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Preparing for the data-driven future of pharma

Ways for companies to unleash the power of precision medicine

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EXECUTIVE SUMMARY

When it comes to advancing technological innovation in healthcare, the tools are here. In fact, most pharmaceutical companies are already using them in some way—whether they're applying artificial intelligence (AI), machine learning (ML), big data processing, and cognitive computing to make advances in the research and development of drugs,[1] or to automate operational processes and workforces.

But there's a problem: The broader adoption of AI in Health is still very low.[2] Reason for this is: Many business leaders aren't sure they're doing any of it right. According to our recent study on the future of health,[3] the majority of pharma executives reported gaps in their own data analytics capabilities and said that they feel constrained by a lack of access to other data, which they believe is valuable for analyzing business opportunities and threats. They want to use AI and ML to harness the power of data more efficiently and effectively, but they are not sure how.

In this report, we will explore the current levels of data and AI maturity in pharma, our expectations for what comes next, and some recommendations for creating long-term value. Our focus is specifically on the expected value from personalized precision medicine and how data and AI can enable scaled value. Now is a critical time for pharma companies to use AI, but first they must reimagine the potential of data — removing it from historical silos, using it instead to connect the dots, and participating in a collaborative ecosystem. We believe that the leaders of data-driven transformation in pharma will be those that build critical capabilities in two areas: namely, (1) cleaning up their own enterprise data to form a company-wide data value chain, and (2) establishing strong partnerships in both the public and private sectors, specifically with a focus on collaborations among healthcare providers and tech companies.

SECTION 1

Where we are now: Understanding the current landscape in pharma

Although it's becoming outdated, many global pharmaceutical companies today still operate their business according to the so-called blockbuster model. They work to develop mass-produced, mostly chemically developed, drugs for widespread health problems, which can then be prescribed to a huge patient population. But this model is expected to change soon, for two main reasons.

Rising costs and changing customer preferences are affecting the industry

First, the industry is facing rising costs — across the value chain, from R&D to manufacturing to marketing. Developing new products has always been expensive, but it has become increasingly so over the past two decades. At the same time, the number of products protected by patents has decreased, leading to an increase in imitation products by generic manufacturers. That reality combined with the growing importance of biosimilars, and re-imports has led to more price pressure in the pharmaceutical market.

