cases, they are already operating in our neighboring countries, so they are planning to expand further. Nearly one in five indicate the Indian market (19 percent), and 17 percent point to China. Other Asian countries are included in the expansion strategies of every tenth company (11 percent). Russia is relatively weak in this setting (6 percent), which is the same number of companies as those interested in reaching the Australian market (6 percent).
Are you planning to enter a (new) international market within the next 12 months?

- Yes: 84%
- No: 16%

Where do you plan to expand?

- Western Europe: 75%
- North America: 42%
- Middle East: 31%
- Eastern Europe: 22%
- India: 19%
- China: 17%
- South America: 11%
- Africa: 11%
- Russia: 6%
- Australia: 6%
- Other countries in Asia: 28%
### Commercialization and Go to Market Strategies

What business models have the startups which took part in the study assumed? The dominant model is the sale of the main product - as indicated by nearly every third company (31 percent). A similar share of startups have adopted a subscription model (29 percent). One in ten mentioned a product, service, or technology licensing. The model based on selling access to API, or charging a one-off fee, e.g. in the form of a license for the software, an application, or an IoT device is preferred by 5 percent of respondents. Freemium models are less popular (2 percent), just like those based on shared revenues for products built to the client’s order (also 2 percent). As many as 12 percent indicate other models, and 5 percent declare that they don’t currently have any sales model. It is crucial to select a model that best fits the given product category, but at the same time allows us to respond to the requirements of the target group. Before such a solution is implemented, it requires a deep analysis of what is the optimal way of using it by potential users.

The main sales models are selling a major product (31%) and subscription (29%).

<table>
<thead>
<tr>
<th>What business model do you operate under?</th>
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</thead>
<tbody>
<tr>
<td>Sales of the main product (e.g. a medical device)</td>
<td>31%</td>
</tr>
<tr>
<td>Subscription</td>
<td>29%</td>
</tr>
<tr>
<td>Licensing of technology/ product/service</td>
<td>10%</td>
</tr>
<tr>
<td>API access</td>
<td>5%</td>
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<tr>
<td>One-off fee e.g. license for software/application/IoT device</td>
<td>5%</td>
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<tr>
<td>Freemium</td>
<td>2%</td>
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<tr>
<td>Shares in the sales of a product built for a client</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>12%</td>
</tr>
<tr>
<td>We don’t currently have a business model</td>
<td>5%</td>
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</tbody>
</table>
"Go to market strategy" – what to focus on

Are you meeting the target group's requirements?
The element vital for product success is a well-devised go-to-market strategy. There are always two key questions when developing a new solution for doctors or patients, namely: does the product address the needs of the target group? and are those needs addressed in other ways in the market? (unique value proposition). The key aspect is to take a look at the idea from the perspective of the patient, doctor, and payor. Ideally, we would conduct proper marketing research, but if we don't have the funds for that we should look for people with a mission who would be willing to share their opinions and to listen to our future customers, at least on social media.

We know from experience that this stage is critical. This is how mySugr was created, which is now used by two million people suffering from diabetes worldwide. A group of enthusiasts, who were themselves suffering, realized that they were lacking the tool motivating them to measure their sugar levels regularly. The whole story and business strategy centered around meeting this need.

Determining the unique need that our solution satisfies will become the basis for future conversations with potential investors and business partners.

Learn the rules of the game
While getting ready to build a strategy for a new digital solution, especially if we're entering a completely new field, we analyze the market. This can be done in-house or with the help of external advisors, or within a trade association representing the Med-Tech industry. This is where we need to invest time and funds. Otherwise, the entire R&D effort may prove useless or be significantly delayed.

When analyzing the regulatory and business environment, let's keep in mind that we should analyze legal regulations, both those currently existing and those that are currently being developed (the GDPR, Regulation (EU) 2017/745 of the European Parliament and Council of April 5, 2017, on Medical Devices). We also need to look at the options for the reimbursement of digital medical solutions, the technical requirements for cooperation with payors’ systems (e.g. HL7), any regulations regarding where to store medical records (in some countries medical records cannot be stored on foreign servers), and the current medical requirements which have to be met by all digital solutions within the given field.

Regulatory provisions in the Medtech industry are forever changing, and this is something which we have observed during the pandemic. Solutions that have been in the market for a long time (such as telemedicine) have entered a new dimension in terms of reimbursement, working with doctors, and serving patients.
There are some positive signals coming from authorities regarding the creation of the Policy for Development of Artificial Intelligence in Poland, which has been approved by the Council of Ministers Board for Digitization, and the Data Release program for 2021-2027.

A properly conducted market analysis will also help us crystallize the future business model for the sales of our product. There may be some pilot programs currently being implemented in our area by the National Health Fund (such as the recent POZ Plus program) or local government (healthcare programs, once they have been approved by the Agency for Health Technology Assessment and Tariff System or screening tests).

Proper market research will also help us identify potential business partners with whom we can commercialize our solution (e.g. telecommunications operators, insurance companies, or other Medtech companies which could complement our products).

In the above-mentioned cases, a positive effect of your product on the target group must be evident (such as the decreased need for hospitalization, fewer medical complications among patients).

**What business model to adopt**

Designing a business model and pricing strategy is a challenge to anyone launching a product for the first time. We know from experience that when licensing a digital solution for a specific period of time the price should correlate with the number of users of the application. Alternatively, as in the case of mySugr, a freemium model can be offered - where the basic functions are available for free and the user can gain access to the remaining features by paying a subscription fee (monthly or annual). In this way customers can get a taste of our digital solution and find out if it’s actually worth paying for the full version.

