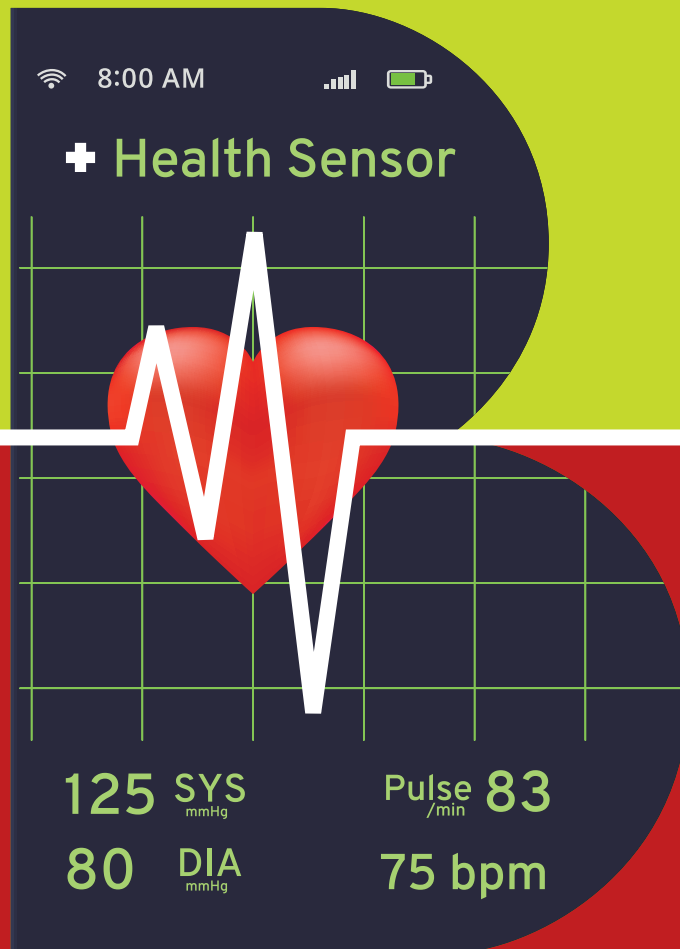


THINK ACT

BEYOND MAINSTREAM



September
2016

Digital and disrupted: All change for healthcare

How can pharma companies flourish in a digitized healthcare world?

THE BIG

3



>200 bn

USD is the estimated value of the digital health market by 2020, compared to USD ~80 bn today.

Page 4

4.5 bn

USD in funding was raised by the digital health start-up environment in the US in 2015 alone.

Page 13

3

stages of the digital transformation of healthcare defined as mirror, identify and implement.

Page 14

Is this the writing on the wall for how digital healthcare will play out?

8:30 am in a primary school in Kitale, Kenya, and English has just begun. The teacher Mr. Kadiri is busy writing on the blackboard, but 9-year-old schoolboy Pravin is frustrated because he just can't make out the letters. At the end of the lesson teacher Mr. Kadiri takes Pravin aside and quickly conducts a visual acuity test using his smartphone based portable eye examination kit.

Able to produce high quality images of the retina, the smartphone app can identify all manner of cataracts and other eye conditions. Fortunately for Pravin, all that he requires to correct the shortsightedness identified by the app is a pair of spectacles.

A smartphone app proves that seeing is believing. 80% of blindness is avoidable, but eye care tools are far beyond the reach of communities in many poorer parts of the world. The appropriately named app PEEK (for Portable Eye Examination Kit) transforms the smartphone into a practical and versatile eye examination tool.

A simple story perhaps, but a game changer nonetheless and an example of the digital revolution in healthcare, which is already happening today.

Fast forward to one evening in the year 2030. Paula – suffering from hyperthyroidism – receives a message on her smartphone: "Hi Paula, your heartbeat is irregular and you are suffering from palpitations, you are not sleeping very well and you seem to be nervous. Why not make an appointment with your physician?"

What happened and why? Paula's smartphone is a universal sensor, tracking her every movement, sleeping patterns, eating habits and other daily routines.

By doing so, her phone recognized changes in her daily schedule, which correlate to the symptoms of hyperthyroidism. Her headphones constantly measure her body temperature when she uses them and her fitness bracelet monitors her pulse and blood pressure. Paula had the foresight to make her medical data available for remote physician consulting.

