BELGIAN
HEALTH TECHNOLOGIES

Belgian
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PRESENTATION OF THE SECTOR

1.1. Introduction to the Medical Technology (MedTech) Industry

The medical technology industry is a dynamic and innovative sector working to save and improve lives. With the vast array of products, services and solutions of medical technology they bring on the market, medtech companies improve patient outcomes and have a beneficial impact on health (living longer) and quality of life (living better). Moreover, through innovative devices and diagnostics, medtech companies not only improve the quality of care and life of patients but also the efficacy and sustainability of healthcare systems.

Medical technology in its many forms can thus be regarded in the same way as any other technology used to save, improve and extend people's lives. This means that medical technologies can be found at every phase of the patient pathway. They can provide support for the prevention of disease, injury or other conditions, e.g. by way of early detection tools, or establishing in vitro diagnostics to identify a specific condition, its development and treatment selection. Medical technologies also allow patients to monitor the status of an injury, disease or chronic condition and treat it. In this sense, medical technology in its various forms is found across the entire care pathway of a patient, even from before birth.

Today, we can distinguish between three main categories of medical technologies:

1. Medical devices (MDs), i.e. products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical, mechanical or thermal means. Examples range from simple devices such as medical thermometers and disposable gloves to advanced devices such as computers or software that assist in carrying out medical testing, implants, and prostheses.

2. In vitro diagnostics (IVDs), i.e. non-invasive tests used on biological samples (e.g. blood, urine or tissues) to diagnose a person's health. In this sense, IVDs provide quality information to healthcare professionals for diagnosis and well informed decisions. Examples of in vitro diagnostic tests include urine test strips, pregnancy tests, hepatitis or HIV tests, blood sugar monitoring systems for diabetics, etc. IVDs are, of course, also vital in the response to the COVID-19 pandemic.

3. Digital health and care, which refers to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle. Digital health and care have the potential to innovate and improve access to care, quality of care and increase the overall efficiency of the health sector.

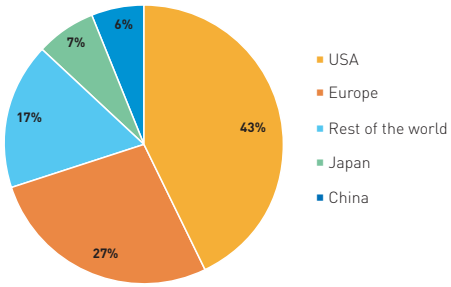
1.1.1. European and Belgian MedTech Markets: Facts and Figures

With a market size estimated at roughly €120 billion in 2018 according to MedTech Europe, the medical technology industry is a driver of economic growth and job creation across Europe. BeMedTech, the Belgian federation of the medical technology industry, estimates that the total medical technology sector in Belgium generates a total yearly

turnover of around €3.5 billion in 2018. Medical technology is thus crucial for Europe's and Belgium's economic well-being, providing quality employment, and makes a substantial contribution to Europe's balance of trade.

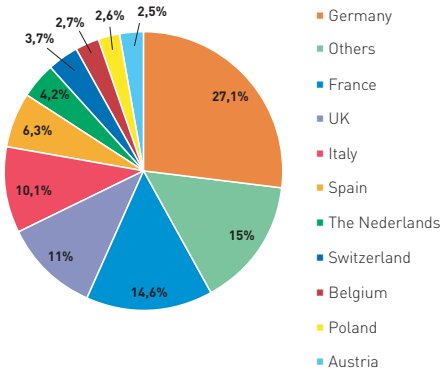
Based on manufacturer prices, the European medical device market is estimated to account for 27% of the world market. It is the second largest medical device market in the world after the US (around 43%). Moreover, the European medical device market has grown on average by 4.2% per annum over the past 10 years. Within the EU, Germany, France and the United Kingdom were the biggest medical device markets, with Belgium coming in eighth at 2.7%.

Europe in the global medical device market (2018)



Source: MedTech Europe, The European Medical Technology Industry in figures 2020

European medical device market by country (2018)



Source: MedTech Europe, The European Medical Technology Industry in figures 2020

Further information on the state of the industry at European and Belgian level to provide a holistic picture of the medtech sector can be found in MedTech Europe's and BeMedTech facts and figures publications, i.e. annually updated reports with robust and reliable industry data compiled from multiple sources. Innovation, companies and employment, and trade balance are some of the key indicators from the publications that will be reviewed here.

a. Innovation

As shown by the high number of patents filed by medtech companies, the industry remains one of Europe's most diverse and innovative sectors, with MedTech companies investing heavily in the development of new technologies that are beneficial for patients and other healthcare stakeholders.

As a result, the average global R&D investment rate (R&D spending as a percentage of sales) in the European medical technology sector is estimated at around 8%. Moreover, in this rapidly evolving industry, products typically have a lifecycle of only 18-24 months before an improved product becomes available.

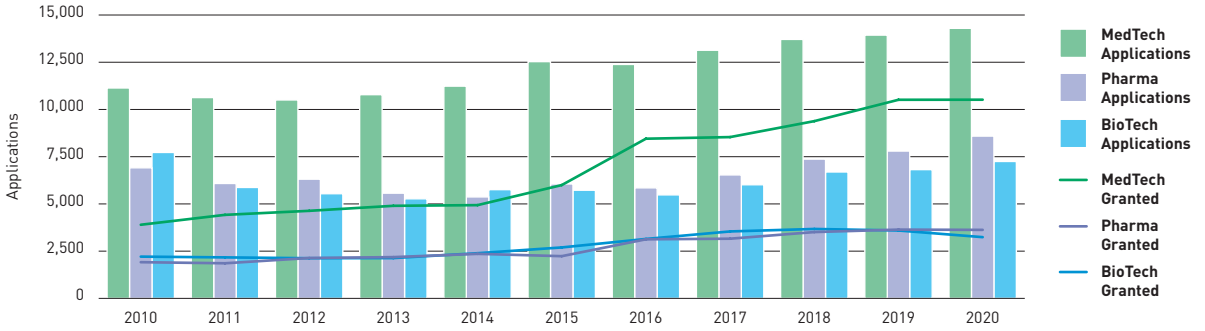
According to pharma.be, the Belgian General Association of the Medicines Industry, Belgium has the highest level of pharmaceutical investments in research and development per inhabitant among all the countries of the European Union. Together with its third position in pharmaceutical R&D employment per inhabitant, Belgium is therefore a leading player in the field of pharmaceutical innovation within the European Union.

In 2019, companies in our country's biopharmaceutical sector invested €3.8 billion in the research and development of new vaccines and treatments (up 7.7% compared with 2018 and up 50% compared with 5 years ago). As a result of the increase in research activities, companies are filing more patent applications; in 2019, there were as many as 359, or almost one per day.

At European level, more than 14,200 patent applications were filed with the European Patent Office (EPO) in the field of medical technology in 2020, representing a 2.6% growth in patent applications compared to the previous year. This means that the medical technology field accounted for 8% of the total number of patent applications, the highest among all the sectors in Europe (before digital communication and computer technology).

Furthermore, the number of EPO filings in the field of medical technology has doubled over the last decade, with the ratio of patents granted in the medtech sector growing continuously to reach 73% in 2020. In comparison, pharma and biotech patent applications were relatively stagnant, with the ratio of granted patents only around 50% for these two segments.

Evolution of European patents by technical field (2020)



Source: MedTech Europe, The European Medical Technology Industry in figures 2020

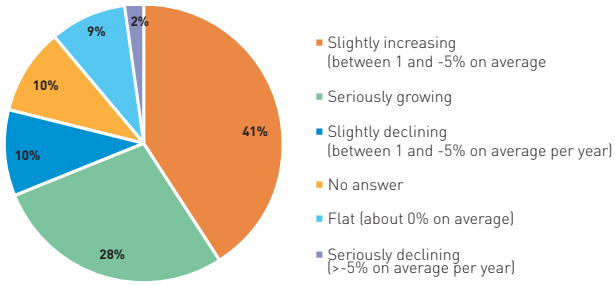
b. Companies and employment

In Belgium, over 200 companies are active in the medical technology sector and over 5,400 researchers were employed in biopharmaceutical companies, i.e. a 26.7% increase since 2015. There are more than 32,000 medical technology companies in Europe, with small and medium-sized companies (SMEs) employing less than 50 people making up around 95% of the medical technology industry. These European medical technology companies directly employ more than 730,000 people, with Germany having the highest absolute number of people employed in the sector. Belgium, for its part, is in ninth place with 17,800 jobs, although its European ranking in terms of medical technology employees per capita is higher. In fact, with 16 people directly employed in the medical technology industry per 10,000 inhabitants, Belgium occupies sixth place on a European scale.

Jobs created by the medical technology industry account for around 0.3% of total employment in Europe. These jobs are also highly productive, as the value added per individual employee is estimated at €160,000.

Moreover, according to a survey conducted by BeMedTech in 2018 among 106 companies in the sector, Belgian medical technology companies also expect their profitability to increase significantly in the coming years. This shows that the medical technology industry has an important economic and societal impact in Europe.

Sales revenue of Belgian MedTech companies – expected trends in the coming 5 years

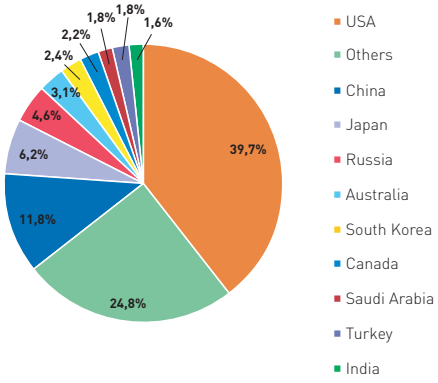


Source: BeMedTech, the Belgian medical technology industry facts & figures 2018

c. Trade balance

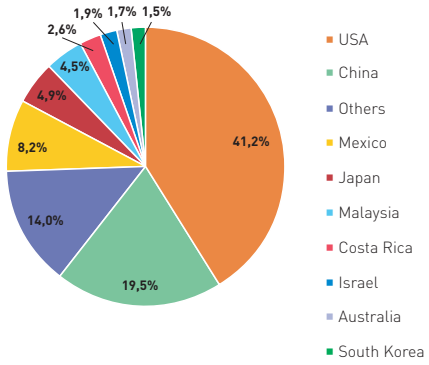
Belgium has strengthened its position as an importer and exporter of medicines, and has become one of the world's major hubs for the distribution and supply of medicines and vaccines. In 2019, Belgian exports of medicines and vaccines increased by as much as 16.3%, almost reaching the threshold of €50 billion. Between 2015 and 2019, exports increased by 21.5%. This exceptional growth is mainly due to the strong increase in exports to the United States, already a main destination for Belgian exports of medicines and vaccines, which increased by more than half. In 2020, Europe had a positive medical devices trade balance of €8.7 billion. The main European medical device trade partners were the US, China and Japan.

Top export destinations of the European medical devices market (2020)



Source: MedTech Europe, The European Medical Technology Industry in figures 2020

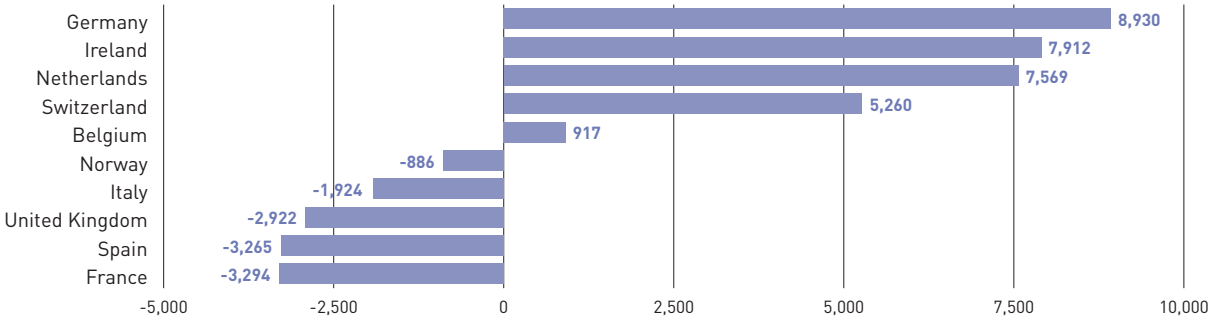
Top import suppliers to the European medical devices market (2020)



Source: MedTech Europe, The European Medical Technology Industry in figures 2020

The medical devices trade balance of individual countries varies a lot across Europe. In 2020, the international trade balance indicator, including European intra-community trade, was highest in Germany and Ireland, followed by the Netherlands and Switzerland. With a positive trade balance of €917 million, Belgium comes in fifth in Europe.

Medical devices trade balance by country, including intra-community trade (million €) - 2020



Source: MedTech Europe, The European Medical Technology Industry in figures 2020

1.2. A look at current trends

Within the medical technology industry, two trends are clearly seen as opportunities: the digitalization of healthcare and the shift of care outside hospitals, closer to the patient's home setting, through eHealth applications.

Driving the digitalization of healthcare and eHealth will help to solve some of the biggest challenges in healthcare and strengthen our healthcare systems at a time of growing shortages in the healthcare workforce, ageing populations and rising rates of chronic conditions.

1.2.1. Digitalization of health

One of the main drivers of progress in healthcare is digital development. In Belgium, a key player in healthcare innovation, the medical technology (or Health Tech) industry is a very dynamic and vibrant sector in terms of creating start-ups. In fact, many leading players in the medical technology industry supply high-quality products, services and solutions to the healthcare sector.

Digital transformation in the healthcare sector is a highly complex and lengthy process. Over the last decade, many applications in the context of administrative automation, eHealth, mHealth, electronic patient records, teleconsultation and telemonitoring platforms and portals have been developed alongside each other by the authorities, healthcare actors and companies. The design, development and implementation of common eHealth services require much time, budget and consultation between private and public stakeholders.

To speed up the integration of these innovations in the sector and to make them available to the patients that need them the most, Agoria, the Belgian Federation for the Technology Industry, beMedTech, the Belgian federation of the medical technology industry, and ABDH, the Belgian Association of hospital managers, have launched HealthTech.Belgium, an umbrella initiative that seeks to increase Belgium's visibility in the area of medical technology innovation and to coordinate existing initiatives in health technology. The initiators of HealthTech.Belgium have therefore defined clear objectives:

- To strengthen, facilitate and fast track the links between clinical needs and entrepreneurship
- To support the rapid and sustainable development of Health Tech start-ups.
- To scale up regional projects and attract local and international projects, have them tested and support them.
- To improve Belgium's positioning and visibility. Belgium should become a major player in Health Tech innovation and leverage its strengths by attracting innovation and talent from around the world.
- To take part and involve entrepreneurs in strong societal challenges, such as value creation, job creation and the practical improvement of our healthcare system.

As there are many Belgian entrepreneurs who demonstrate that they are able to bring added value to the health sector, it was essential for the public bodies in the sector to shoulder their responsibility for supporting them and make Belgium a role model in fostering Health Tech innovation.

The three regional organizations of the medical technology sector (lifetech.brussels, MedTech Flanders and MedTech Wallonia) also jointly implemented the MedTech Accelerator® program (www.medtech-accelerator.eu) to develop innovation as well as several initiatives in the MedTech sector throughout Belgium.

These initiatives are good examples of collaboration between the public (healthcare) and private (medical technologies industry) sectors to enable innovative digital applications to be introduced rapidly and effectively into the healthcare sector, to the benefit of patients.

1.2.1.1. AI and health: what is the place of AI in Belgian hospitals?

A study conducted jointly by AI4Belgium, Ernst & Young (EY) and medical magazine *Le Spécialiste*, in which clinicians, medical directors and hospital board members were interviewed, revealed the rate and modes of adoption of artificial intelligence (AI) in Belgian hospitals.

In fact, AI is a major source of leverage to improve the competitiveness of the healthcare sector and plays an essential role in the development of digital healthcare. Moreover, AI is increasingly present in Belgian hospital infrastructures and healthcare professionals are increasingly willing to participate in AI projects with

numerous potential applications: preventive medicine, diagnostic assistance, simplification of the patient pathway, patient flow prediction, optimization of costs and resources, etc. Today, two types of AI are used in the hospital environment: clinical AI, which involves the care process between physician and patient, and paraclinical AI, which involves the hospital management process.

The main goal of this study is to assess the way in which AI is or can be implemented in Belgian hospital establishments: for improving the quality of healthcare, for medical supervision, for diagnostic assistance, etc. In addition, the study aims to assess the level of importance that hospital establishments attach to AI, their awareness of the issues involved, the associated opportunities and risks, and how hospitals view clinical and non-clinical AI.

It is very clear that AI is considered to be of great importance for the medical/hospital world and for a rapidly changing health sector that is subject to strong economic constraints and increasing patient expectations. However, the health professionals surveyed are generally in favor of adoption in the medium term (five years) rather than immediate application.

Opinions on the deployment of AI solutions vary considerably according to the purpose for which they are intended. The questionnaire also focuses on the potential and benefits that healthcare professionals see in AI, the results of which are shown below as the percentage of responses:

- Increasing the speed and reliability of the decision-making process: 68% of FR and NL respondents
- Reducing the error rate: 62% of FR respondents and 49% of NL respondents
- Freeing up time for higher added value tasks: 51% of FR respondents and 57% of NL respondents
- Enabling a more personalized and adapted patient follow-up 51% and 47%
- Improving the economic performance of the hospital: 28% of FR respondents and 36% of NL respondents
- Improving health and quality of work life: 28% of FR respondents and 10% of NL respondents

The study also made it possible to identify the priorities defined by professionals in the hospital healthcare sector for the use of Artificial Intelligence in the exercise of their profession and activities. For 80% of the respondents, priority should be given to identifying the areas where AI can be applied, whereas for 60% of the respondents, the first priority would be to anticipate the necessary changes in the organization of the work and the transfer of tasks. Finally, 40% of the professionals in the sector consider it a priority to anticipate changes in practices and competencies.

As with any major technological innovation, AI will nevertheless profoundly transform medical practices and professions. The dehumanization of work and the loss of social ties are the major fears of the respondents, followed by the emergence of new psychosocial risks. These results also illustrate the need for changes in work practices and professions to leverage the potential of AI as part of an ethical and humanistic approach.

In fact, from an ethical perspective, one of the fundamental challenges of integrating AI into the medical field in the coming years will be the degree of flexibility that is considered acceptable for its integration. AI could thus serve as an additional reference and decision-making support tool (still driven and controlled by humans) or as an automated decision-making and diagnosis tool (operating fully autonomously without human intervention). Although the medical profession increasingly tends to rely on the support provided by AI, the question is who is medically responsible in the case of autonomous decision making by a machine. Can a physician shirk responsibility for a wrong decision and simply blame the machine for providing him with incorrect advice? In the same vein, to what extent can a physician be held responsible if he/she goes against an AI decision? This area is still unclear.

It is therefore essential to move towards a notion of explainable AI where artificial intelligence explains how and why it has come to its decision. This can be achieved through an automated explanation process or via interpretability logarithms.

