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Capitalizing on precision medicine

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How pharmaceutical firms can shape the future of healthcare

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About the authors

Stephan Danner is a partner and managing director with PwC Strategy& Germany, based in Berlin. He works with global pharmaceutical and medtech clients to design and implement corporate strategies, effective operating models, and performance improvement programs along the entire value chain. Marketing and sales, organizational development and restructuring, post-merger integration, and innovation management are among his areas of expertise. He works with clients to design and implement operating models to develop capabilities for precision medicine. He is the author of several publications and studies.

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Executive summary

Precision medicine holds tremendous potential to remake the healthcare industry. By applying a deeper understanding of diseases with richer patient data and advanced analytics, precision medicine can help physicians tailor medicines to the needs of individual patients, rather than by broader populations, leading to better outcomes at potentially lower costs.

Our survey of global leaders in the pharmaceuticals industry shows that companies are aware of the promise: 92 percent have identified precision medicine as an opportunity, and 84 percent have it on their corporate agenda. Most point to clear advantages in drug development, such as reducing time-to-market and making R&D processes more efficient. Even a conservative estimate puts the cost savings in drug development at 17 percent, leading to a potential annual savings of US$26 billion for the industry worldwide.

Despite this bottom-line impact, however, most companies have yet to harness the full potential of precision medicine. External barriers include insufficient access to high-quality data, an unclear regulatory framework, a lack of standards, and data privacy issues. Internally, many companies lack the capabilities — particularly regarding the generation, integration, and analysis of non-trial-related patient data — that precision medicine requires.

These are not easy issues, yet pharmaceutical companies must begin to address them today. Rather than waiting for regulations and data standards to emerge, companies should actively work with regulators and policymakers to jointly develop standards. Internally, most companies will need to partner with existing players and new market entrants that specialize in data, or possibly hire external experts. Either approach will require a new operating model and organizational culture — one that is more agile and responsive to changes.

Precision medicine will transform the entire pharmaceutical value chain, from early development to companies' go-to-market models, and the next five years will be a crucial window for pharmaceutical companies to capitalize on this promise. Companies simply cannot sit on the sidelines during this period. Instead, they need to take risks and more actively engage with stakeholders throughout the healthcare ecosystem.

The future of medicine

Imagine a discussion among physicians in the near future. Dr. Mike Wang, a U.S.-based oncologist with more than 30 years of experience, chairs a tumor board session with colleagues around the globe, including leading oncologists, pathologists, molecular biologists, and geneticists. During the meeting, these experts discuss the case of a 38-year-old British woman with advanced lung cancer. Using virtual reality technology, they are able to simultaneously review the patient's entire disease profile, including her medical history, lifestyle, molecular genotype and phenotype data, and high-resolution pathology images, among other data.

By comparing the woman's profile with that of similar patients, the experts reach the unanimous decision that the best treatment is a combination of three targeted medications — a combination that is not yet authorized. Using comprehensive predictive analytics, they judge that she has strong chances and additionally enroll her in an artificial intelligence–enabled, real-time disease surveillance program.

This may sound like science fiction but it is not wishful thinking. Precision medicine — which combines a profound understanding of diseases with the generation of far more detailed personal data in huge data sets, and the ability to run and correctly interpret sophisticated data analyses — is coming, leading to more focused treatments for patients suffering from a variety of diseases, and more individually tailored therapies.

Not only can precision medicine improve the way physicians detect, diagnose, and treat diseases, but it can also lead to more preventive healthcare. Using analytics to identify patient risks before they manifest themselves can result in considerably better outcomes, at potentially lower costs for healthcare systems. In this way, precision medicine has the potential to disrupt the entire healthcare industry, including the way pharmaceutical companies develop, manufacture, and market drugs.

Few companies have been able to start capitalizing on the promise of precision medicine. Doing so requires a dramatically new set of capabilities, along with the ability to operate in an environment with regulatory uncertainty and new market entrants — particularly startup companies that are able to collect and integrate patient data in new ways. The challenge is great, but the rewards are commensurate. It is up to pharmaceutical companies to act now.