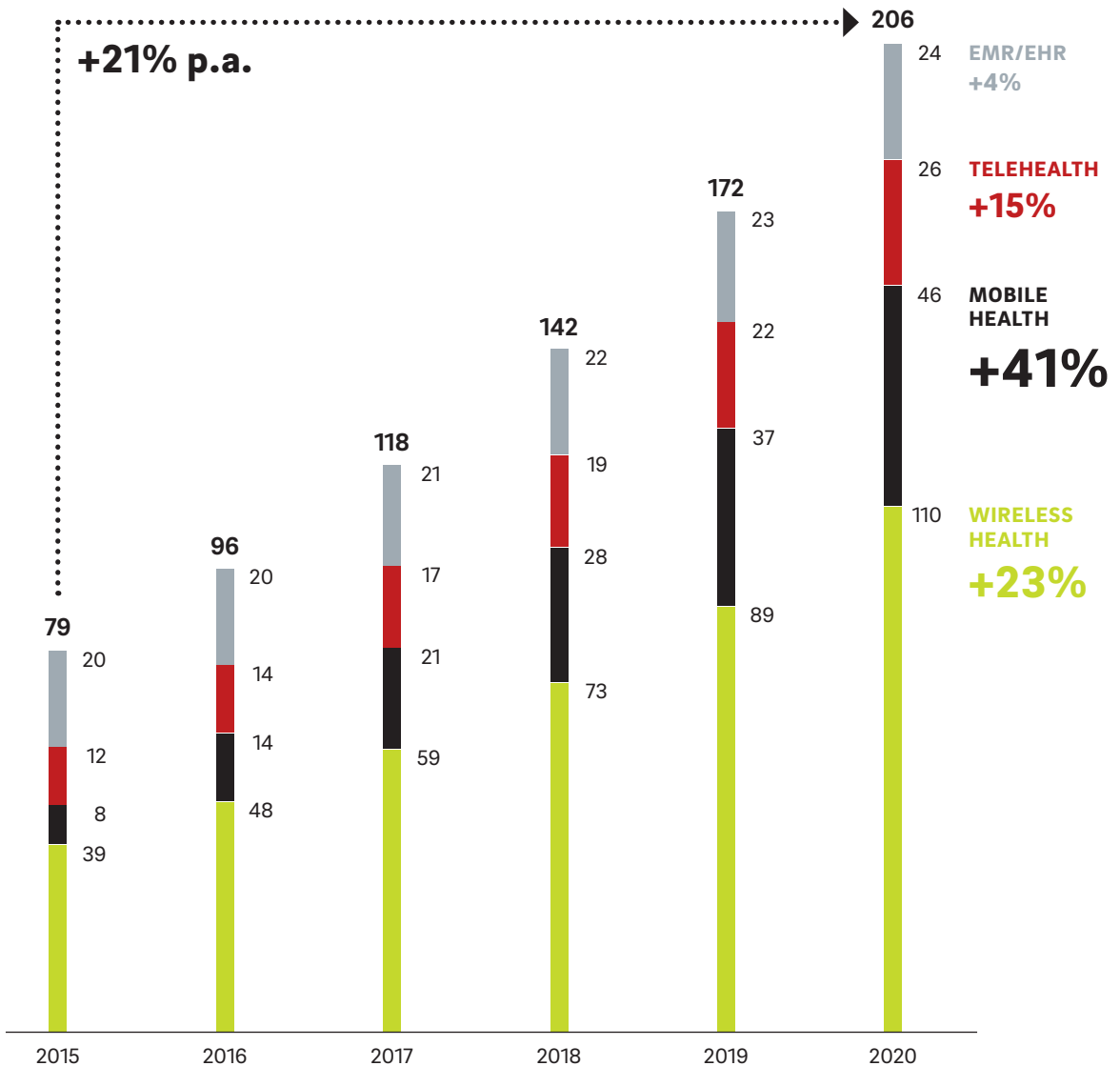
Science fiction? Well, maybe, for the time being. However, judging from what digital health start-ups such as xbird, AuraLife, Fitbit, Bragi and MeeDoc are already currently capable of delivering, it is only a matter of time and a number of minor healthcare reforms before this piece of digital medical fiction becomes just another example of everyday medical reality, one that will deliver healthcare information, products and services right to the customer direct, thus connecting patients and healthcare professionals regardless of location.

And it will be a significant market: Roland Berger estimates that the value of digital healthcare products and services will exceed USD 200 bn by 2020, growing by more than 20% per year. Within the various segments, mobile health applications are the growth leaders. → **A**

A

MOBILE AND WIRELESS APPLICATIONS ARE DRIVING THE HEALTH MARKET

Digital health market development 2015-2020 [USD bn]



EMR = Electronic Medical Record EHR = Electronic Health Record

Source: Allied Market Research, Markets and Markets, Grand Market View, Transparency Market Research, BCC Research, Roland Berger analysis

Taking responsibility: A new role for patients and the implications for healthcare.

Thus far, our interactions with healthcare systems have been clearly defined and static. Patients' principal interface to healthcare services has been a primary care physician. Medical knowledge regarding disease and treatment has been defined and disseminated solely by physicians. While more health-oriented people also tend to seek the advice of pharmacists and patient groups when making decisions concerning their health, interaction with pharmaceutical companies remains unheard of. Clinical history records continue to be off limits to anyone other than the patient and their physician, often end up being lost and are therefore of no use whatsoever for other healthcare professionals.

The internet and widely available digital information have already brought about a major shift in the patient's role. Patients now have access to an extensive network of medical information, both for education purposes and to communicate with other patients via the internet with regard to their health status and treatment options. An increasing awareness of one's own health status is supporting lifestyle changes and actively contributing to the prevention of disease. That said, access to the healthcare system has not changed dramatically. The point of contact for patients remains the physician, who also determines the appropriate course of treatment. Digital solutions and electronic health records are still not available in a wider sense, remain

limited to overall lifestyle habits, and do not (fully) document a patient's illnesses and diseases.