While it is perfectly logical and natural for healthcare professionals to think in terms of AI working in support of "augmented medicine", the monitoring and improvement of the quality and safety of healthcare, the potential areas of application of AI in the hospital environment are not limited to the medical field. In fact, as already mentioned, AI also offers opportunities for the economic and comfort aspects.

From an economic perspective, it can help reduce the financial pressure on hospitals by providing a better analysis or interpretation of the dashboards. AI also helps to expedite certain administrative tasks through voice recognition to alleviate encryption, agenda or even database

management tasks in order to improve the patient triage and flow process by applying algorithms that automatically learn pre-existing protocols. AI can also be a useful support for logistics and provide valuable support in the maintenance of equipment, stocks, bed and space management.

Given the multitude of possible AI applications in the hospital environment, it is important that management and medical teams work together to define an AI strategy, starting from the medical project with the medical staff and subsequently moving towards a (financial and administrative) management strategy. As pointed out by Giovanni Briganti, psychiatric physician at ULB, a hospital physician devotes 85% of their daily schedule to activities that are not directly related to healthcare. In this respect, AI could bring huge time savings, thereby freeing up time to be devoted to the human aspect.

1.2.2. eHealth

eHealth, i.e. the use of different digital applications as support in the healthcare sector, is one of the most promising areas of healthcare innovation. Indeed, as we advance towards a more personalized, predictive, precision healthcare, digital tools will be key.

eHealth applications and medical technologies in the broad sense generate information and data that are critical for the prevention, diagnosis, treatment, monitoring and management of health and lifestyle. In this sense, they play a vital role in improving health outcomes and making health systems more efficient.

Today, more and more of this health data is digitized. It can be stored and accessed on electronic health records and personal devices, shared among patients and healthcare professionals. This makes procedures less complex, and the quality of care is improved. Moreover, the digitization of health data allows for the remote monitoring of patients, moving care from the hospital to the home and empowering patients with information to manage their conditions.

These are just some of the digital health opportunities provided by data generated by medical technologies. Ultimately, through person-centered care, eHealth will facilitate enhancement of the quality of life of patients and their carers as well as the advancement of public health and medical knowledge.

The seamless collection, analysis and use of patient health data can indeed accelerate significant improvements in how care is delivered, measured and improved. Advances in big data, machine-learning and artificial intelligence have the power to transform how we live our lives and protect our well-being. However, in order to realize the potential of data-driven healthcare, a number of issues need to be dealt with:

- legal and regulatory issues (protection of data privacy and safety);
- technology issues (cybersecurity, lack of interoperability and of commitment to common standards);
- business issues (reimbursement policies must offer appropriate incentives for the development of transformative technologies in the area of digital health);
- ethical issues (the advent of digital health affects the traditional doctor-patient relationship and is changing the way care is delivered).

1.2.2.1. eHealthMonitor, measuring the status of eHealth in Belgium

The eHealthMonitor, the first edition of which was launched in 2019 as part of the 2019-2021 e-Health plan, is a recurring survey on the knowledge and use of eHealth applications in the health sector in Belgium. This survey also focuses on expectations related to eHealth applications.

The purpose of the eHealthMonitor is not to provide objective data on the use of eHealth services (such as the number of connections, the number of files, the number of electronic prescriptions issued, etc.), but to document the subjective experiences of healthcare providers and citizens with regard to ease of use, satisfaction or reasons for using or not using a specific application.

The first phase of the eHealthMonitor, conducted between October and December 2019, consists of a quantitative part where more than 9000 healthcare providers and patients shared their experiences in the use of eHealth by completing a questionnaire. Respondents came from six target groups (general practitioners, specialists, pharmacists, nurses, nursing assistants, and citizens) and were asked to answer questions on the use of available eHealth services and the experience of the services.

This was followed in September 2020 by a qualitative part in which the statistical analyses were completed with

comments gathered from healthcare providers and citizens during discussion groups. During these interviews, they were given the opportunity to furnish more in-depth information. With the coronavirus crisis accelerating the digitalization of healthcare, this topic was also addressed during the interviews.

The results of the quantitative and qualitative research are combined in a final report. The quantitative data were also discussed in sub-reports for the respective target groups: citizens, general practitioners, nurses, nursing assistants, pharmacists and specialists. We will here briefly review the general results of eHealthMonitor from the perspective of five different issues. Details on the quantitative data by target group can be found at www.imec.be/nl/expertises/techtrends/ehealthmonitor.

1. E-HEALTH SERVICES AND DIGITAL APPLICATIONS

Healthcare providers (with the exception of medical specialists) were asked about their use of and satisfaction with the eHealth services available to their professional sector. The questionnaire revealed that some e-health services are widely used by healthcare providers, in particular Recip-e, a system that enables the creation and delivery of electronic prescriptions, and MyCareNet, a central, service-oriented platform that allows the simple, reliable and secure exchange of information with health insurance funds.

The questionnaire also surveyed the need for assistance with the use of e-health services by professionals in the sector. The results indicate that the need for assistance across all categories of providers is substantial and covers a much larger group of providers rather than only those that are skeptical about the technology. Moreover, while confidence in digital applications is relatively high among all healthcare providers surveyed, a sense of reluctance is sometimes apparent among general practitioners and specialists requiring increased assistance. This therefore indicates that it is crucial to adopt a supportive approach that promotes the deployment and use of eHealth technologies among healthcare professionals.

2. EXCHANGE OF MEDICAL DATA BETWEEN HEALTHCARE PROVIDERS

Written and telephone communication is the most popular with healthcare providers. In fact, communication between these parties still mainly takes place in a non-digital manner, and the number of available digital communication channels needs to expand.

For their part, citizens must give their informed consent to the digital exchange of medical data between healthcare providers. There is, however, a substantial difference between the number of consents officially recorded in 2019 (more than 82 %) and the number of citizens indicating in the questionnaire that they gave their consent (more than 46%). This difference can be explained by the fact that this matter is often dealt with hastily, or that it is just a small box that patients check without giving the matter much thought. As a result, in many cases consents were recorded without patients remembering having given their explicit consent. It is therefore essential to inform patients in a comprehensible way about what their consent entails and explain to them that they can also withdraw their consent.

3. ONLINE ACCESS, PATIENTS IN CONTROL OF THEIR HEALTH

The majority of healthcare providers surveyed know that patients can access their medical data online via a health portal and also consider it appropriate for patients to have online access to their data. Most of them have even already recommended it to their patients. Moreover, the health crisis caused by Covid-19 has also boosted awareness of these portals, which enable citizens to rapidly retrieve the result of their Covid test.

The majority of citizen respondents indicated their confidence in the use of an online health portal. They also believe that online access allows them to be better informed about their health data and/or treatment. However, the possibility for citizens to access their health data through such portals still needs to be more widespread. More knowledge and information on health portals could be generated.

4. ONLINE COMMUNICATION WITH PATIENTS

The healthcare providers surveyed are generally more reluctant to communicate with patients online. Their main concerns are that medical responsibility is not clearly defined, that online communication will generate a great deal of unsolicited communication, and that it is not appropriate for most of their patients.

Furthermore, online communication makes healthcare providers highly accessible to the patient, but may generate unwanted communications as well as an increased workload. Healthcare providers fear that the additional time they invest in online communication will come at the expense of physical contact with patients, which is still the top priority for them.

However, one advantage of online communication is that healthcare providers can answer questions at the most convenient time for them and even discuss them with their colleagues beforehand. The ability to ask questions remotely also makes care more accessible for some patients who otherwise might not have been present to ask them.

5. SELF-MANAGEMENT AND ONLINE TREATMENT

A minority of general practitioners, specialists and pharmacists have recommended the use of digital health applications. In practice, only a minority of citizens have used digital health applications. However, general practitioners, specialists and patients adopt a more positive attitude toward telemonitoring, where patients measure their own health parameters.

Telemonitoring is mainly seen as a digital tool for the regular monitoring of chronic patients or patients already under treatment. Continuous data monitoring also provides healthcare providers with more detailed information on a patient's health parameters, rather than an overview of the measurements taken during a consultation, which can only improve the continuity and quality of care.

The Covid-19 crisis has accelerated the implementation of teleconsultations, which have improved the accessibility of care when physical consultations were practically not possible. This applies in particular to patients with chronic diseases, but also to a first interview or a short follow-up discussion. It is also more convenient for patients not to have to travel and to plan a consultation more flexibly during the day.

However, the lack of information and the fact that the patient cannot be examined physically are two drawbacks of teleconsultations. Continuity of care must be guaranteed by drawing up a teleconsultation report, which takes time. Healthcare providers are also concerned that patients cannot always speak freely from home, thereby threatening to undermine the human aspect of consultations.

On the whole, Belgian healthcare providers and citizens alike largely perceive the benefits related to the use of eHealth services. However, they also voice some concerns regarding integration and interoperability, user-friendliness or even limited stability due to technical problems.

Furthermore, the first version of eHealthMonitor clearly shows that both healthcare providers and citizens lack knowledge about the possibilities of eHealth. For citizens, this concerns access to the technology - these virtual devices should never lead to the exclusion of certain groups in society that do not have the necessary means to use eHealth services - and to the knowledge required for its use. For healthcare providers, there is an increased need for support and information on eHealth.

The health crisis caused by Covid-19 and the resultant restriction of physical contact between healthcare providers and patients has opened the door for the introduction of several digital tools within the healthcare sector. Examples include the accelerated uptake of teleconsultations, the launch of various new eHealth services or functions, and the need for online communication channels between healthcare providers and patients. This situation has undoubtedly facilitated familiarization with the use of these digital applications by healthcare providers and citizens, and reduced resistance to them by some. Neverthless, healthcare providers and citizens alike indicate that they remain concerned about losing the human aspect due to the extensive digital transformation of care.

This first edition of the eHealthMonitor lays the foundations for the systematic monitoring of eHealth developments in Belgium. By interviewing healthcare providers and citizens at regular intervals, public eHealth policies should result in maximum benefit for society. The intention is therefore to repeat this survey for the purpose of identifying trends and developments, thus helping the authorities to make informed policy decisions.

1.3. The Belgian medical technology sector faces unprecedented challenges in times of pandemic

As the spread of the coronavirus COVID-19 continues to affect the health of people and the economy of countries around the world, the medical technology industry is working to support all ongoing efforts against this pandemic.

Whether by supplying COVID-19 diagnostic tests, ensuring that healthcare professionals can work safely and that citizens are protected by protective equipment (face masks, gloves, protective goggles and suits), or by providing respiratory support equipment during intensive care treatment, medical technology indeed plays a vital role in the response to COVID-19 and in building strategies to shape a 'new normal'.

To emerge from the crisis as soon as possible, a large number of clinical trials for treatment or prevention of COVID-19 are being conducted in Belgium. Furthermore, although the digitalization of healthcare is moving ahead at an unprecedented rate, particular attention needs to be paid to the processing of health-related data.

1.3.1. Belgium, leader in the conduct of clinical trials in Europe

A forerunner in the fight against COVID-19, Belgium has consolidated its leading position in the conduct of clinical trials in Europe, with 526 applications approved in 2019, 80% of which were initiated by the private sector. A clinical trial assesses the effectiveness of a new molecule and is therefore an important step in the development of a new vaccine or drug. Over the past five years, Belgium has consistently ranked among the top European countries in terms of clinical trial authorizations per capita.

The unprecedented health crisis has put pressure on the sector to develop a vaccine rapidly and provide the necessary treatments for COVID-19. Belgium has therefore made the most of its strengths as a benchmark country for clinical trials. According to the Federal Agency of Medicines and Health Products (AFMPS), **in December 2020, 38 clinical trial applications for treatment or prevention of COVID-19 had already been submitted in our country: 32 clinical trials for COVID-19 medicines and 6 for vaccines**. In the race for COVID-19 vaccines and treatments, Belgium's pharmaceutical and medical industry is thus playing a leading role.

In addition, the Belgian authorities have taken measures to further stimulate clinical research on COVID-19 in our country. The Federal Agency for Medicines and Health Products (FAMHP) has developed a fast-track procedure which allows it to obtain approval within a maximum of 4 working days for the clinical trial of a drug for treating or preventing COVID-19. This will enable our country to remain one of the pioneers in the fight against this virus. The FAMHP is not alone in approving clinical trials more efficiently and speedily, as similar developments have been seen at European level. The European Medicine Agency (EMA) has accelerated the approval process for certain vaccines. Steps that are normally performed sequentially are now being performed in parallel.

As mentioned above, most of the ongoing clinical trials are thus related to treatments against COVID-19, with the following taking place in Belgium:

- The Belgian site of the pharmaceutical group **Takeda**, in Lessines (Wallonia), was selected to provide treatments against COVID-19 based on plasma. This relates to a new phase 3 clinical trial to prove the efficiency and safety of this type of therapy in fighting the pandemic.
- The British pharma giant **GSK**, whose world center for vaccines is based in Wavre and Rixensart (Wallonia), tested a monoclonal antibody, initially developed to treat rheumatoid arthritis, for the treatment of COVID-19 symptoms.
- Researchers from **VIB** (Vlaams Instituut voor Biotechnologie), **UCB Ventures** (the venture capital branch of the biopharma group UCB), the Belgian fund for life science **Fund+** and the **SFPI-FPIM** (the Belgian Federal Holding and Investment Company) have joined forces to bring to life the spin-off ExeVir Bio for the purpose of accelerating the development of their antiviral therapy based on lama's antibodies. The new spin-off leverages the technological platform of nanobodies that it has developed to generate viral therapies offering a broad protection against the coronavirus.

Clinical trials against COVID-19 on vaccine candidates have also taken place in Belgium, such as:

- The German biotech **CureVac** started its phase 1 clinical trial in June 2020 on 168 volunteers, aged 18 to 60, in Belgium (in collaboration with the UZGent) and Germany. Its research is financed by the CEPI (the Coalition for Epidemic Preparedness Innovations), whose goal is to financially support research of vaccines for major epidemics or pandemics, such as the COVID-19 pandemic.
- **Janssen Pharmaceutica**, the Belgian branch of the American healthcare company Johnson & Johnson, launched a phase 3 test on 60,000 people all over the world in September 2020. This test followed a previous successful stage with Belgian volunteers that had been tested at the UZGent.

COVID-19 vaccines are also being developed in Belgium namely by ExeVir, a clinical stage company developing single-domain antibody-based therapies that help patients ward off viral infections. Its lead candidate XVR011 is in accelerated development as a COVID-19 therapeutic. Moreover, the company eTheRNA, whose interview can be read on page 44, is developing an mRNA vaccine for SARS-CoV-2 (COVID-19). It is composed of a spike protein and a daisy chain construct with conserved epitopes from structural and non-structural proteins.

In terms of the production of COVID-19 vaccines, Belgian pharmaceutical companies are also among the leaders in Europe namely thanks to the central geographical position of Belgium and its state of the art multi-modal logistics infrastructure. As a matter of fact, **three vaccine-developing groups have decided to carry out part of their production in Belgium: Pfizer, GSK and AstraZeneca**.

The Puurs site of Pfizer has been selected to be part of the four worldwide sites of the American group to produce the vaccine against COVID-19, which is being developed with German laboratory BioNTech. In addition, the Antwerp-based factory plays a major role in the logistics chain.

The Wavre site of GSK will contribute to the production of a billion doses of adjuvants, destined for the COVID-19 vaccine, which are being developed in collaboration with Sanofi.

AstraZeneca entrusted the production of the active substance of its vaccine, which is being developed with Oxford University, to the French company Novasep. Production will be carried out at its Belgian site in Seneffe (Wallonia).

1.3.2. Digitalization of healthcare in times of pandemic

As already mentioned, the pandemic has also accelerated the digitalization of healthcare. The medical technology industry was immediately mobilized to deal with the devastating health consequences of the coronavirus. All kinds of new technologies with high added value have been developed by the industry.

New medical technologies, namely digital health technologies (DHTs) and, in particular, mHealth applications, may offer a solution to the immense challenges facing the healthcare sector during this health crisis period. These DHTs, for example, accessible via smartphones and tablets, keep patients out of hospital and avoid any physical contact between patients and health professionals.

At the same time, these DHTs guarantee the same level of quality and continuity of care. And they do so in a safe home environment. In fact, in the current medical context, the appropriate use of mHealth applications for telemonitoring, telediagnosis and digital therapy is highly beneficial in terms of prevention, diagnosis, treatment, clinical follow-up, healthcare management and medical decision making.

Since the coronavirus crisis is also creating a shortage of medical resources (both equipment and infrastructure), it is particularly important that only patients who really need medical help are hospitalized. In this sense, mHealth applications allow for proper patient triage, both at home to better identify patients who need to go to hospital, and in the hospital itself to make a more accurate diagnosis.

Some applications developed by Belgian medical technology companies have been used for COVID triage in Belgium. They ask relevant medical questions in advance so that physicians are better prepared and appointments can be organized more efficiently. Such applications avoid unnecessary appointments and can be used to determine whether a person is likely to be infected by the virus (screening or even, based on medical images, remote radiological diagnosis) and whether medical consultation or hospital admission is necessary.

Several digital telemonitoring platforms are also fully adapted to monitor possible COVID-19 symptoms. Patients with mild symptoms can thus be monitored remotely using telemonitoring applications that transmit daily information to the physician based on relevant parameters such as body temperature, breathing problems or muscle pain.

These data-driven applications allow the evolution of the epidemic to be analyzed and individuals most at risk to be identified. The use of smart algorithms, for example, allows the collection of all possible data from source documents within the hospital and the creation of a comprehensive register to map treatments and their success rates for the hospital and the government.

COVID-19 puts enormous pressure on the entire healthcare system, which is why non-COVID-19-related pathologies are also supported by DHTs. In fact, to avoid doctor and hospital visits and unnecessary patient contact as much as possible, various digital health technologies enable close and remote monitoring of patients with a pre-existing condition, for example, people with heart disease.

Some patients suffering from chronic diseases such as diabetes are also less likely to visit the hospital now due to COVID-19. However, these people can be easily helped with mobile applications that enable patients to share their glucose values easily and remotely with their doctor on a secure platform. Individuals with other pathologies such as epilepsy, multiple sclerosis, respiratory disorders or skin cancer, can also be closely monitored and treated using digital medical technology.

1.3.3. What will be the benefits of mHealth applications for society after the health crisis?

Twenty-six CE certified mHealth applications are currently listed as medical devices on mHealthBelgium, the Belgian platform for mobile applications that are CE-marked as a medical device (see table below). With their high degree of multifunctionality, these applications, which have proven their security and performance as CE certified medical devices, support remote education, diagnosis and treatment and make teleconsultations perfectly possible. Telemedicine in all its facets and forms is therefore the way forward.

It is true that since the outbreak of the pandemic, many mHealth applications have clearly demonstrated their added value. These digital health technologies in fact provide essential care (monitoring, diagnosis, treatment) and access to education, wherever the patient may be, thus relieving the additional pressure on healthcare providers that is now undeniable. And they can continue to do so after the coronavirus crisis.