On the corporate agenda

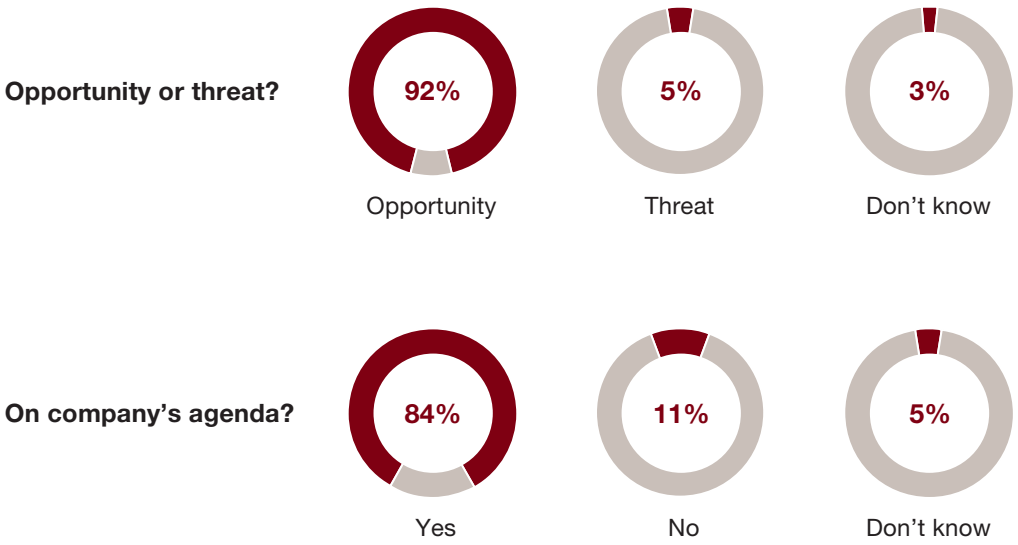
We recently surveyed more than 100 leaders in the pharmaceuticals industry across a range of functions, therapeutic areas, and geographic markets worldwide to gauge the industry's response to precision medicine thus far. (Respondents included leaders at 15 of the top 20 pharmaceutical companies, reflecting 81 percent of the revenue from the top 20, and 52 percent of total pharmaceutical prescription market revenue.) The results clearly show that executives are wrestling with the topic. Among respondents, 92 percent said they regard precision medicine as an opportunity, and 84 percent have it on their corporate agenda (*see Exhibit 1, next page*). As one respondent put it, precision medicine "can only be viewed as an opportunity. Regardless of what the industry wants, technology will continue to be developed, and those willing will make the opportunity."

Regarding specific therapeutic areas where precision medicine will likely be viable over the next five years, the top two responses were oncology, cited by 91 percent of respondents, and orphan diseases, cited by 53 percent. Among geographic regions, the more mature markets are key: 92 percent of respondents cited North America and Europe as the most relevant for precision medicine.

There are valid reasons for the industry's interest: Precision medicine holds the potential to change the way medicine is practiced. Over the past several decades, advances in medicine have increased the life expectancy in most markets, yet patients typically don't receive care until they fall ill, at which point the healthcare system focuses on treating the disease, not the patient. Precision medicine upends this one-size-fits-all approach in favor of in-depth patient profiling and individual treatments based on both personal data and a statistical analysis and comparison of larger cohorts. Exhibit 2, page 10, shows the most relevant types of data for precision medicine, according to survey respondents. Notably, respondents cited traditional data types as the most impactful, including data from clinical trials and electronic health records. By comparison, newer and more innovative types of data such as proteomics and microbiomics were found to be less relevant.

Exhibit 1

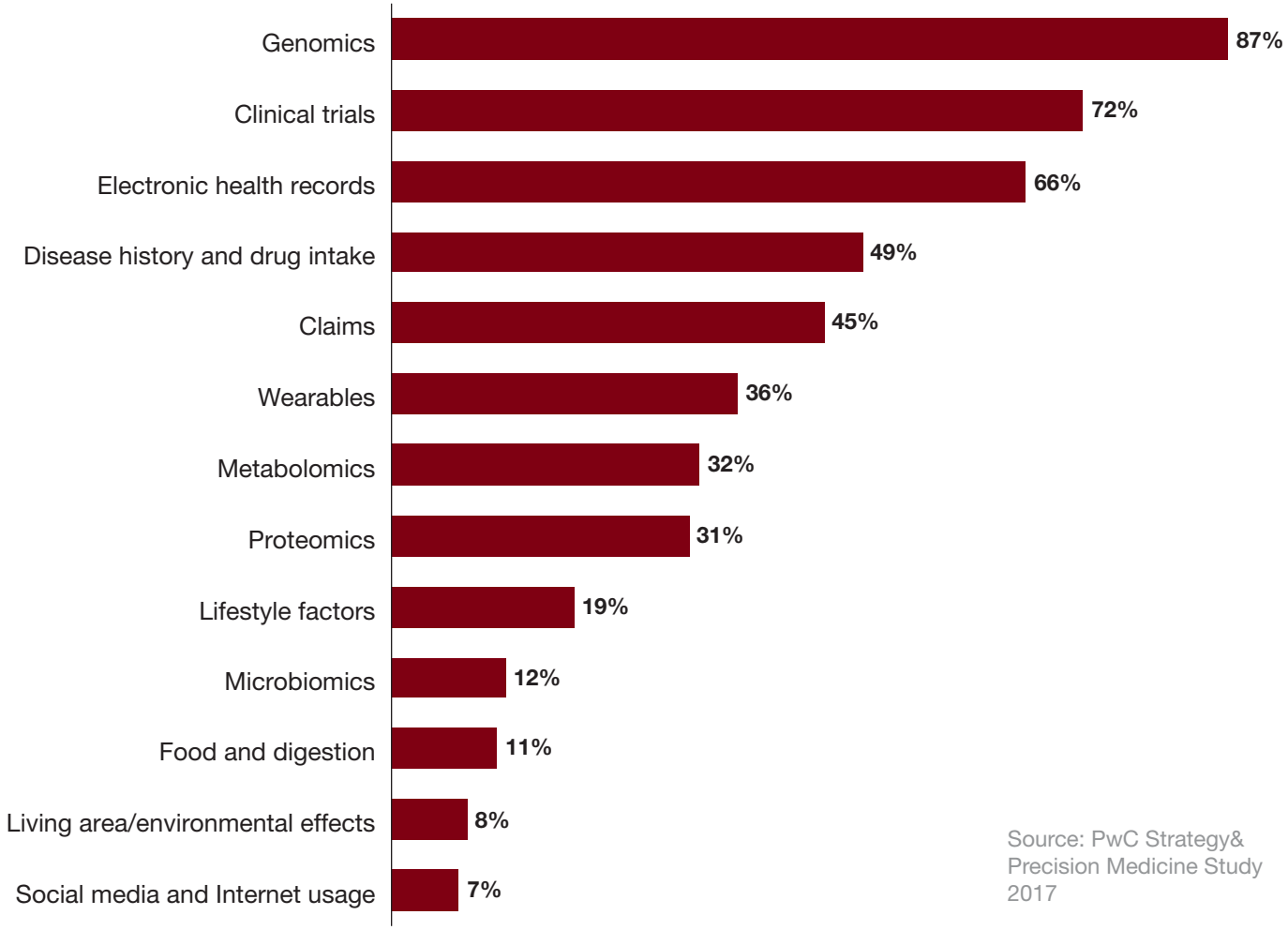
Overall perception and importance of precision medicine for pharma companies



