KPMG

Digitalization in life sciences

Integrating the patient pathway into the technology ecosystem

KPMG International

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Content

Foreword

Patients and consumers are taking charge of their lives. They are more health-conscious and better informed. They believe in prevention rather than treatment. At the same time, life sciences companies are confronted by the twin challenges of reducing costs and enhancing patient outcomes. And all of this in the context of a sweeping wave of digitalization. Our survey covers digitalization; in other words, the use of digital technologies to modify a business model, enabling revenue and value-producing opportunities. Digitization, on the other hand, describes the shift from an analog to a digital form.[1]

Interestingly, life sciences CEOs remain optimistic. The *2017 Global CEO Outlook* from KPMG International revealed that, on balance, life sciences CEOs see technological disruption as more of an opportunity than a threat.

By fully embracing the concept of digital transformation, life sciences companies can achieve superior patient outcomes while also providing care in a cost-effective manner. The effects of this digitalization will be far-reaching, breaking up old structures and shattering traditional value chains. In effect, the industry will be migrating from a business model built around developing blockbuster drugs to one cultivated around a technology ecosystem — which connects all stakeholders and, most importantly, integrates the (prospective) patient deeply into the ecosystem. The result? A more personalized approach to healthcare through customized medicines and bespoke treatment plans.

The KPMG International publication *Pharma outlook 2030: From evolution to revolution* discusses three types of 'archetype' that will prevail in the future industry. One of these is the value chain orchestrator, a company that does not own anything physical but creates various solutions 'virtually'. These companies will own data — lots of it — on therapies, patients, and research. Successful life sciences companies will have an integrated digital data strategy — one that prevents silo mentalities and that can integrate internal and external processes in a seamless manner.

As you will see on the following pages, we believe part of the solution entails building new structures and organizations to get us to the point of full integration of digitalization. We will highlight a number of compelling, real-world examples that we hope will intrigue and inspire the leaders of today's life sciences companies. We will also share our findings from discussions with the leaders of more than 75 companies in the life sciences sector regarding their progress on their digitalization journeys.

We would like to thank all the interviewees and partners for their cooperation, their feedback, and their input. We hope you enjoy the read.

Vir Lakshman
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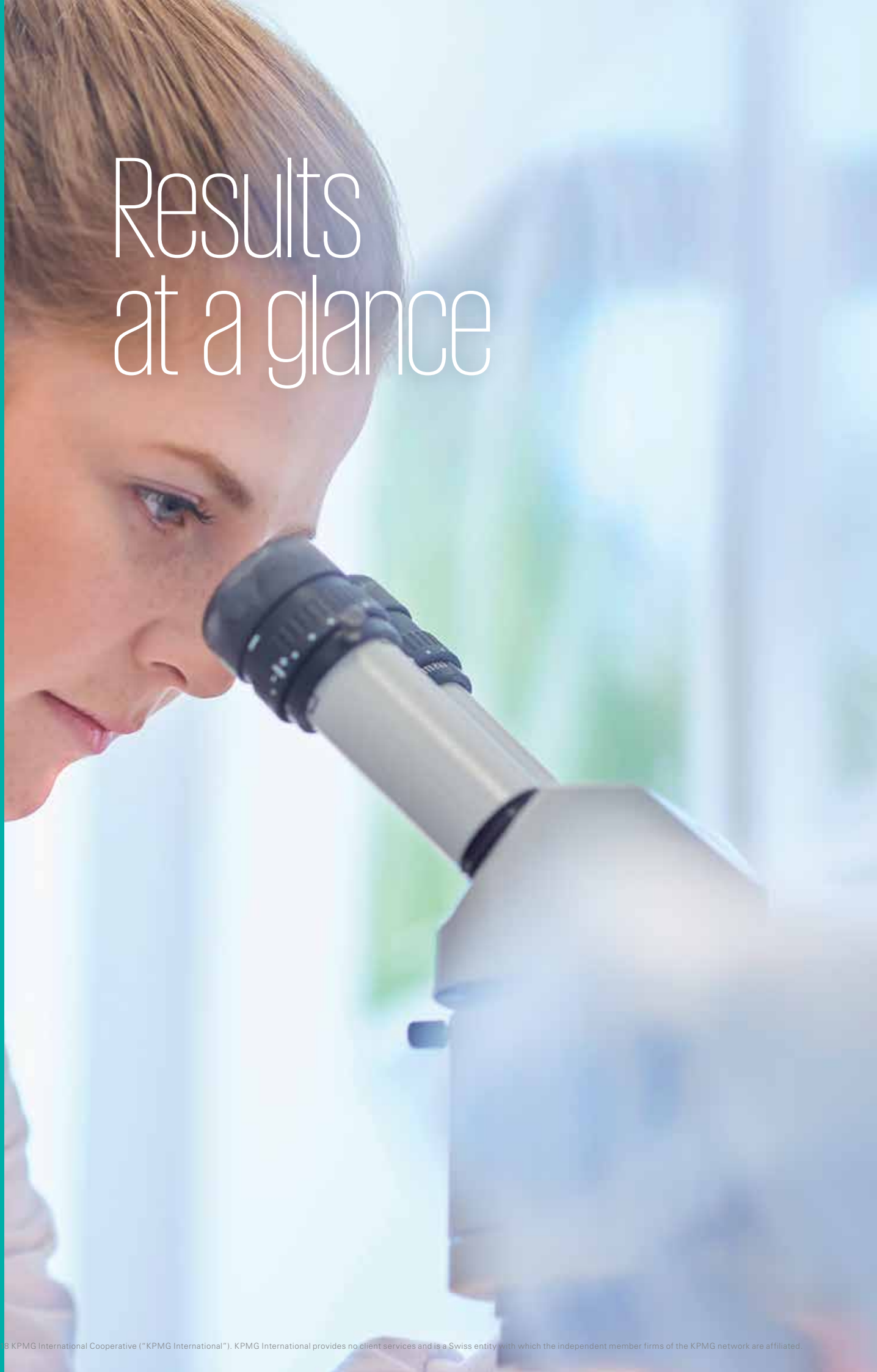
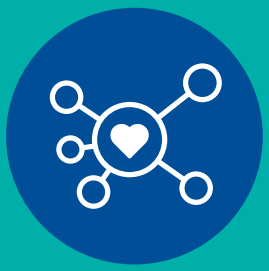
Results at a glance





The interconnections within the life sciences ecosystem are accelerating at an ever-increasing pace. Organizations need to adapt their roles and strategies now.

Imagine a world in which complete traceability of diseases can be assured. Data on genetic features, hereditary diseases, symptoms, and treatments of illnesses are all retained for each individual in a so-called 'healthcare tree', which grows throughout the entire life cycle as information is added. A safe and secure exchange of data with healthcare professionals ensures not only that the healthcare service is personalized, but it also assists in the development of new medicines and limits the impact of potential outbreaks. The visualization on the following two pages shows the KPMG healthcare tree as part of the future ecosystem (Figure 1).

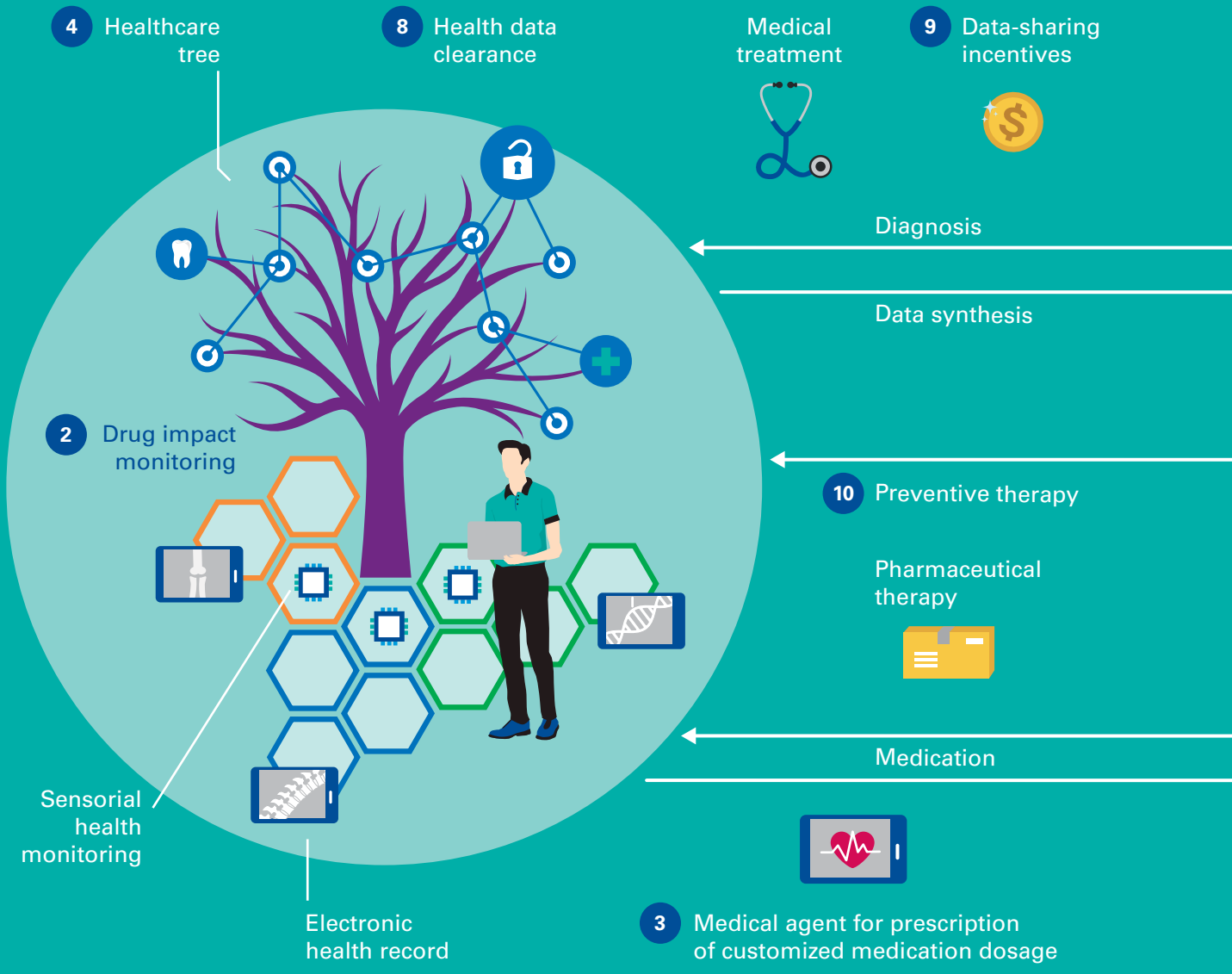
In this world, illnesses could potentially be predicted and prevented. The possibilities include entirely new business models, in which patients receive a proactive healthcare service that is very different from today's predominantly reactive treatment. There will also be mutually beneficial alliances and collaborations between incumbent and new stakeholders (e.g., tech companies) with no past experience in pharmaceuticals.

Without question, one of the most important factors driving this change will be the exchange of information between stakeholders — from patient data, R&D, and production through communication between suppliers, insurers, doctors, and other key influencers. The digitalization of these processes and the exchange of data will be key.