There has, however, been a shift in the role and the ability of the patient to take more responsibility for their own healthcare issues, and this is bringing about a fundamental change in the entire healthcare ecosystem. In the future, the vast majority of patients will have a much more participatory role in their own diagnosis and treatment. Health-related data will be stored in a cloud-based health record, which can be shared with respective doctors and insurance companies. The traditional patient-physician relationship will no longer have the central role it has enjoyed thus far. Instead, we expect mobile online platforms and agencies to be the core interface between patient and medical expert. An interactive approach such as the German start-up Medlanes may well disrupt the healthcare system in the same way as other innovative concepts like Uber have changed our perception of mobility. Patients will no longer rely on a single and local physician, but will be able to access such platforms when they have a specific medical need. A network of physicians linked to the platform will be able to provide initial consultation and advice, before referring to a specialist and scheduling an appointment with the preferred doctor or hospital clinician. Remote medical advice will gradually dissolve national boundaries even further as patients seek the best medical services and specialists.

6 THINK ACT

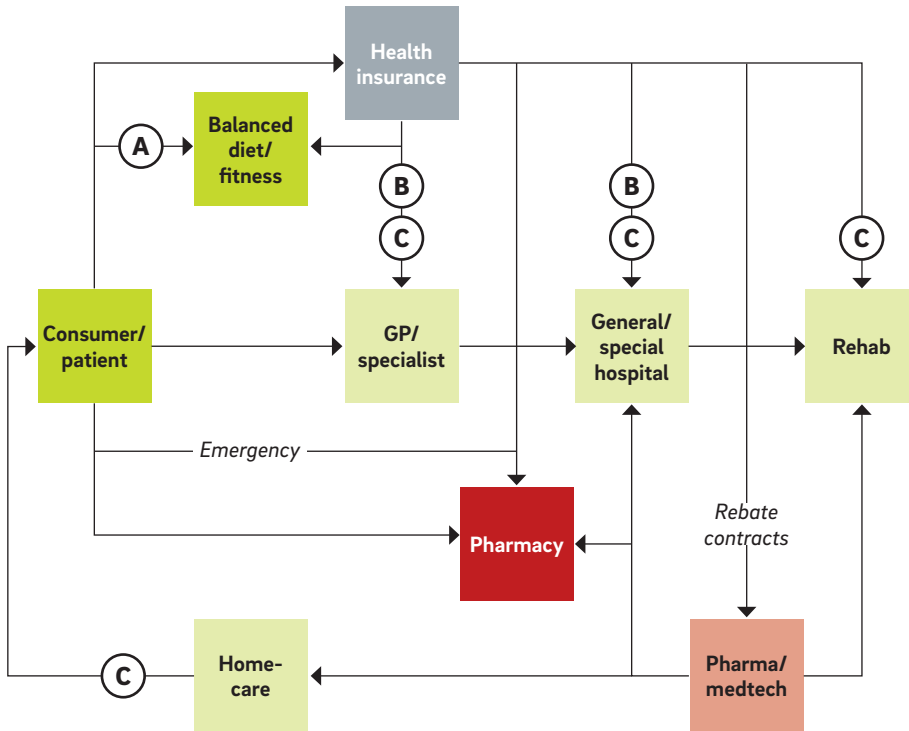
All change for healthcare

B

DISRUPTION OF THE HEALTHCARE SYSTEM

New entrants are challenging traditional healthcare systems and have the potential to disrupt current structures.

HEALTHCARE SYSTEM



Source: Roland Berger

AREA OF DISRUPTION

.....
Ⓐ
HEALTH RELATED BEHAVIOR/ PREVENTION
.....

Ⓑ
DIAGNOSIS
.....

Ⓒ
THERAPY
.....

Electronic health records and digital communication with medical practitioners will give further credence to e-subscriptions while also challenging the traditional business models of pharmacies, which will need to rethink their digital approach and store concepts.

In addition, patients will also be better informed about alternative treatments and will expect a more holistic view not only from their respective physician and insurance company, but also from pharma firms. Direct communication between patient, physician and the pharmaceutical manufacturers will increase, with the latter requiring a different skill set for marketing and

sales as they begin to operate in a more complex, multichannel environment. → **B**

In the future, medical treatment will be supported by a range of diagnostic tools and data provided by smart pills, sensors and metabolite patient profiling. Real-life data on treatment success rates can potentially increase the treatment take-up rate, thus influencing the outcome for patients, insurers and pharmaceutical companies.

Given the backdrop of greater competition with other providers in an increasingly transparent healthcare world, a successful treatment regime is a valuable performance indicator for the physician in charge.

Life-science stake- holders may well face disruption.

Customer-centric healthcare systems and the development of new treatment regimens can potentially disrupt the entire healthcare system. Each stakeholder will have to thoroughly rethink its current business model and position itself within a changing environment that increasingly embraces the concept of P4 medicine, first described by L. Hood as a medicine that is predictive, preventive, personalized and participatory. Health will no longer be defined by the absence of a disease, but will be seen in the more holistic context of a person's wellbeing. This approach will therefore also require the interdisciplinary connection and collaboration of various healthcare players. Roland Berger has evaluated the role of key stakeholders in the healthcare systems of the future. → **C**