Source: PwC Strategy& Precision Medicine Study 2017

Exhibit 2

Most relevant data types for precision medicine



Source: PwC Strategy& Precision Medicine Study 2017

Because it deals with individuals, precision medicine is highly personalized, and for pharmaceutical companies it represents a new approach to innovating and developing drugs, in line with the demand from governments, regulators, and payors for "real-world evidence" of a drug's effectiveness and its value to those stakeholders. With populations in many markets aging, chronic diseases becoming more prevalent, and patient expectations increasing, governments and payors are looking for more evidence of value and positive patient outcomes. As we found in an earlier analysis, reimbursements for any drug or treatment "will be increasingly based on…evidence of the real world impact of the medication." (See "Revitalizing pharmaceutical R&D: The value of real world evidence," Strategy&, 2015.)

This is leading to greater pressure on pharmaceutical companies to create products that deliver markedly, measurably better care, with greater value. One of our respondents phrased it this way: "Demographics and innovation will lead to intensified cost containment pressure. Precision medicine is one promising way to fundamentally support the value story."

Imagining the possibilities

It is against this background of budget sensitivity and the growing need to prove clinical effectiveness that precision medicine has become increasingly important. As discussed earlier, precision medicine combines an unprecedented understanding of disease biology, broader access to patient data (increasingly by nonmedical entities), and computational power to analyze the data. The increased accessibility to patient-level data by nonmedical entities is not as intrusive as it might first seem. Our research has already found that patients are willing to share such data with their primary care providers. (See "Health wearables: Early days," PwC, 2014.) Similarly, some fitness device users, for example, already share their data with the manufacturers for free. Some stakeholders may require incentives, such as free or low-cost devices, discounted insurance premiums, or cheaper or preferential treatments.

If this patient data is available for analysis, what could the future hold? Patients could receive more targeted treatments, tailor-made for them on the basis of their personal data and their specific disease, rather than the current broad-brush approach. This also means that patients can potentially avoid ineffective, unnecessary, and often unpleasant therapies.

Similarly, precision medicine would enable pharmaceutical companies to reduce the uncertainty of payors regarding product effectiveness and cost, as the benefits are more readily demonstrable. Companies will be able to identify new therapy targets based on solid effectiveness analytics. Clinical trials will be more targeted and require smaller statistical pools of patients, leading to greater efficiencies and a faster development process.