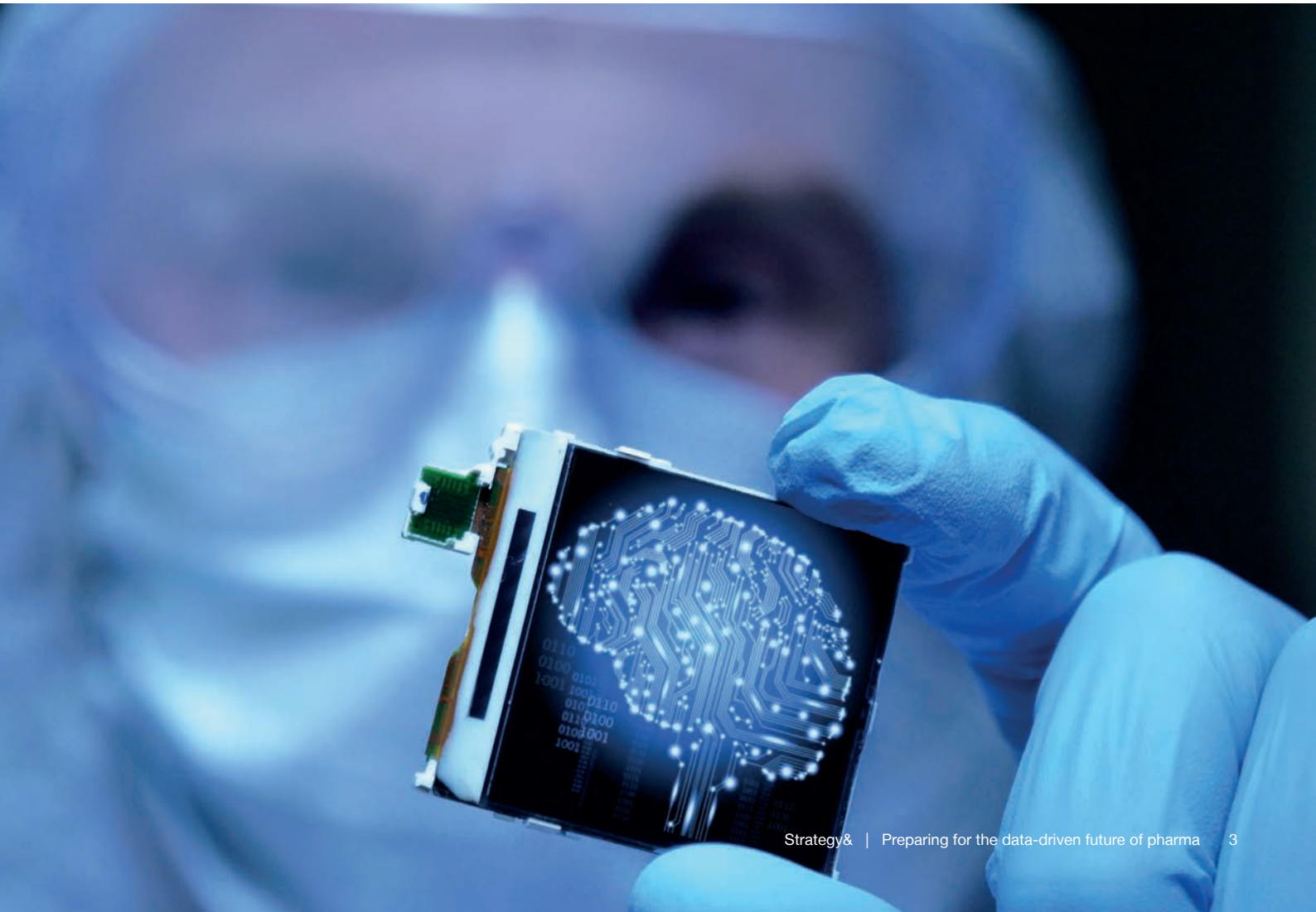
Second, the demand for personalized products rises. One reason for this is that the aging population[4] continues to grow, but also because people of all ages are increasingly aware of their health and wellness. They're looking for advances in medical, chemical, biological, and biotechnological research, as well as for more pharmacological information technology and bioinformatics. Another reason is that the pharma industry is rapidly running out of viable new drug targets[5] that can be intercepted by small molecules or large proteins – and therefore needs to develop completely new modalities. So clearly, data, AI, and ML will play a critical role in this area of innovation. As of 2019, more than 12,000 research studies[6] were published on the potential applications of AI and ML in life sciences. And already, the FDA has approved 64 AI/ML-based medical devices and algorithms.[7] And AI is already being used in combination with modern biotechnologies to develop precision drugs, such as with Tecentriq (by Roche) and Nivolumab (by BMS) for cancer immunotherapy, as well as with Yeskarta (by Kite / Gilead) and Kymriah (by Novartis), which is based on adaptive CAR-T cell therapy. Other possible use cases for computational intelligence include AI-supported diagnosis of disease symptoms (e.g. Arterys[8] and Babylon[9]), determination of the causes of a disease (e.g. Altoida[10] and Freenome[11]), prioritization of new active ingredients (e.g. atomwise[12]), implementation of digital experiments (e.g. twoXAR[13]), and even the selection of study locations and participants (e.g. Phesi[14] and Cliniops[15]) in the development process.

With all the technology available today, pharmaceutical companies face a choice. Either they can become cost leaders or differentiators.

Personalized precision medicine will soon be the "new normal" for pharma and healthcare
Cost leaders strive for the greatest possible market share with a cost-effective product portfolio, mostly based on biosimilars and genetics. Only very few of the large research-based pharmaceutical companies are following this path, while most big pharma companies have sold their generics businesses over the last years (e.g., Merck, Bayer, and Roche).

Meanwhile, differentiators are focusing on new, precision-based medicines that may apply to smaller niches of the population and to rare diseases. Personalized therapies may be created based on genetic and biological characteristics of an individual patient, and they may even include social and environmental factors. For instance, the approval of gene-based precision drugs for diabetes and high blood pressure is expected soon. Precision drugs for many other common diseases are also in development. By 2030, the genes that control the aging process are expected to be found, and by 2040, personalized precision medicine is expected to be the norm that detects a disease before symptoms appear.

Of course, differentiators don't need to make an entire exit or abrupt departure from the classic blockbuster business. In fact, the sales of blockbusters with annual sales of more than $1 billion have increased since 2017,[16] while precision drugs are currently still heavily focused on so-called "rare diseases." But we believe the proportion of personalized precision drugs will increase[17] significantly in the next few years.