The industry has also been very quick to adapt these existing applications and extend their functionality, while at the same developing new applications and platforms that can immediately be utilized in these difficult and confused times where COVID-19 is putting our healthcare system under enormous pressure. These digital medical applications will continue to be widely usable for society after the coronavirus crisis.

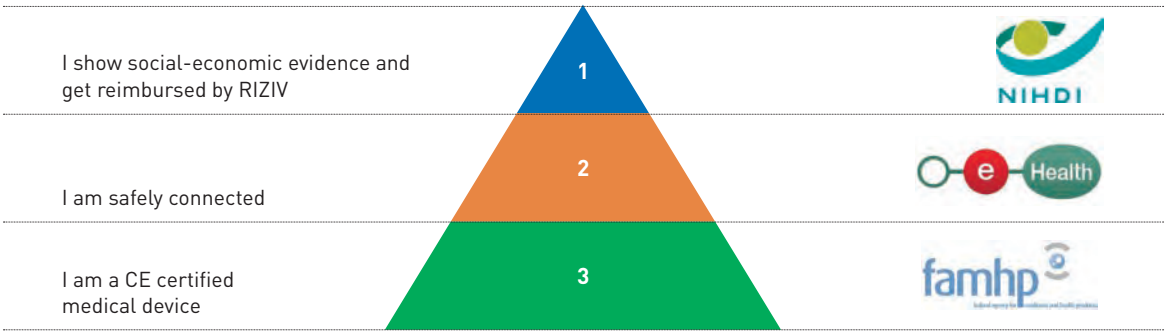
mHealthBelgium, also known as mobile health Belgium, is a unique Belgian platform for mobile apps that centralizes all relevant and required information on mobile apps for patients, healthcare professionals and healthcare institutions in three languages (English, French and Dutch). The information is related to CE marking, data protection, communication security, interoperability with other IT systems and the way in which the app is financed.

With the intention to integrate mobile health apps in the Belgian healthcare system, the mHealthBelgium initiative was launched by the Belgian federal government in 2018 and its platform went live for the first time in January 2019. mHealthBelgium consists of a validation pyramid with three levels. A mobile medical app always enters at the lower level, M1, and can then climb in hierarchy via M2 to the top level, M3.

In order to categorize the various medical digital platforms, mHealthBelgium involves multiple stakeholders. The platform is managed by beMedTech (the sector federation for the medical technologies industry) and Agoria (the sector federation for the technology industry), in close cooperation with three national authorities:

- The FAMHP (Federal Agency for Medicines and Health Products), the competent authority for ensuring the quality, safety and efficacy of medicines and health products, including medical devices, is responsible for M1-level validation.
- The eHealth Platform promotes and supports the provision of a well-organized, mutual electronic service and exchange of data between all healthcare stakeholders while safeguarding data security, the privacy of the patient and the caregiver and respecting medical professional confidentiality, and is responsible for M2-level validation.
- The NIHDI (National Institute for Health and Disability Insurance) is responsible for the refunding of medicines, medical devices and medical provisions and for M3-level validation.

The validation pyramid



Level 1 (M1) determines the basic criteria for an app. Three criteria are applicable:

- CE declaration as a medical device is submitted;
- Voluntary notification of the mobile app to the Federal Agency for Medicines and Health Products (FAMHP), during which the CE marking and compliance with the rules and regulations for medical devices are confirmed and can be checked;
- The app and the parent company declare that they comply with the EU General Data Protection Regulation (GDPR).

Level 2 (M2) is based on interoperability and connectivity to the basic services of the eHealth platform. Mobile healthcare apps that are approved as M2

- meet the basic criteria of level 1;
- have been subjected to a risk assessment (developed by an independent organization and included in mHealthBelgium), after which they have proven to meet all criteria imposed regarding authentication, security and the use of local e-health services by means of standardized tests (where applicable).

Level 3 (M3) is reserved for apps for which the social-economic added value has been demonstrated and which are financed by the competent government authorities, after approval by the NIHDI. M3 apps must meet all criteria of level 1 and the (applicable) criteria of level 2 in all respects.

In this sense, the development of level 3 of the validation pyramid represents a real breakthrough for digital healthcare in Belgium, in particular for all patients who are now assured of better healthcare services, better access to healthcare services, and potential reimbursement for the care provided.

Governments could play a more important role in this respect because they themselves derive many benefits from this digital evolution. Indeed, despite providing essential care to society, there is too little financial support for medical support technology and reimbursement is not yet provided by governments.

Please note that mobile healthcare apps can also be financed by means other than through the NIHDI. For example, hospitals may have their own financing resources, while patients or healthcare professionals may pay for the app themselves or health insurance companies may (partially) support the use of the app.

As of April 2021, there were 26 mobile health applications on mHealthBelgium that all have passed at least level 1 of the mHealthBelgium validation pyramid. Thanks to the validation pyramid, the number of DHTs should increase significantly in the coming years.

For more information please visit www.mhealthbelgium.be

1.3.4. Big Data in health: opportunities and pitfalls

The pandemic has also taught us just how important it is to have access to up-to-date and accurate data to take the necessary health measures and remotely monitor patients. Big Data is beginning to revolutionize healthcare in Europe as it offers paths and solutions to improve the health of individuals as well as the performance and outcomes of healthcare systems. Its potential is thus enormous. The availability of health-related Big Data can indeed have a positive impact on medical and healthcare functions. The collection and correct interpretation of data is therefore increasingly valuable. However, vigilance should be exercised with respect to the privacy of patients and the conclusions drawn from certain figures.

A specific definition of what Big Data means for health research was proposed by the Health Directorate of the Directorate-General for Research and Innovation of the European Commission: "Big Data in health encompasses high volume, high diversity biological, clinical, environmental, and lifestyle information collected from single individuals to large cohorts, in relation to their health and wellness status, at one or several points in time."

As reported by the Study on Big Data in Public Health, Telemedicine and Healthcare of the European Commission, the use of Big Data in healthcare can make a contribution at different levels:

- increasing earlier diagnosis and the effectiveness and quality of treatments through the discovery of early signals and disease intervention, reduced probability of adverse reactions, etc.;
- widening possibilities for prevention of diseases through identification of risk factors for disease;
- improvement of pharmacovigilance and patient safety through the ability to make more informed medical decisions based on information delivered directly to the patients;
- prediction of outcomes.

Starting with the collection of individual data elements and moving to the fusion of heterogeneous data coming from different sources can reveal entirely new approaches towards improving health by providing insights into the causes and outcomes of disease, better drug targets for precision medicine, as well as enhanced disease prediction, prevention and treatment.

Big Data have the potential to yield new insights into risk factors that lead to disease. There is the possibility to engage with the individual patient more closely and import data from mobile health applications or connected devices. These data have the potential to be analyzed and used in real time to prompt changes in behaviors that can reduce health risks, reduce harmful environmental exposures or optimize health outcomes.

However, the complexity of Big Data analysis in the health sector arises precisely from combining different types of information, which are captured electronically. To date, healthcare professionals can indeed benefit from an incredibly large amount of data, which is collected from electronic healthcare records, social media, patient summaries, genomic and pharmaceutical data, clinical trials, telemedicine, mobile apps, sensors and information on well-being, behavior and socio-economic indicators.

Furthermore, the data sharing approach can only improve outcomes for patients by detecting patterns and by turning high volumes of data into actionable knowledge for precision medicine and decision-makers. The potential value of Big Data in improving health is unlocked only when it is leveraged to drive decision making and, in order to enable such evidence-based decision making, it is also necessary to have efficient processes to analyze and turn high volumes of data into meaningful insights. This approach therefore requires all the relevant stakeholders to collaborate and build the technological infrastructure to house and converge the massive volume of healthcare data. In addition to the lack of appropriate infrastructures for data storage, other critical technical and infrastructural issues such as data heterogeneity, data protection, analytical flows in analyzing data could endanger a Big-Data-driven healthcare system.

However, the use of Big Data in healthcare poses new ethical and legal challenges on account of the personal nature of the information involved. Such ethical and legal challenges include the risk of compromising privacy and data security, the commercialization of private data or the use of data contrary to the interests of the people providing the data, as well as effects on public demand for transparency, trust and fairness while using Big Data.

This is why, in 2017, the Consultative Committee of the Council of Europe's data protection convention adopted "Guidelines on the protection of individuals with regard to the processing of personal data in a world of Big Data", the first document on privacy and Big Data to provide suggested measures for preventing any possible negative effects of the use of Big Data on human rights and freedoms.

Therefore, any government that uses Big Data in the health sector needs to establish affirmative policies to protect the health data of individuals in terms of confidentiality, privacy and security, while ensuring that advancements in science can take advantage of the open use of data for community well-being.

The EU Data Protection Regulation (GDPR) also protects patients' privacy and ensures their data can be shared safely for healthcare and research purposes.

Achieving effective and proportionate governance of health-related data will be essential for future healthcare systems, and it requires stakeholders to collaborate and adapt the design and performance of their systems to achieve the maximum innovative potential of information and innovation technology for health.

1.3.4.1 eHealth standardization group (hosting both HL7 Belgium and IHE Belgium)

In Belgium, all national eHealth stakeholders from the Health industry and the care sector are brought together through the **HL7 Belgium** and **IHE Belgium** working groups for the purpose of providing standards that facilitate global health data interoperability. These groups meet on a regular basis to try and tackle interoperability issues or develop guidelines and implementation guides in order to achieve better data interoperability within the health sector.

- **HL7 (Health Level 7) Belgium**

Set up in June 2019, HL7 Belgium is the Belgian affiliate organization to HL7 and a voluntary association of interested parties drawn from the supplier, user, provider and technical expert members of the Belgian healthcare community. It conducts its business according to the requirements of its affiliation agreement with the parent HL7 organization and the aims expressed in its mission statement.

Supported by more than 1,600 members from over 50 countries, Health Level Seven (HL7) International is a not-for-profit, standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information to support clinical practice and the management, delivery and evaluation of health services.

In this way, HL7 Belgium seeks to identify HL7 standards that are applicable to Belgian healthcare without any change as well as those that require adaptation or national implementation guidelines to meet Belgian requirements. Where Belgian adaptations, profiles or guidelines are required, HL7 Belgium proposes solutions that meet the need for consistent national implementation, while avoiding unnecessary divergence from HL7 standards. To this end, HL7 Belgium feeds back national requirements and proposed solutions to its parent body.

Among other things, HL7 Belgium sets out to:

- educate the Belgian healthcare community and healthcare information system developers about HL7 standards.
- promote effective and consistent implementation of HL7 standards in Belgium.
- identify and analyze Belgian healthcare business requirements for electronic communication of healthcare information.
- match Belgian national requirements with HL7 messages and, if necessary, identify the need for specific Belgian messages, profiles and implementation guides.
- report to HL7 on any specific Belgian needs that are not met by existing HL7 standards.

- **IHE (Integrating the Healthcare Enterprise) Belgium**

Established in 2016, IHE Belgium is the Belgian counterpart to IHE, Integrating the Healthcare Enterprise, an initiative launched by the healthcare industry and professionals to improve the way in which computer systems share medical information.

IHE promotes the coordinated use of established standards to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively. Ultimately, these systems enable seamless and secure access to health information that can be used whenever and wherever needed. IHE Belgium will ensure the values of IHE International and disseminate them to maximize their adoption.

1.4. Fully opting for medical technologies involves a number of challenges

As we have seen, medical technologies help patients by enabling the early and accurate diagnosis of health problems, facilitating timely intervention, accelerating recovery and improving outcomes. In this way, modern and innovative medical technologies will support people in living full and healthy lives.

However, that is not all. Timely and accurate diagnostic information also supports and empowers healthcare professionals to make clinical decisions that optimize patient outcomes. By reducing patient recovery times and surgical complication rates, the medical technology sector helps ease the pressure on healthcare professionals by reducing demand. In this way, healthcare professionals can focus on the tasks where they add most value.

Timely and accurate diagnostic information also supports and empowers healthcare professionals to make clinical decisions that optimize patient outcomes. By reducing patient recovery times and surgical complication rates, the medical technology sector helps to ease the pressure on healthcare professionals by reducing demand. This enables healthcare professionals to focus on the tasks where they add most value.

Moreover, by helping citizens to stay socially and economically active and by preventing serious complications of chronic disease, medical technologies can add value to healthcare systems and society. And on top of that, medical technology innovations – such as telemedicine and connected devices allowing for the remote monitoring of

patient's conditions – enhance the sustainability of healthcare.

Despite the considerable benefits of medical technology for patients, healthcare professionals and the healthcare system as a whole, BeMedTech indicates in its 2019-2024 MEMORANDUM that the sector is still facing three major challenges.

First challenge: Making the most of the opportunities offered by medical technologies to ensure the quality and sustainability of healthcare.

In Belgium, the population over 65 will increase from 2.2 million today to 2.9 million by 2030. This demographic development will have a significant budget impact on the healthcare system.

However, according to a recent OECD report, up to 20% of national healthcare budgets could be used more efficiently through the adequate and effective implementation of medical technologies.

In Belgium, the various medical technologies may bring seven specific opportunities for clinical and/or budgetary efficiency gains. However, these could be exploited more optimally.

1. A holistic approach to wound care

An aging population and growing comorbidity are driving up the prevalence of complex and chronic wounds. The opportunities created by new wound management techniques and innovative dressings generate both clinical gains - extended wear time and optimal self-healing - and budgetary gains.

2. Reducing nosocomial infections and antimicrobial resistance (AMR)

Hospital-acquired infections, or nosocomial infections (NI), may affect any patient in a hospital. According to the Federal Center of Expertise on Medical Care (KCE), the number of hospital-acquired infections in Belgium stands at 103,000 per year. Moreover, the financial cost of prolonged hospital stays is estimated to be nearly 400 million Euros per year in Belgium. In addition, in the long term, nosocomial infections increase the administration of antibiotics, which can lead to antimicrobial resistance (AMR). Therefore, the use of the different medical technologies available today could already reduce the cost of prolonged hospital stays by 30%.

3. Encouraging ambulatory surgery where the technology permits.

Continuous incremental improvements in medical technology and associated surgical techniques are increasingly enabling the use of day surgery. In fact, for the majority of patients there is absolutely no need to spend a night in the hospital, they could very well go home the same day. This change from a traditional hospital stay to same-day surgery is expected to generate annual savings of 1.5 to 2 million Euros, which can be used to meet other needs.

4. Clinical decision support - hardware/software

Medical imaging is still undergoing very rapid change: machines are becoming increasingly powerful and the software on which they run is undergoing revolutionary changes. In addition, artificial intelligence and algorithms today allow for much more accurate diagnoses based on digital images. Non-invasive CT scans can thus replace invasive imaging examinations, which is not only more comfortable for the patient but can also reduce unnecessary procedures. To improve the accessibility, quality and sustainability of healthcare services through the use of clinical decision support software and hardware, more financing mechanisms will have to be put in place in Belgium.

5. In vitro diagnostics (IVD)

In vitro diagnostics (IVD) offers many possibilities in terms of prevention, diagnosis, and providing optimal and effective treatment. Moreover, the added value of IVD tests is undisputed: almost 70% of medical decisions relating to the care pathway or treatments are based on IVD test results, for less than 2% of the health budget. In this respect, the increased use of current IVD technologies could create significant potential clinical and economic opportunities

6. Digital health

If properly implemented, digital applications can transform certain care pathways and bring both quality and efficiency gains. With its eHealth services, Belgium remains the front runner in Europe and it can capitalize on these by implementing innovative digital healthcare applications. In fact, the opportunities opened up by teleconsultation, telemonitoring, digital diagnosis and artificial intelligence are increasingly being exploited and should lead to significant health gains.

7. Services & technologies home assistance (STHA)
Continuing to treat patients outside of the hospital can bring increased efficiency if the procedure is of high quality and well integrated. This care is obviously administered in close coordination with front line treatments and the attending physician. In addition, such an organization allows the patient to be treated in a trusted environment.
Over the last two years BeMedTech has worked closely with AFMPS on a legal framework for companies to provide high quality patient care outside the hospital. The legal framework for "Services & Technologies Home Assistance (STHA)", designed to exploit the efficiency gains offered by out-of-hospital care, is almost finalized.

Second challenge: An effective regulatory approach
The technological medical device sector is undergoing major regulatory changes. A first transition period ended in 2020 and a second will end in May 2022. Following these two transition periods, only the new European Regulations will remain in force for medical devices and IVDs respectively.

The regulations will be stricter and more transparent and greater attention will be paid to clinical data before products are marketed. Existing products will again have to undergo a certification procedure.

Although the implementation of these European regulations is welcomed by companies, it requires greater efforts and investments within the industry.

Third challenge: Making Belgium a MedTech Valley
Belgium is known for its innovative medicines and is home to many large national and international pharmaceutical companies. Belgium is therefore sometimes referred to as "Pharma Valley".

The situation is however quite different for the technological medical device sector. The medical technology industry in Belgium is focused primarily on distribution. The numerous SMEs and multinationals in the sector therefore primarily have a local sales and marketing department. And yet, the country has everything it takes to become a "MedTech Valley": a fiscal framework to support research, internationally recognized experts, renowned universities that promote spin-offs, qualified personnel, sufficient support and funding for start-ups. For Belgium to become a veritable "MedTech Valley", it must focus on two aspects: increasing the attractiveness of the market and putting into a place an ideal framework for research, development and, above all, implementation tests.

There is no doubt that the healthcare sector will be able to meet these challenges and truly embark on the path of medical technology.

SUCCESS STORIES IN BELGIUM

INTERVIEW WITH
Shervin Korangy, *President and CEO*

2.1. MEDICAL DEVICES

COMPANY

BVI Medical

REGION

Wallonia

Founded: 2016 in its current form

Location: Global HQ in Waltham, Massachusetts (USA); Liège (Belgium); various other locations on every continent

Number of employees: 1,550

Start of exports: 2016

Share of exports (from Belgium) in turnover: 20%

Website: www.bvimedical.com

Headquartered in Waltham, Massachusetts (USA), BVI (Beaver-Visitec International) Medical is one of the fastest growing and diversified global ophthalmic medical device manufacturers with a mission to deliver high quality solutions and innovation for advancing eye surgery and improving the vision of patients suffering from cataracts – the clouding of an eye's lens – and other eye diseases.

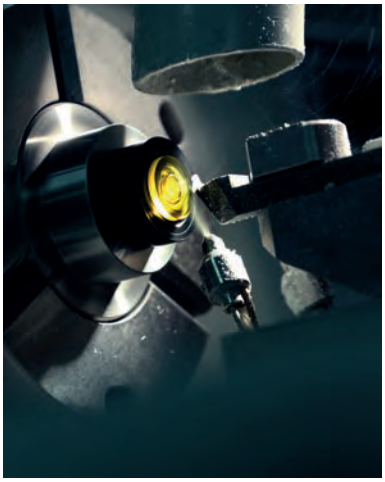
"Today, the ophthalmic and other specialty microsurgical products our company develops, manufactures and markets are distributed in over 115 countries worldwide, either directly or through our network of trusted distributors", says Shervin Korangy, President and CEO of BVI Medical.