Key survey findings

Potential benefits from precision medicine range across all aspects of the pharmaceutical value chain: research, development, market authorization, and post–product launch. Regarding the R&D and market authorization processes alone, several advantages stood out among respondents:

- More accurate identification of new drug targets
- Greater clarity regarding the target patient profile
- More targeted clinical trials requiring smaller statistically valid pools of patients, leading to better trial outcomes and faster time-to-market
- Greater likelihood of regulatory approval
- More certain reimbursement and adoption of medicines
- Longer market exclusivity

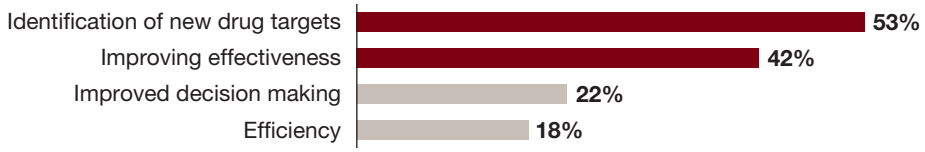
However, respondents also identified meaningful advantages later in the value chain: rapid label extension, more controllable risks, and, most important, improved outcomes through continuous therapy (*see Exhibit 3, next page*).

More than 75 percent of our survey respondents were confident that precision medicine will help reduce the roughly 10-year R&D cycle by about eight months on average, with one in three respondents saying reductions of a year or more are possible. In terms of R&D expenditure, 72 percent of those able to judge such spending (which was 77 percent of the total respondent base) predicted a reduction, averaging 17 percent of costs (*see Exhibit 4, page 15*). Considering that global R&D spending for the industry is currently about US$150 billion, that translates into a potential annual savings of $26 billion (nearly $19 billion for the U.S., Switzerland, and the five largest European Union countries). Some respondents were even more optimistic — roughly a third said cost

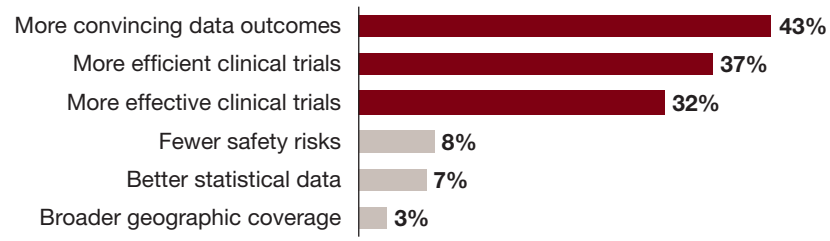
Exhibit 3

Expected priority benefits along the pharma value chain

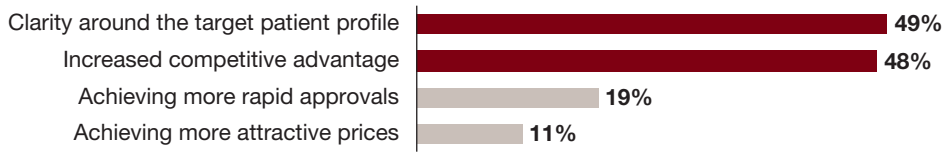
Research



Development



Market authorization

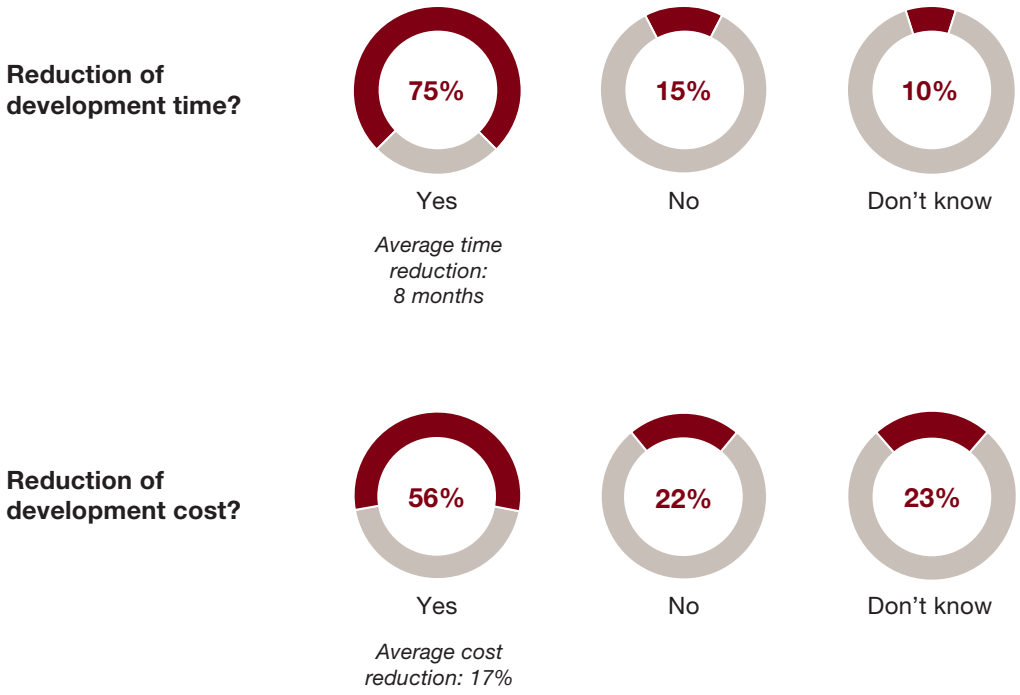


Note: Respondents were asked to select as many as five options across any of the four stages.