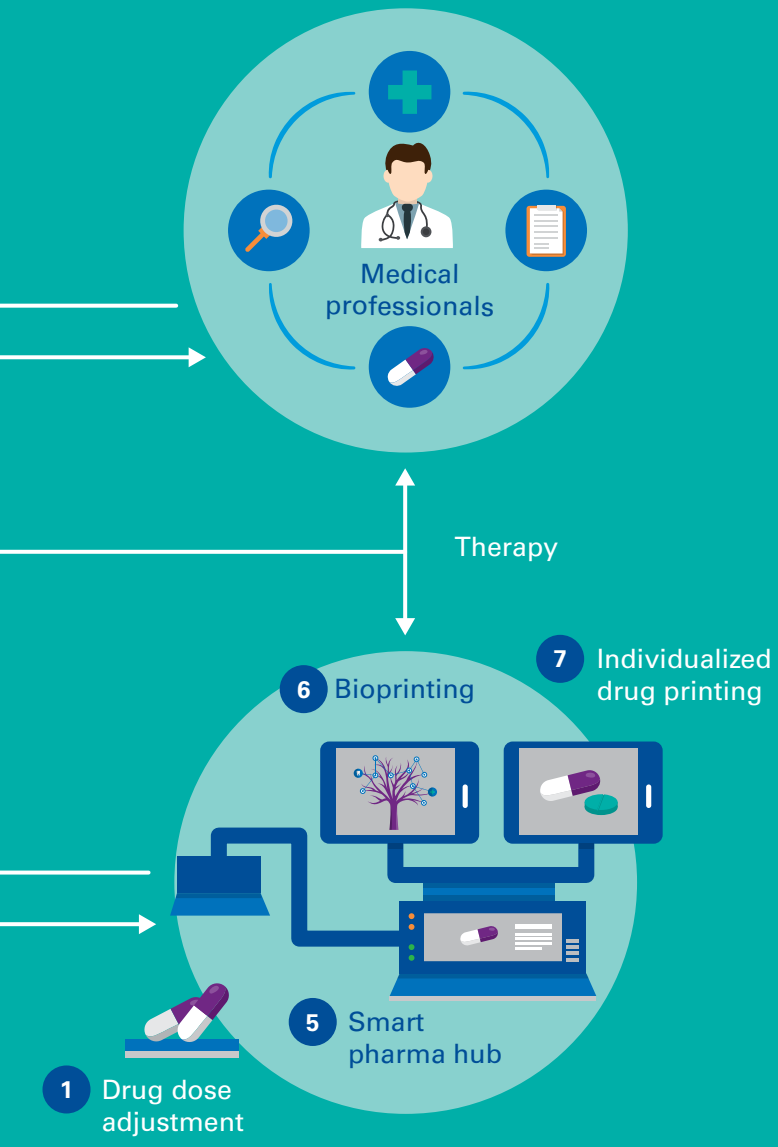
85%

To a large extent, companies in the life sciences industry have already recognized that digital transformation will lead to changing roles in the ecosystem. 85% of respondents see tech companies as the driving force of digitalization in their industry, and 63% see these companies as possible cooperation partners within the next year.

Figure 1: The KPMG healthcare tree as part of the future ecosystem



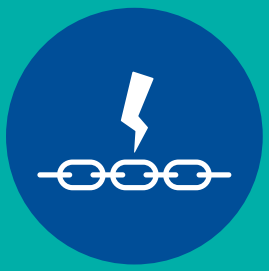
Trends



1. **Drug dose adjustment:** Dosages will be customized for each patient depending on the stage of illness and the customer's characteristics.
2. **Drug impact monitoring:** Monitoring of the medication impact in real-time to get ad hoc feedback.
3. **Medical prescription agent:** Smart, technological agent for prescription and medication dosage.
4. **Healthcare tree:** A personal lifelong health report including all treatments. Its visualization will include the roots as the background and causes of illness and diseases, helping to personalize treatment and prevention.
5. **Smart pharma hub:** A smart drug production hub where customized pharmaceuticals can be produced via robotic and 3D printing methods.
6. **Bioprinting:** Ad hoc bioprinting of organic fabric to heal damaged body parts.
7. **Individualized drug printing:** Ad hoc printing of the adjusted drug dose for each patient.
8. **Health data clearance:** Private medical health records will contain all of a patient's data; the protection of this data in decentralized blockchain ecosystems has the highest priority.
9. **Data-sharing incentives:** Incentives support people to share their data for improved healthcare development and prescriptive medication.
10. **Preventive therapy:** Identification of health provenance and personal health consultancy support will allow therapy even before medication is needed.

We used the KPMG Research Cloud to develop our view. For further information, please refer to the methodology on page 46.

Source: KPMG Research Cloud, KPMG in Germany, 2017



Efficient internal processes will be a prerequisite for anyone who wants to play an important role in the future ecosystem.

Companies looking to communicate efficiently with other stakeholders must ensure that the internal information flow matches the requirements of such a strategy. As most companies have already implemented a variety of independent digitalization projects, the key focus should be on integrating and aligning these with the long-term strategic goal.

The potential is enormous. Imagine a company in which manufacturing teams have direct access to data from marketing and sales, enabling precise demand and utilization forecasts. Or a scenario in which a research department transmits data signatures and contracts via blockchain, enabling the easy, secure exchange of data with other collaborating partners without the involvement of intermediaries. Twenty-four percent of respondents believe these technologies are already — or within 2 years will be — contributing to finding treatments for diseases that are difficult to cure or that are currently incurable. It is interesting to distinguish between those playing a 'wait and see' game and the companies that are prepared to go it alone. This is particularly evident in the application of blockchain technology where a small handful of life sciences companies have recognized the potential of this technology and have embarked upon projects in the area of clinical trials and serialization in the supply chain.

Clearly, such significant and far-reaching changes are much more likely to be implemented successfully when management demonstrates clear dedication and commitment. As a result, those companies that take these issues to the C-level, e.g., with a Chief Digital Officer (CDO), should be in a much better position to align and implement the necessary measures in a timely manner. At the same time, it is also important to understand that only with the right competencies in-house is it at all possible to recognize the potential and the synergies of a digital strategy. This is not something that can simply be outsourced.

46%

The majority of companies have recognized the importance of digitalization: 46% of respondents place the responsibility regarding digitalization at the C-level and 15% of those have already created or are planning a CDO role.

Holistic digital strategies: Shining the spotlight on the patient.

In the new life sciences ecosystem, the patient takes center stage. Many companies are slowly beginning to understand how digitalization is absolutely instrumental in this important step. While 17 percent of respondents named 'patient-centricity' as a current benefit of digitalization, 24 percent were of the opinion that this will be a key focus within the next 5 years.

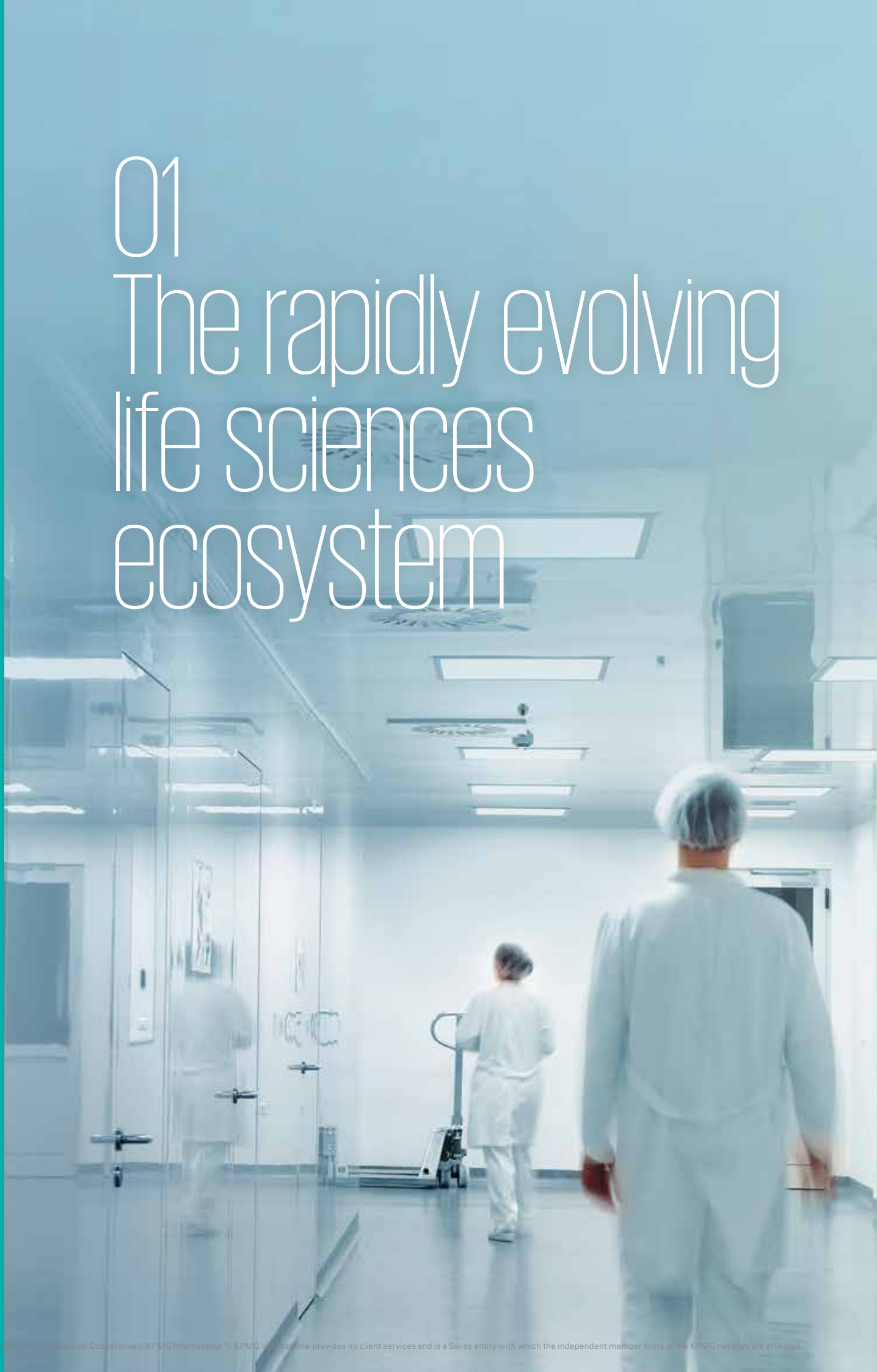
How can companies achieve the goal of absolute patient-centricity? The potential of combining the most promising healthcare-related technologies with data and analytics is a game-changer. Today, virtually all complex diagnostic procedures are carried out during hospitalization. Soon, however, this could be a thing of the past, as several of these procedures could be carried out at home via ingestible sensors or other on-body devices. In addition, wearable fitness trackers, which are already used by millions, could facilitate health monitoring in the future. Technology is now so far advanced that in the field of oncology, artificial intelligence is already being used to create an individual patient-specific treatment plan based on a combination of data from the patient as well as relevant studies. This technology not only benefits the patient but also provides fundamental support for the physician.

The benefits of data generated by sensors, devices, and other technologies for the life sciences companies are obvious. If companies are able to create comprehensive client journeys, the path leads from supplying a single drug to providing individualized, holistic health solutions. As a result, life sciences companies or disruptive new entrants could play an integral part throughout patients' lives. The KPMG International publication *Pharma outlook 2030: From evolution to revolution* suggests that some successful life sciences companies will opt for the 'virtual value chain orchestrator' archetype. This is where the life sciences company owns all the relevant data — on therapies, patients and research — and guides patients through a complex healthcare value chain, from cradle to grave, supporting healthcare practitioners to provide tailored care each time. Developing a digital strategy by taking the entire value chain into account is a first step in the right direction.

55%

Some life sciences companies have already embarked on the journey toward a holistic healthcare solution. 55% of companies interviewed have already implemented or are planning to implement a comprehensive multi-stage digital data strategy.

01 The rapidly evolving life sciences ecosystem



The newly emerging, patient-centric ecosystem changes not only the day-to-day processes in the life sciences industry, but also the very roles of the incumbent players as new companies continue to enter the playing field.