SECTION 2

What comes next: Emerging opportunities for the pharma sector

This is just at the beginning of the age of personalized precision medicine, and already differentiation seems to be the strategy of choice for most big pharmaceutical companies. It's a promising one — if not necessarily easy.

Success in personalized precision medicine will require a range of new capabilities, including individual diagnosis of the patient; digital sequencing and analysis of the individual biological characteristics of the patient; mass-customized production (and personalized delivery) of the active ingredient; and the individual follow-up control of efficacy and contraindications. Today, most pharmaceutical companies are not yet set up for offering such an individual end-to-end care service from diagnosis to control, but they can be if they start focusing on building their enterprise-wide AI and data analytics capabilities.

AI and data-driven transformation will play a bigger role in business innovation

We already know that the future of health depends on advancing technological capabilities at an enterprise level, and not just for personalized medicine. Most recently, for instance, we saw the world's fastest vaccine development during the Covid-19 pandemic, taking months rather than the usual years to deliver. And that was largely because of technology advances led by innovative biotech companies, Moderna[18] and BioNTech.[19] The fact is that those two small biotech companies did much of the pioneering work to develop, test and produce a complex, RNA-derived vaccine at unprecedented speed — and they were ready to do it also because of their ongoing work in computational intelligence.

So far, BioNTech's work, in collaboration with Pfizer, has only resulted in a single vaccine against COVID. But what if different vaccines could be made that would be more effective for certain subgroups or for people with certain pre-existing conditions? AI-based methodologies are expected to help make better use of data, by combining and analyzing multiple research studies. And drug target identification and prioritization is an AI-model that can be used for researching and developing new drugs. It analyzes data to see if, for example, certain subgroups respond better to a slightly different mix of treatments or different doses than the average. It is precisely this type of use of AI that will be the future of pharmaceutical research and development.

For example, bioinformatic algorithms can now create correlations between the molecular structure and the chemical function of an active ingredient or a protein, etc. In addition, genomic-transcriptomic algorithms can identify abnormalities and mutations in heterogeneous diseases such as cancer, and integrative algorithms can combine genomic, biological, and clinical information.

The BLAST[20] search engine could find sequence similarities without AI, but complex chemical, biological, and medical problems — such as predicting the three-dimensional folding of proteins — have only become solvable through machine learning. In 2020, for example, the AlphaFold system from DeepMind,[21] a subsidiary of Google, correctly predicted the three-dimensional structure of a virus for the first time. This artificial, neural network shows

the potential for continuing advancements in AI-driven innovation. In this respect, the further development of AI in bioinformatics is equally important for the realization of precision drugs as are the advances in biotechnology, such as the discovery of the CRISPR/Cas system[22] for cutting DNA. And more recently, Google announced the launch of a new company in the U.K. called Isomorphic Labs, which will use AI software to create new drugs and medicines.

But effectively bringing new drugs and medicines to market requires a mix of capabilities — both human-centric and technological. First, there needs to be the clear identification, understanding, and segmentation of target groups, as well as access to and processing of individual data from affected patients. Then, AI tools are often required to solve the complex algorithms necessary for the development of personalized precision drugs.

AI and data-driven transformation will reconfigure the pharma value chain

The most successful modern biotech companies have two things in common. First, AI and data are at the core of their value proposition. Second, they use scalable digital platforms. For example, after sequencing the Covid-19 virus genome, the development of Moderna's vaccine took only a few days thanks to the company's "operating system"[23] based on Amazon Web Services.

All pharma companies have a unique wealth of data and knowledge, as well as the experience to successfully market and sell pharmaceutical products. But to create value over the long term, it will be increasingly important to build a platform business model, which will offer pharmaceutical companies the potential to scale their existing competencies even further and at the same time focus on the differentiating company core.

The future of pharma will necessitate an evolution toward platform ecosystems

For most pharmaceutical companies, the question of the relevance of technology platforms no longer arises, but only the question of the best partner: Merck and Novartis work with Palantir. Moderna, as well as Bayer and Boehringer, use AWS. GMS, Sanofi, and Pfizer partner with Google. Novartis works with Microsoft. Currently, these collaborations are primarily focused on technological issues, but in the medium term they harbor the potential for a "commodification" of parts of the pharmaceutical value chain through standardized platform services.