Source: PwC Strategy& Precision Medicine Study 2017

Exhibit 4

Expected increase in R&D efficiency



Note: Sums may not total 100 due to rounding.

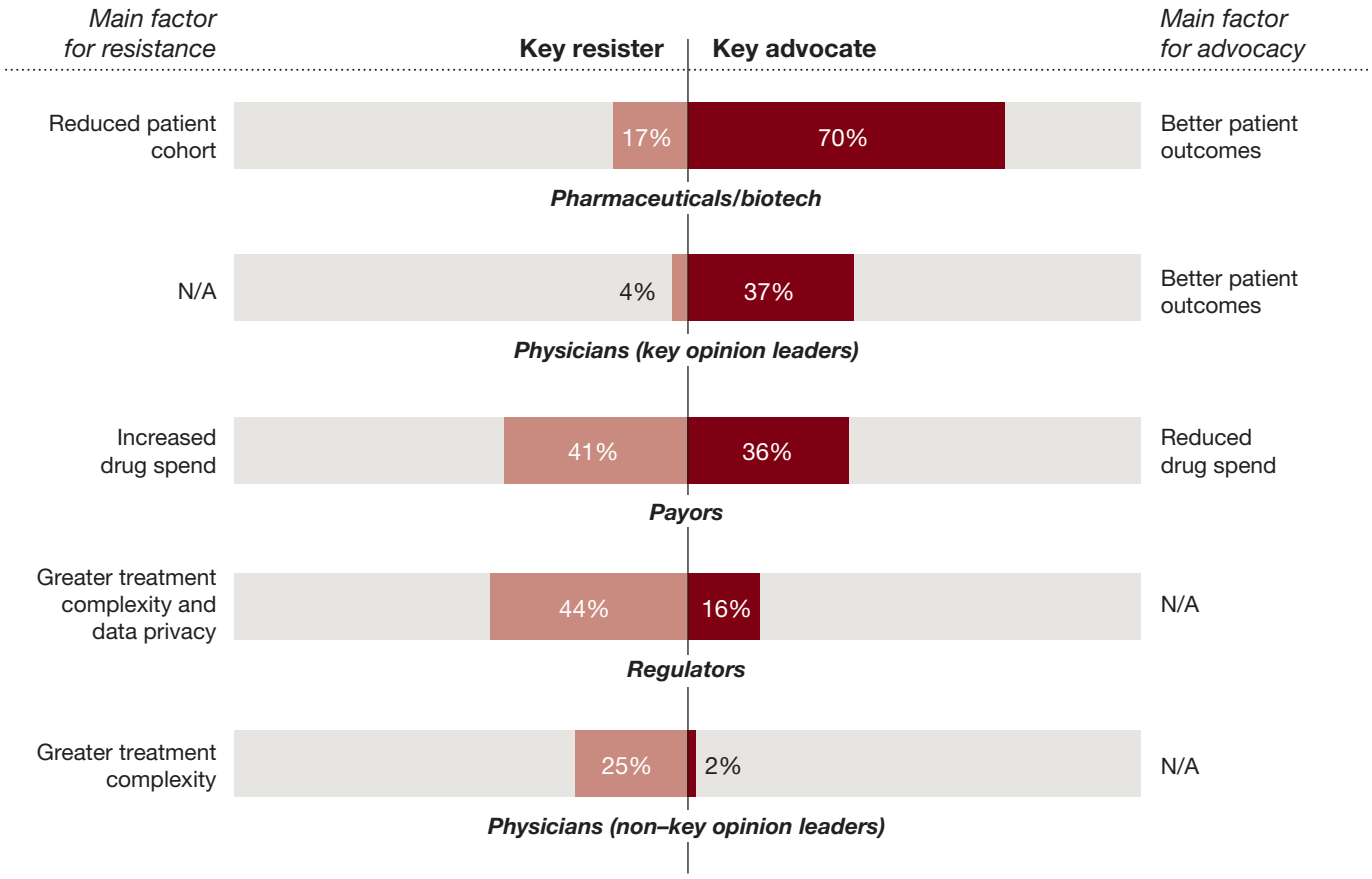
Source: PwC Strategy& Precision Medicine Study 2017

savings of 20 percent or higher were possible. And this does not even factor in the potential boost in sales.

Notably, the survey respondents saw themselves — the pharmaceuticals and biotech industry — as the leading advocates for precision medicine, with physicians and payors trailing significantly behind (*see Exhibit 5, next page*). Yet the situation may not be as black-and-white as it would seem from our survey results. Strategy&'s own analysis shows that a significant number of precision medicine startups have emerged across the value chain — emphasizing just how disruptive they could be to the pharmaceuticals industry's current business model.