One third of digital health study participants (31 percent) said that their business model was based on selling a product or device. 29 percent declared that they sold their solution through subscription.

An interesting way of valuing digital services has emerged among companies that provide artificial intelligence systems that read radiological pictures. The companies take the hourly rate for the work of a radiologist and estimate how much time the clinic would save by adopting their AI-based solution. The most important thing is to select the model best suited to the product in question and which allows us to respond to the requirements of the target group.

In conclusion, we would like to quote the words of Frank Westermann, one of the founders of mySugr: “The source of mySugr’s success in the diabetes community and the subsequent acquisition by Roche was a combination of different elements: the right product (made by patients for patients), the right time (we started when the first iPhone was launched), a strong team of founders with a common vision, and shareholders who could always be counted on”.

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**Adam Hołubek**  
Digital Solutions Manager, Roche Diabetes Care Polska

**Jakub Chwiećko, M.D.**  
Medical Director, Roche Diabetes Care Poland
As many as 36 percent of companies do not generate any revenues from the sale of their main product or service at the moment and, perhaps surprisingly, this was the most common response in our study. Nearly three startups out of ten generate revenues regularly through this channel. One in five declare frequent, but irregular revenues. An additional 14 percent obtain revenues intermittently.

**Does your company generate revenues from selling the main product or service?**

- Regularly: 29%
- Frequently, but irregularly: 21%
- Intermittently: 14%
- No: 36%

**Flexibility and current activity analysis are the key elements of startup success**

Among the surveyed startups as many as 36 percent declared that they do not generate revenue from the sale of the main product and service. This reflects well what we ourselves observe at SiDLY. The concept of a startup in our market differs significantly from the way we define startups in the Western markets.

Many local innovators design amazing solutions using the latest technologies with great simplicity.
The problem arises when an attempt is made to turn an invention into an operating company that generates revenue.

Looking at our recent experience, I see a few key components that need to appear so that business can be conducted successfully. The first one is the ability to analyze current activities and flexibility if needed and if the market requires it. The ability to anticipate and adapt to the current and future market situation is important.

Many entrepreneurs are emotionally attached to the approach that the market has generally adopted. This can be disastrous. Recent changes in the market with the pandemic at the fore have led us as SiDLY to once again verify the customer segments to which we address our telemedicine wrist-band.

The hospital market has gained in importance, with the bands helping to ensure better patient monitoring in hospital wards with COVID-19 patients. Medical personnel can reduce their direct contact with patients (and thus reduce the risk of infection) and at the same time keep a constant eye on the patient’s condition, for example by monitoring saturation every 90 seconds. Without this technology, without the telemedical bands, this is not possible.

We can simultaneously ensure the safety of the staff and cost reductions - something that all doctors and hospital managers expect. ■
Startups use an extremely broad range of financing methods, of which the most important are the funds from the National Centre for Research and Development (NCBR). More than half of the companies reach for funding from this source (52%). The number of companies indicating their own sources of funding is 10 percentage points lower. Bootstrapping helps them postpone the moment of acquiring an investor. One third finance their activity by selling their own service or product (32%). The same percentage used the support of a domestic venture capital fund. In the case of foreign VCs, the percentage is 10 percent. The Polish Agency for Enterprise Development (PARP) finances 30 percent of the companies. The role of business accelerators is also quite significant - 16 percent of startups benefit from taking part in domestic accelerators and 14 percent reach out to foreign ones (e.g. EIT Health). Every ninth company finances its activities with the support of a strategic industry-based investor. The role of banks in this area is slightly smaller - one in ten companies has taken out a bank loan. Polish start-ups relatively rarely decide to support themselves through crowdfunding (4 percent). A large group of respondents indicated that they used other grants which were not defined in the survey (18%), and 14% of them have chosen yet another form of financing.

### What sources of financing have you used so far?

- **NCBR**: 52%
- **Bootstrapping with own funds**: 42%
- **Customers**: 32%
- **Domestic VC fund**: 32%
- **PARP**: 30%
- **Domestic accelerator**: 16%
- **Foreign accelerator (e.g. EIT Health)**: 14%
- **Strategic industry-based investor**: 12%
- **Foreign VC fund**: 10%
- **Bank (loan)**: 10%
- **Crowdfunding**: 14%
- **Academic incubator**: 0%
- **Other grants**: 18%
- **Other sources**: 14%
It’s not just about money

Seed? Startup? Growth? Expansion? Regardless of what stage your project is in, NCBR is the right address for you to go to if you want to develop in terms of technology or business.

Grants awarded in contests, transferred through Venture Capital funds, and investments by the latter are the most popular support instruments on our part. As a government agency we have access to resources, mainly from European Funds, and, thanks to the experience that we have accumulated over a decade, our cooperation with the business community as well as international partners, we have the appropriate know-how. More and more often we present new technological challenges, while at the same time we do not forget to support entrepreneurs and scientists, who have their own business ideas based on high-level technologies. While supporting startups, we take on most of the risks associated with the potential failure of the project.