Moreover, the company also has a direct link with Belgium. As a matter of fact, in 2019, BVI Medical acquired the Belgian based ophthalmic company PhysIOL Group SA (PhysIOL), which has enabled the company to offer a more inclusive, innovative set of technologies and products for ophthalmic procedures. "PhysIOL's broad product offering, scale, and strong footprint across a wide range of geographies made the company a strong strategic fit for BVI Medical", explains Korangy.

TREATING A VAST ARRAY OF EYE DISEASES

From its beginnings in surgical knives and blades nearly a century ago, BVI Medical has expanded into a fully comprehensive solution provider for ophthalmic surgery and consistently added innovative products and technologies to its portfolio by adopting a patient-focused approach. "We use innovative ophthalmic technologies to meet specific surgical requirements. We have quite simply been developing what ophthalmic surgeons and patients have been telling us they need", continues Korangy.

"Although the majority of our business irrefutably focuses on cataract treatments, our most recent product launches and a strong pipeline provide the opportunity to address additional eye diseases, including vitreoretinal diseases, and glaucoma."



In addition to its full range of state-of-the-art ophthalmic single-use instruments, accessories and consumables, BVI is also the world leader for providing customer-specific procedure packs that leverage technology to increase surgical efficiency and thus enhance customer experience in the treatment of a vast array of eye diseases.

"Although the majority of our business irrefutably focuses on cataract treatments, our most recent product launches and a strong pipeline provide the opportunity to address additional eye diseases, including vitreoretinal diseases, which affect the retina and the vitreous, and glaucoma, a condition damaging the optic nerve. As a matter of fact, new innovations like CryoTreq — the first single-use handheld cryo-surgery device, which can revolutionize the cryo-treatment of retinal tears and detachments — have established BVI as a leader in categories across the ophthalmologic spectrum", declares Korangy.

ACQUISITION OF PHYSIOL GROUP

In order to expand its ophthalmic portfolio, the American company regularly acquires companies active in the sector. In 2019, for example, BVI Medical signed a definitive agreement to acquire PhysIOL, a Belgium-based ophthalmic company specializing in the research, development and manufacture of innovative intraocular lenses (IOLs) for cataract treatment as well as ophthalmic surgical equipment. This means that BVI Medical's portfolio now covers the full range of intraocular lenses, from traditional monofocal to premium trifocal, a market which PhysIOL pioneered in 2011. In addition to IOLs, PhysIOL offers a suite of related ophthalmic products, including phacoemulsification equipment and surgery consumables.

"As PhysIOL's high-quality products were used by surgeons across the globe, the transaction has allowed BVI to expand its portfolio, furthering the company's transformation into a fully integrated, technology-enabled ophthalmic player", explains Korangy. "The addition of PhysIOL marks an important step in BVI's transformation into a comprehensive ophthalmic platform focused on providing unique solutions to our customers", he adds.

FAVORABLE DEMOGRAPHIC TREND

BVI's ability to consistently develop new products, as well as add innovative companies and technologies to its portfolio, has allowed the company to grow continuously and become one of the major players in the industry, while adapting to an ever-changing healthcare landscape at the same time. "As a result, the company now offers products and services for all aspects of ophthalmic surgery, including cataract, refractive, oculoplastic and vitreoretinal sub-specialties as well as other specialty microsurgery procedures", continues Korangy proudly.

In addition, in the wake of the COVID-19 pandemic, the fast pace of investment in new medical technologies will allow BVI Medical to continue its rapid global expansion. "On average, 1.5 million patients are treated thanks to our products and solutions every year. Maintaining the high quality of our products will drive the tailwind for our ophthalmic products and our company as a whole", the President and CEO believes.

Moreover, as populations are living longer, more cases of eye disease and vision defects often appear, which should mean considerable opportunities for BVI. "The current demographic trend is incredibly powerful for our industry because the biggest correlation to the prevalence of eye disease is age. Furthermore, this ageing of the global population creates an additional opportunity for BVI to expand market share at a pivotal time when health and wellness are key considerations for elderly patients", he adds.

Ultimately, the American company's growth will always retain its focus on the customer and patients. "It is amazing the impact our products have on the quality of life of the patients who receive treatment. By staying focused on listening to our customers and delivering for our patients, the business should certainly continue to flourish", Korangy concludes.

"New innovations have established BVI as a leader in categories across the ophthalmologic spectrum."

INTERVIEW WITH
Ewout Vansteenkiste, *Co-Founder*

2.1. MEDICAL DEVICES

COMPANY

MOLECUBES

REGION

Flanders

Founded: 2015, as a spin-off of the engineering & physics departments of the University of Ghent

Location: Ghent, with a subsidiary in Boston (United States) since 2018

Number of employees:
± 25 FTE's (mostly in Belgium)

Turnover (2020): Around €5 million

Growth: About 20% each year since 2017

Investments: Seed investment in 2015 of €1.9 million

Start of exports: 2015 (when the commercialization process started)

Share of exports in turnover: 96% in 2020

Prizes, awards:
(2015): Innovatiehelden Award by the Agentschap voor Innovatie door Wetenschap en Technologie (IWT)
(2019): iF Design Award in the Product category – Medicine/Health
(2021): Export Lion Award - FIT

Website: www.molecubes.com

MOLECUBES
MODULAR
BENCHTOP
IMAGING

MOLECUBES manufactures and sells high-end preclinical molecular imaging PET, SPECT and CT CUBES, which enable researchers and laboratory scientists to achieve high-quality images supported by fast and simple workflows. The X-CUBE, ɣ-CUBE and ß-CUBE are among the most compact micro-CT, micro-SPECT and micro-PET scanners in the field of molecular small-animal imaging. They are designed to work both as stand-alone units and in modular combinations.

MOST PERFORMANT IMAGING SYSTEMS IN THE FIELD

"We provide scanners that are used on a daily basis in the development of new drugs, new therapies, the investigation of rare diseases and lately also vaccines. What we do is we image small animals, mostly mice and rats, to look at the way metabolisms work, the way tumors can be treated, and the way new drugs affect organisms inside the body. What differentiates us is that, at the moment, we have the most performant imaging systems in the field. They are not only user friendly, they also have a very small footprint and at the same time our cameras have the highest specifications. Our scanners are aimed at biotech and pharma companies, universities and university hospitals that either have their own pre-clinical research lines or use these systems as contract research organizations for university groups or for external companies", clarifies Ewout Vansteenkiste, co-founder of MOLECUBES.

"It was a deliberate choice to build, design, source, manufacture and sell everything from Flanders."

"It took us 10 to 15 years of development back at university to get to the technology that was able to do that kind of imaging at that small scale. Apart from the detectors that come from Asia, all the parts inside the systems are either made, built, developed or sourced within Flanders because we have such a dense network of electronics providers, mechanical engineers, design engineers, software and FPGA-programmers. As such, it was a deliberate choice to build, design, source, manufacture and sell everything from Flanders. Thanks to

this, we have very stable imaging systems, which is very important because they have to be up and running all the time", he continues.

HIGHER TROUGHPUT AND SPECIFICATIONS

As to what differentiates MOLECUBES from its main competitors, Vansteenkiste explains that "the big differentiator is the size of the product and the fact that the others combine the different modalities into one gantry, whereas MOLECUBES splits them apart to achieve a higher throughput. Another advantage of decoupling the different modalities is that you can reach higher technical specifications on each of the individual systems. You don't need to compromise because of a lack of space or because of interference from electronics. Finally, I would like to point out that, if you have a problem with one of our CUBES, the other ones still keep functioning. If some of the components break in an all-in-one system, then it is completely down".

The COVID-19 pandemic also partly changed the way in which MOLECUBES conducts its business. "In 2020, we were forced to do all the installs, all the training, all the servicing and maintenance and all the upgrades remotely. Nobody was able to travel any more and everything had to be done from home. Luckily, our systems are small in footprint and they were also already being operated, upgraded and monitored remotely. So being able to access overseas systems and data from Belgium also gave us a competitive edge", according to Vansteenkiste.

"The core of our company is its people."

DENSE NETWORK OF HIGHLY SKILLED PROFESSIONALS

He also affirms that Belgium is an ideal location to start a health tech company: "above all, there is a very solid and dense network of highly skilled subcontractors in Belgium, who are all very close by. Secondly, we are located at the heart of Europe, so from Brussels we can fly and ship to virtually everywhere. Even during the pandemic, we encountered few problems getting our products to countries like Japan, China, Australia and the United States". Vansteenkiste goes on by stating that because of the dense network of universities and university hospitals, MOLECUBES has access to a large pool of very talented people. "The core of our company is its people. We have a highly skilled team of professionals that were all educated in and around Ghent, so we will never relocate our R&D activities to anywhere else".

Although, in the five years since the company was founded, MOLECUBES has already become the global benchmark as far as the footprint of its products is concerned, there are still many challenges that lie ahead. "We now have a market share of 15-20%, so we are on target as far as the

growth we anticipated is concerned. We want to reach a turnover of about €10 million by 2024 and increase our market share by at least 5%. If we achieve that, then we will have established ourselves as a valid player in the field. If you look at tenders, the installed base and customer feedback, we are already up there with our main competitors, who have been around a lot longer than we have. We want to be number one in terms of compact benchtop systems, without making any compromises on quality, and at the same time we want to keep assisting our customers in every way we can during the lifetime of the product", Vansteenkiste points out.

He concludes by saying that in the future the goal of the company remains to keep sourcing everything from within Belgium. Expanding MOLECUBES' Boston-based subsidiary is also still very much a priority: "I think we will need an even larger permanent presence on both the east and the west coast of the United States to reach the volume growth we want. Our presence in China kicked off in 2019, so in the near future the focus will also be on starting a subsidiary in that market. Our small footprint, easy-to-operate systems are very attractive for companies that still need to establish their market in that field".

INTERVIEW WITH
Ward Servaes, *Co-founder & Director*

2.1. MEDICAL DEVICES

COMPANY

MoveUP

REGION

Brussels

Founded: 2015

Location: Brussels and Ghent

Number of employees: 23 FTE

Turnover (2020): €250K

Growth (2020): three-digit growth

Investments (2020): European Innovation Council grant of €2.7 million, Innoviris €300K subsidy for R&D projects with the VUB

Start of exports: 2018 in France, 2019 in the Netherlands, 2020 in Germany

Expected share of exports in turnover: 80%

Prizes, awards: 2nd prize in Galenus competition 2019 of best innovative medical device

Website: www.moveup.care

moveUP

Launched in 2016, moveUP is a Belgian company operating in the field of digital therapeutics which has developed an eponymous CE-approved medical device to follow up patients after an orthopaedic or bariatric surgical intervention. The digital solution elaborated by the company is currently available to the general public, used in about 20 hospitals in Belgium and is incorporated in multiple partnership deals.

"Thanks to the moveUP digital platform, patients benefit from having a support system and a personalized healthcare path available at their fingertips to optimize their recovery. We provide our solution directly to hospitals, healthcare professionals and patients, while also collaborating with international pharma and medtech companies in order to support their recovery programs and product launches", says Ward Servaes, Co-Founder and CEO of the company.

ORTHOPAEDIC AND BARIATRIC SURGERIES

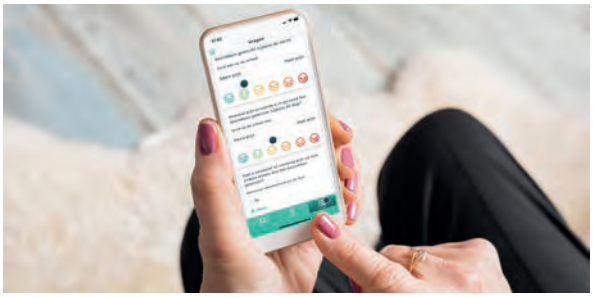
moveUP enables close monitoring of the recovery of patients who have undergone an orthopaedic intervention – such as a hip or knee replacement surgery – and weight loss surgery. As a matter of fact, the moveUP app allows patients to rehabilitate safely from the comfort of their own home by following a personalised rehabilitation plan with daily follow-up by a team of rehabilitation experts. This makes it possible to identify and treat complications at an early stage.

"The success of a surgery largely depends on what and how a patient does when leaving the hospital."

"Patients have more influence over surgery outcomes and convalescence success than they may realize. By closely following a personalized rehabilitation plan consisting of personal exercise programs, information and education tools such as photos and videos, and a messenger function to communicate directly with care teams providing medical advice and personal coaching, moveUP empowers patients to get a grip on their own recovery process. Because the success of a surgery largely depends on what and how a patient does when leaving the hospital", affirms Servaes.

ALREADY FULLY REIMBURSED IN BELGIUM

Today, the remote medical guidance application developed by moveUP is ISO13485 (quality management) and ISO 27001 (IT security) certified. The moveUP care pathway after hip- and knee replacement is also one of the first to successfully pass the 3-level certification process of the e-health validation pyramid, designed by www.mhealthbelgium.be. "Level 3 (M3) is reserved for apps for which the social-economic added value has been demonstrated and which are financed by the competent government authorities. This means that for patients who use moveUP with the daily personalized recovery including activity tracker, the full package is reimbursed through their health insurance", declares Servaes



A RESILIENT COMPANY IN TIMES OF PANDEMIC

During the pandemic, hospitals needed to focus on acute care only. "For us, this meant that patients could suddenly no longer be treated through our platform because orthopaedic surgeries were being postponed", explains Servaes.

However, the company rapidly reinvented itself and put its platform at the service of the healthcare sector, also building up credibility in its solutions. "By adapting our platform with a COVID-19 specific care plan, COVID-19 patients were able to interact with healthcare professionals such as GPs, pneumologists, geriatricians, etc. This way, their fever, respiratory, taste and smell symptoms were monitored on a daily basis and healthcare professionals could provide advice to patients remotely. In addition, by keeping track of COVID-19 patients' health status from their home setting, hospitals could also save their capacity for the most severe cases", he adds.

"We also used the momentum to finalize our 2nd core digital therapy, being the preparation and follow-up of patients before and after weight loss surgery. A recent KCE report on bariatric surgery clearly stated the importance of multidisciplinary follow-up for improving the chance of success for implementing a new lifestyle. Belgian Insurance company Ethias immediately understood the importance of this new development and decided to support the full patient pathway before and after the surgery.

After the most acute phase of the pandemic, we received an increased interest from hospitals in our programs for reducing hospital stay and making consultations more effective, while keeping the highest standards on complication prevention. So COVID-19 brought us short term constraints in terms of business continuity, but the overall increased awareness of continuous personalized recovery at home accelerated the adoption of our services by multiple care teams", he adds

THROWING ITSELF AT FOREIGN MARKETS THANKS TO A EUROPEAN FINANCING ROUND

With the demand for remote healthcare solutions continuing to rise, moveUP has successfully completed a €3.65 million financing round co-led by Karista and White Fund in a European consortium with Nina Capital, CAREvolution and Qbic. In this way, the company hopes to further develop and scale moveUP's value-based healthcare concept in orthopaedics, bariatrics and beyond, both in Europe and the US.

"The financing will enable us to further develop our solution and reinforce our presence in the Netherlands (where an agreement has been reached with healthcare insurer CZ for the reimbursement of the solution), France, and Germany, while accelerating our international expansion, namely in the US", says the CEO. "Furthermore, since the core platform of moveUP is also used by several major biotech, pharmaceutical and medical device companies as a backbone to support the development and delivery of data-driven care pathways, international partnerships should also be strengthened", he continues.

"The financing will enable us to further develop our solution and reinforce our presence in the Netherlands, France, and Germany, while accelerating our international expansion, namely in the US."

NEW MARKET OPPORTUNITIES

Together with the Belgian biotech company KiOmed Pharma, moveUP is now developing a cutting-edge mobile health platform for the personalized conservative intra-articular treatment of patients suffering from osteoarthritis. moveUP will develop this application using its innovative healthcare platform, while exclusive global marketing rights are to be granted to KiOmed, who will market it across selected markets alongside their innovative single-shot intra-articular injection for the treatment of knee osteoarthritis.

"By joining forces with KiOmed Pharma, we are taking a major step towards more personalized and cost-effective treatment of patients with osteoarthritis, an incurable debilitating pathology affecting hundreds of millions of patients worldwide. We are convinced that our combined expertise will lead to finding a solution with high value for both physicians and patients alike", believes the company's CEO. "By further applying our value-based healthcare principles in existing therapies while also targeting other therapeutic areas, I believe we will contribute to the advancement of the global healthcare system", he concludes.

INTERVIEW WITH
Brice de Behault, *Managing Director*

2.2. MEDICAL SOFTWARE

COMPANY

EarlyTracks

REGION

Brussels

Founded: 2009 as spin-off of UCL; 2015 as a commercial entity

Location: Brussels

Number of employees: 18

Turnover (2019): €615,000

Growth (2019): +40%

Investments (2020): €1.4 million in raised funds

Start of exports: 2021

Website: www.earlytracks.com

Specializing in health information management, the Brussels-based technology company EarlyTracks develops solutions to address organizational issues concerning medical records. "Our goal is to improve the quality of medical records in hospitals and care institutions and to valorize the medical information stored in Electronic Patient Records (EPR's). In order to do so, we have developed two distinctive technologies: one in Natural Language Processing (NLP) and another in Terminology Management", explains Brice de Behault, CEO of EarlyTracks.

"Through such advanced technologies, we help hospitals and other care institutions to better manage their medical records. Turning medical records into data-driven innovation, our approach addresses the foundational issues in knowledge management and data engineering. Doing so, we make possible to move from a document view of the patient towards a data-centric view of the patient", he asserts.

DATA IS THE NEW OIL

The qualitative mastery of health data through new technologies is one of the major challenges of contemporary medicine. Over the last decade, Medical ICT has indeed turned paper records into digital content. Moreover, Electronic Patient Records have gained in maturity and information has become more accessible to health professionals and patients alike. "The promise of data automation will entail disruptive innovation and improve healthcare through technology. We could say that data is the new oil", affirms de Behault.

"Turning medical records into data-driven innovation, our approach make possible to move from a document view of the patient towards a data-centric view of the patient"

Unfortunately, while these administrative tasks could have strong added value in medical terms, EPRs are also too frequently perceived as administrative or even compulsory tasks by medical practitioners. In addition, computerization also means that intra-hospital as well as extra-hospital physicians are increasingly being swamped with administrative tasks, such as filling out EPRs during the care pathway. This results in the quality of the medical information collected often remaining relative.

This is why automating part of the EPR process carried out by practitioners without disrupting their medical responsibility and externalizing these efforts to other healthcare personnel within a hospital will allow practitioners to better manage their medical records. EarlyTracks' technological solutions can precisely support hospitals and care institutions in addressing this concern by improving the quality of the information entered in pre-existing EPR software and thus allowing for better organization and valorization of this information.