Exhibit 5

Relative advocacy for and resistance to precision medicine, based on survey respondents



Source: PwC Strategy& Precision Medicine Study 2017

Barriers to overcome

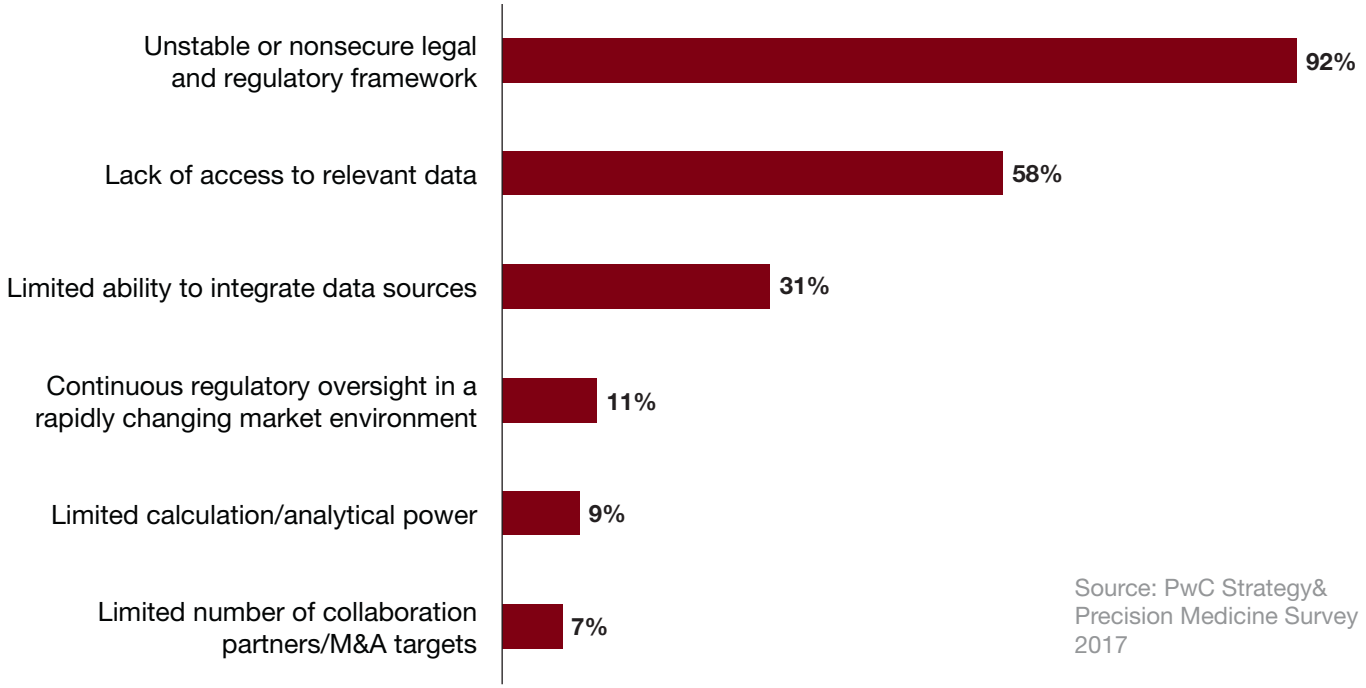
In terms of external barriers, our respondents were fairly clear; they felt that a lack of data was an issue, though one that could be overcome through collaborations, possibly with new market entrants that specialize in data collection and integration. However, there are other barriers — specifically, the uncertain legal and regulatory framework surrounding precision medicine, a limited ability to integrate data sources due to a lack of widely accepted standards and methods, and continuous regulatory oversight with rules that were written for a previous generation of healthcare and data (*see Exhibit 6, next page*).

In particular, a lack of clear regulations makes it challenging to plot the best course of action. However, rather than waiting for these issues to get resolved, pharmaceutical companies should engage more closely with regulators, payors, providers, and policymakers. Because the playing field is currently so open, companies can help themselves by playing a direct role from the outset and helping to define the rules of the game (see "Broader impacts on society," page 20).

What about internal barriers? The biggest is a lack of capabilities, cited by 79 percent of respondents (*see Exhibit 7, page 21*). In particular, most pharmaceutical companies don't yet have the capabilities in place to generate the relevant data about patients, analyze and interpret that data, and apply the insights from clinical outcomes to change future drug development.