PHARMACEUTICAL COMPANIES: MANAGING BENCHSIDE TO PATIENT AND BACK

Pharmaceutical companies will be disrupted by the digital transformation in healthcare. New entrants and disruptive business models are already challenging incumbent pharmaceutical firms. For selected indications and diseases, digital treatment regimens will compete with traditional medication. Even today, we see the FDA and EMA approving software solutions to treat serious conditions such as depression¹. Smart pills and sensor-supported treatment programs will further encroach on the business of the established pharmaceutical players or they will embrace them by information-guided therapy programs such as that on offer from Roche and Foundation Medicine. Furthermore, recent discoveries in biomedical medicine enabling the direct and individual use of a patient's genomic information for personalized

treatment programs via engineered stem-cells and genome editing have the power to revolutionize the concept of treatment far beyond the scope of classic pharmaceuticals. However, it's not only the products that will change in the future but also the way in which a pharmaceutical company interacts with its environment. Currently, major players are embracing the multi-channel approach aiming for holistic interaction with customers. This will reach physicians, pharmacies and other healthcare professionals, and further facilitate the integration of patients into the product lifecycle. Pharmaceutical companies will have to close the last mile to the patient, in order to actively collect and interpret real-life data used to assess, approve or price their products. Hence, pharmaceutical companies will be able to accelerate clinical testing, significantly reduce the development cost of new products and improve their propensity for innovation. As access to such data will still be restricted by law, direct-to-patient models will be required to collect data on a voluntary basis with data access and use being strictly regulated.

MEDICAL DEVICE COMPANIES: GATEKEEPER TO PATIENT DATA?

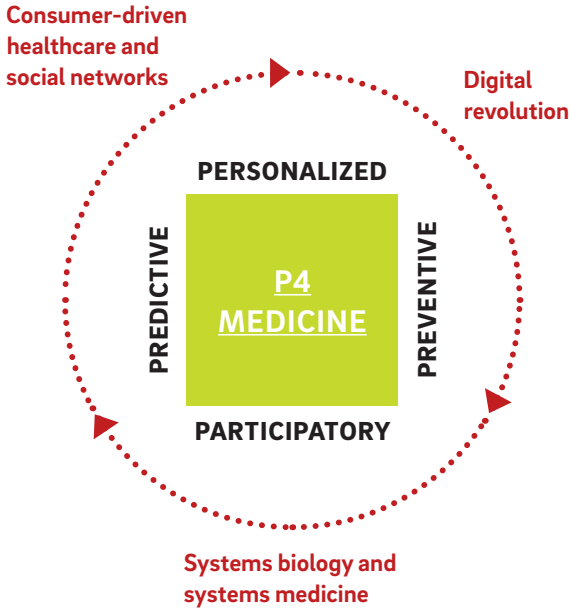
As patient data and insights are becoming increasingly important, the patient interface will be a key success factor for future digital business models in the healthcare environment. While smartphones and apps will continue to be convenient tools for monitoring patient wellbeing, medical devices are critical to gaining greater medical insights into the human body, as well as to addressing and/or treating health issues. Through digitization, better

¹ E.g. Gaia's depression

C

MAKING HEALTHCARE LESS REACTIVE AND MORE PREDICTIVE

P4 medicine concept



"The convergence of systems biology, the digital revolution and consumer-driven healthcare is transforming medicine from its current reactive mode, which is focused on treating disease, to a P4 medicine mode, which is medicine that is predictive, preventive, personalized and participatory"

LEROY HOOD, M.D., Ph.D.
 P4 Medicine Institute Chairman and
 Institute of Systems Biology President

connected medical devices will allow real-time monitoring of clinical parameters. Drug-device combinations will assume a much more important role for all forms of medical treatment, embracing advanced therapies and medicinal products (ATMPs) rather than just being confined to conditions such as diabetes. We already see medical device companies acting as the patient interface, which sets them up well for the future. However, for many med-tech companies the question remains how they can shape the transition into the digital era and emerge the winners.

HEALTHCARE PROVIDERS: A NEW AGE SERVICE PROVIDER?

Healthcare providers and medical practitioners will experience severe disruption. The traditional patient-doctor relationship will cease to exist and GPs will have data analysis supporting them in their new role as treatment managers. Online platforms offering easy-to-use tools to compare and choose a specific physician or clinic will be available to patients. Doctors and hospitals will therefore have to rethink their value proposition and establish their own individual business models to set them apart from both local and international competitors. This is the only option they have if they want to remain relevant players in a field where big data systems such as IBM Watson Health are able to diagnose diseases solely on the strength of digital patient information. Doctors will increasingly listen to patients and treatment will follow on the basis of decisions made jointly by doctors and patients with the benefit of much higher compliance and adherence rates than was previously thought possible. At the same time, globalized healthcare will create new payment models with increasing weight and willingness for out-of-pocket payments. The availability of electronic health records will also dismantle traditional patient-physician relationships. Access to patient medical records will no longer be limited to those individuals directly involved in the generation of data. Additionally, remote patient monitoring will be another lever encouraging the exodus of treatment to outpatient facilities, thus challenging the role of hospitals, too.