Looking ahead, large technology platform providers like Google, Amazon, Microsoft, and Apple will have the increasing potential (and the ambition) to deliver not only the digital infrastructure, but also parts of the traditional pharmaceutical value chain through integrated, digital platform services. For instance, here are a few examples of how these big tech players are already working in the pharma space:

- Google has a number of subsidiaries including DeepMind[24] (explained above), Verily[25] (genome analysis), Calico[26] (longevity), Google Fit[27] (tracking of health data), and Cloud Lifescience[28] (healthcare application and infrastructure platform). In addition to collaborating with biotechnology and pharmaceutical companies, Google is also a leader in investing in digital health startups.

- Through AWS, Amazon currently operates the world's leading cloud platform. AWS also offers a dedicated industrial solution for all segments of the pharmaceutical and healthcare sectors called "AWS Biopharma."[29] In addition, after the acquisition of PillPack[30], Amazon also offers a platform for the direct sale of drugs.

- Microsoft is now also moving on a multi-track basis, with Microsoft Genomics,[31] Health NExt[32] (AI solutions), and a dedicated industry solution[33] for the health sector. Microsoft is particularly important for the telemedicine (teams) area.

- Apple laid the foundation of its health offerings with the acquisition of Gliimpse (a personal data platform) in 2016. And now Apple has significantly expanded this cornerstone — with Apple Health,[34] the Apple Watch, and various healthcare and research platforms including HealthKit,[35] ResearchKit,[36] and CareKit.[37]

Today, many large companies in the pharmaceutical industry are still predominantly structured as they were in the 1950s — fully integrated across all phases of value creation from development to marketing in one company. But as companies move toward greater differentiation through personalized precision medicine, the platform ecosystem business model will become increasingly valuable.

> "BigTech companies have both the potential and the ambition to provide the digital infrastructure as well as parts of the traditional pharma value chain through integrated digital platform services. For most pharma companies, there is no more question about the relevance of digital platforms, but only the question of the best partner."

SECTION 3

Two key recommendations for creating long-term value in the pharma sector

Pharma companies clearly have the tools they need to collect and analyze data, but many are still struggling to do it effectively and efficiently. Here are two possible ways that leaders in the pharma sector can start to create more value through AI and data-driven transformation.

1. Clean up your own mess

You probably already have access to a lot of data — for example, from your drug research and clinical studies, as well as from your production, supply chain, marketing, and sales functions. The good news is that this kind of historical company data can be excellent for training algorithms to forecast the effects of complex market changes and simulate scenarios. Ideally, however, the data needs to be available in a unique and unambiguous form, as a "single point of truth." And most pharma companies do not currently have their data organized in this way.

Nowadays, the data of a pharmaceutical company is "locked" in a multitude of functional and technological silos. These silos are usually incompatible with one another, when both the technologies used and the underlying data models are concerned. The increasing digitization of the pharmaceutical company is exacerbating this problem, as it does not reduce data silos, but mostly creates new data silos. To scale the value of data and make AI more effective, these silos must be broken down and the data must be brought together into a common ecosystem. Here's how to do that:

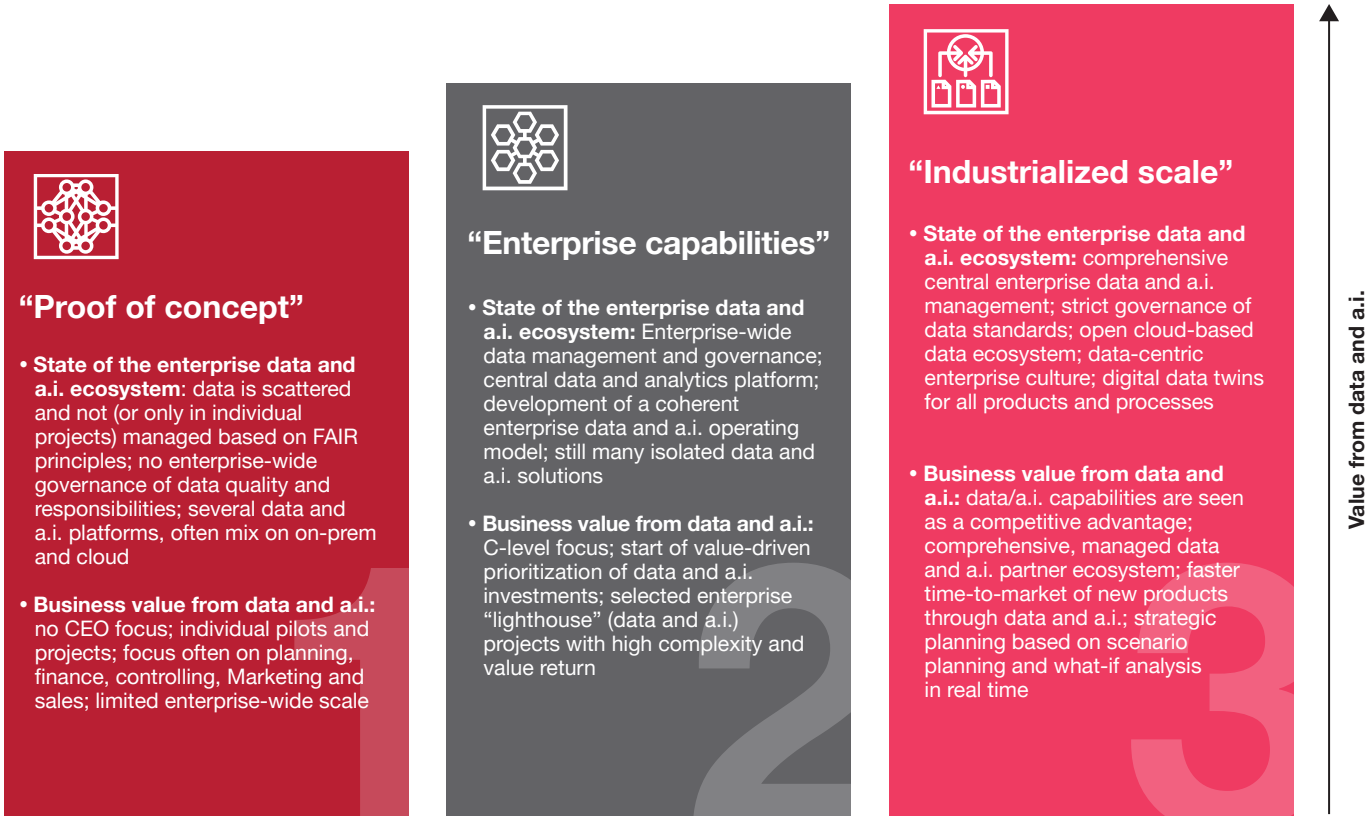
- **Free the data:** The idea of bringing together data from technical silos isn't new. But today, breaking up data silos is more important than ever, and more advanced cloud technology now enables new possibilities related to this objective. The cloud not only allows for the outsourcing of data center services; it also offers a new paradigm for enterprise data and technologies because applications and data from different sources can be combined in one ecosystem. The cloud enables comprehensive calculations and algorithms to be carried out with almost unlimited performance and speed.

- **Bring in tech experts to manage complexity:** For data to be processed by AI algorithms in a cloud-based data ecosystem, it must be FAIR[38] data. In other words, it must be findable, accessible, interoperable, and reusable. These principles not only require the technical integration of the data sources, but also the creation of a company-wide data register or catalog. This can, of course, be challenging. Fortunately, however, as seen with electronic health records,[39] using the cloud and AI can help: Learning algorithms can be trained to recognize similarities in the data and to determine structures in the heterogeneous data. Technology companies and biotech startups are the pioneers in AI. To gain access to this knowledge, it makes sense for legacy pharma companies to form strategic partnerships with these emerging leaders.

- **Scale value from data and AI:** To achieve significant value from data and AI, tools, algorithms, and analyses are not just developed for one-off needs; they are made available across the company. One way to do this is to start with a three-part process, as illustrated below (*see Exhibit 1*).

  Moreover, with time, even greater reach and scale will come from expanding access to patient and health data, which requires openness to greater collaboration with other health and tech companies. *Exhibit 2, next page* gives a partial overview of the diverse landscape of AI providers within the convergent value creation system.

EXHIBIT 1
Typical patterns for data and AI value at pharma companies



Typical use cases at this stage:
Marketing and sales (e.g., "next-best action", Marketing mix optimization), supply chain (e.g., predictive maintenance, planning), manufacturing (e.g., utilization and yield Improvement)

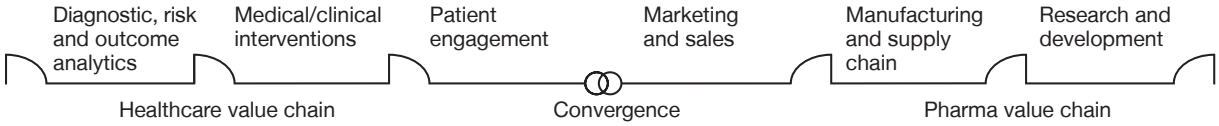
Typical use cases at this stage:
Research (identification of new biomarkers or active ingredients), development (intelligent trial design, trial location optimization), sales (launch optimization); finance (revenue forecasting, cost optimization)