NCBR funding can be obtained in several ways. The most popular, and confirmed by the data presented in the report, is by taking part in grant competitions, where non-refundable funding reaches up to 80% of the project value. Each year we organize several dozen calls for proposals: European Funds (so far nearly 15 percent of the submitted applications were for medicine and medical biotechnology), domestic programs, and competitions within international programs. In the context of the current EU financial perspective, it is worthwhile to pay particular attention to those recently announced - many of them are addressed specifically to micro and small enterprises. The budgets of these contests are small, but participation in them is a great opportunity to establish and develop cooperation with international partners and gain exposure to other markets.

Support, not only financial, but can also be obtained from the VC or CVC (corporate venture capital) funds launched by us in the BRIdge fund family. More than 50 BRIdge Alfa funds are currently conducting investment activity in the seed funding segment - this is the second most popular source of financing for MedTech start-ups. “Alfa funds” seek the best ideas of scientists and entrepreneurs and support them at seed and preseed stages of development, when the risk of failure is the greatest.
Project teams or young technology companies can also apply directly to the funds. A list of funds together with their specializations can be found at www.ncbr.gov.pl/bridgealfa. There are also other “bridging” venture capital and corporate venture capital funds which invest in technology companies at the stage of growth or expansion: TDJ Pitango Ventures (VC), Cogito (VC), EEC Magenta (CVC), SpeedUp Energy Innovation (CVC), Icos III (CVC). What is important is that the funds are constantly investing, so those startups which are looking for business and financial support do not have to wait for the announcement of new contests.

Regardless of the industry that you work in, the amount of experience you possess or the business model you have chosen, we invite you to join us. We’re waiting to respond to your questions at the Information Point: info@ncbr.gov.pl. Take a look at the possibilities that we have on offer as you can surely benefit from some of them.

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**National Center for Research and Development**

The role of NCBR is significant – 49 percent of financing for the development of Polish digital health startups comes from this source.

**What is the percentage of NCBR funding in the financing of your company’s development?**

Average: 49%

Which specific NCBR programs are most frequently used by the beneficiaries? More than half of the funds come from the Fast Track Program, sub-measure 1.1.1, which is part of the Smart Growth Operational Programme (SGOP). There is a subsidy for conducting research and development works aimed at developing innovative products, services or technologies that fit into the framework of national smart specializations. Every fourth startup with the support of NCBR takes advantage of BRIdge Alfa funds allocated for the implementation of ideas at the seed stage, where the risk of investment failure is the greatest, but the idea can be verified at a relatively low cost. On the other hand, support for the commercialization of R&D results with the participation of capital funds within BRIdge VC is declared by 14% of the respondents, and 8% mention other sources of funding, undefined in the survey.

**Which program have you taken part in?**

- **“Fast Track”** (sub-measure 1.1 SGOP) 54%
- BRIdge Alfa (BRIdge Alfa funds) 25%
- BRIDge VC (Joint Polish Investment Fund, TDJ Pitango Ventures, Cogito, SpeedUp, Energy Innovation, EEC Magenta) 13%
- Selling API access 8%
The dominant share of grants

At first glance, the characteristics of digital health startup funding sources are similar to other sectors.

According to Startup Poland’s report, “The Polish Tech Scene”, over 60 percent of startups are financed from public funds (NCBR, PARP), while in the MedTech sector more than half of them take advantage of The National Centre for Research and Development programs and 30 are funded by the Polish Agency for Enterprise Development.

Nearly a quarter of the survey participants declared that they have obtained funding from another type of grant defined in the study. Why does public funding enjoy such a high share? This is probably due to the fact that almost half of the startups are in the product development phase, where huge amounts of money are needed for R&D work, proof of concept, or obtaining the necessary certifications.

A typical feature of digital health startups is the amount of funds raised - one startup out of four received funding in excess of PLN 10M. In other industries, only 2% of startups can boast such a result.

Venture capital

Differences, on the other hand, can be seen in the participation of venture capital investors in financing medical startups. Over 40 percent of Polish start-ups have a VC investor on board, while among medical startups only one third received support from a fund.

Startups often highlight a lack of understanding of their products, or sector, as well as the long and costly process of development and registration of medical devices as the main barriers in cooperation with investors.
The amounts that startups have obtained in financing rounds raised to date from all sources are extremely diverse. Most often they amount to between PLN 1 and 3 million (23 percent), or above PLN 10M (22 percent). Other ranges of amounts are spread quite evenly, 13 percent obtained funding between PLN 500k and 1M, 11 percent indicated amounts of under PLN 100k, from PLN 100k and 500k and between PLN 3M and 5M. Slightly fewer companies obtained funding in the amounts of between PLN 5M and 10M (9 percent).

**Bootstrapping**
Due to the huge financial outlays required to produce the finished product, the share of funding from its own resources is 10% lower than in the case of the whole sector.

**Sales**
Sources of financing also include the sales of the main product or services, but only 36% of digital health startups have achieved this.

It is a blessing in disguise that nearly a quarter of them declare that the COVID-19 pandemic has positively influenced their business. We hope that these changes will become the basis for lasting effects and, in the coming months, they will become even more evident, especially in the area of cooperation between startups and corporate clients and hospitals.

Perhaps this will also change the investment focus slightly, both among the domestic and international investors, as financing is the dominant need among startups, not only in the digital health sector. ■

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**Magdalena Jagieło**
Board Representative Development, Startup Poland

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The amounts that startups have obtained in financing rounds raised to date from all sources are extremely diverse. Most often they amount to between PLN 1 and 3 million (23 percent), or above PLN 10M (22 percent). Other ranges of amounts are spread quite evenly, 13 percent obtained funding between PLN 500k and 1M, 11 percent indicated amounts of under PLN 100k, from PLN 100k and 500k and between PLN 3M and 5M. Slightly fewer companies obtained funding in the amounts of between PLN 5M and 10M (9 percent).