PAYORS: THE PROSPECT OF BEST-IN-CLASS GLOBAL HEALTHCARE SERVICES

Once a diagnosis has been made, payors today have access to the most comprehensive medical health records

possible. Data analysis and consumer insights complement the picture, aggregating data to an almost holistic view of an insured person's health status. The introduction of electronic health records will enable physicians to access a patient's entire clinical history. Combined with initial online advice for patients, this approach will potentially significantly decrease office and emergency visits and therefore reduce healthcare costs in general. Innovative treatment supported by digital tools to increase patient adherence will offer further cost saving potential to insurance companies without lowering the quality and output of the healthcare services on offer. Real-time data will feed predictive modeling algorithms, which will revolutionize case management. In addition, the increased use of metabolite profiling will facilitate deeper and more precise insights into the health economics of various treatment options. Even patient-specific risk profiles and risk-adjusted insurance fees could be a feasible option if regulatory hurdles can be overcome. Nevertheless, more global and connected healthcare provision will force insurance companies to develop new business models offering patients access to worldwide and best-in-class healthcare services. At the same time, this attractive vision may also increase the complexity payors will have to deal with in the future. The easy access to healthcare services apps may facilitate a tremendous increase in physician consultation requests. More detailed and precise diagnostics and therapies will also likely come at a higher price. Payors will have to be open to more patient-focused diagnosis and treatment procedures and adjust their service portfolio to match.

PHARMACISTS: ADJUSTING TO A NEW ROLE

Pharmacists have been the keystone between the pharmaceutical industry and patients for a very long time. Whether or not their role will be more or less important in the future will depend on the pharmacist's ability to change, adapt and digitize their service. Increasingly, patients are seeking direct contact with pharmaceutical manufacturers to learn more about diseases and the relevant treatment options. Digital physician consultation and e-prescriptions will further reduce stationary pharmacies' influence on treatment. Online pharmacies will become more utilized. Additionally, technology trends such as 3D printing may offer new opportunities to revolutionize traditional business models. In August 2015, the FDA approved the first 3D-printed drug, SPRITAM

for the treatment of epilepsy. This kind of technology may well provide the framework for a revolution in personalized drug dosing and medication. Pharmacies able to manufacture such products themselves would be able to take their business model out of the traditional value chain.

The pharmacist's skill set and profile will also change significantly, with much more emphasis being placed on the advisory role, thus enabling a more intimate relationship with the patient and smart data access to pharmaceutical companies.

3D printing is likely to impact the prevailing business models of pharmaceutical wholesalers. That said, 3D-printed and customized pills are likely to remain a niche segment rather than becoming the norm. Wholesalers will continue to play a role in the healthcare system of the future. With the availability of a connected health system and e-prescriptions, however, as medicine becomes more stratified and personalized, increasingly direct-to-customer shipments will become more and more relevant for wholesalers keen to exploit new opportunities. New business models such as these may also lead to increased margins in an environment that remains highly competitive. In order to survive and prosper, wholesalers will have to build expertise in B2C business with particular focus on healthcare management, marketing and sales.

GOVERNMENTS AND AUTHORITIES NEED TO PROVIDE A FRAMEWORK FOR INNOVATION

Thus far, governments have controlled the level of healthcare expenditure and regulated the market using a system of approval and access procedures. Also, it is crucial to ensure that the right of a healthy individual to personal data protection does not stand in the way of those patients that may benefit from advancements in health data science, thus pre-empting their right to the best possible treatment. Realizing that analogue-based regulations are not the ideal foundation for change, they have already started the process of careful digital adaptation. However, Dr. Google has already leapfrogged the regulations, and the clock has been ticking faster ever since. Given the savings potential within healthcare, governments need to open up and drive this industry shift further by providing the infrastructure and regulatory cornerstones. Secure data management, providing global access to healthcare services and driving a culture of innovation will be the key challenges for national bodies.

The transformation of pharma and medtech.

Is healthcare ready for digital?

Digitization and digital transformation are probably the most obvious buzzwords and current trends in healthcare today. New digital products and technologies are significantly changing prevalent industry structures and habits. Nevertheless, traditional pharmaceutical players are only now beginning to recognize the nature of this transformation and are starting to address changing industry needs with specific initiatives and partnerships.

Prominent examples are Novartis' collaboration with Google on smart lenses, which are already expected to begin clinical human trials in 2016 as well as Roche's work with Foundation Medicine for genome profiling in cancer immunotherapies. More recent examples include the partnership of Japanese Daiichi-Sankyo on an AFib remote patient monitoring pilot with Partners HealthCare; GSK and Boehringer Ingelheim's collaboration with Propeller Health on connected inhalers; and Otsuka's partnership with Proteus Digital Health on the development of a drug-sensor combination for the antidepressant Abilify.

It would appear that pharmaceutical firms have finally seen the light and, recognizing the economic value of digital products and solutions, are about to start the commercialization of their first digital products. However, many initiatives still lack a holistic view of the healthcare system of the future and remain isolated beacons rather than examples of a comprehensive, in-

tegrated digital approach. The design and development of such products will require providers to take a view of the healthcare system of the future and the new role of each stakeholder embedded in this changing environment.