Exhibit 6

External barriers for precision medicine



Source: PwC Strategy& Precision Medicine Survey 2017

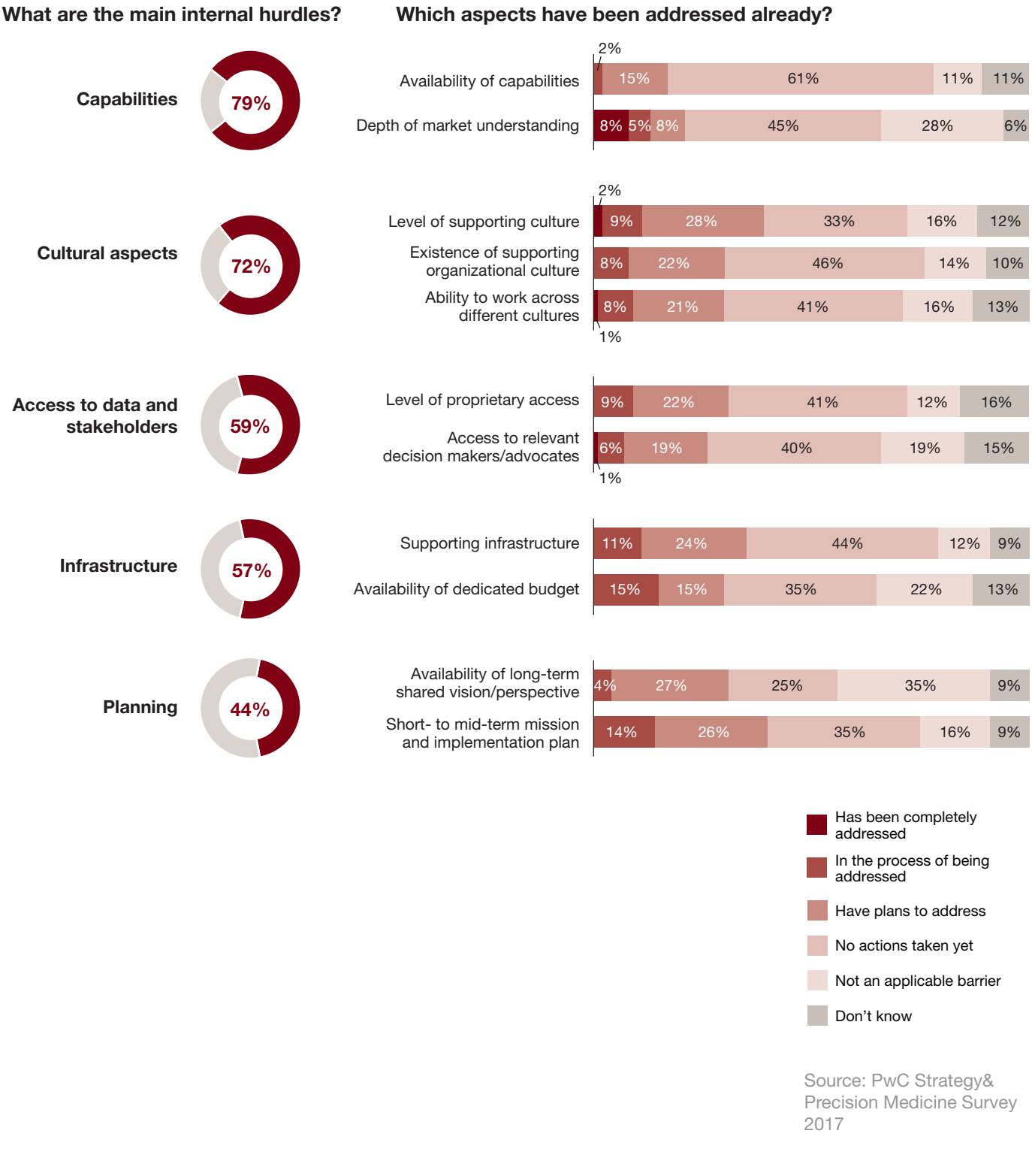
Broader impacts on society

Precision medicine holds the potential to remake healthcare, which could trigger a far broader set of impacts on society at large. For example, the ability to peg lifestyle decisions — such as whether to smoke, or exercise, or eat fatty foods — to health outcomes will require careful thought to prevent employers or payors from refusing to cover specific diseases. Similarly, in markets like the U.S., where employers cover health insurance for employees, policies will need to be crafted that prevent hiring decisions on the basis of health and health-related lifestyle data. Last, although precision medicine could dramatically extend a population's life span, at potentially lower costs, it could ultimately lead to other healthcare expenses, with an older population requiring more direct care.

These issues may seem to lie beyond the purview of pharmaceutical companies, yet they will ultimately affect the industry's bottom line, and thus they should be on the agenda of pharmaceutical leadership teams.

Exhibit 7

Internal hurdles to the adoption of precision medicine



Source: PwC Strategy& Precision Medicine Survey 2017

Build or buy?

Since data capabilities are critical for precision medicine, we asked respondents to choose the most viable means by which they could develop them. Building these capabilities internally, although a viable choice for some companies, is slower and not necessarily cost-effective. The overwhelming choice, cited by 87 percent of respondents, was for "targeted collaborations beyond pharmaceutical firms" as the way forward, followed by the hiring of external experts, cited by 65 percent (*see Exhibit 8, next page*).