### What is the amount of funding obtained from all sources to date?

- **Over PLN 10M**: 22%
- **PLN 5M to 10M**: 9%
- **PLN 3M to 5M**: 11%
- **PLN 1M to 3M**: 24%
- **PLN 500k to 1M**: 13%
- **PLN 100k to 500k**: 11%
- **up to PLN 100k**: 11%
Digital health is primarily about improving the availability and quality of medical services. However, it has a measurable value, both for technology creators and companies introducing solutions to the market, as well as for whole economies. The importance of digitization in this area is all the greater because innovative solutions allow not only to reduce costs - including social ones - but are the driving force for other market sectors, e.g. in the area of cybersecurity.

Estimates for the global market talk of significant growth - up to the level of about 212 billion Euro in 2023. They need to be corrected because of consumer research before the pandemic indicated a slowdown in the implementation of digital solutions in medicine. The coronavirus has become a catalyst for digitalization and thus a chance to improve the market position of companies. This is confirmed by data from the report, which indicates that among the surveyed entities, it recorded more cases of growth (25 percent) than decreases (18 percent) in turnover and profits.

It is worth noting that almost 80 percent of companies have so far obtained financing of less than 10 million PLN. In my opinion, this is an opportunity for the dynamic development of this sector, all the more so because financing from NCBR and VC funds will still be available.

More than half of the companies already use the resources provided by the Center, especially the European Funds. As the examples of Polish MedTech companies show, it is possible to finance technological and business development from various NCBR programs.

Regardless of the number of technological or business challenges, developing the right business plan is one of the keys to market success in this highly resource-intensive sector, right from the R&D stage.

Przemysław Kurczewski
Deputy Director, NCBR
BARRIERS TO THE DEVELOPMENT OF THE SECTOR
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Financing turns out to be the dominant need for Polish startups in the digital health sector – almost two-thirds of companies (65%) declared that this was the case. Slightly more than one third indicated that their most important need is to acquire qualified employees (35 percent).

The surveyed companies also mention needs related to cooperation with other entities in the medical industry, such as access to patients (28%) and clinical trials (21%). Almost every tenth company indicated the need for access to specialized equipment.
The most important challenge that the surveyed startups must face is attracting new customers. Such a declaration was made by as many as 40 percent of them. Further development of the product or services is a challenge for more than one in four startups (28 percent), while hiring competent employees is slightly less than a quarter (23 percent).
Commercialization of products and hiring experts are the key challenges

We are a Polish technology company. Our innovative solutions for medicine are revolutionizing the way humans can be healed, and their lives saved. We are taking part in one of the fastest-growing industries in the world.

This dynamic development brings many challenges with it and nowadays our key task is to commercialize products – this is the moment which is the biggest test for startups and is sometimes the turning point in a company’s history.

In order to be able to think about entering the market, on the one hand, we had to meet the high requirements and regulations related to certification, and on the other hand, we had to build a team that could handle it. Today we can boast about achieving the level of quality confirmed by a class CE IIb medical device certificate, which gives us an advantage over the competition, but the process of building our team is still an ongoing one.

If we want to position ourselves as a company operating on international markets,
we need experienced specialists who are not only proficient in the areas dedicated to them but also know how to find their way around the issues of technology and innovation in the field of medicine.

Once such employees have been invited to join the team, the question of their retention and motivation arises. How to motivate, for example, a high-class clinical research specialist to work in a start-up that may not be able to afford high salaries and compete with a large corporation in this area?

Following in the footsteps of Western experiences, this problem can be solved by introducing incentive plans based on shares or warrants, which make the conditions of the entire remuneration package more attractive.

For many people, this is a very motivating model of cooperation which, in addition to the salary aspects, also allows them to identify themselves with the company to a greater extent and feel co-ownership. The role of a leader is also important, as well as the team’s confidence in the company’s imminent success. In these conditions having to work hard for success is not a barrier, but it actually encourages commitment.

Krzysztof Mędrala
Chairman of MedApp SA

The opposite category of challenges refers to financial issues. Every fifth startup declares that they have no capital reserves for the next 6-12 months (19 percent), and another 14 percent complain about the lack of financial liquidity. For 7 percent, delays in payments from their clients cause financial difficulties. Nearly one-fifth of companies (19%) face the problem of a prolonged product certification process and 16% of them do not have access to the possibility of testing their solution on a larger group of profiled recipients. According to the declarations of 14% of the respondents, they are struggling with delays in research and development work. Difficulties related to foreign expansion - the internationalization of its activities - are indicated by every ninth company (12%). Accordingly, 5 percent of the surveyed companies are currently struggling with implementing remote work procedures, lack of necessary infrastructure, and a drop in sales of a product or service.

Support from the public sector and administrative and legal facilitation to support the development of innovation help the development of startups in Poland. However, there are still difficulties resulting from intellectual property valuation, patenting, complicated administrative procedures, or shortcomings in the environment supporting commercialization.
Companies mainly struggle to acquire new customers, develop their offers, and hire staff.

What are the main challenges you are currently facing at your startup?