THE IMPORTANCE OF MEDICAL RECORDS MANAGEMENT

Today, EarlyTracks has succeeded in convincing 16 Belgian hospitals to adopt its solutions in order to better structure and improve the quality of the information contained in their medical files and databases. This makes medical, clinical, therapeutic and even operational and administrative decisions taken within hospital environments more effective.

"The semantic use of medical data for decision-making and operational purposes is in fact critical for many aspects of the daily management of hospitals and care institutions. We have listed and organized more than 40 different types of applications that globally address 4 types of aims: improving public health through better patient knowledge and the provision of medical decision support, enhancing the experience of care through coordination, integration and prevention, reducing per capita cost through improved risk and activity monitoring, and providing a better practitioner experience through EPR ergonomics", the CEO declares.

Moreover, even if certain specific features exist within each hospital, particularly in terms of the EPR software used, the technologies of the Brussels-based company are easily compatible with each of them. "By enhancing the quality of medical records by way of a generalist view, we indeed produce high-quality content and improve organizational structures within hospitals. Furthermore, as a company, we do not extract value from the data obtained in Electronic Patient Records, the responsibility for which remains in the hands of the hospitals themselves as owners of this content", de Behault says.

€1.4 MILLION IN RAISED FUNDS

After the medico-functional validation of the effectiveness of its solution in Belgium over the past few years, EarlyTracks is now aiming for international growth and expansion. To this end, the company has been able to count on fundraising of 1.4 million euros from the public (Innoviris, Finance & Invest Brussels) and private (White Fund, private investors) sectors.

"Thanks to this fundraising, commercial expansion beyond Belgium is now a short-term prospect for our company. Our ambition is to explore the market potential in the rest of Europe according to a hospital logic rather than a geographic logic. As a matter of fact, because European hospitals often share the same international EPR software provider, we can easily gain access to a vast network of healthcare institutions", explains de Behault.

Projects for the integration of EarlyTracks' technological tools for information management purposes are currently underway in the Netherlands and France. "In these neighboring countries and in other European countries, the needs for our technological solutions in hospitals are the same as in Belgium. This means we can easily replicate our model in other European healthcare environments", he continues.

In this way, over the next four years, the company hopes to generate the majority of its income abroad. "Now that our solutions are integrated into the EPRs of Belgian hospitals, we will shift our focus from Belgian to European health environments with the ambition of generating 80% of our income abroad in as many EU countries as possible" de Behault claims. Our growth efforts will be fueled by the conclusion of strategic partnerships as done in Belgium with players like IQVIA or local medical ICT providers.

As a concluding remark, the CEO believes that the pandemic will be a game changer for its field of activity. "Even if we did encounter delays in certain projects with hospitals due to the pandemic, we have also been able to concentrate our efforts on strengthening our technology and our functional methodology in order to better structure our growth. Moreover, in the wake of COVID-19, hospitals are keener to address the question of the quality of medical records and authorities also seem to be seizing this momentum by supporting the healthcare sector more generously. Over the long term, the pandemic will definitely be a medtech accelerator."

INTERVIEW WITH
Wim Van Hecke, *CEO*

2.2. MEDICAL SOFTWARE

COMPANY

icometrix

REGION

Flanders

Founded: 2011, as a spin-off company of the universities and university hospitals of Leuven and Antwerp

Location: Headquarters in Leuven, with a subsidiary in Boston (United States)

Number of employees: ± 55

Turnover (2020): €3 million

Growth (2020): 30%

Investments (2020): None. Funding round of €16 million closed in 2019

Start of exports: 2011 (from the very beginning of the commercialization process)

Share of exports in turnover: 95%

Prizes, awards: WSA (United Nations) winner, Digital Health 150 (CB Insights), Finalist Eye for Pharma entrepreneur award, Jury price best innovation pitch by European Brain Council, EIT Digital award winner for health and wellbeing

Website: www.icometrix.com

Founded in 2011, icometrix strives for data-driven insights and personalized patient care, supported by artificial intelligence. icometrix offers a portfolio of AI solutions to assist healthcare with various challenges; icobrain extracts data from brain MRI and CT scans for the radiological reporting and clinical management of neurological disorders such as multiple sclerosis, brain trauma, epilepsy, stroke, dementia, and Alzheimer's disease. icompanion, a digital platform, and the mobile app helps people with MS and their care team to monitor clinical symptoms and treatments efficiently and objectively. Today, icometrix is internationally active and integrated into more than 100 clinical practices. In addition, icometrix collaborates with healthcare providers and pharmaceutical companies on the evaluation of drug research for neurological disorders.

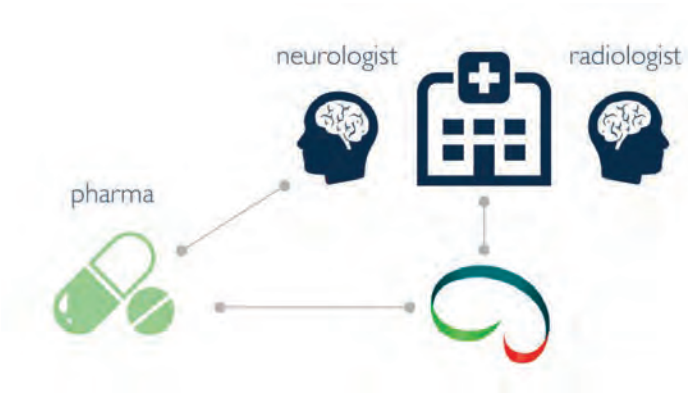
MORE PERSONALIZED HEALTHCARE

"I saw that the MRI and CT brain scans contained a lot of information, but the radiological report didn't contain any numbers and was still very qualitative, descriptive and radiologist dependent. Because of that, we started to develop

"As a healthtech company, you somehow want to change or improve the patient's life."

software solutions that can extract meaningful information out of these brain scans and send these data back to radiologists so they can improve their workflows and to clinicians so that they can make better decisions for patients. This is all part of the movement towards more personalized healthcare", states Wim Van Hecke, CEO of icometrix.

He continues by explaining why they have developed mobile apps for patients as well: "imaging is important for diagnostic and monitoring purposes. However, in the end it's the clinician who makes decisions based not only on imaging, but also on other clinical information and the latter is always very subjective and clinician dependent. There is a lot of valuable information that gets lost between visits, so we try to capture that part through our icompanion-app. That way, whenever someone visits a clinician or neurologist, all the data information is



present to make the most optimal decision in favor of that particular patient".

Icometrix primarily works with hospitals in different countries that use their software, which is cloud-based and fully integrated. In return, these hospitals pay a license fee for the use of this software. Icometrix also collaborates with biotech and pharmaceutical companies to include their technology in clinical trials or gather real world data and evidence for them.

Even though icometrix is the leading company in its specific field, there still remain certain obstacles that it has to overcome. For example, MRI scans are reimbursed by the health insurance fund, but the use of icometrix software to analyze these scans is not yet reimbursed. "It would make our lives a lot easier", acknowledges Van Hecke. "If you see that the quality of a lot of the scans acquired isn't of the highest standard, then it's a shame that our software, which could significantly enhance the results obtained, is not yet reimbursed. In the end, we will probably reach a point at which the cost of the software is refunded, but that will take some more time".

SYNERGIES BETWEEN BIOTECH AND HEALTHTECH

icometrix conducts most of its business internationally because, as far as the health technology field is concerned, the Belgian market is simply too small to really make a huge difference. Van Hecke clarifies the decision to look abroad: "as a healthtech company, you somehow want to change or improve the patient's life and that ambition shouldn't stop at the border. The fact that the possibilities in our home market are limited has forced us to look abroad at other countries. Even though our home market is rather small, being headquartered in Leuven does have its advantages, especially because of the vast experience Flanders already has in the biotech industry. There are a lot of synergies there with healthtech companies like ours, which is an ideal environment."

The reason for icometrix to set up a subsidiary in Boston was influenced by the fact that it has a big pharmaceutical and biotech community where a lot of companies active in the field of brain disorders have their offices. In addition, there is a large academic network present with important hospitals like Mass General, which is the #1 research hospital in the United States. "At the moment, the Boston subsidiary is more a commercial organization", Van Hecke explains. "The people that work for us in the US have to be close to the hospitals, where they have their network".

icometrix employs its own salesforce to promote its AI software solutions. Van Hecke points out the reasons why the company has developed and expanded its own commercial department: "first and foremost, we want to be very close to our customers. We are active in a field that is changing and growing at a rapid pace and that's why it's very important to have a good match of technology with what clinicians or radiologists want. On the other hand, we are starting to look into partnerships with both hardware vendors and companies that distribute our software to see how we can leverage their networks on a large scale so that we can reach more hospitals".

DEVELOPING DIGITAL TWINS

Van Hecke concludes by saying that what drives the people at icometrix is "the will to help patients on a daily basis. There is a huge need for solutions for brain disorders because, statistically, one in three people will suffer from one. The imaging technology is crucial because it is typically the best predictor of disease outcome and therapeutic response. Thanks to our AI solutions and by complementing that with other outcome data, we hope to be able to develop digital twins of patients. That way, we would no longer need to try out a treatment on an actual patient and see if it really works over the course of a few years. We could then actually use the data to try out medication virtually and see what works best in terms of outcome treatment models for any particular patient. More personalized healthcare is something that is absolutely needed, but we are not there yet."

"More personalized healthcare is something that is absolutely needed."

INTERVIEW WITH
Benoit Tas, *CEO*

2.2. MEDICAL SOFTWARE

COMPANY

Neuropath

REGION

Wallonia

Founded: October 2016

Location: Enghien, BE – Chicago, U.S.

Number of employees: 8

Investments (2020): €640K in equity, €3.2 million non-dilutive grants (Flemish Brabant, Wallonia, Europe)

Prizes, awards: 2nd Prize Polsky ANVC challenge, Polsky Center for Entrepreneurship and Innovation, University of Chicago

Website: www.neuropath.eu

Created five years ago, the young Walloon start-up NeuroPath (NP) provides a multi-channel Digital Health Platform to connect the daily living of Persons with Parkinson's (PwP) and their personal care bridge team with their interdisciplinary clinical team of care providers. The ambition of the company is to commercialize its solution by the end of 2021 and to become the reference multi-channel digital health platform for neurodegenerative disorders.

"Our platform gathers structured and unstructured data from patient-centric, non-intrusive technologies (i.e., smartphone, video, voice analysis, wearables) in order to capture motor and non-motor symptoms, patient-reported Quality of Life (QoL) results, medication intake and daily activities. We provide a single view of big data, applying artificial intelligence and advanced analytics to improve Quality of Life for patients, insights and tools for providers, results for payers, and real world evidence for pharma and research.", states Benoit Tas, Founder and CEO of NeuroPath.

"NeuroPath's multi-modal and patient-centric digital health platform provides a portfolio of functionalities to create a holistic view of PwP and their QoL based on a library of data."

A COMPLEX NEURODEGENERATIVE DISORDER

With an estimated 10 million people diagnosed worldwide and over 50,000 in Belgium, Parkinson's disease (PD) is the fastest growing neurological disorder and a global concern. Recent forecasts estimate a doubling of patients by 2040 due to the ageing of the population, the continued use of chemicals and by-products from industrialization processes.

"PD is a slowly progressive and complex neurodegenerative disorder presenting over 60 symptoms that occur in unique combinations. PwP's may indeed experience motor symptoms such as tremors, bradykinesia (slowness of moment), limb rigidity, gait difficulty and balance problems, as well as non-motor symptoms including cognitive impairment, hallucinations, mood disorders, sleep disorders, speech problems, loss of sense of smell, etc.

In this sense, a patient can thus experience dozens of different symptoms, which generally develop slowly over years and vary greatly from individual to individual—both in terms of their intensity and how they progress. A personalized

care path is therefore critical for the quality of life of the patient", explains Tas.

A PERSONALIZED CARE PATH TO IMPROVE QOL

Very often, when early motor and non-motor symptoms appear, clinical uncertainty can lead to a delay in PD diagnosis. Moreover, the standard care path for a person diagnosed with Parkinson's is 1 or 2 visits per year to the neurologist, depending on the severity of the disease, compounded by a growing shortage of trained PD neurologists.

In addition, these consultations are often not even representative of the patient's day-to-day life. As a matter of fact, due to different progression rates of PD in patients and the highly individualized nature of the disease, more frequent and comprehensive monitoring is needed to provide the necessary data from the activities of a patient's daily life.

"The lack of touchpoints between the patient, the neurologist and other care providers can create delays in adapting the personal care path. This affects the patient's quality of life and increases health costs unnecessarily, thus placing a tremendous burden on patients, their families and the healthcare system", emphasises Tas.

This is where Neuropath's Digital Health Platform comes in: to connect the daily life of patients with the interdisciplinary team of care providers and clinicians. "By using real-world data generated by the patient from daily activities through state-of-art technology, we create a holistic, inter-disciplinary view of the patient and define a personal care path to improve QoL with a lower burden for all. Our goal is to help improve communication between a patient and the care team in a way that has not been possible before. In this way, the valuable insights generated will allow the clinical care team to provide timely interventions while providing compassionate care through an understanding of the patient's daily struggles", declares Tas.

INTERNATIONAL GROWTH THROUGH HEALTHCARE INCUBATORS AND ACCELERATORS

In addition to seed capital provided by Founder and CEO Benoit Tas and other private investors, Neuropath has raised subsidies and grants from Belgian public authorities, more specifically the Walloon Region through their health cluster BioWin and the Province of Flemish Brabant Smart Hub, and even from the European Commission under the Horizon 2020 framework programme, to develop its platform.

In addition, thanks to the Chicago-based healthcare start-up incubator Matter, which selected Neuropath as the first European start-up to participate in the Chicago Innovation Mentors (CIM) Program, and to the accelerator program of the Polsky Center for Entrepreneurship and Innovation of the University of Chicago, the Walloon company has been able to further refine and internationalise its solution.

NeuroPath's current projects are also largely concentrated in the U.S., where it deploys its technology among a variety of actors. "We were selected to participate in an innovation program across 4 sites of the American Veterans Health Administration (VHA) and collaborate with Movement Revolution, a personal training company specialising in neuro-intensive exercise programs, and with Texas A&M. We are finalizing collaboration agreements the first movement disorder clinic worldwide and associated thought leaders in PD and movement disorders, and with the largest PD advocacy group. In Europe, as part of the Horizon 2020 programme, we are currently implementing our solution at HUS Helsinki, Finland", affirms Tas.

GROWTH POTENTIAL OF THE TECHNOLOGY FOR OTHER MARKETS

As previously mentioned, NeuroPath's multi-modal and patient-centric digital health platform provides a portfolio of functionalities to create a holistic view of PwP and their QoL based on a library of data. These data collection capabilities also have enormous potential according to Benoit Tas: "aggregated data gathered from PD patients around the world will be scalable and expanded to other conditions that demonstrate similar symptoms or challenges. The immediate markets for NeuroPath after PD would include other neurodegenerative diseases such as Alzheimer's and Multiple Sclerosis, which cause patients to suffer from similar issues around QoL and movement disorders. Our technology could be easily modified to account for these patient's needs".

As the CEO notes, there has been a dramatic increase in the use of telemedicine in the U.S. and Europe in response to COVID-19. "The use of our technology in conjunction with telemedicine is likely to accelerate as it increases clinicians' ability to remotely analyze a collection of relevant information collected in the patients' homes. Due to such benefits, this trend is therefore expected to continue post COVID-19. It is important for us to seize this telehealth momentum", concludes Tas.

INTERVIEW WITH
Herman Verrelst, *CEO*

2.3. TESTING

COMPANY

Biocartis

REGION

Flanders

Founded: 2007

Location: Mechelen, subsidiaries in Jersey City (New Jersey, US) and Italy

Number of employees: Approximately 500

Turnover (2020): Revenues of €31.9 million (+32% compared to 2019) and operating income of €55.6 million (+47%)

Growth (2020): Number of Idylla™ instruments installed grew by 335 to 1,581 and the number of cartridges sold amounted to 230,000 (+31% compared to 2019)

Investments (2020): €45.8 million in R&D

Start of exports: 2015 (when the commercialization process started)

Share of exports in turnover: 99% in 2020

Prizes, awards:
(2011): 2012 Technology Pioneer by the World Economic Forum
(2016): Galenus Prize for Most Innovative Medical Device
(2016): Red Dot Award: Product Design 2016

Website: www.biocartis.com

Biocartis is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Its proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in almost any setting. Biocartis is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus on oncology, which represents the fastest growing segment of the MDx market worldwide.

Biocartis started commercialization in 2015, after the CE-IVD marking of its Idylla™ platform and its first test for melanoma. The first focus was on Europe and other markets accepting the commercialization of CE-marked products. In Europe, Biocartis has gradually expanded its own direct sales team, covering most of the European countries today. From 2017 on, it expanded commercialization into countries like the United States, Canada, China and Japan. In its distributor markets (= the world excl.

"Today, Biocartis can call itself a global molecular diagnostics company with activities in over 70 countries worldwide."

Europe, US and China), Biocartis has an indirect sales network in which it collaborates with a vast network of distributors. Today, Biocartis can call itself a global molecular diagnostics company with activities in over 70 countries worldwide.

NEED FOR EASILY ACCESSIBLE DIAGNOSTIC TESTING

"In 2020, the worldwide COVID-19 pandemic clearly showed the undebated value of high quality, rapid and easily accessible diagnostic testing", comments Herman Verrelst, CEO of Biocartis. "Unfortunately, it also showed that MDx testing today still suffers from many inefficiencies, which delay results and impact patients. The Idylla™ platform provides a unique solution in this context: it is a fully automated workflow with little to no hands-on time and offers superior performance in one single unique and versatile

platform that can be used both in oncology and infectious diseases. In addition, the results are available in minutes or hours instead of days or weeks", he adds.

The Idylla™ platform is composed of a console (display), an instrument (stackable up to eight) and a disposable cartridge, a plastic consumable with all necessary reagents on board to process a clinical sample and to detect the molecular biomarkers of interest. All cartridges share a common hardware design, but are made application-specific by their reagent content, test execution protocol (software) and labelling.

With Idylla™, Biocartis is leading rapid and easy-to-use precision diagnostics in a global molecular diagnostics market with a value of $6.5 billion. In this market, oncology is the fastest growing segment with high double-digit annual growth rates. Biocartis is serving a large, global and expanding customer base in oncology, and is now diversifying into the infectious disease market. As a result of the COVID-19 crisis, Biocartis has seized the opportunity to develop its 2020 pandemic test menu. Verrelst explains that "what was initially designed to help offset the impact of COVID-19 on oncology test volumes now clearly represents a longer-term strategic opportunity to support the patient journey in the intensive care unit (ICU), including rapid triage and therapy selection of critically ill patients".

"Biocartis wouldn't be where it is today without its highly skilled employees, at all levels of the company."