Typical use cases at this stage:
All business functions and divisions; value driven use case funnel, typically based on rolling planning and prioritization

Source: Strategy& analysis

EXHIBIT 2

Examples for AI in converging healthcare and pharma markets



Digitization of healthcare stakeholder interaction

Digital-to-Patient

Do-it-yourself healthcare		Patient services beyond-the-pill		Outcome-oriented care	
Digital healthcare information	WebMD, MedialNewsToday, Healthline, Harvard Health Publishing	Personal coach	mySugr, Ginger, Happify, Pathmate, Kaia Health, Lyra Health, 2Morrow	Lifestyle programs	Healthy Choice, dacadoo, Nandoo, Discovery Vitality, yodorun
Digital Diagnostics	Babylonhealth, HealthTap, K Health, Healthily, Buoy Health	Digital therapy	Akili, RESET, Voluntis, Propeller Health, Proteus Digital Health	Pay-for-performance	NICE, Omada Health, Spark Therapeutics
Patient-to-patient exchange	MedHelp, HealthUnlocked, PatientLikeMe, BrainTalk Communities	Ailment management and adherence support	Kaiku Health, Carevive, GetWellNetwork, Px HealthCare, Cureety		
Self-Metering and DIY tests	AliveCor, Quantified Self, Color, Helix, Freenome, Healthy.io, OnlineDoctor, Viome				

Digital-to-HCP

Connect to a doctor		Augmented healthcare data		Digital drug development	
Find a doctor	Haodf.com, Practo, Docplanner	Electronic health record	DoctorBox, Vivy, ImpfPassDE, TK-Safe	Digitized development	Atomwise, Genesis Therapeutics, Aria Pharmaceuticals, Navartis
Online consultation	Doctor on Demand, Sogou, Inc., Kry, Teladoc Health, Push Doctor, MDLive	Medical data integration and treatment pathway	Practice Fusion, Health Gorilla, REDOX, PatientPoint, Philips AI-enabled solutions, CrelioHealth, Cambridge Cancer Genomics	Digital drug design and trial planning	CliniOps, Phesi, Science 37, Antidote
Doctor support	Wanlicloud, Enlitic, Medscape, Arterys, RADLogics, Aidoc	Digital biomakers	Altoida AG, Floodlight Open, Freenome, Syntropy	Precision medicine	XALKRI, MYLOTARC, Rituxan, Glivec, Glybera, Luxturna, Kymriah, Yescarta
One-stop-shops	Ottonova, Ping An Good Doctor, Oscar Health, Inc.	Health data management and new digital insights	Google Genomics, Verily, IBM Watson Health, Flatiron, Explorys, AWS Genomics, iPhone Health App	*AI-based personalized health startups*	Health Nucleus, Ardigen, BERG,

Digitization of information and communication | **Digitally enhanced therapies and data management** | **Digitally enabled new therapies**