- Acquiring new customers: 40%
- Product or service development: 28%
- Hiring competent staff: 23%
- Lack of a capital reserve for the coming 6-12 months: 19%
- Prolonged product certification process: 19%
- Lack of opportunity to test the product on a larger group of profiled recipients: 16%
- Financial liquidity: 14%
- Delays in research and development: 14%
- Internationalization: 12%
- Delays in payments from customers: 7%
- Implementation of remote work procedures: 5%
- Lack of infrastructure: 5%
- A drop in sales of the product/service: 5%
- Employee retention: 0%
- Lack of legal support: 0%
- Other: 12%

There are also voices that the problem actually lies with the startups, which often can’t present direct measurable benefits of their solutions in a simple and convincing way while the implementation of such a solution on a broad scale is a very complex and costly process. Decision-makers must always take into account the cost/effectiveness analysis.
Financing supported by public funds should be adapted to the given product

We encounter numerous barriers at various stages of development in our activity, the most important of which are the level of financing, the issue of own contribution, communication with the investor, problems with manufacturers, cooperation with the Office for Registration of Medicinal Products, and even difficulties with raising round B of funding. In my opinion, financing with the support of public resources should be adjusted to the product that the startup is implementing. It is not possible to apply the same measure to a web application and a cardiac surgery device.

Level of financing
The level of financing available on the market and the structure of eligible costs do not meet the requirements for financing the development and registration of a Class III medical device. The cost of the process is about PLN 4-6 million. Financing to the tune of PLN 1 million (e.g. in the BRIdge Alfa program) is sufficient to make it through the stage of proof of concept and a patent claim.

The further stage of implementation, i.e. registration of the medical device, requires a so-called clinical evaluation. It is performed on the basis of one or even two clinical trials. The cost of one study is between PLN 1 and 3 million.

Hopes were raised by the Medical Research Agency - however, we still don’t have an offer for startups financed in large part by NCBR funds.

Own contribution
The Fast Track Program requires its own contribution at the level of about 20% and costs several hundred thousand Zlotys. You can declare that you will cover the costs from future profits, but it is unrealistic because a startup developing a Class III medical device will not start selling it on its own for a few years.

In addition, the structure of eligible costs makes it impossible to conduct clinical trials that have to be outsourced. Therefore, there are no programs dedicated to higher class medical devices, which could help finance the development of the device from concept to production in Poland, without selling the technology on the way.
Communication with a MedTech investor
Poland lacks a place - a communication platform - for investors and startups from the MedTech industry. Most of our projects were presented to investors with expertise with completely different market segments.

Lack of manufacturers
Unfortunately, there is still a shortage of large manufacturers of high-quality medical devices in Poland, who would be potential final recipients of the technology. Such manufacturers could become partners of the startup already at the stage of technology development and coordinate the process, with the intention to quickly initiate production.

Universities
Unfortunately, many universities and research institutes in Poland are not fit to cooperate with startups. This is due to a lack of procedures, a precise legal form, and experience. Often the regulations of these institutions often state that they will take control over the technology being developed, which is obviously impossible. The only thing startups can do in this situation is to pay for research as a service, which is an external cost, often perceived as unqualified.

Office for Registration of Medicinal Products, Medical Devices, and Biocides (ORMP)

ORMP should be a natural partner to the companies implementing new medical technologies. Help is required in the scope of drawing up clear guidelines as to what research and work should be carried out in the process.

Those guidelines must be very precise so that at the end of the project, when all the funding is spent, it doesn’t turn out that ORMP requires another regulatory study which will cost more than the remaining financial reserve in the project’s budget. This will immediately put the entire project in a difficult position.

Round B
It is worth noting that the second round of financing in the case of Class III medical devices is mainly for regulatory testing and these almost always constitute external orders. I believe that in the case of Class III devices, the public investor should take this into account and make this process possible through increased financing. Otherwise, by investing too small amounts of funds in the A round they expose the technology itself to failure along with its own (public) funds.

Grzegorz Suwalski, M.D.
Heart Surgeon and CEO at Quantum Innovations

What barriers in cooperation with government institutions do startups in Poland complain about? The key problem is excessive bureaucracy and an overly long legislative process in areas concerning their functioning. These issues are indicated by as many as 68% of respondents. Also, a significant part of them mention the lack of understanding of technology and the possibility of using its potential (54%). Less than 30 percent see a reluctance to cooperate on the part of government institutions. Only 7 percent of respondents declared that they do not see any problems between the company and the government.
The ordeal of Polish MedTech companies

It’s the year 2016. We have just started a new project with the purpose of building an automated hospital pharmacy. Along with a team of 8 enthusiasts, we are launching a moon shot, but we don’t know that at the time. Our first success was obtaining EU funding. We hire more people, and the work gets off the ground... that’s where we encounter the first obstacle:

**How to get the drugs to perform the tests?**
Our device is meant to repack 13,500 doses of medicine per day, so we have to obtain some out of date drugs for testing purposes.

But in Poland, this is simply impossible. Neither an official letter from NCBR confirming their support for the project nor any of the numerous legal opinions from our lawyers help us open any doors. CPI, NHF, MoH, pharmacies, wholesalers, they all remain deaf to our requests, because “the law does not allow it”. Yet, just like any startup, we don’t give up and we find a solution - we begin to pack beans and candy to simulate pills.