BELGIUM NUMBER ONE IN EUROPE FOR BIOTECH

In 2020, for the third year in a row, Belgium ranked number 1 in Europe for biotech with 24% of the total market value of all public biotech companies in Europe. Despite the pandemic, the value of Belgian biotech companies increased by no less than 56% to €42 billion in 2020. The reasons for locating Biocartis in Flanders are consequently pretty obvious to Verrelst: "we can count on the strong supportive network both from government & network associations such as FlandersBio and Flanders Investment and Trade (FIT), academic centers such as KUL and others. We also have easy access to funding with a strong investor & banking network in biotech." Another reason that is essential for the success of health technologies in Belgium is the presence of academic centers, which provide nearby access to a large pool of talent. "Biocartis wouldn't be where it is today without its highly skilled employees, at all levels of the company. We are grateful for the collaboration with several universities and schools, who put talent management at the top of their agendas", Verrelst asserts.

He continues by stating that broader public awareness of the importance of medical technologies has increased not only in Belgium, but around the world as well due to the global pandemic. "I think there is a high level of awareness of the difference that technology and proper testing infrastructure can have for the entire society. I hope our policy makers will remember this as a long-term lesson: that it's important to make investments in infrastructure. A small investment in testing infrastructure now can avoid a big cost afterwards. I think that's perhaps for me the larger lesson learnt, and I hope our policy makers here in Belgium and abroad can do what is necessary".

EXPANDING THE MENU OF TESTS

Verrelst concludes by saying that the future looks bright for Biocartis: "although the year 2020 was a struggle for us in certain ways, we have stood strong financially and operationally and have now come out of it in a position of strength with a more diversified offering, with good visibility and a good customer base. We have not yet reached a critical mass, but we have been able to grow steadily and we have shown that there is an appetite for the type of products we offer. The next thing we are looking to do is to build an even broader menu of tests on our platform. We have demonstrated that we can create very reliable, qualitative tests that the market really appreciates, so the next phase is to double down on that and do more on the platform and grow even further internationally. Myself and the entire team here at Biocartis are working hard to become an even more self-sustaining organization in the next couple of years".

INTERVIEW WITH
Thierry Leclipteux, *CEO*

2.3. TESTING

COMPANY

Coris Bioconcept

REGION

Wallonia

Founded: 1996

Location: Crealys Science Park, Province of Namur

Number of employees: 33

Turnover (2020): €12 Million

Growth (2020): double-digit growth

Start of exports: 1996, in the UK and Italy

Share of exports in turnover: 85%

Prizes, awards: Nominee for Essenscia innovation award 2019

Website: www.corisbio.com

Established in 1996, the Belgian-based medium-sized company (SME) Coris BioConcept specializes in the development, manufacturing and marketing of rapid diagnostic kits, which are mainly based on the principle of immunochromatography to detect pathogens of respiratory and enteric infectious diseases, as well as pharmaceutical molecules in urine.

"These rapid diagnostic tests are extensively used in microbiology laboratories worldwide for the detection of human respiratory and gastro-enteric infectious pathogens (bacteria, viruses and parasites) as well as for the detection of antibiotic resistance markers", explains Thierry Leclipteux, Founder and CEO of the company.

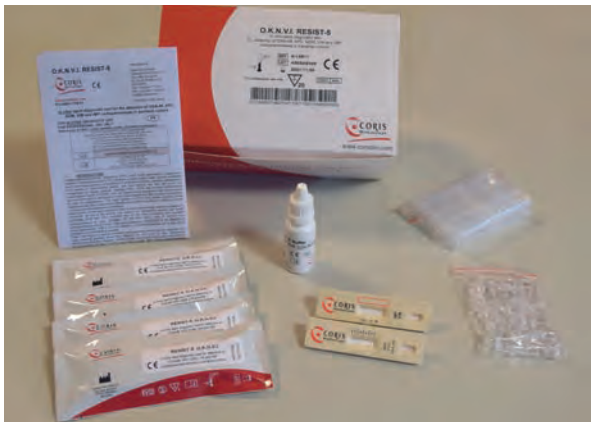
To complement this extensive range of fast and accurate immunochromatographic tests, the company has also developed an innovative automated platform that performs multiplex Polymerase Chain Reaction (PCR) amplification and detection on a microfluidic cartridge (TRAPIST® system). This molecular multiplex platform allows the detection of bacteria involved in sepsis as well as their antibiotic resistance markers.

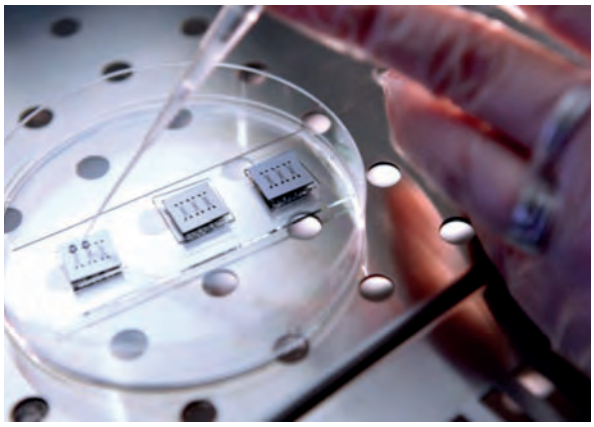
Today, the company is ISO 13485 certified and all of its products comply with the CE marking requirements. "Coris BioConcept provides services for custom test development and contract manufacturing in more than 60 countries across Europe, Asia, South America, Africa and Oceania. In addition, Coris BioConcept is continually involved in collaborative projects with Belgian and European Research Institutes, laboratories and companies for the development of groundbreaking new solutions", adds Leclipteux.

IMMUNOCHROMATOGRAPHIC TECHNOLOGY

An immunochromatography test (ICT) is a is a ready-to-use assay that provides results within about 10 to 15 minutes. The membrane-based immunological technology used by Coris BioConcept makes it possible to detect specific agents – pathogens – in biological samples.

"To this end, a biological sample is collected and diluted in a dilution buffer provided before being dispensed on a dry conjugate pad zone of a nitrocellulose membrane containing capture antibodies directed against the targeted pathogen. Once loaded, the sample rehydrates the dried conjugated antibody. If the sample contains the targeted antigens, the rehydrated conjugated antibody and antigen interact with each other and a colored line will appear on the test line indicating that a person is infected by a pathogen", explains Leclipteux.





NEW TECHNOLOGIES

In order to cope with the new technological environment, Coris BioConcept launched two new programs aimed at developing new products, i.e. electrochemical assays and isothermal amplification assays.

The electrochemical test allows the detection of beta-lactamase and is based on the use of a beta-lactam-derived substrate sensitive to overexpressed cephalosporinases, ESBLs and carbapenemases. In the presence of bacteria producing these types of enzymes, the substrate is hydrolyzed to an electroactive product, i.e. capable of generating an anodic oxidation current measurable by voltammetry in an electrochemical detection. These tests will improve the company's expertise in the field of antibiotic resistance.

The LAMP tests is a molecular technology allowing the detection of living organisms in 10 to 20 minutes by an isothermal amplification of RNA or DNA. The first tests developed are aimed at the diagnostic of respiratory viruses including SARS-CoV-2 and Influenza A&B.

COVID-19 AG RESPI-STRIP

As a result of international collaboration with various laboratories and hospitals, Coris BioConcept has developed a rapid diagnostic test to detect the SARS-COV-2 virus in patients with severe infection. "Speed is clearly one of the crucial issues in the fight against the pandemic. This test allows for the widespread screening of patients and is an excellent complement to the molecular biology screening methods currently used in hospitals", states the company's CEO.

Unlike the serology and molecular biology tests currently available, which often take several hours or even days to deliver results, this test detects the presence of viral antigens in the patient's respiratory sample obtained from a nasopharyngeal swab. It takes 15 minutes to diagnose an infection in more than 9 out of 10 patients with a high viral load. Furthermore, the COVID-19 rapid antigen test developed by the Walloon company has also proven to detect all the alpha, beta, gamma and delta variants of the coronavirus.

In addition to its antigen test, Coris BioConcept has also partnered with two other Walloon companies (Unisensor and Bio-X) to produce a rapid serological test that can detect immunity against COVID-19. "This rapid serological test reveals – or not – the past presence of the virus according to two markers: the presence of antibodies against the NP protein but also the presence of antibodies against the RBD proteins claimed to be neutralizing antibodies which will further protect the patient in the event of new exposure to the virus. The principle of serological tests is therefore to demonstrate the immune response of the population to COVID-19", says Leclipteux.

"As a result of international collaboration with various laboratories and hospitals, Coris BioConcept has developed a rapid diagnostic test to detect the SARS-COV-2 virus"

FOREIGN AMBITIONS

As a company, Coris BioConcept has always striven for constant improvement while being committed to providing a high level of quality for the entire range of diagnostic services and products. "We manage the company according to a customer-oriented strategy, with the customer remaining our central priority. For us, this is the only way to establish and maintain a long and fruitful relationship with our partners", affirms Leclipteux.

Today, Coris BioConcept is well established on the European and South American markets. "South America is a growing market for us because of its accessibility. We also hope to certify our antigenic and serological tests in the US. Unfortunately, regulatory aspects make it more difficult for us to tackle the Asian market. However, what remains the most important thing for us is to continue to conduct our molecular research in order to bring new products onto the market", concludes Leclipteux.

INTERVIEW WITH
Dr. Sofoklis Kyriazakos, *CEO*

2.3. TESTING

COMPANY

Innovation Sprint

REGION

Brussels

Founded: 2016

Location: Brussels

Number of employees: 15

Turnover (2020): €633k

Growth (2020): +34%

R&D grants awarded (2020): 1.7M€

Start of exports: 2019

Share of exports in turnover: all commercial projects are currently outside of Belgium

Prizes, awards: Selected in the Covid-X contest among the Medical Devices used to fight Covid-19

Website: www.innovationsprint.eu

The young and R&D-driven Brussels start-up Innovation Sprint is active in the Life Sciences domain, more specifically in the healthcare and clinical research sectors, providing solutions in Big Data analytics and Artificial Intelligence on Real World Data and promoting innovation.

"Contrary to clinical or lab test data, Real World Data can be collected in the field directly from patients. Our company's flagship product, the eClinical platform Healthentia, has been developed precisely to capture real world medical insights from patients", explains Sofoklis Kyriazakos, CEO of Innovation Sprint.

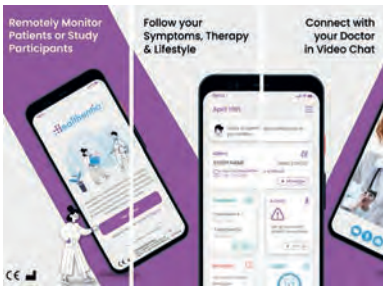
A DUAL OPERATIONAL CONTEXT

In order to develop its Healthentia personalized healthcare solutions and improve clinical and healthcare processes, Innovation Sprint relies on experts from the clinical, ICT, signal processing and machine learning fields. Today, the company's eClinical solution can operate in a strict clinical context during clinical research carried out by pharmaceutical companies or as a medical device for the patients themselves – who may or may not be under the supervision of healthcare institutions – who can download the platform and use it to report their symptoms.

"The digital platform conceptualized by Innovation Sprint has been a lifesaver for many medical institutions and organizations in times of the present pandemic."

"Healthentia supports pharmaceutical companies in optimizing their clinical trials by accelerating the trial processes, reducing failure rates, and validating drug or intervention efficacy and effectiveness with Real World Data insights. By collecting data from subjects in a clinical trial under very strict protocols, the pharmaceutical world can achieve cost savings while obtaining valuable insights to improve the design of drugs with higher efficacy", explains Kyriazakos.

In addition to supporting the pharmaceutical industry, Healthentia also offers patient-centric services to care institutions and health individuals. "By capturing and analyzing health and lifestyle data from mobile devices, our platform provides AI-driven smart services and virtual medical advice to patients as part of a hospital monitoring process or purely individual follow-up", the CEO goes on.



As a matter of fact, except for severe pathologies such as last stage cancer or Alzheimer's disease, individuals suffering from all types of illnesses can monitor their conditions using Healthentia. "As long as they have the physical and mental capabilities to keep a record of their situation, our platform is generic and does not exclude particular diseases. Of course, it can also be used when an individual is not ill to monitor his/her physical activity or sleep. In this sense, Healthentia is used more as an everyday health diary or logbook", Sofoklis says. At the end of the day, the company's ambition is to maintain a good equilibrium between the two pillars but also to build a bridge between clinical research and medical applications.

A PROVIDENTIAL TOOL IN TIMES OF PANDEMIC

The digital platform conceptualized by Innovation Sprint has also been a lifesaver for many medical institutions and organizations in times of the present pandemic. In fact, when the pandemic began in March 2020, the company immediately decided to make its digital tool available free of charge to organizations wishing to conduct clinical studies or to hospitals wishing to use it to predict and/or monitor COVID-19 infections. In this sense, it is entirely reasonable to say that the pandemic has been a catalyst for the medical technology industry and for Innovation Sprint in particular.

"Within the clinical context, research and non-for-profit organizations have been able to use Healthentia free of charge in order to carry out clinical trials. However, when a sponsor, such as a pharmaceutical company, wanted to conduct a clinical study on a cohort of patients to test a particular vaccine, therapy or drug, our solution came at a price. This process enabled pharmaceutical companies to measure the efficiency of particular preventive or curative treatments against COVID-19. However, let us also bear in mind that, even if we offer our digital solution for free, this does not mean it is evident to integrate in health processes", Kyriazakos asserts.

"Today, our Healthentia platform is of course multilingual and 90% of our clients and partners are located outside of Belgium."

Outside the clinical context, Healthentia was used in a hospital environment or directly at home as a Medical Device with a CE mark. "Healthentia allowed the remote monitoring of patients with chronic diseases. Since it was very difficult for these people to go to the hospital in times of COVID-19, we reduced the risk of potential infections for these patients. In addition, individuals could also keep track of possible COVID-19 symptoms by reporting their health status on our platform, enabling potential infections to be detected and determining the actions to be taken", he continues.

INTERNATIONAL PROJECTS

The company's CEO strongly believes that Belgium is a pioneer in the field of medical technologies and has one of the strongest life sciences ecosystems in Europe. "In our development, we have received support from Belgian regional authorities such as hub.brussels, lifetech.brussels and Innoviris. Moreover, Belgian federal authorities have also put in place the unique Belgian platform for mobile apps, mHealthBelgium, also known as mobile health Belgium, which centralizes all relevant and necessary information on mobile apps for patients, healthcare professionals and healthcare institutions in three languages (English, French and Dutch). mHealthBelgium consists of a validation pyramid with three levels. Today, we are at the first level and hope to reach the second level by the summer", affirms the CEO.

Moreover, Innovation Sprint has also received substantial support from the European Commission to conduct projects throughout Europe. "Today, our Healthentia platform is of course multilingual and 90% of our clients and partners are located outside of Belgium, mainly in Italy. It goes without saying that, within the framework of the European GDPR regulation, electronic informed consent (eConsent) is included in the Healthentia platform in order to safeguard patient data regardless of the country in which our solution is implemented", Kyriazakos says.

The Brussels company is now targeting the US to further develop its business outside Europe. "Due to the different regulatory framework in the US, we had to go through a long and daunting process to obtain certifications and compliance with US standards, such as 21 CFR Part 820. We should be able to commercialize our solution by the end of this year or by the beginning of next year in Uncle Sam's country", concludes Kyriazakos, full of ambition.

INTERVIEW WITH
Michael Mulqueen, *VP Business Development*

2.4. VACCINATION

COMPANY

eTheRNA immunotherapies

REGION

Flanders

Founded: Established in January 2013 as a spin-off company from the 'Vrije Universiteit Brussel' (VUB), following the development of its TriMix mRNA technology.

Location: Headquarters in Niel, Belgium

Number of employees: ± 70

Website: www.etherna.be

eTheRNA is a clinical stage biotech company dedicated to the design of mRNA-based immunotherapies for cancer and infectious diseases. eTheRNA was established in January 2013 as a spin-off company of the 'Vrije Universiteit Brussel' (VUB), Laboratory for Molecular and Cellular Therapy. In 2016 and 2019, eTheRNA secured its funding by a strong international syndicate of investors. eTheRNA's proprietary mRNA-based TriMix technology boosts dendritic cells (DCs) – the crucial antigen presenting cells that prime T cells - leading to a more comprehensive, sustainable and safer enhancement of the patient's immune system. The primary goal of eTheRNA is to develop TriMix into an injectable in vivo product that can be made available "off-the-shelf", which makes it a commercially attractive and convenient option for various patient populations.

ETHERNA'S THREE STAGES OF GROWTH

"We can break the history of the company down into three stages of growth", according to Michael Mulqueen, eTheRNA's VP of Business Development. "The first few years, directly after the spin-off was established, were devoted to building up our core platforms and further enhancing them".

"The ability to manufacture mRNA-based products at scale is still emerging as an industry."

"During the second phase, which started in 2019 and ended at the beginning of 2021, we expanded the manufacturing side of the company. The ability to manufacture mRNA-based products at scale is still emerging as an industry. We recognized very early on that the production of our molecules was going to be a key bottleneck in the development process due to the fact that the COVID-19 pandemic has really stretched the industry's capabilities to its limit. That is why we set up a small-scale production facility of our own right here in Belgium: one unit is devoted to producing materials that we can use in our laboratories for our experiments and to validate the technologies, while the second one is a GMP grade plant that we could use to produce materials for clinical trials on humans. It must be mentioned though that these production plants are not scaled to produce massive amounts of materials for commercial sale. We would look to a partner to help us do that, but it does

mean that we can move our own programs rapidly through development and not wait and rely on other people to make our materials for us."

Mulqueen notes that eTheRNA has only recently started its third growth phase: "We are now looking to do our series C funding round, with the idea of taking our products into the clinic and then further develop them through partnerships so that they can eventually be brought to market."

FOCUS ON ONCOLOGY AND INFECTIOUS DISEASES

Although eTheRNA has primarily focused on oncology as its main therapeutic target up to now, it is also active in the field of infectious diseases, including COVID-19. The company is now even starting to look into the use of RNA therapeutics in other areas such as auto-immunity. "Right now, we are only just at the cusp of proving mRNAs as therapeutics and bringing them forward. Exciting times are definitely ahead of us", according to Mulqueen. "The pandemic, as bad as it has been for everybody, has been positive news for our industry, as it has brought RNA to the attention of the public and proven that RNA therapeutics can actually be life-saving. We are hoping to build on this wave of popularity to help develop our own products in other therapeutic areas as well as in infectious diseases."

One of the important technologies eTheRNA took with it when it spun off from the VUB is a molecule called TriMix. This is a very potent molecule used as a key stimulant in eTheRNA's therapeutics and is one of the unique features that the company has access to. "As you might already suspect from its name, TriMix is actually three molecules mixed together", explains Mulqueen. He goes on by stating that "these three molecules are very powerful in stimulating the immune system. When correctly used, the idea is that someone gives the patient these three molecules, plus some other cancer specific or infectious disease-specific molecules. This combination should then induce an immune response, which helps the patient to either reject the cancer or, in the case of COVID-19, reject the infection and protect you against it."