The key, defining characteristic of the new life sciences ecosystem is that, unlike today, the patient is the absolute center of the universe. This change reflects not only the trend toward increased personalization, which is taking place across industries, but also the changing economics of a healthcare landscape in which there will be far fewer blockbuster drugs than in the past. And while this move toward increased patient-centricity and personalization represents significant challenges, it also presents the industry with some very attractive opportunities. Imagine a world, for example, in which a patient purchases not just one specialized drug but, rather, a lifelong healthcare service. At the same time, as the system migrates from treatment toward diagnostics and even prevention, pharmaceutical companies could mature from their current roles as drug manufacturers to more holistic health service providers. From the standpoint of a business model, these companies could go from helping patients with specific problems to being an integrated part of their lives.

Then, of course, there is the data side of the equation. In the new life sciences ecosystem, the patient data generated is some of the most valuable raw material for the development and execution of these future services. This includes data around patient habits, patterns of use, frequency of drug use, reactions to certain medications, and so on. By harnessing the power of data to better understand factors such as tolerance and effects, drug companies could get to know patients on a truly unprecedented level. In turn, this new, deeper level of knowledge can clear the way for new R&D initiatives and improved products and services.

24%

of companies think that digitalization has a **significant role in finding active ingredients and therapies** for incurable or difficult to cure diseases already today or will do so in the next 2 years.

Source: KPMG in Germany, 2017

The new life sciences ecosystem is characterized by an unprecedented symbiosis between patients and providers. Before we can reach that utopian state, however, there are some pressing questions that need to be addressed, including:

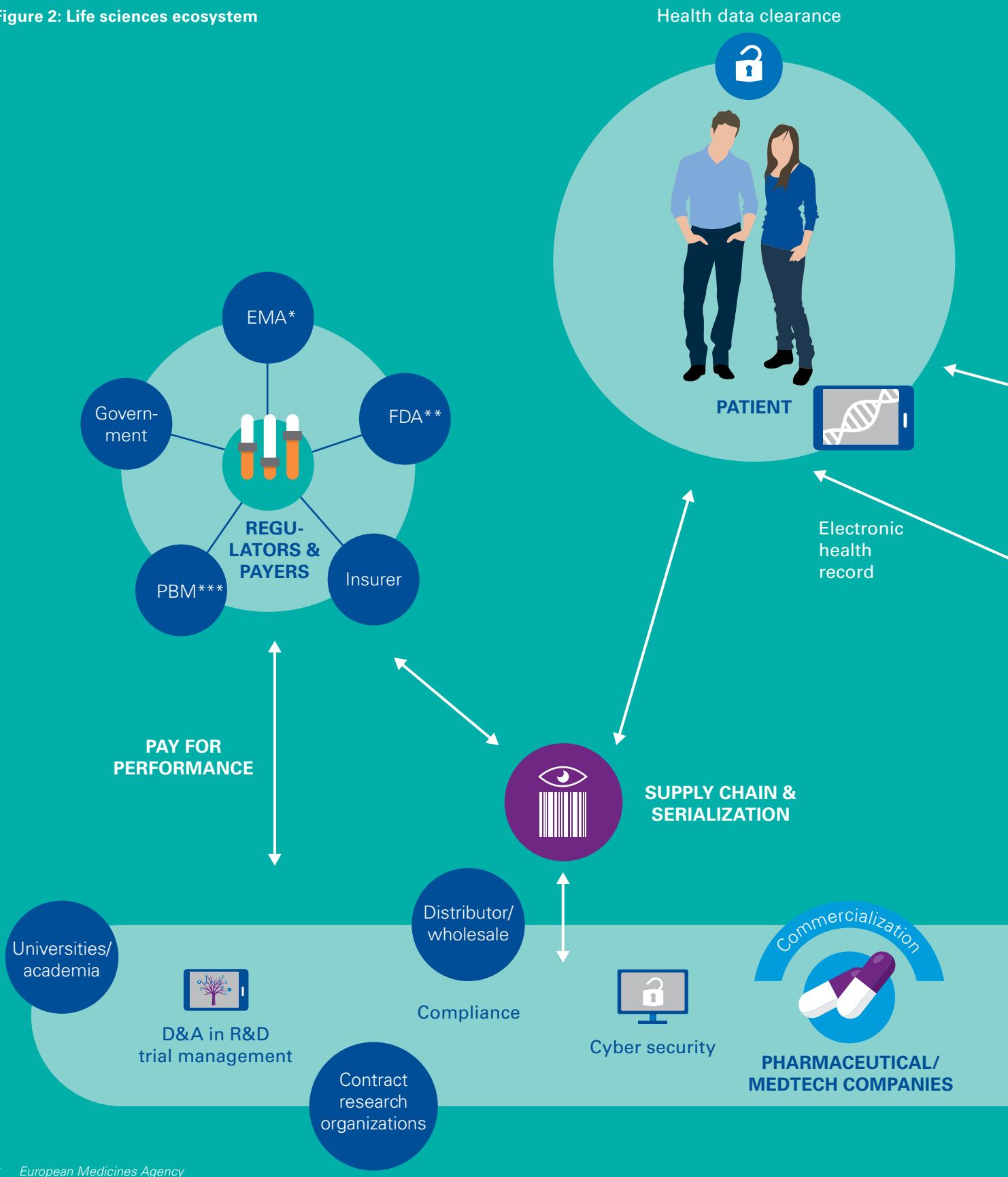
- What data is required?
- Which technologies can be used to produce, analyze, and employ the data?
- How should we treat this very sensitive data?
- To whom does this data belong? The patient? The pharmaceutical company that delivers the drug? The technology company that delivers the device which generates the data?

The current ecosystem remains rooted in old, established organizational structures. Over time, however, the 'silo mentality' that dominates today has to give way, since digitalization can only work properly within an integrated system. The size and scope of this pending transformation is far-reaching and has significant implications for all major stakeholders. For example, imagine a healthcare system in which:

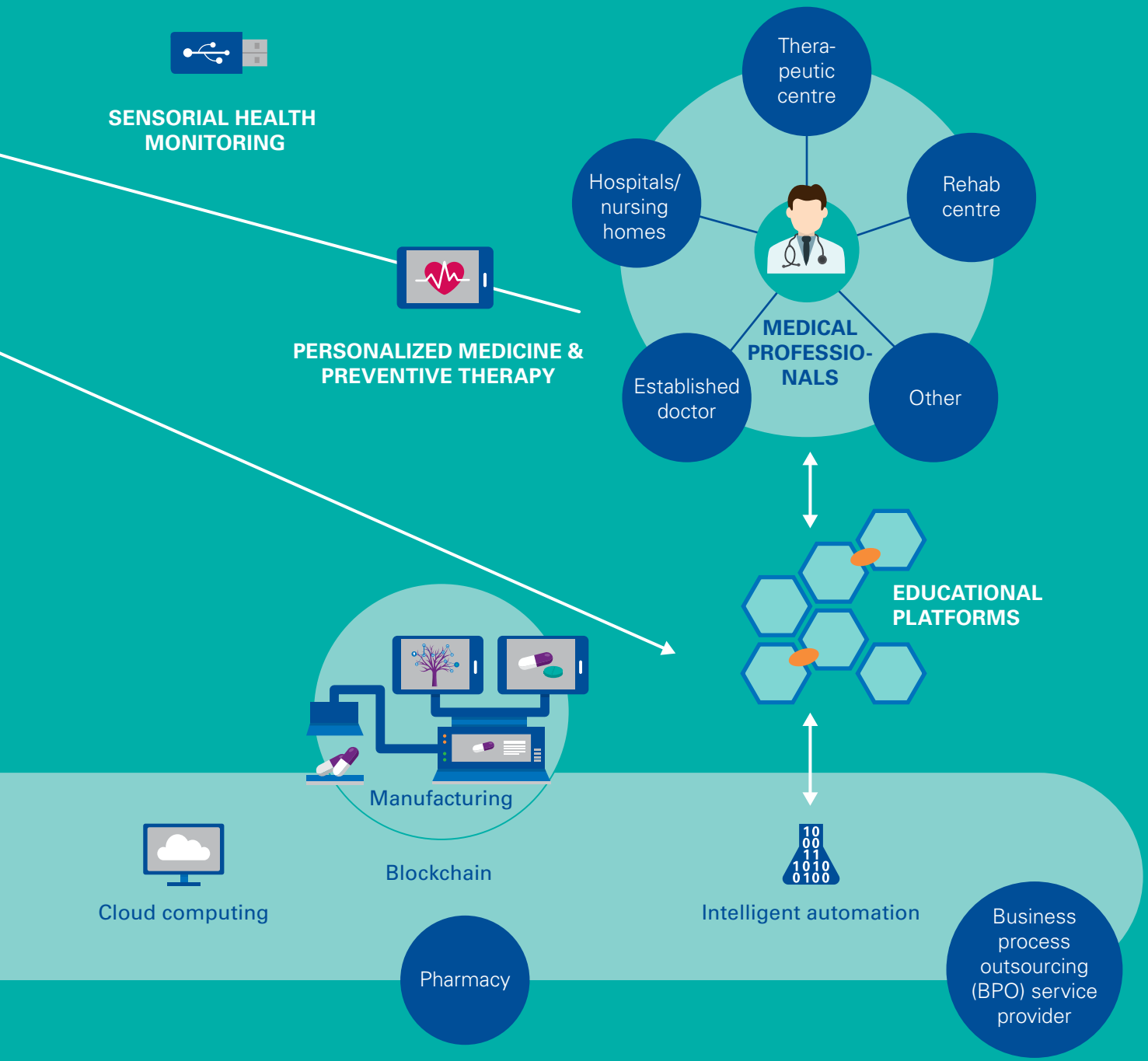
- Insurers and governments pay for the health system, but can apply greater pressure on pharmaceutical companies with value-based pricing.
- The patient is more integrated, informed, and, in that way, empowered, as their data is digitalized, facilitating the cooperation of physicians and making it easier for them to keep track of their state of health and treatment.
- Pharmacies, distributors, and retail clinics are connected with pharma companies through serialization, allowing for far better control and monitoring of the distribution process.
- Hospitals are equipped to use technologies to make better diagnoses.
- Contract Research Organizations (CROs) and regulators are connected with the pharma companies by the cloud and blockchain to provide a safer and faster data exchange.

These changes bring about sizable challenges and opportunities for industry players. Ultimately, we expect these stakeholders to be not only better integrated into the system, but to proactively drive change and enter into cooperative relationships with one another. The life sciences ecosystem is pictured on the following page (Figure 2).

Figure 2: Life sciences ecosystem



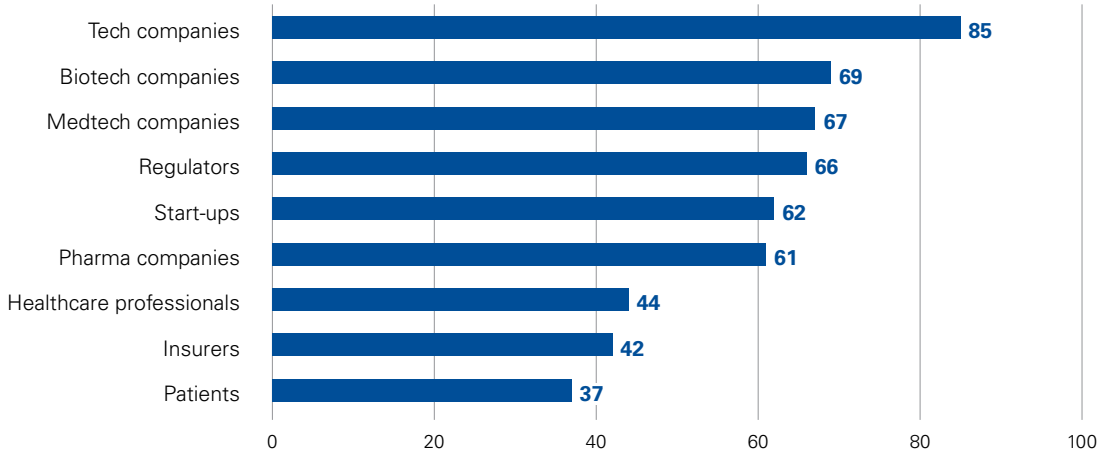
* *European Medicines Agency*
** *US Food and Drug Administration*
*** *Pharmacy benefit manager*



Source: KPMG in Germany, 2017

Eighty-five percent of respondents to our survey said technology companies such as Microsoft, Cisco, IBM, Amazon, and Google are serving as the driving forces and initiators of digital transformation in life sciences. And while biotech companies (69 percent) and medtech companies (67 percent) are seen as strong drivers, respondents did not feel that patients and insurance companies were among the driving forces of digital transformation.