Digitization of healthcare interventions and therapies

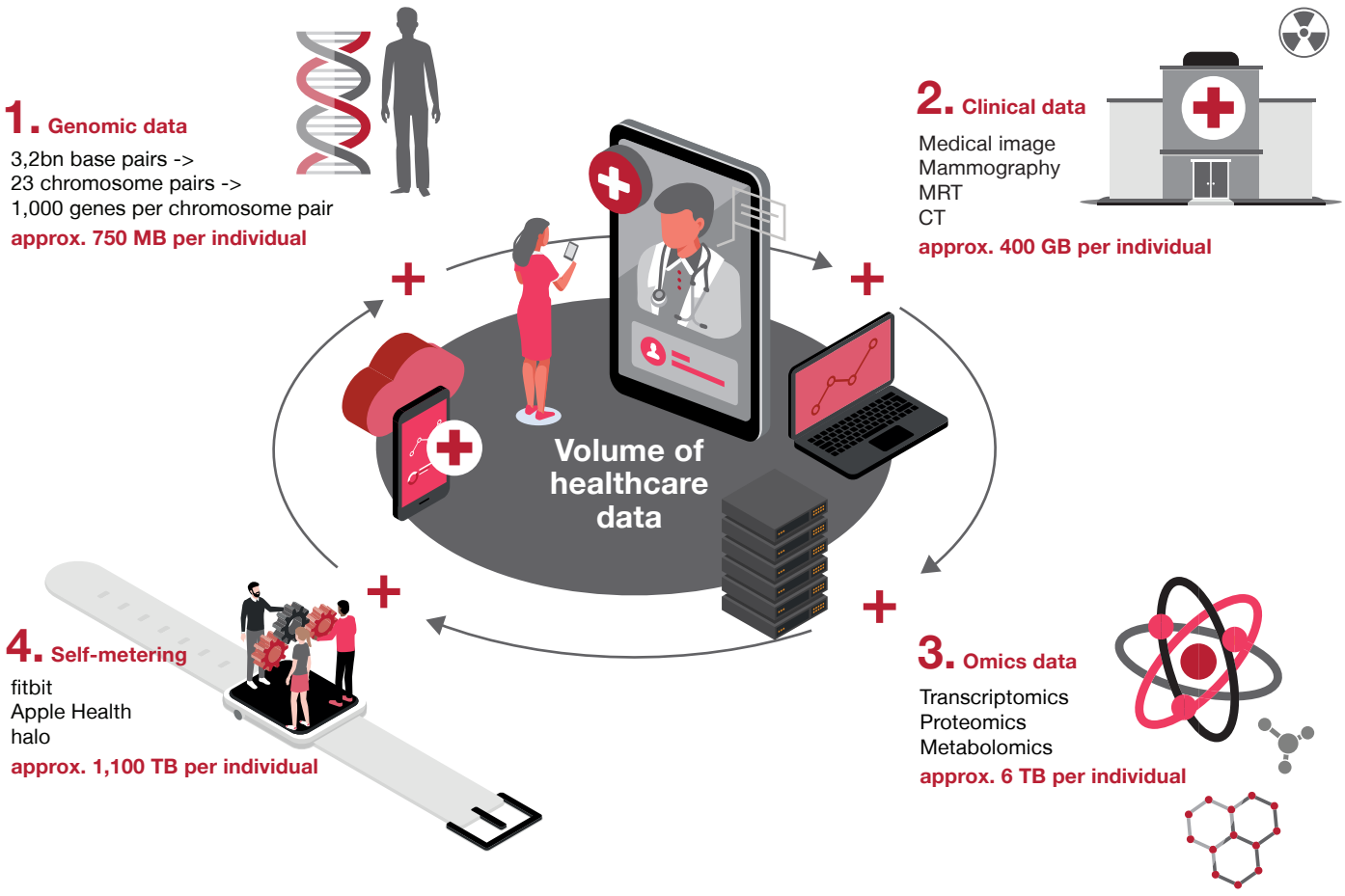
Source: Strategy& analysis

2. Collaborate with other healthcare providers, tech companies, and the public sector

Simply said, it's virtually impossible to succeed in AI and data-driven transformation without collaboration. Take, for example, personalized precision medicine: A healthy person has her genome and other biological features such as proteome and metabolome digitally sequenced and stored. Her doctor then accesses this data as part of preventive care or disease diagnostics. If a risk factor is determined, an active ingredient is tailormade for this person. But the crucial question is, then: How does the producer of the active ingredient, the pharmaceutical company, get access to individual characteristics and risk factors to develop new active ingredients?

Central recording and storage of these characteristics within a comprehensive "health avatar"[40] seems to make sense, as it would simplify many of the processes described above. There are, however, several challenges, including privacy concerns. Individual medical data is an asset that is highly worthy of protection. Other obstacles include extremely high volumes and costs of data storage (*see Exhibit 3*):

EXHIBIT 3
Illustrative volume of all healthcare data



Source: Strategy& analysis

For instance, 750 MB may be sufficient to store the individual genome but storing X-Omics data from an individual person already takes up terabytes. If you add the storage of real-world data, we are in the range of petabytes, and calculated on the world population in the exabyte range. Such data storage is therefore associated with immense effort and expense. In addition, pharmaceutical companies are now sometimes in competition with the large technology companies that are building their own partnerships with hospitals and health organizations.

However, despite these significant challenges, the need for a systematic collection and analysis of individual medical data for the development of new active substances and treatment methods is undisputed. Companies can take the first step by opening and sharing some of their own data. They can also work with data aggregators and service providers; partner with hospitals through studies and also through joint research centers; cooperate with diagnostics companies; and work with technology companies that collect health and patient data themselves. In addition, cross-company alliances for the exchange of health data are being created. Data from sequencing of molecules are provided by commercial non-commercial tools.