THREE INDUSTRY LEADERS

eTheRNA has to compete with a lot of competitors in the RNA area. "There are three giant companies active in the field of RNA: BioNTech, Moderna and Curevac", Mulqueen points out. "They are now all billion-dollar public companies, but they all started out from very much the same place we did, with RNA therapeutics in the early days of the industry. They have subsequently grown to the size and place they are now. We as eTheRNA are ambitiously anticipating not exactly the same, but a similar kind of growth for ourselves. Apart from the three aforementioned companies, there are about twenty to thirty smaller companies in Europe doing research on RNA. They are still probably slightly behind us in the technology development, because we have a good lead over them thanks to our collaboration with the VUB during the first few phases of our company."

"The pandemic has proven that RNA therapeutics can actually be life-saving."

Mulqueen concludes by stating that in the near future eTheRNA will "increase its focus on partnering when its programs will have matured to the stage where they are ready to be partnered. In the next growth phase of the company, we are looking to expand our network of contacts to start entering into some strategic collaborations with big pharmaceutical companies both in Europe and increasingly also in America and Asia. We do see Asia as being a region that is going to expand in the area of healthcare. It is now already overtaking Japan as the second major medical market in the world and it is forecast to surpass America in the next five years. Now that we have established our platform and have our technology base in place, we are looking forward to bringing a string of products onto the market."

SUMMARY

eTheRNA immunotherapies is driving mRNA technology and therapeutic product development to deliver an innovative generation of RNA chemistries, RNA process technologies and a new and advanced generation of therapeutic and vaccine products. eTheRNA uses its established R&D foundations and in-house GMP manufacturing facilities and builds on its proprietary mRNA, mRNA adjuvant and mRNA formulation platforms to progress technology innovation and product development.

INTERVIEW WITH
Hughes Bultot, *CEO*

2.4. VACCINATION

COMPANY

Univercells

REGION

Wallonia

Founded: 2013

4 locations in Belgium: Brussels, Nivelles, Jumet, Gosselies

Number of employees: 340 (2021)

Turnover (2020): 7,9 mio €

Growth (2020): constant

Investments (2020): 19,1 mio €

Start of exports: 2017

Share of exports in turnover: 100%

Prizes, awards:
Excellence in Pharma: Bioprocessing & Manufacturing – CPhI Awards 2019
Pharma Innovation Awards – Pharma Manufacturing 2019
Le Beffroi de Cristal – 16 01 2019 – for Univercells
And for José Castillo & Hugues Bultot: Chevalier du Mérite wallon – 17 10 2019.

Website: www.univercells.com

Univercells
Biologics for all

The innovative Walloon company Univercells produces novel manufacturing technological platforms for biologics and offers comprehensive solutions to make biologics available and accessible to all. By combining the best of technology innovation we can rapidly deploy low-cost, localized bioproduction facilities.

"We are committed to revolutionizing the availability of biologics around the world, by making essential medicines accessible to all, in both quality and price. By locally deploying cost-effective manufacturing platforms, we enable 'in-country, for-country' biologics production, creating value for all: manufacturer, healthcare systems and patients", asserts Hugues Bultot, CEO and Co-Founder of Univercells.

Fortified by rapid growth and success, Univercells established two affiliate companies in 2020: Univercells Technologies and Exothera. "Launched with the support of private equity fund KKR, Univercells Technologies is a global provider of innovative biomanufacturing technologies to achieve cost-effective viral production from R&D to commercial scales. Exothera, our CDMO, capitalizes on our expertise with these manufacturing technologies as well as traditional platforms to offer best-in-class bioprocessing services to deliver bespoke process development and GMP clinical and commercial production of viral vectors. Additional affiliate companies will be launched soon", affirms Bultot.

"During the pandemic, we played a particularly important role in the provision of manufacturing equipment to major pharmaceutical companies producing COVID-19 vaccines."

THREE MAJOR MARKET OPPORTUNITIES

Comprised today of four affiliate companies, Univercells Group work to solve the problem of access to bioproduction in three main ways: technology-driven affordability; access to training and skills; and constant innovation.

For both established markets like vaccines (including COVID-19) and nascent markets like gene- and cell-therapy, to achieve cost-effective viral production, the company offers a technology portfolio based on engineering principles of intensification and chaining. "The two major manufacturing technological solutions we have brought to the market are the scale-X™ bioreactor, an intensified fixed-bed technology for cost-effective and scalable viral production, and the NevoLine™ Upstream platform, which

enables intensified and automated virus production. Our equipment allows for a COGS and CAPEX reduction by 5 to 10 compared to other manufacturing techniques", explains the CEO.

Univercells is also addressing other barriers to bioproduction and market entry – such as skills and training. Familiarity with complicated bioproduction processes is one of the reasons why biological therapies are rarely produced in low- and middle-income countries. Univercells Group combines a focus on creation of physical bioproduction infrastructure with efforts to develop partner human capital and capabilities. "Current bioproduction models often prevent a global supply of affordable biosimilars. This is why Univercells has complemented our technology platforms by developing a comprehensive training program for bioproduction, starting with a collaboration in Latin America for manufacturing of monoclonal antibodies. Our training program, which can also be delivered virtually, improves the skill base of the local workforce and addresses another barrier to local production of critical biologics", Bultot states.

The last market opportunity the company is seizing revolves around new classes of products, namely RNA. COVID-19 vaccines saw extraordinary leaps forward in scientific innovation, but to support access, these new products must be combined with manufacturing technologies able to supply sufficient quantities at an affordable price. "Reaching and sustaining global immunization can only be achieved via novel production and delivery models. Univercells is using our historically-validated approach to combine science, engineering and entrepreneurship to re-engineer how RNA vaccines are made so that there is a simple, scalable and cost-efficient way to produce RNA-based drugs", he continues.

PANDEMIC PREPAREDNESS OPPORTUNITIES

At the outbreak of the pandemic, Univercells made the decision to add a second building dedicated to COVID-19 to its planned Jumet campus. This meant that Univercells could additionally offer bioprocess and drug substance manufacturing services to partners developing COVID-19 vaccines. "During the pandemic, we played a particularly important role in the provision of manufacturing equipment to major pharmaceutical companies producing COVID-19 vaccines and, more recently, in the supply of vaccines from our CDMO Exothera", explains Bultot.

Furthermore, recognizing the forthcoming vaccine manufacturing bottleneck and the demand for control of production, Univercells created a business unit dedicated to the dissemination of biomanufacturing capacity. This means that pharmaceutical companies wanting to tech-transfer their production capacities in low and middle-income countries have also been able to rely on the project management and training capabilities and, if needed, Belgian infrastructure of Univercells. "For example, in order to strengthen the local West African technological capacity for ongoing bioproduction and biomedical research, Univercells announced a collaboration agreement with Senegalese stakeholders (including Institut Pasteur de Dakar). We believe in autonomy - supporting Senegal to produce their own Covid-19 vaccines", he adds. Our facilities, both in Belgium and for partners, are designed to be modular and flexible, in order to adapt to changing market needs. "In this sense, the COVID-19 crisis has illustrated that our vision was pertinent", believes Bultot.

SUPPORTED BY THE BILL & MELINDA GATES FOUNDATION

It goes without saying that all countries, regardless of income, should have access to medicines and vaccines. By tech-transferring both technology and know-how to partners, including in developing countries, Univercells aims at building a sustainable business whilst having an impact on global health. This vision was supported by the Bill & Melinda Gates Foundation, who funded Univercells for their breakthrough vaccine manufacturing platform and to scale that platform for Polio, Measles and Rubella vaccines.

In the short term, by relying on the excellent Belgian health technology ecosystem, Univercells' next ambition is to be specifically active on every continent. "The next big step for us would be to build infrastructure and bioproduction centers throughout the world where patients could access needed products manufactured using our equipment", concludes the CEO.

"By tech-transferring both technology and know-how to partners, including in developing countries, Univercells aims at building a sustainable business whilst having an impact on global health."

INTERVIEW WITH

Prof. Dr. Patrick R MAHY,

Administrator – Treasurer

2.4. VACCINATION

COMPANY

Vac4EU

REGION

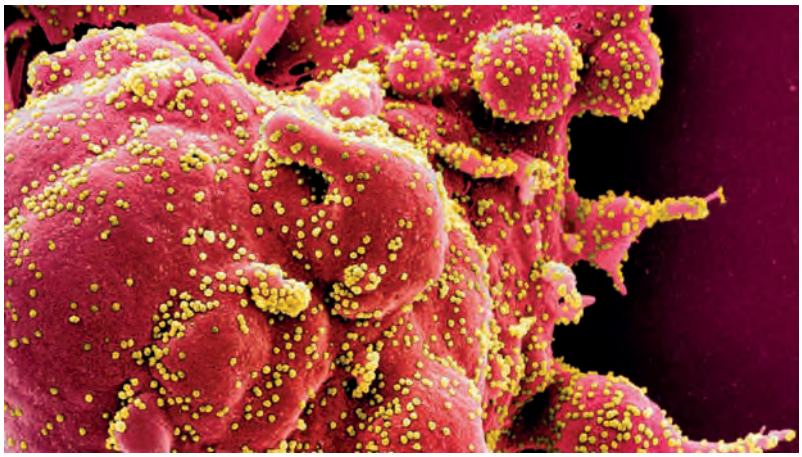
Brussels

Founded: 2020

Location: Brussels

Number of member organizations: 29

Website: www.vac4eu.org



VAC4EU (Vaccine monitoring Collaboration for Europe) is the sustainability solution of the ADVANCE project, which was funded by the Innovative Medicines Initiative (IMI) from October 2013-March 2019. The ADVANCE project has demonstrated that the wealth of existing real-world health care data in the EU can be used to generate actionable evidence on vaccine coverage, benefits and risks. Based in Brussels, VAC4EU implements the ADVANCE vision, system and blueprint and enables robust and timely evidence-generation on the effects of vaccines in a collaborative manner in Europe for use by citizens, health care professionals, public health organizations and regulatory agencies. VAC4EU is a multi-stakeholder international association with a study network to run studies and an open community for scientific debate.

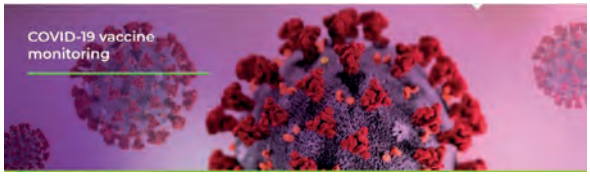
CONTINUATION OF THE ADVANCE PROJECT

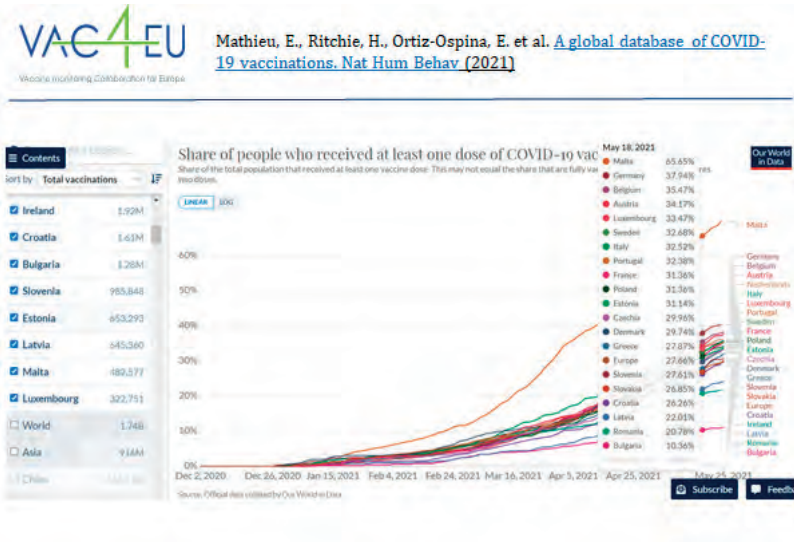
"VAC4EU is the real-life continuation of the ADVANCE project", explains Prof. Dr. Patrick R Mahy, VAC4EU Administrator-Treasurer. "In the ADVANCE project, we had 47 different members and most of them are aware of VAC4EU. Some of these former ADVANCE members have subsequently joined VAC4EU and others are looking from the sidelines to see how VAC4EU grows before taking a decision on whether to join or not. Unlike the ADVANCE project, VAC4EU is no longer a European project but, rather, a private non-profit international association. Some of the former ADVANCE project members have difficulties joining VAC4EU, mainly because, in order to become a member of VAC4EU, they have to apply for membership and pay membership fees. In certain cases, organizations that were part of the ADVANCE project simply cannot meet these requirements because of their statutes prohibiting them to pay membership fees. Pharmaceutical companies and other private organizations that are listed on the stock exchange are excluded from becoming a VAC4EU member as VAC4EU wants to emphasize its independence from the pharma industry."

"VAC4EU acts as a facilitator and intermediate between those asking for studies and the members."

"The objective of VAC4EU is to provide quickly available, honest and transparent information on vaccine coverage, effectiveness and safety in

VAccine monitoring Collaboration for Europe





Europe", Prof. Dr. Mahy continues. "You could say that VAC4EU acts as a facilitator and intermediate between those asking for studies and the members. VAC4EU will provide all the facilities and tools needed to move forward in applying and performing the studies. VAC4EU's power lies in its network covering health data on roughly 120 million European citizens." He clarifies the role of VAC4EU by saying that when, for example, the European Medicines Agency (EMA) opens a call to perform a study, VAC4EU quickly conducts a survey to find out who amongst the members wants to participate in it. In the survey, members have to state their willingness to participate and confirm they have sufficient human resources and time. In the end, when VAC4EU has obtained all the survey results, they discuss with the members that have answered positively to select the Lead Operating Centre (LOC). Subsequently, it is this LOC that will respond to the call and become the lead on the study in collaboration with all other implicated members.

"VAC4EU's objective is to provide transparent, upmost scientific and reliable information to those who have to decide what is the best vaccine strategy in the event of another major pandemic."

Prof. Dr. Mahy points out that another goal of VAC4EU is to help public political decision-makers with vaccine strategy: "it is obvious that we may encounter another pandemic in the future, so based on the experience gathered from the influenza flu vaccine of 2009 and the anti-COVID-19 vaccine now, VAC4EU's objective is to provide transparent, upmost scientific and reliable information to those who have to decide what is the best vaccine strategy in the event of another major pandemic."

ADVANCE – THE PREDECESSOR OF VAC4EU

The reason VAC4EU exists today is because of the ADVANCE project, which was established after the 2009 influenza flu pandemic. At that time, the authorities as well as the vaccine manufacturers, public health institutes, universities and other stakeholders involved with vaccines realized that the best possible way to combat a pandemic is to gather resources and face it together. Prof. Dr. Mahy states that "in the past, it was not possible for some of the public health institutes and universities to share data with pharmaceutical companies and vice versa. Everyone was working on their own without knowing what the others were doing. This led to some things being duplicated, which was a waste of time and resources. After the 2009 pandemic, people finally realized that it was inefficient to work in this way. That is why the pharma industry, mainly the vaccine manufacturers, started the ADVANCE project together with some of the public health institutes under the umbrella of the IMI. The ultimate goal was to look at the possibilities on how to enter into a fair collaboration. In the end, this was the smart thing to do."

Although it is still somewhat unclear at this moment what the future holds in store for VAC4EU, Prof. Dr. Mahy is quite confident that the organization will keep on growing: "I hope that, in ten to twenty years from now, VAC4EU will have become one of the major actors in the vaccine domain. Right now, we have 29 member organizations, but we want to increase that number. It's a pity that as of yet we don't have more members from Eastern European countries, but I expect that we will develop more collaboration arrangements with them over time. We are also still responding to EMA calls and still receiving requests to run studies from the pharmaceutical industry. We were only created less than one year ago, so if you see where we are already and what we have been able to accomplish in that short timeframe, then I am quite confident that the future looks bright for VAC4EU."

STAKEHOLDERS

SECTION 3

STAKEHOLDERS

3.1 OFFICIAL PARTNERS

FPS Foreign Affairs

The promotion and defense of Belgian economic interests abroad is a top priority of the Federal Public Service (FPS) Foreign Affairs. This is done in a number of ways. FPS Foreign Affairs coordinates Belgium's ambitious trade and investment protection policy, it monitors market access problems and it provides diplomatic support to Belgian companies abroad. Moreover, FPS Foreign Affairs supports Belgian businesses in their international activities by coordinating the economic missions of HRH Princess Astrid, as Representative of His Majesty the King, and through the State visits led by His Majesty the King.

FPS Foreign Affairs also actively promotes Belgium's international image as a good place to do business, by participating in international forums, such as the International Expositions and the World Economic Forum, by organizing bilateral visits and by ensuring Belgium's multilateral action in the relevant international organizations.

KINGDOM OF BELGIUM
Foreign Affairs,
Foreign Trade and
Development Cooperation

Follow us on: www.diplomatie.belgium.be/en

Flanders Investment & Trade

Flanders Investment & Trade (FIT) promotes international entrepreneurship in Flanders in a sustainable way as a key factor in the social and economic development of the region. FIT does so by supporting the international activities of Flemish companies and by attracting foreign investors to Flanders. FIT assists, supports and stimulates companies in international business and offers tailored advice and guidance. Companies can call on its network of contacts both in Flanders and abroad. And FIT provides financial support and information on a wide range of financial incentives, country specific business practices and market opportunities.

Flanders has many assets for ambitious Flemish enterprises and SMEs as well as for interested international companies. For companies based in Flanders, its region acts as a perfect gateway to global markets. For them, FIT tries to lower the threshold to doing business abroad and offers all Flemish companies worldwide publicity. FIT promotes its services, provides information and knowledge about export and offers networking opportunities between entrepreneurs and brings them into contact with potential partners abroad.

Flanders is a pole of attraction for foreign companies: thanks to its central location in Europe, its strongly developed infrastructure, its innovative clusters and R&D friendly incentives, open economy and numerous other strengths. FIT adopts a tailored approach to potential investors and convinces them of the opportunities for their company in Flanders. Furthermore, FIT focuses on existing investors in Flanders planning to expand their businesses locally. Innovative clusters are of key importance to Flanders as a knowledge region. FIT assists these clusters in their internationalization process and tries to attract foreign investors capable of strengthening clusters to grow into major international players.

FLANDERS INVESTMENT & TRADE
Flanders State of the Art

Follow us on: www.flandersinvestmentandtrade.com

Wallonia Export-Investment Agency (AWEX)

The Wallonia Export-Investment Agency (AWEX) develops and manages the international economic relations of Wallonia, the Southern region of Belgium. The agency, which employs more than 400 people, promotes the competitive advantages of Wallonia internationally.

AWEX makes use of its global network of more than 100 offices to strengthen in a sustainable way the image of Wallonia abroad. To promote international business relations, AWEX exchanges commercial information with both the international business community and Walloon companies.