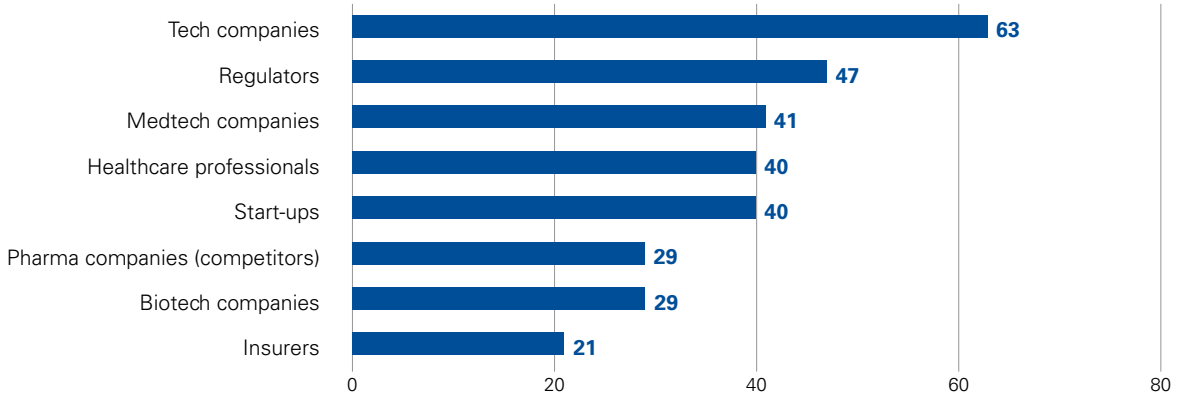
Figure 3: Who do you see as the drivers and initiators of digital transformation in life sciences (multiple choice, in %)?



Source: KPMG in Germany, 2017

Likewise, 63 percent of companies said they would choose tech companies as cooperation partners for joint projects within the next year. Perhaps surprisingly, healthcare professionals are fourth choice (together with start-ups), as they were not seen as one of the major driving forces of digitalization in life sciences.

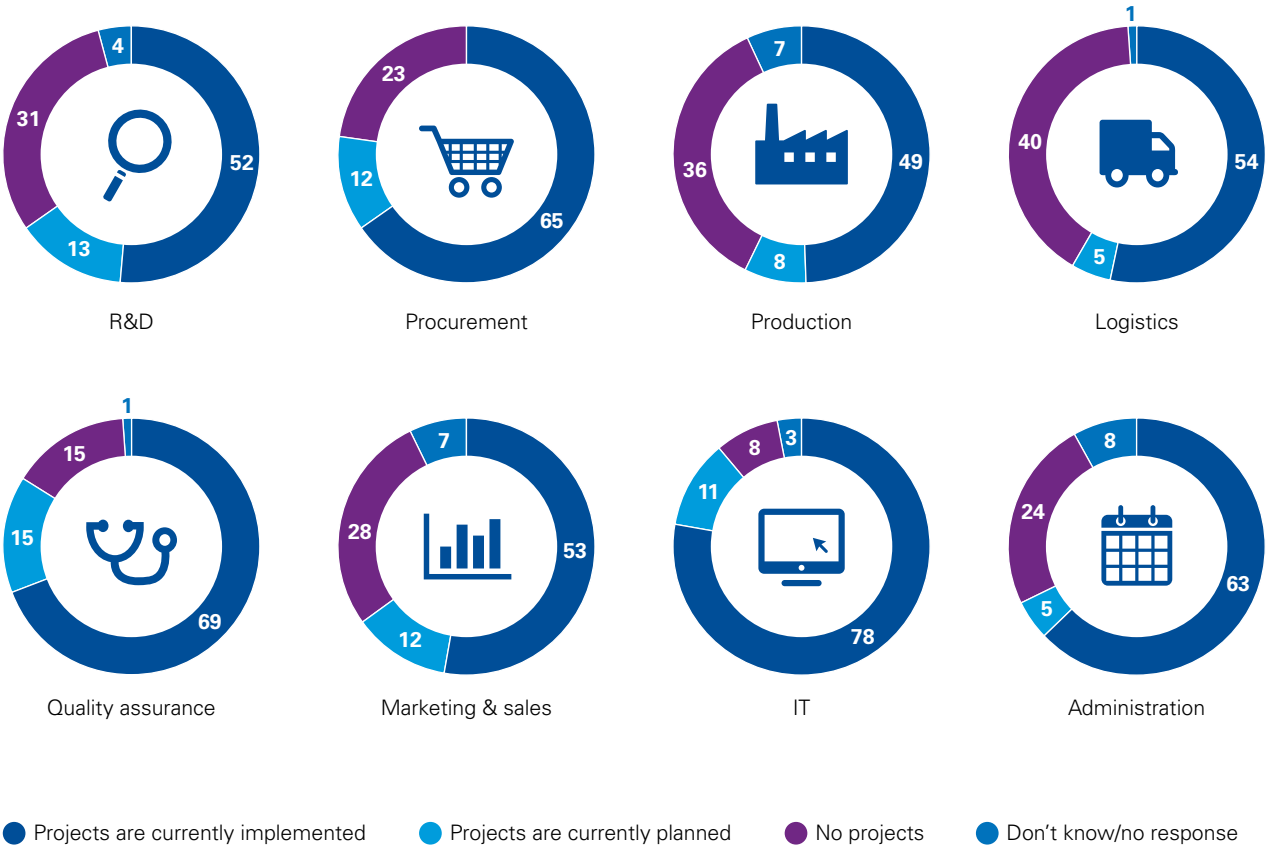
Figure 4: Who would be your preferred partner for a joint project in the coming year (multiple choice, in %)?



Source: KPMG in Germany, 2017

In addition to new levels of cooperation and the integration of new players, more companies are internally digitalizing their departments. At the moment, most projects are implemented in IT departments (78 percent). Our survey results show that most projects are managed by in-house resources. As such, the respondents appear to be underscoring the importance of building their own core competencies.

Figure 5: Overview of implementation of digitalization projects in internal departments (multiple choice, in %)



Source: KPMG in Germany, 2017

One of the key questions concerning companies is where to locate the responsibility for digitalization. Forty-six percent prioritize digitalization at the highest level of the company. Of those, 7 percent have created a CDO role and 8 percent plan to do so. Medtech companies assign even more importance to the topic than pharma companies: Sixty-five percent of medtech companies locate digitalization at the C-level, whereas only 26 percent of pharma companies do so. This might be a course of action for pharma companies to promote digitalization even more than they are doing currently.

46%

locate the topic 'digitalization' at the C-level.

Source: KPMG in Germany, 2017

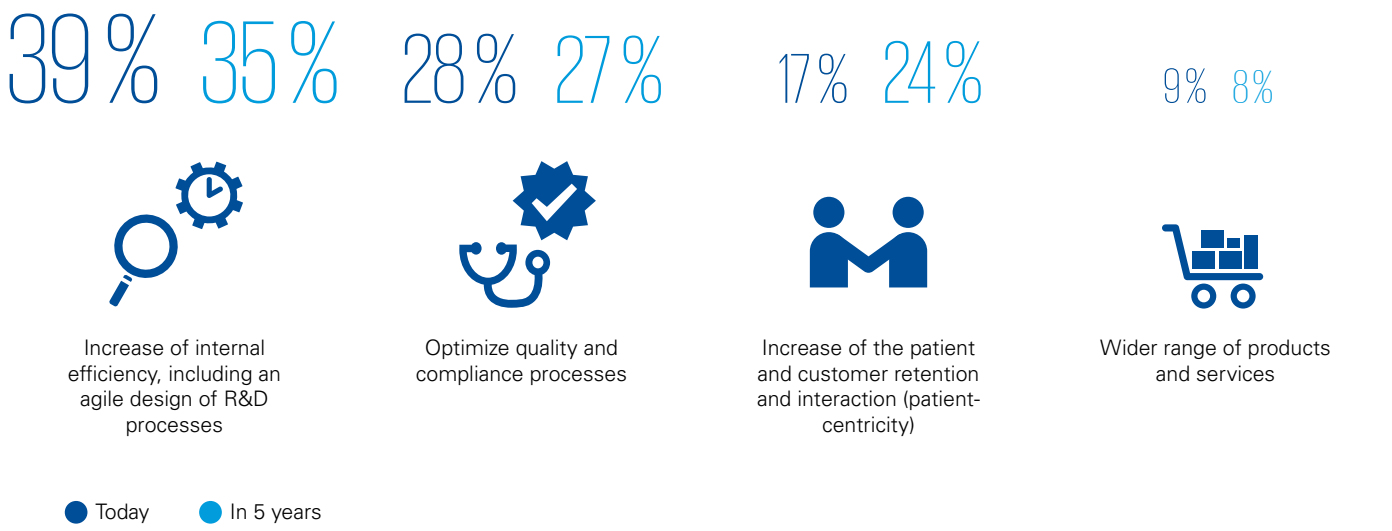
Companies expect wide-ranging benefits from digital transformation. Today, the focus is on increasing internal efficiency, including an agile design of R&D processes (39 percent), However, in 5 years, the focus on patient-centricity increases, as 24 percent of companies see this as their main benefit.

Two-thirds

of companies plan to hire more employees by 2020 to implement digitalization.

Source: KPMG in Germany, 2017

Figure 6: What do you see as the main benefit of your organization's digital transformation project, both today and 5 years from now (single choice, in %)?



Source: KPMG in Germany, 2017

The next chapter will focus on those technologies which improve efficiencies throughout the value chain. Not only does this have an immediate effect on costs, but it is also a prerequisite for the next stage, which is to focus on patient-centricity and the development of new products. We refer to this as 'integrating the patient pathway into the new ecosystem', which is described in the subsequent chapter.

02 Disrupting the life sciences value chain

45%

of companies have already implemented technologies to generate and analyze production and distribution data automatically in order to increase internal efficiency, or plan to do so.

Source: KPMG in Germany, 2017

The life sciences industry is facing a challenging future, with increasing development costs and more competitive markets on the horizon.

Faced with these very real challenges, the industry will need to focus on developing structures to increase internal efficiency and optimize quality and compliance processes. Internal digitalization is a prerequisite for successful transformation that will ultimately lead to more competitive organizations.

The move to digital is a long-term strategy, one that requires considerable investments, not only in equipment and services, but also in human resources. However, a successful transformation could result in significant improvements, such as more flexible (and less risky) production systems, faster, more collaborative development processes, and the improved monitoring of the effects of drugs. Of course, such opportunities do not come without risk. When processes and data go digital, the risk of cybercrime increases. As a result, a thorough cybersecurity strategy should be an integrated part of a digital value chain.

Technology represents a major opportunity for the industry to rethink not only business models and how to approach patients, but also to transform the entire value chain, which has remained relatively unchanged for decades. The ensuing examples on the use of data and analytics in R&D, the application of blockchain technology and the various cooperations between life sciences and tech serve as a benchmark for companies to check the progress of their respective digitalization journeys.