In addition, of course, the necessary legal and policy frameworks must be done at the national level and through the creation of transnational standards and rules. Some countries, including Germany, are currently laying the foundations for the digitization of the healthcare system by setting up appropriate legal rules, technical infrastructures, and, for example, the statutory introduction of digital patient files. These investments represent an important step for the digitization of the healthcare system.

> “Our two key recommendations for creating long-term value through data and AI in pharma: Clean up your data mess, and start collaborating on data with other healthcare providers, tech companies, and the public sector.”

CONCLUSION

The future will require different players to work as a community of solvers

Clearly, pharma companies must prioritize building their own data and AI capabilities, but if they want to be successful, they can't do it alone — or in silos. As explained in the previous section, we expect to see continuous innovation in the converging areas of health, pharma, and tech over the next 20 years. Already now, the potential of AI and data-driven transformation is tangible, and it's only beginning. This viewpoint has focused on the AI potential in research and development, but there are many more implementable opportunities for AI e.g., in operations, marketing, and sales, which shall be discussed in upcoming Strategy& publications. The conclusion that can be drawn already now is: This is an optimal time for pharma companies to organize their own data, build new capabilities, and form strategic partnerships.

Despite the vast potential from data and AI in pharma — in particular, related to making progress in personalized precision medicine — building basic data and AI capabilities alone is not a "golden ticket" into new health benefits and pharma revenues. In fact, there are many hurdles[41] that still must be overcome:

- First, there is a trade-off between traditional, evidence-based medicine on the one side, and new precision health on the other side. For example, one open question is how tolerability of a drug that is personalized for an individual patient can be proven without evidence from clinical trials in a larger patient population. But considering the way Moderna has built its business on top of a digital "operating model," the answer to this question may be found in developing digital precision health platforms and operating models, instead of just individual products.

- Second, applying AI to larger datasets (both those related to healthcare and to other real-world factors such as social determinants) may help researchers identify disease predispositions and causes, but it may also be a double-edged sword. Current methodologies such as gene-wide association studies often fail to identify sharp causalities[42] between diseases and the underlying data. There are several reasons for this, including, for example, that a large data pool such as the human genome can also generate a number of statistically significant associations — even when there are no medical or biological causes. So, simply combining health data with the latest AI tools will not lead to a "general problem solver"[43] for pharma and healthcare. Instead, there are still human interventions needed to formulate hypotheses for causalities, and to pivot efforts of proofing trials.

- Finally, we must acknowledge that analyzing real-world data as well as formulating and proofing medical causalities in detected patterns is a "Herculean task." The effort of executing this task (and also accepting the risk of failure that comes with it) should not be on the shoulders of a single pharma or healthcare company. Instead, it will require intentional cooperation and consortia. Of course, creating joint value is likely to require new data tools to bridge data syntax and semantic boundaries across organizations. And while there are already early initiatives in this direction such as ICD,[44] SNOMED CT,[45] and the Pistoia Alliance,[46] a unified oncology-driven data integration framework still needs to be developed.

When pharma companies start collaborating to solve these hurdles, it will lead to a new breed of business models[47] in the digital healthcare ecosystem. Likely new roles in the data-driven healthcare ecosystem will include (1) solution providers, which can offer personalized solutions for specific diseases and wellness needs; (2) orchestrators, which can leverage data analytics to match ideal solutions to an individual customer's needs; and (3) platform providers, which can maintain the physical and technology platforms for orchestrators and solution providers to develop and deliver their offerings. In the end, each pharma company needs to make a deliberate decision about how they will benefit from data and AI-driven innovations. Will you wait for the changes to happen and then collaborate with the new players in the ecosystem? If the development of the consumer electronics sector – particularly smart-phones – is any guide though, the intersection between pharma and data / AI will become the most profitable part of the value chain. Pharma companies that are not active in this segment therefore risk turning into a mere "contract manufacturer" – with diminished profitability and long-term growth prospects – for the new players who seized the new data- and AI-powered businesses.

The alternative is that you start using data and AI now to re-invent your business into a solution provider, orchestrator, or platform provider model (or a combination from these models), to participate in the change and seize the opportunities. The choice is yours.

> "The potential of AI and data-driven transformation is tangible, and it's only the beginning. Pharma companies should start using data and AI to re-invent their business models into solution providers, orchestrators and platform providers."

ENDNOTES

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