In 2017, our product achieves the first level of maturity, and we begin our search for an investor. We manage to reach the largest publicly noted medical companies. But they all expect us to demonstrate a working prototype installed in a pharmacy or a hospital. Here we encounter the second obstacle:

**Which hospital will trust an automated pharmacy which is repacking beans?**
Finding a hospital that will trust us takes us a whole year. Thanks to Prof. Piotr Kuna and Prof. Maciej Banach from Łódź, we launch our solution in a hospital. Before we do that, we have to clear any doubts at the institution regarding the patients’ personal data,
we prove that our device is not only safe, but it also won’t impose any risk on the hospital. Next, we prove that our device is safe from any hacker attacks. Then we make arrangements regarding the business conditions and means for rewarding the hospital employees who will help us implement our project so that there are absolutely no legal doubts. The following step is the integration with the Hospital Information System, which nearly drives us to bankruptcy and finally gathers all the data in order to create a “case” allowing other parties to make the decision to purchase our solution.

In 2018, in our opinion, the product is ready and it meets all of our assumptions. We want to take part in the recently announced tender procedure. We are fighting head to head with a leading company in the market for automated pharmacies. And here comes another issue:

**Tenders have long been a playing field for large companies**

Nobody trusts a Polish company which recently started dealing with robotics. Hospitals are afraid of the risk, and the new technology. Insurance companies don’t want to provide the necessary contract insurance, after all, we don’t have any experience. We can’t get any loans, because as a startup we don’t have any credit history or turnover. Many people pat us on the back, trying to convince us that “it’s great that someone finally does something like this in Poland”, and at the same time they inform us that they will happily become our third or fourth client because they can’t “take the risk of being the first”.

Nonetheless, we submitted the best offer in a tender for over PLN 10 million. And we wait another 12 months to sign the deal…

That same year, we took part in an acceleration program in the US. We learn how American hospitals work and we see how our technology can save them a lot of money, even though they’ve gone through years of experience and optimization and improvements of medicine management. In the US, medical errors related to distributing wrong pharmaceuticals are the cause of 65,000 deaths each year. Pharmacy automation allows us to save 8-30 percent of the cost and removes 99% of errors.

If that’s true, the savings in Poland could amount to 1 billion PLN each year, and more importantly, save many lives. But…

**How to prove that what’s obvious for the Americans can also be implemented in Poland?**

We return to Poland and try to put together some statistics for Polish hospitals. Yet, in Poland, the data regarding “pharmaceutical errors” and their consequences are not publicly available. Many hospitals actually argue that they don’t make any such mistakes. So we decide to raise the interest in our project at the Ministry of Health and again, we face another problem.

**Public offices and institutions only have time for proven solutions**

It turns out the Ministry doesn’t have the resources to speak to any startup that tries to “fix” healthcare services.

In the meantime, we’ve reached March 2020, and along with it comes the COVID-19 pandemic. Like many others, we feel pressured to help in the situation. As quickly as possible. At a time when the safest thing to do is to sit at home, we decide to build a medical breathing support machine.

Our goal is to create a simple life-saving device. With absolutely no necessary parts on the market, by about April we already have a prototype based on parts from the automotive industry, and at the same time we realize that our device is not yet a working respirator, but only a ventilator, which used incorrectly can cause more harm than good. At the same time, many other companies begin similar work, including some of the very well known brands, global corporations with access to immense financial resources and experts in the field.
We analyze their solutions, and their results are not much better than ours. So we begin our work from scratch.

In August 2020 we have a working device and promises from many countries in the world that they will buy our respirators. We begin the process of medical certification, and again we have a problem:

You praise what you don’t know because you don’t trust your own
The Health Ministry, just like the Marshals’ Offices, are not interested in a Polish-made product, which even though it is new, it is available on site. None of the domestic institutions has the authorization to validate this type of device against compliance with high norms and all European institutions have long waiting lists.

Yet another project which isn’t developing as quickly as we’d like it to, and as quickly as it could...

Such collisions of a medical startup with bureaucracy don’t allow it to quickly create and react to the dynamically changing needs in the market. They stop it right where the state should support the companies which have the purpose of fueling technological advancement. There are three things which could help change this situation.

First, is the creation of the National Center for Medical Research (a small hospital with perhaps 100 beds), with the purpose of allowing medical startups to test and implement their solutions in everyday practice.

Second is the cooperation between this Center and the Polish Center for Research and Certification in order to provide for faster and more efficient certification. And, finally, the development of a platform for the exchange of knowledge and cooperation between startups - in case of many projects instead of creating parallel solutions it would be much more effective to join forces and share resources.

Jakub Musiałek
Chairman of Pixel and UnitDoseOne
Medtech and public institutions

Considering the multitude of public institutions and people working in them, it is not easy to clearly state whether there is a problem in the cooperation between medical startups and the private sector. Medtech itself is a very specific industry - very often the user and the client are not the same people. By providing software or hardware for doctors working in the hospital, we make them the users.

Most often our paying customer is the hospital or, if we are lucky, the NHF/Ministry of Health. This distance between the service provider and the payer means we have to convince more people than in other industries.

And it is the people who create the institutions and, although they are very kind, they often operate in a system that is not very agile. It is worth showing empathy and understanding, and most importantly, check beforehand whether there are any legislative problems, because this is often not influenced by the people of the given institutions.

In our mind, there is a cognitive disorder called the status quo bias, which makes it hard to convince people of solutions which are actually better just because we undermine the current state of affairs. In reality, people do not like change.

As AIDA Diagnostics we went through this process. It is not easy, but feasible. The first step is always to find early adopters, people who are not afraid of innovation if it brings with it promises to improve the chosen process. Such people should be sought in the public institution with which we want to cooperate.