Data and analytics in R&D and clinical trials

With the application of modern technology in research and clinical trials, cumbersome processes such as data analysis can be slimmed down to save costs and time.

There are two main factors behind the ever-increasing costs of pharmaceutical research: Time and the risk of failure. And beyond the R&D process, it is primarily clinical trials (particularly the third phase) that drive costs upward. Accordingly, reducing the complexity of these processes and the time it takes to complete them should have the highest priority. Through the application of modern data and analytics technologies, we can both improve the return on investment but, more importantly, ensure that there will be faster, safer treatments for diseases.

There are virtually endless ways to apply technology in the R&D process. One of these is to use artificial intelligence to structure and classify data and publications, which can free up valuable time, allowing the researcher to focus on more value-added tasks.

Artificial intelligence can also help relate different areas with one another. For example, connections and correlations that might not be obvious to a human researcher could be detected by a technological assistant, revealing gaps for future research approaches.

In the case of clinical trials, one could use data and analytics to help find the right patients for a given study, thereby increasing safety and cost efficiency. Companies are also using digital platforms to communicate with patients and doctors.[2]

29%

of companies have digitalized or plan to digitalize their clinical trial processes. 34% have already applied or plan to apply big data in R&D, production, and distribution. However, there is an urgent call for action as this still leaves a vast number of companies that are not using digitalization in clinical trial processes.

Source: KPMG in Germany, 2017

Digitalization in clinical trials

A life sciences company has implemented a platform to communicate with patients and doctors in the course of clinical trials. This enables studies to be performed on a remote basis. Previously, patients and physicians often had to bear a high organizational burden for participation in a study. They had to visit clinics or other medical facilities for monitoring applications on a regular basis over the entire duration of the study, sometimes up to 7 years. Under such conditions, it is difficult to recruit new participants for studies. By using wearables and other remote devices, monitoring can be carried out while patients remain in their daily routine. This simplifies not only implementation for the patients, but also for the clinical study team, since data can be collected in 'real-life'. Thus, discontinuation rates are lowered and new participants can be found more easily. The protocols become more patient-friendly and the compliance and quality of clinical studies is increased.

Source: KPMG in Germany, 2017

Maintaining data self-determination using blockchain

Blockchain will become key in dealing with the increasing amount of sensitive data and transactions arising from a growing number of stakeholders in the industry.

Blockchain, which uses a highly secure, distributed database technology, holds a number of advantages for life sciences companies. It is well suited for use in areas such as supply chain management, serialization, identity management, transaction processing, contract and licensing management, and document management (e.g., medical records). With the help of blockchain, companies will be able to significantly increase the integrity of data related to the development, testing and distribution of drugs.

The functionality of blockchain applies as follows: The ledger (that is what the blockchain actually is) is distributed around all involved parties, enabling them to agree on the state of the process. These agreements are digitally signed, time-stamped, and stored in the ledger so that there is cryptographically irrefutable evidence of the agreements and actions. These smart contracts claim that they can enhance security while lowering transaction costs.

As blockchain facilitates secure online transactions, the technology makes it possible to pass on patient data in a reliable manner. The result? Patients get a tamper-proof option to release personal records on their way through several stages of the healthcare system. In addition, based on the same underlying technology but under more stringent legal conditions, anonymized data from the electronic health record could be made accessible to the pharmaceutical industry. Estonia has already taken the lead in this area by implementing electronic health records using this digital ledger technology.

But questions remain:

- Who will own the blockchain and the data within it in healthcare?
- How do you economically value a blockchain and assess its cost effectiveness?
- Which blockchain technology will win the day?
- Can patients remove themselves if they wish to ‘opt-out’ of blockchain?

83%

Despite the tremendous upside, blockchain has not made its way to the front line of life sciences. 83% of respondents say they have neither implemented nor plan to implement blockchain to increase the efficiency of internal processes.

Source: KPMG in Germany, 2017

Using blockchain to improve the efficiency of clinical trials

Pharmaceutical research and development processes are very complex tasks, which are not only time-consuming, expensive, and difficult to execute, but also involve multiple partners, including research organizations, regulatory organizations and patients. Often, parts of trials are outsourced to contract research organizations (CROs), which comes with the known issues of hiring contract operators such as logistics, coordination, or abuse and fraud concerns. Further, handling data still entails considerable expenditures. This is where blockchain steps in.

The trial protocol, which is part of every clinical trial, ensures adherence and timelines are distributed as a smart contract and can now be checked constantly by CROs. Hence, every participating party has reliable information about the state of the process at all times. Smart contracts can ensure that clinical trials will proceed in the correct chronological order, leading to more reliability, security, and transparency, which results in a consistent step toward reproducibility.

In addition to clinical trial data, another opportunity offered by blockchain is the storage and exchange of patient records. In 2007, the Estonian government became the victim of a cyberattack and had to find ways to make its electronic infrastructure more secure. Guardtime, a company specializing in finding blockchain solutions, helped the government establish the country's health records in a secure infrastructure, based on blockchain technology. The integrated electronic healthcare information system combines fully electronic medical records, an e-prescription system, and the National Healthcare Insurance Fund. Using this technology, the Estonian government now has the ability to trace every access and change to a health record, allowing it to better combat insider fraud and provide a higher level of security. The blockchain solution ensures data never leaves the premises of the originator. Instead, a data signature of that information is transferred and stored. Guardtime, which offers its services to governments and enterprises alike, has invested substantially in the integration of its blockchain solution. Add-ins can enable a simple implementation within systems already in use.[3]

"Engage regulators early on in the process and make sure they're fully supportive and in line with the goals of deploying blockchain."

Mike Gault
CEO of Guardtime

The big network: The many benefits of cloud computing

As data and analytics gains importance, so too do the tools needed to deal with them.

Life sciences companies are increasingly using cloud computing to optimize complex processes. The use of computing and storage solutions and the service of sharing IT resources can improve the performance of infrastructure and applications while reducing the cost of doing business.

Among the benefits of cloud services are user-based pricing models, which pave the way for a lower degree of capital investment and operational costs. And growing interest in cloud services will continue to drive innovation of more sophisticated products and advanced services. Cloud-based solutions can improve the availability and the quality of data to support sales or make relevant data available worldwide to people responsible for clinical trials while meeting security and regulatory requirements. Further, the cloud offers elasticity for cognitive computing to ingest and analyze the large volume of data from IoT and real-time devices.

The enhancement of cloud-based services, beyond data storage and exchange, will lead life sciences enterprises to cloud-based analytics. Cognitive technologies can cover the gap between big data and data and analytics in decision support and the day-to-day decision-making process in decentralized organizations.

However, there are implications in the transfer of personal data cross-border for cloud providers. This becomes particularly relevant for those which have data centers outside of the EU, with the implementation of the General Data Protection Regulation (GDPR), which will be enforceable on 25 May 2018.

64%

The majority of life sciences companies have acknowledged the benefits of this technology: 64% of companies already apply cloud structures in their IT environments or plan to do so. Cloud technology is one of the top priorities in enhancing internal efficiency.

Source: KPMG in Germany, 2017

Besides using technologies to store and transfer data, companies need to implement tools to monitor their internal data generation as well as other data processes. These tools can support compliance teams and avoid penalties. The technologies are increasingly in use in various corporate functions, including areas such as tax compliance.

GE Healthcare finds a flexible, scalable cloud solution in Microsoft Azure

GE Healthcare, a division of General Electric, offers various medical technologies and services in the field of patient monitoring systems and drug discovery and manufacturing technologies. Their customers are healthcare providers around the world. What most of these solutions have in common is the management of highly sensitive patient data. In order to meet the growing requirements within data management, GE Healthcare decided to implement Microsoft's Azure cloud platform with its infrastructure-as-a-service (IaaS) supply. This would support the need for flexible and scalable solutions that do not require the customer to invest in further on-premises solutions at the same time.

This move to the cloud brings with it a number of benefits. First, software can be centrally distributed and managed. Second, the Azure environment ensures the fulfillment of compliance requirements of its customers, as healthcare providers have to deal with highly sensitive patient data. Third, because Azure can be integrated with other development platforms, older IT structures can still be used.[4]

Protecting the crown jewels: The importance of cybersecurity

It is crucial not only to protect the increasing amount of data, but also to lay down a clear strategy to deal with any security breach that might arise in the future.

In May 2017, the global cyberattack by the WannaCry cryptoworm made headlines around the world. The attack demonstrated how easily an IT system could be hijacked via ransomware. Apart from such an extreme scenario, however, networking always entails some risk of spying. While the Internet of Things (IoT) makes life easier for us, many of the applications and devices have significant security gaps. With denial-of-service attacks, botnets or other attack methods, hackers can steal data, interfere with processes and blackmail companies.

These types of threatening events lead to diffuse fears about loss of sovereignty within an organization. Putting suitable defense strategies in place is critical. Because no organization can afford to protect all processes with the highest level of security, it is important to identify the 'crown jewels' and ensure the highest level of security for these most important assets.

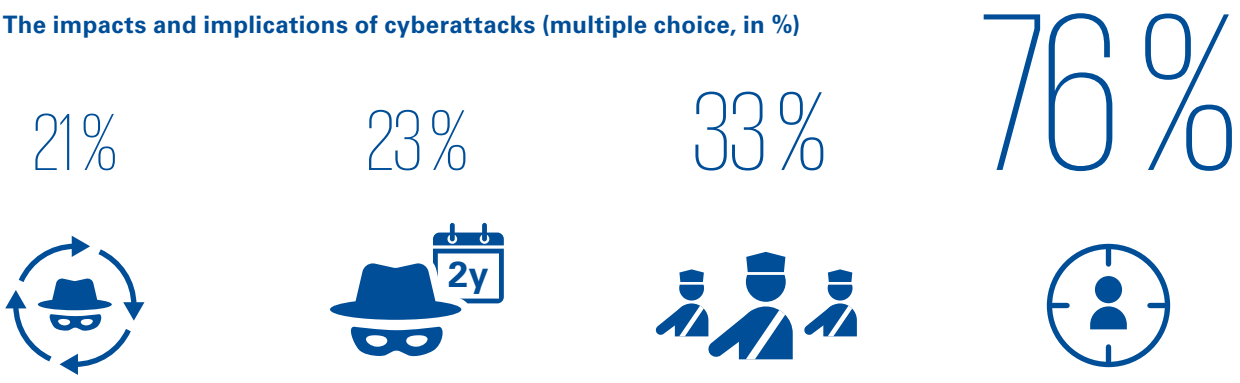
The findings of the recent KPMG LLP publication *Life sciences innovation and cybersecurity: Inseparable* indicate that companies are elevating cybersecurity to a strategic imperative but at a pace that lags behind their desire to adopt digital technologies to drive innovation.

To implement the right level of security at the right place, a regular exchange between different stakeholders is necessary, including business people, application owners, IT people from governance, operations, software developers, lawyers, HR, etc. Since security is only as strong as the weakest link, suppliers should be involved in the process as well.

Even though 76% support the premise that the risk of their company becoming a victim of e-crime is increasing, only about **one in three** life sciences companies has set up a cyber defense team to ward off attacks. The awareness of attacks should be converted into action.

Source: KPMG in Germany, 2017

Figure 7: The impacts and implications of cyberattacks (multiple choice, in %)



Source: KPMG in Germany, 2017

Undertaking a security transformation

Threatened by various cyber risks, one of Europe's leading pharmaceutical distributors wanted to explore new solutions. The company was in urgent need of a refreshed cybersecurity strategy. The first step in developing such a strategy is to understand the structure and, therefore, the vulnerable areas of the company. There were a number of priorities. First, the availability of the system had to be guaranteed. The impact on the operations of a company, or a hospital, which may be reliant on correct and in-time supply, would be disastrous in case of a breakdown. Second, the protection of sensitive data resulting from the sale of prescription drugs at pharmacies is a high priority. It is vital to protect this data because of the possibility to reconstruct a whole patient history, particularly with the advent of personalized medicine.