TRANSFORMING PHARMA AND MEDTECH: THE IMPACT OF DIGITAL

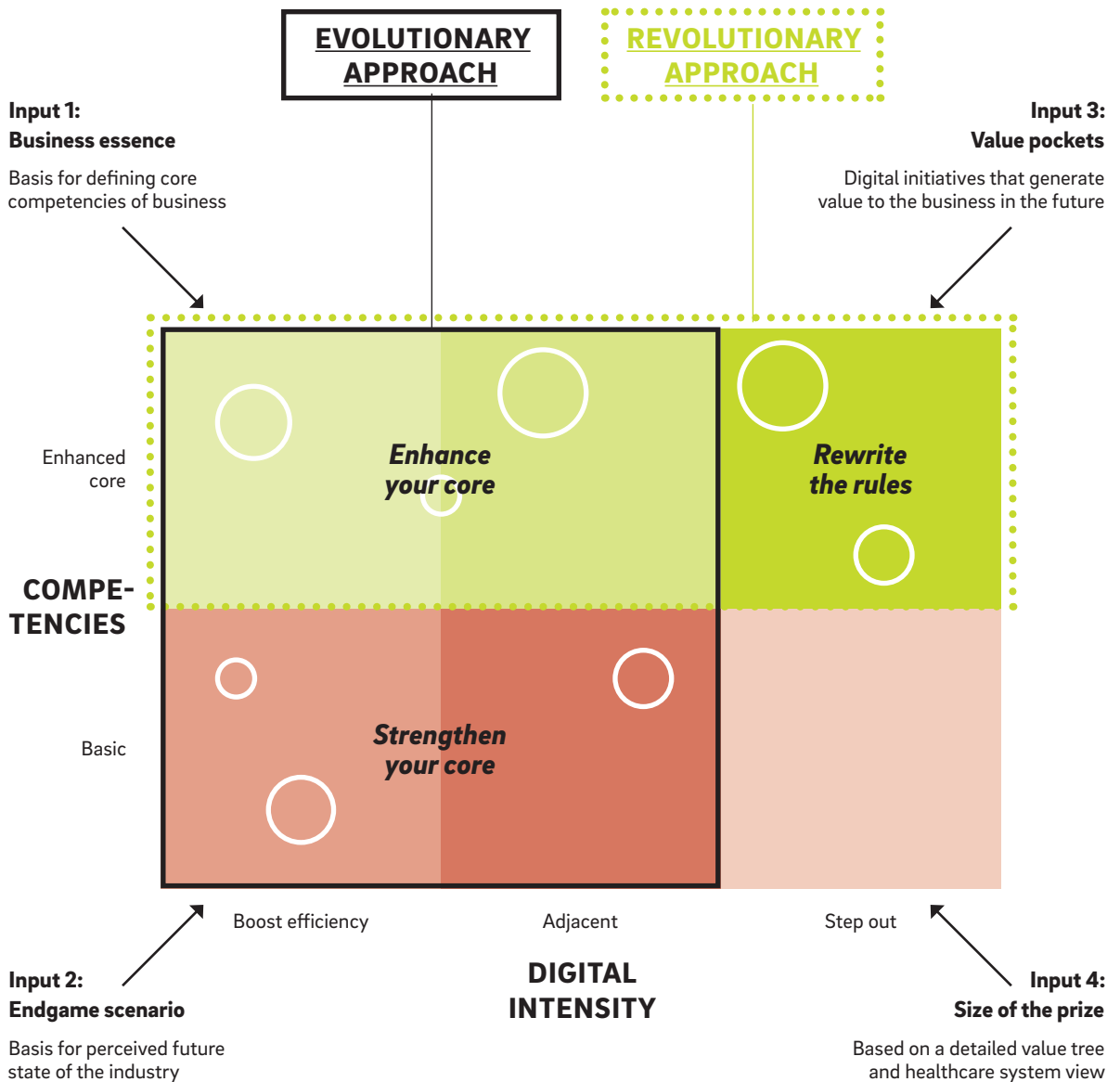
Pharma's key competency is to provide cutting-edge therapies to consumers, patients and physicians that address strong medical needs and improve people's health conditions. Medtech is providing the corresponding diagnostics, more critical than ever in a world of personalized medicine as well as complementary therapeutic solutions. How can suppliers leverage digitization to enhance this value proposition and to succeed in a fully digitized society?

In order to help companies navigate the hype and exploit the full potential of digitization, we have invented the value pocket concept. It helps companies understand how their market segment will change through digitization, what the profitable value pockets will be based on, their specific business essence and how much needs to be invested where for what return. A rigid analysis around the four pillars of endgame scenario, business essence, value pockets and size of the prize will provide the clarity management requires to make the right decisions. → **D**