Fortunately, there are organizations in Poland that can help startups reach such people. Among the best partners of this type that we have had the pleasure to work with,
it is worth mentioning the Polish Federation of Hospitals and the KIDS Foundation. You should also be aware that the current Minister of Health is known for his willingness to optimize costs, of course with the highest standards of treatment, and more importantly, he understands how startups can change healthcare. I would expect that soon there will be an innovation cell in the aforementioned ministry, similar to the one created at the NHF. However, a positive attitude alone is not enough to knock on the door of the Minister of Health. You have to be professional and have evidence that your product will not harm anyone. Primum non nocere applies to MedTech as much as it does to other branches of medicine.

If I were to give advice on how to start working with public institutions, it is worth being visible in the first place. You can't expect that even with the best idea in the world, someone will immediately believe in you. To be noticed, a startup must build up the position of an expert in its field. This is a time-consuming process, but crucial to achieving success. I personally highly recommend using social media, especially the often overlooked portal LinkedIn. It is surprising how many innovation-oriented public sector employees alone use this portal. Often, these are the people who can make the one decision to speed up our project by many months.

At one point in our project, we went to the Impact’19 conference. Our goal was to meet one of the vice-ministers of health at the time, who was at the same event. Thanks to a short conversation, we managed to get his e-mail address, and this led to a meeting which in an hour allowed our project to move light-years. Standing in front of someone in such a position, keep in mind that these people often have a very positive attitude to innovation, and they also want to demonstrate their effectiveness.

As creators of solutions based on artificial intelligence we always suffer from a shortage of data. You have to be aware that the data we need may be available in the public domain. We were very surprised when it turned out that institutions such as Regional Blood Donation Centers are happy to share their data. From our first e-mail, it took us 3 working days to obtain data from the RBDC in Kielce, and on the way we discussed exactly what it was we needed by phone. It was one of the more pleasant collaborations in the history of our company.

To sum up, cooperation with public institutions can cause difficulties, especially at the beginning of the startup path, particularly if health is involved. However, if we knock on the door long enough, it will eventually open and our desired early adopter will appear on the other side.

Mateusz Pawelczuk
CEO, AIDA Diagnostics
RECOMMENDATIONS
Digital health is an area where the relation between technology, economics, law, and political and social aspects is particularly important. Each of these areas influences the dynamics of digital health development and its key role of bringing medical services closer to the patient. The use of the potential of digital health depends primarily on the development and implementation of innovation, as well as the effectiveness of the systems used to meet the needs of patients. The COVID-19 epidemic showed the extent to which digitization can support healthcare and how much the E-health project, implemented by the Ministry of Health since 2017, is needed in Poland. Recent events have also pointed out the areas for improvement. It was a test of the wide acceptance of digital health solutions by society and the efficiency of the solutions implemented so far.

On the basis of the experience gathered from the functioning of digital health providers, supported by the rapid spread of digital services during the pandemic, we have developed the following recommendations which, if implemented, should allow for more effective, efficient, and wider digitization of healthcare in Poland. Their aim is to ensure equal, safe, and free use of digital healthcare services by patients and they should be taken into account in the national strategy on digital health currently being developed.

The following postulates are particularly important at the moment, because the efficiency of the healthcare system, of which digitization is a key element, is of great importance for us to be able to fully return to the normal activity of the whole economy and all industries.
Linking digital investments to healthcare objectives

Following our recommendations will allow us to overcome the investment and technological barriers in the development of digital health in Poland. Open and transparent cooperation between business, academic, and non-governmental organizations is recommended. This will minimize the risk in the control of health data and technologies, which is a huge challenge for European governments, as emphasized by the World Health Organization. Poland should also continue to invest in the methodologies and tools that utilize the potential of data and actively use them in order to provide safe, high-quality healthcare services and create stable healthcare systems. EU funding mechanisms can play an important role in developing IT solutions for digital health and supporting data infrastructures.

Providing support for development of innovation and digital health by the public sector in the administrative and legal area

For several years we have been observing an increase in support from the public sector and the development of administrative and legal facilities to support innovation. This helps startups in Poland to develop creative solutions used in the area of digital health thanks to cooperation between startups and corporations. However, there are still difficulties, resulting in particular from the valuation of intellectual property, patenting, complex administrative procedures, or deficiencies in the environment supporting commercialization, which should be analyzed with the participation of experts from the scientific and business community, and the change in these areas should concern not only regulations but also public sector practices. The development of innovation in the field of health, including digital health, is more often associated with the risk of failure than in other sectors, so public institutions should accept the larger scale of the cost of innovation by allowing the failure of more projects developed over a longer period of time. Moreover, in the area of health, it is not clear whether the solution developed with a small initial commercialization potential will be more successful in the future than the solution with a larger initial implementation potential.

Therefore, the public sector should support the development of the digital health sector especially now, when it is difficult to determine the long-term perspective and effects of the pandemic. We have very uncertain investment conditions in which innovators and suppliers of technological solutions have to find their place, and at the same time, it is difficult to predict under these uncertain conditions which solutions will be successful.

In the area of digital health, administrative and legal support should focus primarily on increasing the amount of program financing, financing of digital implementations in medical facilities, and regulating for greater access to medical data for research purposes for the development of new tools.

At the moment, even if a startup gets funding and prepares a solution for implementation in the area of digital health, it is very difficult to commercialize such a solution. The reason is the lack of financing programs in medical facilities of the public healthcare system or a system of payment for the services carried out by doctors through the use of digital tools. Therefore, some startups are more successful in international markets than on the Polish market, and the increase in the number of funding programs for digital medical institutions may significantly change this.