With the support of KPMG in Germany, the company started with a fundamental assessment of its cybersecurity capabilities. The assessment took organizational and technical countermeasures into account and identified the critical business processes and applications. The approach included the company itself and its supplier and service provider ecosystem. All identified gaps were risk-assessed and prioritized, clearing the way for a three-year security roadmap with measurable results.

The security transformation project focuses on the protection of the most critical information and applications by implementing controls such as encryption and access management. Vulnerability scans are also performed for all critical and internet-facing applications to reduce the specific attack surface. Policies have been updated and a training and awareness program established, including a campaign to raise awareness of tactics such as 'phishing'.

Having planned and implemented this comprehensive strategy, the company is able to protect its own infrastructure and data, which is located in a secure ecosystem, and has insurance in place in the event of an attack.

Source: KPMG in Germany, 2017

Gaining critical information through a cyberattack simulation

To be prepared for the growing number of cyberattacks, a pharmaceutical company asked KPMG in Germany to simulate such an incident. Fighting these attacks is the core task of the incident response team, the main target group for this exercise. The security of information and data of the company mainly depend on the frictionless and effective operation of this team. Wrong or delayed decisions can lead to the breakdown of manufacturing operations or the loss of highly sensitive data.

In the first phase, internal processes and documents were analyzed. Which departments are usually involved in cyberattacks? Which interfaces exist? Which tools and methods are used?

The chosen scenario was an infection via crypto-malware, a so-called ransomware attack. In collaboration with one of the company's own IT experts, the KPMG team arranged a realistic, company-specific simulation.

A plan of operations with prepared 'injects' was constructed, including prepared events and information that was released to the participants at predefined points in time to direct the course of simulation.

During the execution of the simulation, the participants received indicators and symptoms of the cyberattack and had to seek information to analyze the attack, restrict the damage, and eventually fight off attacks.

Subsequently, feedback from the participants was obtained and a final report was compiled in which the performance was analyzed, with the goal of optimizing the reaction to future cyberattacks and diminishing possible damages.

Source: KPMG in Germany, 2017

Pay for performance: Simplified through real-world data

By improving patient satisfaction at an affordable cost, value-based pricing (VBP) shows the shift in the balance of power toward a more patient-focused system.

With pharmaceutical companies being showcased in the public and political limelight, there is an increased need for these companies to shift their business models from a 'volume' focus toward a more 'value-based' approach. It is no longer enough to show the effect of a particular drug. Now, the possible health gains (over established therapies) also need to be proven. And then, of course, there is the increasing pressure on costs, along with the push for the use of real-world evidence to substantiate the benefits of a particular course of treatment.

However, not every type of drug or treatment is a suitable candidate for VBP. As discussed in the publication *Value-based pricing in pharmaceuticals* from KPMG International, VBP necessitates that the results are measurable and directly attributable to the product. Second, there should be no cheaper, generic alternative available, as this would negate the cost side of the use case.

Should a drug fit these criteria, however, there are several challenges that need to be overcome before successfully implementing VBP. It is crucial to establish a clear definition of the outcomes. It is also important to underline the importance of working with healthcare professionals during this initial phase of the project. This requirement is not only to ensure measurability and the determination of causality, but also to ensure that clear criteria have been set for the selection of patients for clinical trials. In addition, there should be an appropriate data infrastructure for measuring outcomes in an accurate and reliable manner. Should this infrastructure not be available, its construction should be priced into the costs. Another point for consideration is the impact of legal and regulatory barriers. Some countries simply cannot introduce VBP due to the ban on payments outside of legally mandated reimbursement systems (assuming they do not support the deployment of VBP).

22%

apply digital approaches to enhance the quality and security of VBP.

Source: KPMG in Germany, 2017

However, when implemented successfully, VBP can benefit all stakeholders in the healthcare system. The patient gets access to better treatment and the payer gets better healthcare at a lower cost. Payers and life sciences companies have started collecting data to understand better the costs and benefits of different treatment pathways.[5]

Intelligent automation is gaining traction in many areas of life sciences

Intelligent automation is seen as the most important technological application to increase the internal efficiency of life sciences companies.

In the manufacturing industries, industrial robots are enhancing or replacing human work. In the back office, software automation can replace periodic scheduling tasks. However, the rapid pace of automation technology in sensitive areas of life sciences is surprising, even for industry insiders. Today, most life sciences organizations are already using some form of automation to support their work. Automation technologies are evolving in such a way that they can not only improve processes, but also disrupt the traditional, stringent chain of processes. Advanced forms of automation, from robotic process automation to cognitive technologies, are now finding their way into the life sciences industry, with several companies having already initiated back office projects.

Robotic process automation (RPA) refers to the automation of manual processes based on a combination of process automation software and artificial intelligence. Intelligent automation refers to work that is performed by RPA systems.

Today, most research-based pharmaceutical companies use high throughput screening methods, which allow them to test hundreds of thousands of compounds against a specific model of disease simultaneously. Robots do much of the mundane, routine tasks that used to be performed by humans.

44%

Already, 44% of respondents have completed or are in the process of implementing automation, making it, together with cloud computing, the most frequent method to increase internal efficiency.

Source: KPMG in Germany, 2017

In addition, specialized development platforms can now take over even complex automated processes performed during development. Depending on the supplier and requirements, modular systems or complete robotic platforms can cover the entire development process, from the development of experimental design, selection, and processing of samples to evaluation and data analysis. Member firms of the KPMG network are working closely with life sciences clients to automate processes and implement automation to undertake time-consuming, repetitive tasks. The relevant steps are discussed in the KPMG LLP publication *Intelligent Augmentation.*

Supply chain and serialization

In the more personalized and patient-centric ecosystem of the future, real-time monitoring of the supply chain will be a requirement.

The initial stages of digitalization of pharmaceutical supply chains were driven primarily by initiatives to optimize resource allocation and planning, to increase response capabilities, and to enhance supply chain visibility.

Early digitalization projects and infrastructure investment focused on fast-moving stocks, fully utilized facilities, assets and inventory, as well as flexible product and core workforce availability. As a result, data for order processing, recording of material stocks, invoice verification, and production planning and management can be provided in real-time or through autonomously initiated actions. In addition to cross-company networking, the integration across value-added networks of suppliers, partners, and research institutes is at the heart of these activities.

54%

of companies have implemented analytics and automation of their supply chain to increase internal efficiency, or are in the process of doing so. A possible next step is the application of predictive analytics in production planning: **21%** of companies say they are taking actions in this area.

Source: KPMG in Germany, 2017

Achieving higher profitability through end-to-end supply chain transparency

By using a holistic data and analytics tool, a leading healthcare company was able to enhance its supply chain efficiency. To analyze the current situation and gain transparency, two different business models (consignment and loaner business) in three different markets were examined in detail.

A state-of-the-art data and analytics tool enabled the current situation to be analyzed, providing full transparency throughout the supply chain.

Basic process understanding was achieved through interviews and gemba walks in the client's logistics facilities as well as in hospitals. The insights were then processed and transferred into the holistic data and analytics tool.

The combination of customer, order, inventory, sales, and cost data facilitated full transparency on customer and product profitability. Based on this new level of data transparency, more than 60 levers along the supply chain for one of the analyzed markets were identified, for a total potential margin improvement of 3.5 percentage points. Improvements will be mainly achieved in the following areas: Customer (life cycle) management, revenues, inventory, and cost to serve.

After showcasing the initial results, defined measures were implemented quickly to fully realize the identified potential. This example illustrates that end-to-end supply chain transparency drives higher customer and product profitability.

Source: KPMG in Germany, 2017

51%

In the context of serialization, 51% of pharmaceutical companies already apply or intend to use predictive analytics or big data analyses to improve their supply chain quality and security.

Source: KPMG in Germany, 2017

For life sciences companies, the monitoring of supply chain activities has an even higher relevance than in other industries. To help neutralize the lucrative trade in counterfeit medicines, the serialization of pharmaceutical packaging is increasingly becoming a focus for regulators. EU regulation 2016/161 ('Falsified Medicines Directive') was published in February 2016, making the allocation of a serial number to a drug, including individual production data, mandatory as of February 2019.

The requirements of serialization are twofold. First, serialization is the informational tagging of a product to prove originality. This tag might vary according to the guidelines of local authorities, but at least the unique product ID (serial number), expiration date, and batch number need to be contained as machine-readable information. Second, a tamper evident seal has to be attached to the product to protect and verify the contents.

The new regulation will compel prescription drug makers in all but three EU countries to incorporate new safety features on their product packaging. This means pharmaceutical companies and distributors are required to set up and use logistics processes and IT systems with track-and-trace capabilities for product labeling, documentation, and reporting of each unit in commercial circulation. KPMG in Germany has developed a methodology that rapidly assesses the top and bottom line impact of serialization and has assisted companies to implement processes and systems to meet regulatory requirements. The current status of readiness to meet the November 2017 US Drug Supply Chain Security Act (DSCSA) requirements and their intention to leverage associated value-added opportunity is discussed in the *2017 Serialization & Traceability Trends* from KPMG LLP.

03 Integrating the patient pathway

17%

Individual, holistic health solutions will be a desirable strategy in the years to come, as just 17% of companies say they are taking actions around these prevention, diagnosis and cure solutions.

55%

However, 55% of respondents say they have implemented or planned the creation of a holistic digital data strategy of the entire value chain as a first step.

Source: KPMG in Germany, 2017

While patients increasingly have the desire to be actively involved in the healthcare ecosystem, life sciences companies are still struggling to find the right way to approach this. Successful first-movers could gain a huge competitive advantage.

For the most part, patients are still passive recipients of whatever drug or treatment has been assigned to them. This is a paradigm in which the patient can be left to feel invisible or even neglected. This can be even more acute when treatments go through various stages with different doctors and other healthcare professionals. The lack of involvement and understanding on the patient side can, in some cases, contribute to higher risk of failure. Consider the increasing tendency toward self-sevice, where patients are required to carry out certain procedures at home (such as regular measurement of glucose levels).

As an active participant, a patient may deliver faster and better data. As a result, not only will the patient win, but the underlying system will gain valuable insights. The trend toward an increasing focus on prevention (as opposed to treatment) is just one step in this direction and is supported by the urge of patients to gain insights into their health data.

In addition to the numerous fitness trackers and apps that are used to monitor physical and mental health conditions, self-tests such as fertility or allergy tests can now be enhanced with apps. We are at a point now where the sensor technology does not need to come from sophisticated medical devices but, to a certain extent, already exists in many households, such as that in video game cameras.

We know that patients want to take part in an active exchange of knowledge. Internet-based communities and platforms for such purposes will surely see strong growth over the coming years. This presents both a challenge and an opportunity for the life sciences industry to get involved. Of course, this shift does not need to be limited to patients. Using health education platforms, organizations can take the step toward approaching physicians and other healthcare professionals directly.

Ultimately, when challenges regarding data safety and management have been overcome, the transformation of the patient pathway is expected to lead to an enormous rise in patient and other market-related data. As a result, at an operational level, the biggest changes are likely to take root in areas related to data analytics, such as supply chain management and product portfolio management. Further down the line, this could also be used directly for product development (both drugs and other services). The opportunities are far-reaching: By teaming up with healthcare professionals, life sciences companies could design individualistic health solutions for the patient across the entire journey of treatment instead of being just a one-time product distributor.

The fundamental shift offered by sensorial health monitoring

Technological advancements will radically change the way pharmaceutical companies interact with patients and develop new drugs.