D

DIGITAL ESSENCE MATRIX

Your Digital Essence shows you the way through the digital maze



○ Digital value pockets. Size of bubble represents size of the prize

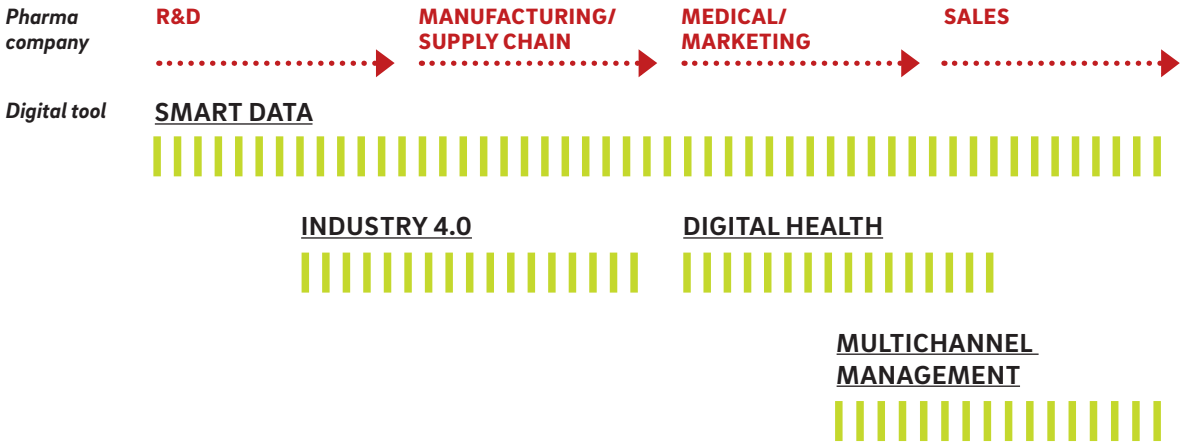
12 THINK ACT

All change for healthcare

E

DIGITAL VALUE POCKETS ALONG THE VALUE CHAIN

Understanding how digitization will impact your market segment

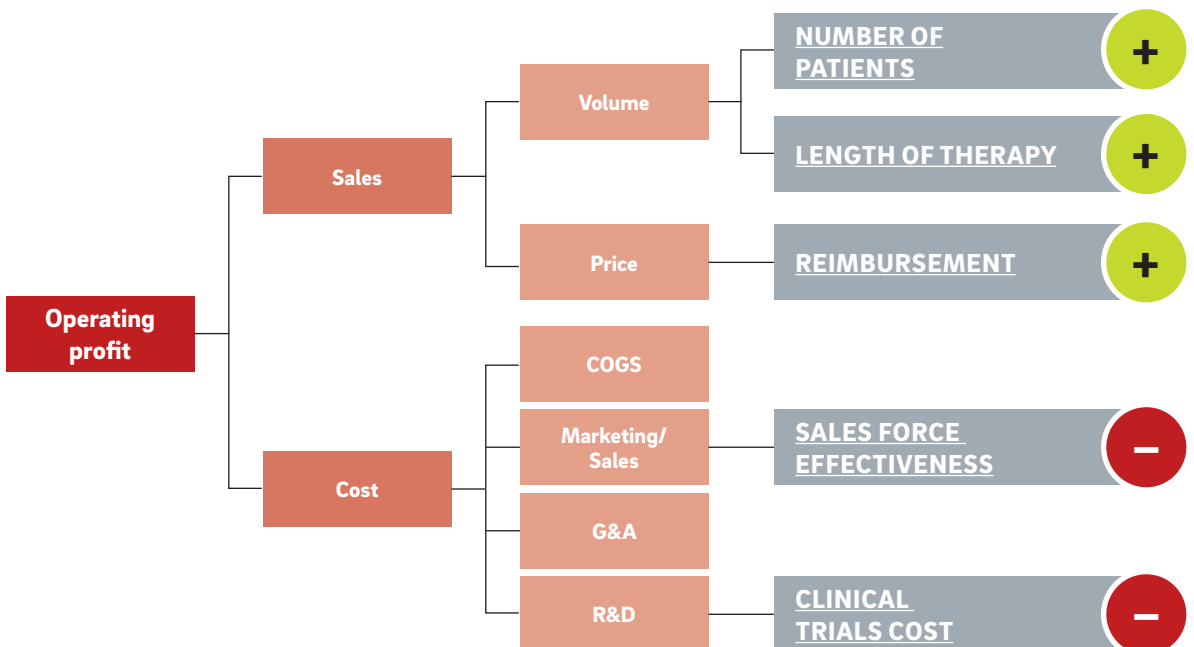


Source: Roland Berger

F

QUANTIFYING THE VALUE POCKETS

Impact of digital health solutions on the value tree



Source: Roland Berger

Translated into the value chain of suppliers, digital value pockets are substantially different at each level of the value chain. Whereas data analytics can help support R&D, production and digital health (management) services, predictive maintenance can clearly support manufacturing while closed loop systems and electronic patient record technologies are critical to support the patients to manage their disease. → **E**

QUANTIFYING THE VALUE OF THE DIGITAL TRANSFORMATION

Ultimately, for each company it comes down to how the transformation impacts the financial KPIs. Hence, each investment must impact positively and the underlying assumptions are key to understanding the financial mechanics as well as the size of the opportunity. With a value tree methodology, Roland Berger teams assess the financial impact, opportunities and risks of the digital health transformation process and support company leaders in making the right decisions based on a full understanding of the underlying facts. According to our experience, digital health can help increase sales by improving the competitive positioning, as well as enhancing profitability by doing the right things more efficiently. In Figure F the Roland Berger value tree shows how we assess the financial impact of health digitization. → **F**

Digitization can help increase the revenue streams, either via market share gains vs. (generic) competition or via pricing and reimbursement agreements for digital services. The latter are already being employed in healthcare systems such as those in the UK and Germany and are helping stabilize the top line. Digital solutions for disease management have a supportive impact on the core business, especially in areas of low to medium differentiation such as generics, biosimilars and patented drugs in competitive market segments, e.g. some cardiovascular diseases.