The agency provides exporters, importers and potential investors with information on:

- the region of Wallonia and its export potential by means of macro-economic data
- Wallonia-based companies and their products/services
- the potential of Wallonia-based companies for international partnerships

Furthermore, AWEX assists companies based in Wallonia with a wide range of services in regard to their international activities such as:

- gathering information on foreign markets
- carrying out individual market studies upon request
- organizing trade missions, group stands at international fairs, and visits to Wallonia by foreign dignitaries and captains of industry
- promoting commercial contacts with international organizations
- providing financial incentives for export activities
- organizing professional training of specific commercial skills
- increasing awareness of international business opportunities

In addition, AWEX has a key role in the expansion or development of the business of potential foreign investors. It offers its expertise in how to establish a business in Wallonia, as well as provide them with detailed information and tailored made assistance on local investment opportunities.

Wallonia.be
EXPORT
INVESTMENT

Follow us on: www.investinwallonia.be & www.awex-export.be

hub.brussels

hub.brussels, the Brussels Agency for Business Support is offering free-of-charge solutions and advice for start-ups and scale-ups in Brussels and beyond, as well as services focusing on strategy, financing, clustering and internationalisation.

One of the missions of hub.brussels is indeed to facilitate the internationalization of Brussels' economy by helping Brussels businesses compete in global markets. More than 90 economic and commercial attachés located on every continent provide free support to SMEs, approach potential local prospects and partners, organize networking events, ...

A "Welcome Package" is available to potential investors, providing them with fully equipped office space for three months and a wide range of services so that they can experience the advantages of setting up business operations in Brussels.

hub
.brussels
our business is to help yours

Follow us on: www.hub.brussels

3.2
HEALTH TECHNOLOGIES PARTNERS

Agoria eHealth Technology Club

Agoria is the Belgian federation for the technology industry. We pave the way for all technology-inspired companies in Belgium that increase our quality of life through the development and application of tech innovations. Agoria wants to use its unique position, special know-how and extensive international network to create the context to strengthen the dream marriage between entrepreneurial drive and technology.

Our members:
www.agoria.be/WWW.wsc/rep/prg/Applcontent?FAction=MEMBERSLIST&vWebSession-ID=16001&vUserID=999999&ApplMenuID=4645

Follow us on: www.agoria.be

.AGORIA

beMedTech

beMedTech is the Belgian federation of the medical technology industry and has more than 200 affiliated companies. Its members are manufacturers and/or distributors and are divided into five product segments: in-vitro diagnostics (IVD), consumables, implants, medical investment goods (MES) and Extra Muros solutions, including Digital Health. Together they represent over 500,000 technologies for an annual turnover of € 2.4 billion not including export and they account for approximately 16.820 FTEs in Belgium. beMedTech estimates that the total medical device industry in Belgium has a turnover of about € 3.5 billion and employs about 20,000 people.

beMedTech has a clear vision: by uniting the Belgian manufacturers and distributors of medical devices the association strives to emphasize their positive role for the healthcare sector. The beMedTech members invest in innovative medical technologies and in the training and education of health professionals. Together with its members, the federation contributes in a responsible manner, both to the quality of patient care and to the sustainability of the healthcare system.

Our members: www.bemedtech.be/nl/over-bemedtech/onze-leden

Follow us on: www.bemedtech.be

be MedTech
Medical Technologies Belgium

Bio.be (part of essenscia)

Bio.be is the Belgian federation representing the biotech and the life sciences industry. It is the recognised voice of the biotech community and operates under the umbrella organisation essenscia.

Belgium is considered to be one of the world's most prominent research nations. Our Belgian ecosystem is highly valued internationally, confirmed by the many foreign investments and transatlantic partnerships. Our entire value chain – from knowledge, to biomanufacuring processes and products – has a global impact and is very much cherished. As such, our voice is not limited to Belgium. Bio.be is also our members' contact for EuropaBio, the European Association of Bioindustries, and ICBA, the International Council of Biotechnology Associations.

By joining bio.be, our members become part of an effective advocacy and regulatory voice representing the collective interests of the Belgian life sciences and biotechnology industry. We have the tools to help our member's business reach its full potential - from R&D to growth and excellence in biomanufacturing - through advocacy, communications and membership services.

bio.be
Biotech and Life Sciences Industry in Belgium
PART OF essenscia

Follow us on: www.essenscia.be

BioWin

BioWin is the Health Cluster of Wallonia, Belgium, the regional reference holder for all stakeholders in health biotech and medtech research and innovation projects.

Its mission is to accelerate innovation to:

- meet tomorrow's public health challenges.
- develop the knowledge, employment and competitiveness of all players in the health sector ecosystem in Wallonia

by bringing together all the innovation system players in Wallonia's life science field, with the goal of stimulating regional economic redeployment. The cluster is also involved in implementing the sector's industrial policy (industrial innovation and research, training, support for business growth). The purpose of this is to develop and anchor skills, knowledge and jobs.

Our members: www.clusters.wallonie.be/biowin-fr/membres.html?IDC=1350

BIOWiN
THE HEALTH CLUSTER OF WALLONIA

Follow us on: www.biowin.org

BlueHealth Innovation Center

The BlueHealth Innovation Center (BHIC) is a unique combination of top players (local governments, companies, research centers and care institutions) who share the same common goal. Its mission is to support the digital transformation of healthcare through digital innovation. BHIC specifically stimulate young entrepreneurship in health tech.

BHIC aims to coach students, start-ups and care professionals in the development of innovative digital projects, be it in cure, care or prevention.

Our members: www.bhic.care/en/get-know-our-start-ups

Follow us on: www.bhic.care/en

flanders.bio

flanders.bio is an independent life science cluster, and a member driven organization with currently more than 330 members from Belgium and abroad.

flanders.bio and its members want to be the proud advocates of a reputable global-impact ecosystem in life sciences. flanders.bio is doing this by

- improving the translation from academic research to innovative products;
- facilitating cross-technology, cross-sector collaborations and stimulate the development of integrated life sciences solutions, sourcing from expertise in biotech, medtech, digital sciences and other relevant domains;
- performing early pilot trials or test products in view of obtaining marketing authorization
- ensuring appropriate focus in funding strategies and provide information on dilutive & non-dilutive funding options;
- taking actions to attract talent to life science companies, identify the talent gaps, and actively pursue a strategy to close these gaps.

flanders.bio serves its members by organizing networking and training activities, supporting internationalization, providing services and building expertise.

Our members: www.flanders.bio/en/member-directory

Follow us on: www.flanders.bio/en

Flanders.Health

Flanders.Health is a consortium of Flemish bio-, nano- and med-tech sector and is a collaboration of flanders.bio, DSP Valley and Medtech Flanders. The organization is the cluster for personalized medicine in Flanders.

Flanders.Health is supporting businesses with by developing and validating ideas enabled by such things as biomarker discovery and validation for early onset detection, data gathering and analytics (including life style and wearable data), digital modelling and prediction of medical interventions, smart implantables, advanced manufacturing techniques for personalized drugs or prosthesis, artificially intelligent diagnosis, smart logistics for cell therapy, ...

The cluster of Flanders.Health is developing new approaches to better manage patients' health and targets therapies to achieve the best possible outcomes. By using new technologies, the era of truly personalized care is realized.

Follow us on: flandershealth.tech

GIBBIS

GIBBIS, the employers' federation of the associative private sector of healthcare institutions in Brussels, represents 52 member institutions spread over more than 55 sites in Brussels and covering the 19 communes of the Brussels Capital Region. The federation aims to be a reference partner for the political world, both at Brussels and at federal level, for the different stakeholders in the Brussels healthcare sector. GIBBIS's mission is to defend the values of the associative private sector of healthcare in Brussels: the quality of care, the empowerment of the various actors in healthcare, the independence of management and the allocation of resources in healthcare institutions, the patient's freedom of choice, therapeutic freedom and equal access to care. To adapt the sector to change, GIBBIS is convinced of the importance of innovation. Among other things, GIBBIS supports the need for e-health, an essential issue to enable efficient cooperation among healthcare providers. The sector must be able to invest in innovative projects with a high return on investment, such as digitisation of information. GIBBIS strives to facilitate the sector's use of new technologies, in particular by informing its members and raising their awareness of its members about the importance of innovation and by enhancing cooperation with the various Brussels stakeholders, in particular through its participation in the e-health.brussels platform.

Our members: www.gibbis.be/fr/nos-membres

Follow us on: www.gibbis.be

Imec

Imec is a micro-electronics research center in the hearth of Flanders. It leverages deep-tech knowhow and combines it with software and system knowledge to build up an exceptional portfolio of advanced technologies. This is supported by the three pillars in R&D:

- a unique infrastructure that includes a 2.5-billion-euro 300mm semiconductor pilot line
- more than 4,500 expert scientists from over 95 countries
- an ecosystem of more than 600 world-leading industry partners and a global academic network

The combination of these technologies and know how opens the door to smart, sustainable solutions in domains such as healthcare, clean energy and Industry 4.0.

Follow us on: www.imec-int.com/en/lifesciences

Imec developed a breathalyzer which analyzes the particles exhaled by a person to detect for the presence of the coronavirus.

Follow us on: www.imec-int.com/en/expertise/life-sciences/coronavirus-breathalyzer

Innoviris

The Brussels funding agency Innoviris stimulates and funds research and innovation in the Brussels-Capital Region.

To strengthen the innovative ecosystem, we empower and connect companies, non-profit organizations, research institutes, STEM partners and citizens. The European Innovation Scoreboard 2021 underlines the position of the Brussels Capital-Region as an Innovation Leader.

Follow us on: www.innoviris.brussels

JLABS @ BE

JLABS (JLABS) is a global network of open innovation ecosystems, enabling and empowering innovators across a broad healthcare spectrum including pharmaceutical, medical device, consumer and health tech sectors to create and accelerate the delivery of life-saving, life-enhancing health and wellness solutions to patients around the world.

JLABS @ BE is the first incubator of J&J in Europe and accommodates life science start-ups focused on innovations across the entire healthcare spectrum, including pharmaceuticals, medical devices, consumer and health technology.

JLABS, focusses on removing obstacles to success by helping innovators unleash the potential of their early scientific discoveries, by giving access to state-of-the-art laboratory instrumentation and equipment. JLABS is a no-strings-attached model, which means en-

trepreneurs are free to develop their science, while holding on to their intellectual property. JLABS also produces campaigns to seek out the best science called QuickFire Challenges. www.jlabs.jnjinnovation.com/locations/jlabs-be

Follow us on: www.jlabs.jnjinnovation.com/JLABSNavigator/location/Beerse

Lifetech.brussels

Lifetech.brussels is the public Brussels HealthTech cluster. It aims at facilitating and stimulating the attractivity and success of high potential HealthTech solutions with a focus on social and environmental impact. The main goal is to accelerate the availability of innovative healthcare solutions at the service of patients' wellbeing and professionals' needs. The cluster promotes collaborations and synergies between entrepreneurs, researchers, makers, practitioners and industries.

Main services:

- **Individual coaching through the Lifetech Studio**: free of charge personalized guidance to turn innovative idea into a commercial solution (business model, financing strategy, subsidies, partnerships, innovation management, internationalization, regulatory requirements awareness,...).
- **Collective coaching through the MedTech Accelerator®**: 6-month of a collective and individual coaching program to boost the development of (connected) medical devices with the help of seasoned experts and dedicated coaches (50+ startups helped since 2016; 6th edition in 2021). For more information: http://www.medtech-accelerator.eu/.
- **Prototyping through the MedTech Atelier®**: complete the individual coaching of the Lifetech Studio as well as the collective support of the MedTech Accelerator by offering support, in terms of skills and technological equipment, for the early prototyping of healthtech solutions.
- **Lifetech Cluster:**
  - Networking: animation of a vivid HealthTech community (workshops, pitching sessions, ...)
  - Visibility: to increase the visibility of the members and the development of their network
  - Internationalisation: support the internationalisation of the cluster members through the organization of missions abroad, the support of a broad network of trade advisors worldwide and from a EU team to find EU funding and potential technological/commercial partners.
- **Prevention Project**: facilitate testing, validation, and adoption of innovative solutions for primary, secondary, and tertiary healthcare prevention.

The list with the member companies of lifetech.brussels is available on the following website: www.lifetechbrussels.com/our-members/

Follow us on: www.lifetech.brussels
Contact: lifetech@hub.brussels

Mecatech

MecaTech is a Competitiveness Cluster in Mechanical engineering based in Wallonia, Belgium. Its mission is to create jobs and activity and contribute to the reindustrialization of the Region. This objective is achieved mostly through the development of large collaborative industrial innovation projects (more than 134 since 2006) developed with a network of 340 members. Members include SMEs, large companies, universities, research and training centres. MecaTech supports this ecosystem to develop innovative products, equipment and industrial processes with higher added value.

This network is active in 4 technologies: Advanced Materials, Advanced Manufacturing, Mechatronics, Data Technologies. The sectors addresses are extremely varied: Energy & Environment, Medical Device, Defense & Security, Transport & Mobility, Manufacturing.

MecaTech's key strategic focus is digitalization, and particularly the implementation of digital technologies (such as IoT, AI & Data analytics, AR/VR etc.) in manufacturing activities & equipment. MecaTech developed activities & services to support manufacturing companies in their transformation journey (both process & product innovation), but also helps technology company to upgrade their competitiveness. As a result, over 60% of the regional innovation projects developed by MecaTech involve a digital component.

Our members: www.polemecatech.be/fr/le-reseau/

Follow us on: www.polemecatech.be

MECATECH CLUSTER
WALLOON COMPETITIVENESS CLUSTER IN MECHANICAL ENGINEERING

Medtech Flanders

Medtech Flanders is a network organization of Flemish medical device companies together with research partners, subcontractors and partner-organizations.

Medtech Flanders wants to promote and advance the medical technology sector in Flanders. It also aims to build and improve the Medical Technology ecosystem, by promoting the sector with potential customers, investors, potential employees, politicians, and others. But also improving the ecosystem itself by organizing network events and assisting in the search for talent.

The core members of the organization are companies developing and/or producing medical devices according to the European Medical Device regulation, directive 93/42/EG for Medical Devices, Active Implantable Medical Devices (directive 90/385/EEC) and In Vitro Diagnostic (IVD) Medical Devices (directive 98/79/EC).

Companies developing other medical devices can be a general member of Medtech Flanders.

Follow us on: www.medtechflanders.be

MedTech Flanders

Medtech Wallonia

MedTech Wallonia is the entry point and the advisor for projects and startups in the field of Digital Health and medical devices in Wallonia. Our aim is to be the relevant impulse for MedTech companies in Wallonia.

Our missions:

- Give a clear perspective of relevant support for MedTech companies.
- Maximize available resources in our territory and strengthen the whole value chain of the MedTech landscape.
- Promote the Walloon MedTech Industry at a national and international level.
- Improve global MedTech activities and create new jobs in Wallonia.
- Foster innovation trough collaborative projects supported by the two clusters and the Walloon Region

Together with our partners, we want to create the best field for efficient and meaningful innovations. We are making the best of the expertise, the infrastructure and the ecosystem available in our region to bring up new opportunities.

Follow us on: www.medtech-wallonia.be

MEDTECH WALLONIA

Orsi academy

Orsi Academy facilitates in an ecosystem of people who are passionate about improving the best practices in minimally invasive surgery. In this 'bruising melting pot', healthcare professionals, the medical devices industry and academics strengthen each other, rather than working in isolation. Orsi considers working together the key to success, benefiting from each other's insights, knowledge and expertise, combined with a multi-disciplinary work environment.

Orsi Academy offers a wide variety of training models. From basic skills tests on the simulator, plastic anatomical pelvic & thoracic models, 3D printed models, isolated organs to dry-lab animal models. Finally, we have a team of veterinarians and animal caretakers providing guidance during training programs on anesthetized porcine models. The academy also offers robotic surgical training.

Follow us on: www.orsi-online.com

ORSI ACADEMY

PAQS

Created late of 2013, the Platform for Continuous Improvement of Quality of Care and Patient Safety (Plateforme pour l'Amélioration continue de la Qualité des soins et de la Sécurité des patients – PAQS ASBL) aims to promote, support and organise the development and implementation of initiatives of continuous quality of care and patient safety improvement in Brussels and Walloon healthcare institutions.

PAQS's vision is to promote a healthcare sector aiming for excellence in its practices and structural function through the standardization of continuous improvement practices. To do so, PAQS:

- positions itself as a Centre for expertise and innovation recognised for its know-how on quality and patient safety in the healthcare sector, through the development of knowledge along with general and specific competencies and the widely spread of them to the healthcare sector, develops global, consistent and effective services attuned to the sector's needs, based on three principles: support, education and resources;
- positions itself as a privileged interlocuter to private bodies and the authorities or regional, community, federal and international public organisations regarding the area of quality and patient safety in the healthcare sector;
- develops and maintains a network bringing together stakeholders active in the field of quality and patient safety in healthcare, and works to link the various existing (and future) initiatives.

Follow us on: www.paqs.be

pharma.be

pharma.be, the General Association of the Innovative Medicines Industry, brings together more than 125 innovative (bio)pharmaceutical companies active in Belgium. Our members focus on research and development of new medicinal products for both human and veterinary use and employ more than 40,500 employees in Belgium.

Science serving life

We place health at the center of life and aim for the best life possible for all people in Belgium. Therefore, it is our mission to provide the care that will make Belgium the healthiest place in which to grow up, live, work and grow old.

We are passionate about science, as long as it allows us to positively impact lives.

While the world is changing fast, with new pathologies and viruses, an ageing population and ever-increasing digitization, many new questions arise. Scientific progress rarely follows a straight line. In our business, failures greatly outnumber breakthroughs. We cannot change this. But as true scientists, we do not surrender, we never give up. It is our responsibility to try harder, and to look for the best health outcomes for every single individual.

We are not in this alone. Along with patients, doctors, hospitals, mutual health insurance providers, pharmacists, universities, research bodies, regulators and the government we are united by the common desire to guarantee the best possible healthcare.

Together we are determined to ensure a healthy life for all.

Follow us on: www.pharma.be

VIB

VIB is widely recognized as an established and world-leading knowledge center in life sciences and biotechnology with an excellent reputation in technology transfer. The unique combination of strategic basic research and a clear focus on innovation & business is one of the major contributors to its success. VIB is highly committed to being the driving force behind the growth of the dynamic life sciences cluster in Flanders.

VIB operates in close partnership with the five universities in Flanders – Ghent University, KU Leuven, University of Antwerp, Vrije Universiteit Brussel and Hasselt University.

Follow us on: vib.be

ViTalent

ViTalent is the first specialized training center for pharma and biotech industry in Flanders, located in Niel. It has a focus on operational, lab and packaging functions.

It has 1500 square meters of teaching rooms, laboratories and a fully functioning cleanroom to simulate working conditions in pharma and biotech companies under real working conditions.

Follow us on: www.vitalent.be

Vito

Vito is an independent Flemish research organization in the area of cleantech and sustainable development. The research of Vito focusses on health, environment and safety, by developing safety assessments, air quality management systems, in vitro inhalation testing, biomarker discovery, assay assessment, and analytical platform development. This research is done together with research partners, government and industry.

Follow us on: www.vito.be/en/theme/sustainable-health

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