The observation of diseases and general health conditions is an integral part of the treatment process and a prevention mechanism. Until recently, this type of monitoring was an expensive and time-consuming process — one that interfered heavily in patients' daily lives. However, as technologies such as sensors are becoming both smaller and less expensive, more and more parts of the monitoring process can be performed outside the hospital, without the direct and constant control of healthcare professionals. There are numerous fields of application, such as stress, epilepsy, or toxicity monitoring that can affect patient well-being considerably during the measurement process.

The monitoring of patients with type 2 diabetes is an excellent example of the patient-friendly development in this market. Instead of using finger sticks twice a day, there are sensors that automate the glucose measurement process. As a result, the process is not only easier and more convenient, but it also generates more reliable data, as the risk of human error is removed from the process.

The application of sensors in the monitoring process is not limited exclusively to extracorporeal data. Conditions that were difficult to detect without radiation, such as intestinal processes, can also be deduced more easily. For example, the 'smart pill' developed by Proteus contains an ingestible sensor which transmits a signal to a patch on the body. Data collected on blood pressure or the patient's sleeping rhythm is transferred to the patient's mobile device and to the Proteus cloud, to which doctors have secure and controlled access.

In addition to all the monitoring processes prescribed by healthcare professionals, millions of consumers already voluntarily track themselves with apps, wearables, and other devices. The benefit of prevention instead of treatment is firmly established in health-conscious consumers' minds and the process of generating and evaluating data is a daily routine for the consumers. Once again, this underscores the industry's continuing shift from treatment to prevention.

42%

Life sciences companies are also using web-based services, such as apps, more commonly. Already, 42% of companies have implemented these services and an additional **17%** plan to do so. Further, wearables, devices, or sensors are deployed by 21% of companies for diagnosis and 30% for monitoring services.

Source: KPMG in Germany, 2017

The KPMG International publication *Pharma outlook 2030: From evolution to revolution* envisages the 'niche specialist' as a life sciences archetype of the future. These companies focus on a single therapeutic area or disease, and look at the entire patient pathway from prevention to real cure. A prominent example is Novo Nordisk, which focuses on diabetes.

All of the prescribed and voluntarily performed monitoring and tracking processes generate a huge amount of data. It is not clear yet if and how all of these data can be used, but it is certain that they can revolutionize treatment procedures and might also be used in clinical trials, thus potentially improving and shortening the development process of the drug itself.

Medtronic and Qualcomm devise a better way for those with diabetes to monitor glucose

Faced with a growing number of patients with type 2 diabetes, especially in developing countries, device company Medtronic is teaming up with tech firm Qualcomm to develop a continuous glucose monitoring (CGM) system. Their aim is to design an easier-to-use device that provides glucose data to the patient and the healthcare team.

Measuring glucose levels is still problematic for patients with type 2 diabetes: Previous systems require the patient to keep to a schedule and to deal with challenging technology, which can be impediments to getting reliable and comprehensive glucose data.

The new product, expected to be launched in 2018, will have considerable advantages. It will not only be fully disposable and smaller in size, but because the system will be worn for a short but constant period of time, data will be of a much higher quality. 24/7 sensor monitoring will make using finger sticks a thing of the past, which will be a huge advantage for patients. Moreover, patients will be able to operate in real-time mode so that they can actually see the data (in contrast to current systems that do not show any data).[6]

Using Microsoft Kinect to better monitor the progression of multiple sclerosis

Multiple sclerosis (MS) is a disease of the nervous system which affects about 2.5 million people around the world. The most common symptoms are autonomic, motor, and sensory problems. The unpredictable and erratic progression of this disease makes diagnosis and monitoring a major challenge. Although physicians have standardized tests to evaluate the course of treatment, these ratings are quite subjective, such that symptoms might be rated differently from physician to physician. This makes a scaled-up evaluation of symptoms (across physicians) difficult.

Novartis wanted to create a method to measure the course of treatment more objectively. The pharmaceutical company recognized the opportunities of a technology that Microsoft released in November 2010 to solve this problem: The Kinect system is a motion-sensing input device, originally designed for playing video games without the need for a game controller. This allows the user to interact with the device orally or via gestures. In practice, the clinical assessment of MS can now be supported by an advanced version of the Kinect system, measuring a patient's motor ability in a more uniform and consistent way.

Besides the usage of computer vision, the collaboration between Novartis and Microsoft went one step further. The companies took the opportunity to establish a new field of application for machine learning. The machine learning experts designed algorithms that could measure the disease's progression and, as more pictures and patient data are added to the software, it can deliver even more consistent results. For the researchers, the next step is to employ the system in practice and to find further applications in other fields of therapy.[7]

Personalized medicine and preventive therapy

Integrating the patient into the life sciences ecosystem as an active participant is an important step toward perceiving them as an individual. The focus is on using intelligent and highly advanced technologies to conceive this individuality and replace the big blockbuster drugs.

Today, doctors can analyze and diagnose a patient to a level of detail that was not thought possible even a few years ago. Data from medical examinations, as well as from preventive monitoring, can be used to adjust drugs and treatments precisely based on the condition and requirements of the patient. It is already possible to use 3D printers for the production of prostheses. Potentially, we will be able to 'print' organs the same way. Any company engaging in these technologies can expect to enjoy a competitive advantage.

23%

While 23% have implemented additive manufacturing as a production approach or plan to do so, only **10%** personalize their products with this technology or plan to do so. Regulatory issues might be an obstacle to this innovation.

Source: KPMG in Germany, 2017

Using 3D printing to create a pill that is easier to swallow

Aprecia Pharmaceuticals uses a specially designed 3D printing technology platform to produce pills that are easier to swallow.

The idea behind the deployment of additive manufacturing in the production of drugs is to focus on each patient individually: Medication adjusted specifically to the body and disease of a patient can improve treatment results while lowering the patient's physical stress.

Certain groups of patients, such as children, the elderly, or patients suffering from cancer, have problems swallowing pills. To facilitate ingestion, patients might crush or break a pill. However, this can impact the efficacy of the medication.

Using 3D printing technology, Aprecia Pharmaceuticals can produce high-dosage drugs in a swallow-safe form. In the process of printing, multiple layers of active ingredients in a powder are blended by an aqueous fluid, resulting in a higher degree of consistency throughout the pill.

Companies need to consider the radical change in the pharma value and supply chain: Warehouses and inconvenient distribution channels are a thing of the past if hospitals, doctors, or eventually the patients themselves can print drugs. New business models will arise and first-movers will have a significant advantage.[8]

7%

Although this technology requires a high degree of specialization, 7% of companies have already implemented or plan to implement direct-to-consumer tests.

16%

16% are adding web- and data-based services to ensure a holistic treatment approach.

Source: KPMG in Germany, 2017

With the decoding of our human genome, life sciences companies have the opportunity to raise personalized treatment to an even higher level. Genetic testing, which is quicker and easier than ever with today's direct-to-consumer tests, can be used to treat severe illnesses such as cancer and can also be used for preventive purposes (for example by nudging people to maintain a healthier lifestyle). For example, the US-based company GRAIL is developing a blood test to detect cancer in its early stages. Diagnosing cancer earlier can translate into survival rates that are five to ten times higher. GRAIL combines leading approaches in computer and data sciences with population-scale clinical trials and ultra-broad and ultra-deep sequencing. The concept of early detection is so promising that the company could raise over US$ 900 million of financing from a consortium of investors which includes Johnson & Johnson, BMS, Celgene Corp. as well as Amazon.com Inc.[9]

The rise of direct-to-consumer testing

Over the past 40 years, technological advances have allowed us to decode the information contained in our genes at ever-increasing speeds and lower costs. This has laid the foundation for the rapidly evolving genetic testing market. While genetic testing has traditionally been carried out by healthcare institutions, direct-to-consumer genetic testing (DTC-GT) is becoming a viable alternative. The global DTC-GT market is expected to be valued at US$ 500 million to US$ 1.1 billion by 2020.

A London-based company has developed the first DNA-based service with the aim of guiding consumers toward a genetically optimal buying behavior. The service is based on a database that matches the nutritional values of manufactured food products with genetic characteristics. The information is delivered through a wearable device or mobile app.

At a retail counter, consumers select a DNA cartridge and input saliva via a cheek swab. The cartridge is inserted into a portable, purpose-built analyzer. Minute quantities of DNA are then analyzed automatically in about 15 minutes. The results, which are confidential to the user, are transmitted to the company's cloud database via blockchain security. These are then analyzed using a secure mobile phone app, which personalizes the shopping experience with bespoke 'scan and shop' recommendations of the products that are genetically optimal for the user.

Privacy and security play key roles when offering genetic-based services and products. By taking the required test, individuals surrender sensitive information about themselves. Should this information end up in the wrong hands, they could potentially impact employment prospects, relationships, and insurance premiums.

Threats to genetic information security include the cracking of weak database passwords, server hacking, storage device theft, and intentional misconduct of data custodians. Furthermore, if information is stored and processed by branches of the service provider or its corporation partners residing in another country, the initial privacy agreement of the customer may become subject to local laws, which could differ from those where the parent company is located. The importance of privacy and security creates new opportunities for blockchain technology, which can be used to guarantee data security.

Source: KPMG in Germany, 2017

IBM Watson and Novartis team up to find better ways to treat cancer

Oncology research has advanced rapidly over the last two decades, resulting in new, almost daily insights into the structure of tumors and possible ways to treat cancer.

However, these new forms of treatment do not necessarily automatically result in increased life expectancy. To reach this goal, clinicians must first identify the suitable treatment form for each of their patients due to the patient's individual etiopathology.

Intelligent technology, such as IBM's Watson, can step in and support clinicians in this time-consuming process. Watson has a wide variety of capabilities in data analytics and machine learning. In a healthcare context, it can help to analyze data such as medical records or relevant articles. Based on this, it can examine treatment alternatives such that clinicians and patients are guided along their way in finding the best-fitting, unique treatment option.

Furthermore, artificial intelligence can help to match patients to clinical trials and specify clinical practice guidelines. In order to improve outcomes in cancer care trials, Novartis and IBM Watson have announced a collaboration, starting with a special focus on advanced breast cancer. However, they are already planning to expand their cooperation to the wider oncology field. In this collaboration, real-world patient data will be used with the ultimate goal of improving patient outcomes.

A recent study has shown that IBM Watson's health recommendations already matched 90 percent of the recommendations made by an expert board.[10]

Hungarian start-up uses predictive modeling to prescribe better cancer therapies

The rise of personalized medicine might be the solution for defeating cancer in the near future. Studies have shown that combining different drugs into one treatment therapy significantly increases success ratios compared to single drug treatments. However, finding the right combination among billions of possibilities requires years of research and the traditionally used in vitro experiments are very costly.

Turbine, a Hungarian startup supported by Bayer's Grants4Apps accelerator, aims to virtually design effective combination therapies for cancer by employing artificial intelligence. With gene sequencing, Turbine can simulate the best combination for any cancer patient by constructing a simulated cancer cell.

By describing cancer development as a dynamic network of interconnected nodes, the system can temporarily assume any state from billions of possibilities. Turbine finds treatments that effectively kill cancer cells by running millions of simulations to reveal the effects of all available therapies and their combinations on the system.

This concept offers several possible benefits for pharmaceutical companies. First, the simulations increase the return on investment by cutting months or even years of trial time when identifying the right chemotherapy. Even if no clinical research or treatment guides exist for a patient's cancer type, Turbine's artificial intelligence can test millions of treatment combinations to find the ones that are most likely to work. Second, even a combination of already approved drugs can potentially uncover new off-label effects and mechanisms. Third, the use of simulations negate many of the safety concerns normally arising in traditional R&D environments.[11]

14%

The application of artificial intelligence is the way forward: However, only 14% are implementing the technology to interact with the patient or plan to do so, and only **12%** apply it in R&D or plan to do so. This offers a competitive advantage to companies that embrace the potential of artificial intelligence.