While apps supporting compliance/adherence of drugs, such as the Merck Group's Rebif Smart inhaler, or various chip-in-a-pill solutions in the UK have the power to increase sales short term by magnitudes of 5-10%, companies are increasingly looking for breakthrough solutions that give them moonshots rather than incremental growth.

One such company pushing the boundaries of innovation in personal medicine is Roche. With the purchase of Foundation Medicine, a US based company

focusing on analyzing large amounts of genomic data, they intend to strengthen their leadership in personalized medicine. The CEO of Swiss rival Novartis, Joseph Jimenez, is said to have invested USD 2-5 bn in bolt-on acquisitions including for companies within the two main segments of innovation he sees in pharmaceuticals, regenerative medicine and digital health. According to his estimations, 25% of healthcare investment today is wasted – this is clearly an opportunity for new technologies. For pharma and medtech corporations, digitization may also be used to reduce costs significantly either in R&D, where innovative pharmaceutical companies invest 15-20% of their sales, or in General and Administration cost positions. In clinical development where R&D spending is highest, Amazon data services have shown cases in which they have been able to reduce clinical trial costs by USD 450k, and reduce patient numbers as well as the costly time period of trials by 30%.

ENTRY OF NEW PLAYERS IS PERHAPS THE BIGGEST CHALLENGE TO TRADITIONAL BUSINESS MODELS

Supported by new technologies providing much greater insight into a patient's medical condition, clinical knowledge and expertise are no longer the preserve of traditional healthcare players. Electronic health records and metabolite profiling open up data for new and non-healthcare players, too. The healthcare start-up environment is currently experiencing a major boom with highly innovative business models and ideas challenging more traditional approaches and further driving the transformation of this industry.

In the US alone, the digital health start-up environment raised USD 4.5 bn in funding in 2015, surpassing medical devices and closing the gap to biotechnology. Most of the funding was raised for consumer engagement solutions and personal health tools, areas that traditional pharmaceutical players have thus far neglected. Similar to other industries, such as consumer retail or automotive manufacturing, technology giants like Amazon and Google have already targeted healthcare as a key future investment area and will come up with more high-impact innovations, such as Google contact lenses for measuring diabetes and data analytics services provided by Amazon and Google to create and leverage critical new data insights for pharma and healthcare.

The essence of digital transformation: Understand your digital objectives and identify the means to achieve them.

Many players are already starting to prepare for change. They have decided how they want to move forward, choosing to minimize the risk of failure, while at the same time exploring new options such as establishing a venture capital approach to digital health start-ups or building partnerships. However, the future of healthcare and the process of transformation remain unclear. Opening up closed organizations for innovation from a cultural, process and structural point of view continues to be a major challenge. Companies will have to choose the right operating model to take their place in the digital health environment of the future. In order to best support pharmaceutical companies on their journey toward a digital future, Roland Berger has identified two very different approaches.

From our experience, digital strategies in the pharmaceutical industry typically suffer from two major shortcomings: the first is a lack of understanding of the company's digital objectives and the second is a failure to identify and quantify the value of specific actions. Roland Berger's approach toward digital transformation thus helps our clients define their digital objectives more clearly and draw a clear picture for all embedded organizational stakeholders.

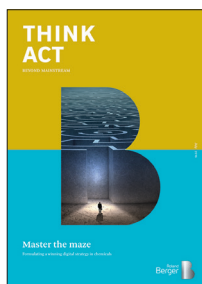
In a three-stage approach, Roland Berger first mirrors the digital objectives of the future against the core competencies of the organization to identify potential gaps and close them. Then digital initiatives are identified and their economic value for the company assessed. A final phase sees execution and implementation by leveraging Roland Berger's Berlin-based digital hub SPIELFELD, incorporating innovative approaches such as rapid prototyping and design thinking workshops.

Three steps to heaven is not quite what the pharmaceutical industry wants to achieve for the healthcare environment of the future. Three steps to better healthcare provision thanks to the careful and comprehensive implementation of powerful digital technology, however, sounds like just what the doctor ordered. ♦

ABOUT US

Roland Berger, founded in 1967, is the only leading global consultancy of German heritage and European origin. With 2,400 employees working from 34 countries, we have successful operations in all major international markets. Our 50 offices are located in the key global business hubs. The consultancy is an independent partnership owned exclusively by 220 Partners.

FURTHER READING



MASTER THE MAZE Formulating a winning digital strategy in chemicals

Digitization is disrupting the value chain. Chemical companies often don't get digital. What are the strategic options? Most players think bilaterally: evolution vs. revolution. In other words, adopting proven technologies within industry norms (an evolutionary approach) versus disrupting the conventional industry structure with breakthrough innovations or procedures (a revolutionary approach). Evolutionary is the more obvious strategy in chemicals. It allows you to identify value pockets and find a path through the digital maze.



RADICALLY DIGITAL Shaping the digital transformation Questions top managers should be asking today

The future is not what it used to be. Digitization is here to stay and has changed everything. It is not as if digitization just arrived out of the blue. Boardrooms everywhere have been making their plans for some time. Executives have been tasked with bringing their firms into the digital era. The problem is simple: They set their sights too low. Welcome to Terra Numerata. Be radically digital. Forget your competitors. Focus on your customers. Conquer the mountain.

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