The need to regulate greater access to medical data for research purposes for the development of new tools boils down to the development of new rules for access to research data, precise
definition of rules for anonymization of data, broadening the circle of entities obliged to provide access to research data (currently these are mainly research institutes and universities), as well as the introduction of legal regulations relating to the voluntary transfer of data by patients (the so-called "data donation") - medical data obtained in this way would be a significant help in the development of new solutions in the area of digital health in Poland.

**Introducing interoperability between the various digital health solutions and the entities responsible for their implementation**

The cooperation and compatibility of all the elements that make up the digital health system, which at the same time should not be too complicated, is crucial to ensure equal access to it for patients and also to ensure that practitioners work efficiently. For example, interoperability did not work very well during the pandemic when patients wanted to take advantage of electronic sick leave certificates. Many doctors were afraid to issue them after a teleconsult because of the audits that followed, which undermined the legal basis for issuing leave. e-sick-leave certificates were questioned in particular under the provision of the Medical and Dental Professions Act, which states that "a physician shall pronounce a person's state of health after prior personal examination or examination through information and communication systems or systems and after analysis of the available medical records of that person. Although the provision seems to clearly indicate the possibility of remote examination, the phrase "prior examination" during a pandemic has sometimes been interpreted as a need for personal examination. The lack of legal contraindications to issue e-certificates after the teleconsult also strengthens the provision of the law, according to which the doctor decides on the health condition of the patient on the basis of the methods and means of diagnosis available to him, which seems to exaggerate the possibility of issuing e-certificate after the teleconsult (Article 4 of the Act on the Medical Profession). Therefore, in order for interoperability in the area of digital health to work, there is a need for both efficient technological solutions, as well as the readiness of the entities to implement and apply them, cooperation between providers, but also the interpretation of the existing legal regulations in a way that makes it possible to use digital health services.

**Implementation of fully digitized medical documentation**

This will require the maximization of measures to ensure the security of integrated medical data, which are currently scattered across multiple databases of medical service providers. It will contribute to increased cooperation between healthcare providers and more comprehensive use of digital health solutions by enabling full access to medical records for both medical personnel and patients. This recommendation is also important from the perspective of interoperability in the area of digital health and the need to analyze medical records resulting from the Act on the Medical Profession, as many healthcare providers still do not exchange medical records in an interoperable way.

**Implementation of modern cryptographic solutions in the area of digital health**

This will ensure the greater security of sensitive medical data, thanks to the increased resistance of modern cryptographic solutions to IT system failures and cyber-attacks (blockchain is an example of such a solution).

**Participation of technology experts in drawing up digital health regulations**

The increasing use of new technologies revolutionizing the healthcare sector requires systemic changes in legal regulations, their interpretation, and their application. When introducing
changes in regulations due to the digitization of healthcare, it is necessary to involve technology experts in the process of developing those legal regulations, who, thanks to their technological knowledge, can show trends in the development of new technologies in the area of healthcare, enabling the creation of statutory regulations adequate to the dynamics of the digital health market.

**Taking into account the needs and opinions of patients when implementing technological solutions applied in the field of healthcare**

This is crucial in Poland because of the demographic situation caused by the aging of our society, which requires the rapid and wide implementation of digital health systems, and simultaneously due to the still existing digital exclusion among the "older generation" or the lack of trust of this group in technological solutions. It is necessary to respond to the needs of citizens who prefer the traditional healthcare system, who are at the same time the most numerous group benefiting from healthcare in Poland, as well as to carry out social campaigns and training at the local level, building acceptance and trust towards the solutions present in the area of digital health.

**Permanent implementation of solutions have proven their value during the COVID-19 epidemic into the area of digital health**

The epidemic has accelerated the use of digital health services by many citizens in Poland and showed how solutions such as teleconsultation, e-prescription, e-sick-leave-certificate, or the e-referral pilot, obligatory in Poland from January 2021, are needed. Those proven solutions are worth implementing on a permanent basis, especially since the end of the epidemic will cause a lack of legal basis for many mechanisms.

A good example of this is the way of confirming the identity of the patient, which during the epidemic is possible with the use of ICT systems. Until now it was necessary to provide proof of identity before a healthcare claim was made. Confirmation of identity through ICT systems used in the course of the epidemic has enabled the wider use of medical teleconsultations across Poland.

From the perspective of the aim of our report, which is to stimulate cooperation between the public sector, innovative companies, the academic community, and non-governmental organizations, the postulate of linking digital investments with the objectives of public healthcare and using the potential of start-ups and companies offering the latest solutions in the field of diagnostics and treatment of diseases is of particular importance. The need for broad and international cooperation in the field of public health is also emphasized by the World Health Organization in the study on the global strategy for 2020-2025. We believe that our report shows the directions of such cooperation and will contribute to popularizing a policy of openness, especially to startups that can offer solutions adequate to the needs of the digital therapy and diagnostics market which, like the innovative technology companies operating in Poland, is very dynamic and innovative.

The Startup Poland Team
1 Badanie zostało zrealizowane metodą CAWI (Computer Assisted Web Interview) na panelu Ariadna w dniach 22 lipca - 13 sierpnia 2020 roku

2 Raport Dealroom i Polskiego Funduszu Rozwoju Polish and CEE tech ecosystem outlook, lipiec 2020.