Source: KPMG in Germany, 2017

Empowering patients and healthcare professionals with direct communication via platforms

Networks, forums, and other platforms enable direct communication between patients and healthcare professionals. Moreover, these are excellent tools for educational purposes.

The increasing popularity of platforms shows how patients are willing to participate actively in order to gain insights and knowledge. The issues discussed between patients can range from symptoms to treatment procedures, including support where needed. Discussions between healthcare professionals focus primarily on the transfer of knowledge and the exchange of state-of-the-art treatment procedures.

Life sciences organizations, on the other hand, can use these channels to establish a dialog with medical professionals and to communicate their latest developments. In doing so, it is of great importance to distinguish between delivering real services and value, and merely advertising products.

54%

Educational platforms are realized or planned by 54% of companies. **34%** of companies have implemented or plan to implement platforms for exchange with or between patients.

Source: KPMG in Germany, 2017

"We currently have a wide range of mature products for mobile healthcare on the market, including healthcare apps, healthcare management, online healthcare shopping, education and training, etc. Rather than the functions of those products, I would say it is the influence brought by these products that have to a large extent changed people's idea of health, for instance, from passive to active prevention. With good platforms, doctors can talk directly to the patient, provide professional consultation, increase the number of target customers, and build personal brands. Doctors no longer physically rely on hospitals to practice. They can go out and practice on multiple sites. Also, with a digital platform, medical training and education is not restricted by location. Medical practitioners can acquire knowledge and enhance competencies on continuing medical education platforms.

In this regard, China can act as a role model for other countries, even and especially for mature healthcare systems."

George Mao
Partner and Chairman, Shanghai Pinzhi Investments Management Co., Ltd., Shanghai

Shaping the future of professional healthcare education in China

Education and training is essential for health systems worldwide to overcome challenges such as demographic change and the shortage of specialized health workers. Moreover, practicing medicine is a dynamic process as new methods, processes, and knowledge are developed at an ever faster pace.

In this regard, continuing medical education (CME) is the key requirement for high-quality medical work. Besides the traditional offline methods, today there are online components ranging from lectures to practical training to e-learning. These methods help to maintain and develop competencies and to enhance patient care.

In order to raise medical knowledge, national and international experts are needed to provide the best medical practice. An eCME platform (electronic continuous medical education) can be a possible solution. To ensure appropriate and effective education, these platforms can be used to host online CME content from all over the world. Exclusive partners are needed to operate the platform and to provide not only regional but also international content. This forms an international network and provides access to a worldwide knowledge-sharing platform covering the latest medical topics. Such an integrated e-learning platform makes CME accessible around the clock, flexible, engaging, and cost-effective. This ensures a consistent educational standard among physicians, who are required to collect CME credits to maintain their practice licenses.

In China, for example, the National Health and Family Planning Commission (NHFPC) established a state-driven eCME platform. It has a collaboration with the Capacity Building Continuing Education Center (CBCEC), which organizes and hosts the educational content. The platform is currently in the test phase and will provide the first lectures for an estimated 10.7 million medical professionals, including 2.2 million physicians, by 2017/2018.

Source: KPMG in Germany, 2017

Commercialization: The importance of having a digital data strategy

As the focus on big blockbuster drugs is waning, patient-centricity will be core to the business. As a result, commercialization strategies have to change.

Considering all the significant advancements in the supply chain and the inclusion of the patient pathway in the ecosystem, life sciences companies need to develop a digital data strategy comprising all business units and stakeholders. All of the technological advancements in the different steps of the supply chain that generate data, from intelligent automation to value-based pricing, serialization or predictive analytics, should be considered in a holistic concept.

In this process, all of the available data from the different departments of a company should be used to establish a consistent, multi-channel strategy. Pharmaceutical companies can no longer only use the traditional way of having personal meetings with physicians and clinics to generate sales. Rather, they have to use digital measures to get in touch with healthcare professionals. A successful, multi-channel commercialization would include some of the technologies and approaches mentioned in this study, such as apps, wearables, communities, or networks.

51%

Already, 51% are planning or working on a multi-channel distribution mix. It is the second most common digital tool for patient and customer retention. Technological approaches like predictive analytics, data mining, or automated forecasts are also becoming mainstream: **34%** of companies apply or plan to apply one or more of these technologies to enhance commercialization.

Source: KPMG in Germany, 2017

Multi-channel digital data strategy

A leading international life sciences company is using data, analytics, and innovative tools to build a comprehensive healthcare ecosystem and better serve patients, physicians, and other stakeholders. They have started by enhancing their core capabilities. For example, they have collected and analyzed prescription claims in a specific therapeutic area across the USA. This will subsequently be integrated with other data such as patient longitudinal, medical claims, electronic medical records, social data, patient services, and CRM. Over time, it intends to supplement and add emerging digital data sets that provide more information on the needs of specific patient cohorts. Ultimately, the company is planning to use mobile health and digital tools to differentiate between competing treatments and to change the delivery of care.

Source: KPMG in Germany, 2017

04 The way forward

80%

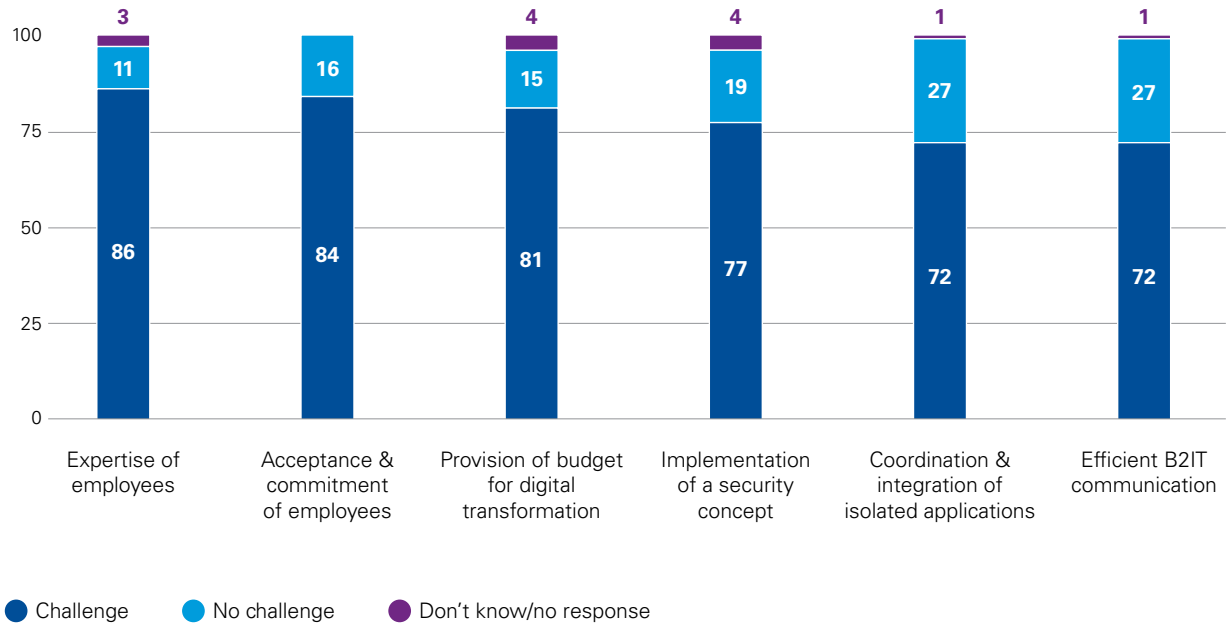
The three biggest challenges for more than 80% of companies are the lack of digital competencies, employee acceptance, and approved budgets for the digital transformation.

Source: KPMG in Germany, 2017

Companies see developing their digital competencies and convincing their employees of the benefits as their biggest challenges. However, they should not forget to focus on the patient.

As industry players explore the new life sciences ecosystem, they will identify their roles and perceive the flow of information in the industry. The next step is to identify data and processes that are key for successful business operations. Although this transformation is already underway, several challenges still have to be addressed on the road to a new life sciences ecosystem.

Figure 8: What are the biggest challenges facing life sciences companies (multiple choice, in %)?



Source: KPMG in Germany, 2017

When asked about the biggest challenges in the coming years regarding digital transformation, companies mentioned the availability of qualified and committed employees and sufficient financial resources most frequently.

Developing the right employee competencies and expertise is the biggest single challenge for life sciences companies, with 86 percent of companies saying the skills shortage is a problem. Companies from the medical technology sector in particular had doubts about their ability to develop the right expertise.

In this regard, a critical parameter in the digital transformation process is a clear definition of the employee qualification profile that will be required in the future. Education and training systems, as well as the labor market, will have to adapt to these requirements. Once the requirements are clearly outlined, the appropriate qualification programs can be developed, employees can be reskilled, and new employees can be recruited.

The next big challenge is the provision of a budget for digital transformation (81 percent). In addition, the actual implementation and the collaboration of IT teams and business operations seems to be challenging: Seventy-seven percent see the implementation of a security concept as problematic, while 72 percent find the coordination and integration of isolated applications challenging. Likewise, efficient communication between business and IT units is a real challenge for 72 percent of companies. Developing the right capabilities, controls, and culture will be key to driving the digital transformation success.

On the other hand, only 41 percent see no challenge with the direct communication with patients. However, one should be careful in interpreting this figure. Even if companies do not see this as a big challenge, there are few that actually employ web-based services to design individualized health solutions for the patient or have created apps, multi-channel marketing solutions, or platforms to get in touch directly with the patient. For companies that want to be industry leaders, it is not sufficient to digitalize internal processes.

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Methodology

The study 'Digitalization in life sciences' discusses the changes to customers, business relationships, and value chains through major technological innovations and the increasing digitalization of the economic environment.

Between May and June 2017, KPMG in Germany and Kantar Deutschland GmbH anonymously interviewed a total of 75 CDOs, COOs, CIOs, and purchasing heads in Germany (50 interviewees), Switzerland (15 interviewees), and Austria (10 interviewees) about their views on digital transformation in the life sciences industry. The participants represented 35 pharma companies, 20 medtech companies, and 20 other companies from the wider life sciences industry. Forty-one companies had revenues of under EUR 500 million and 34 companies had revenues of over EUR 500 million.

The aim of this survey was to provide an overview of the effects of digitalization on the life sciences industry, the changes that arise for the individual companies, and how the industry is shaping the future. We have focused on the degree of digitalization in life sciences companies. The selection of survey results displayed reflects this overall objective. We reserve the right to show the results in an aggregated form.

In addition to the survey of experts from KPMG's international network, the project team identified use cases and examples in internal projects and via desk-based research to shed light on trends and their effects. This included robotics, digitalization, and technological developments in the business model, the labor market and economic policy framework conditions. The results of the studies were compared with findings from expert interviews, and various statements were weighted against one another and subsequently discussed in digital workshops.

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KPMG Research Cloud

Our view of the evolving life sciences industry is visualized in the life sciences ecosystem, which is derived from the KPMG Research Cloud. This overview of merging ecosystems highlights the major technological developments and approaches envisaged by the KPMG product team.

The KPMG Research Cloud is a platform that collects, structures, and visualizes information in real-time. Using natural language processing, data can be analyzed in terms of its semantic correlation.

Information is searchable through the input of search phrases and is illustrated in a network of interconnections and linkages. It is displayed in a semantic trend graph that shows the relationships between numerous key performance indicators (KPIs), such as funding, acquisitions, publications, jobs, innovations, threats, and patents that are linked to the search phrases.

The KPMG Research Cloud calculates growth predictions through a newly developed impact-offset model based on the KPIs that evaluate the development of the requested search phrases, and provides an outlook of the future.

KPMG in Germany, 2017

Notes

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