However, this kind of data collection and direct engagement with patients lies outside the traditional realm of expertise for most pharmaceutical companies. As a result, striking the right collaborative partnerships will be tricky. There is a flood of new market entrants working on data issues, frequently from nonmedical fields such as personal technology and consumer devices. Some of these companies specialize in specific aspects of data — such as generation, collection and integration, analytics, or interpretation and usage — yet others are integrated across the full data value chain (*see Exhibit 9, page 24*). Pharmaceutical companies need to understand who is out there, what they are good at, and who would be a likely strategic partner.

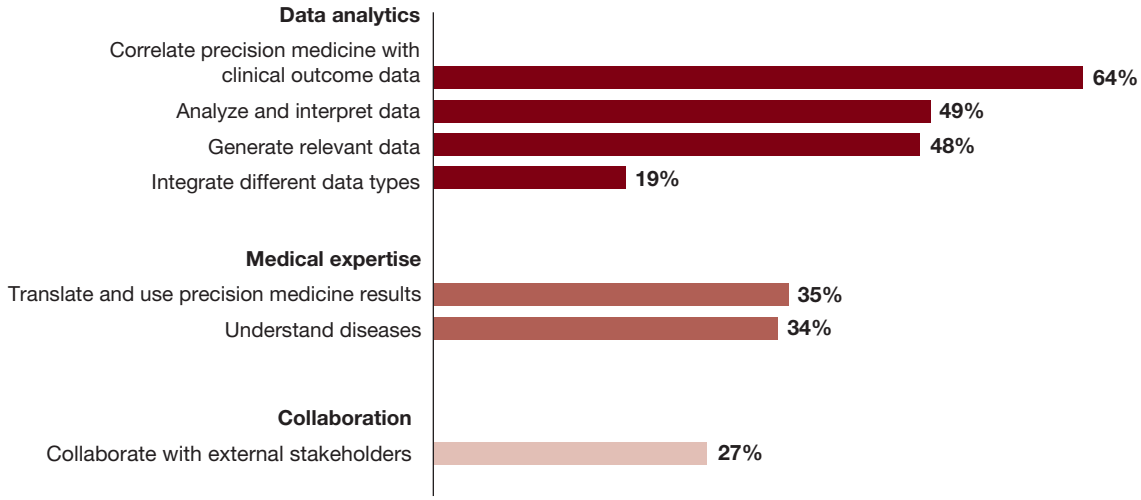
Companies that partner with external players (both private companies and research institutions) need to trust that the data and analyses their partners provide are both accurate and complete. Companies will also need to sort through a range of issues such as data protection, access and usage rights, and changes in the way clinical trials are set up.

Many of these topics will be new to pharmaceutical companies, and thus will require strengthening in-house resources such as legal and compliance in these new data-related areas. In addition, companies will need to forge the right working relationship between their established organizational culture and the "new kids on the block" that have the required data technology skills. Notably, our survey found that the industry does not yet see its potential partners as equals, particularly in terms of medical expertise.

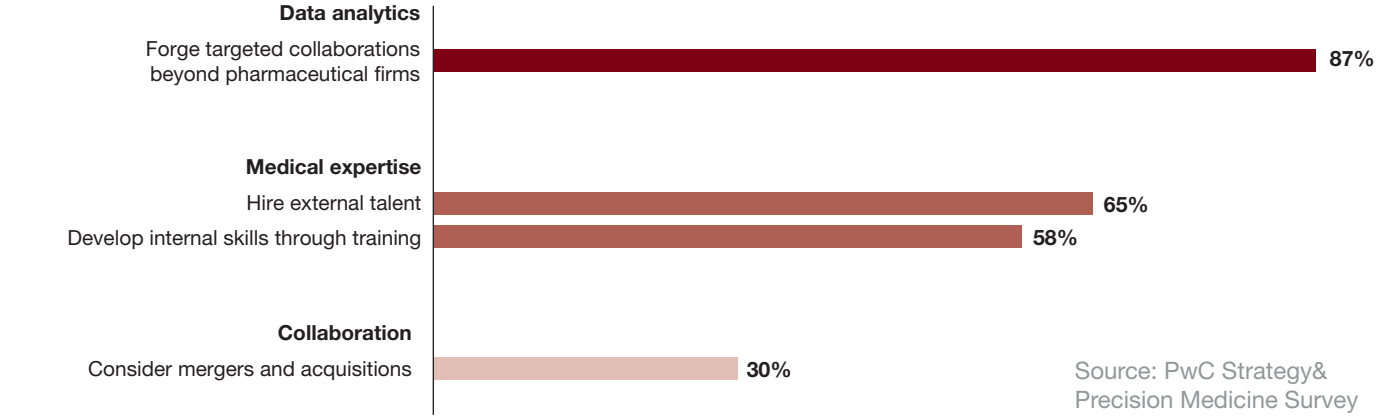
Exhibit 8

Main capability gaps and how pharmaceutical firms plan to close them

Main capability gaps



How to best close the gaps?

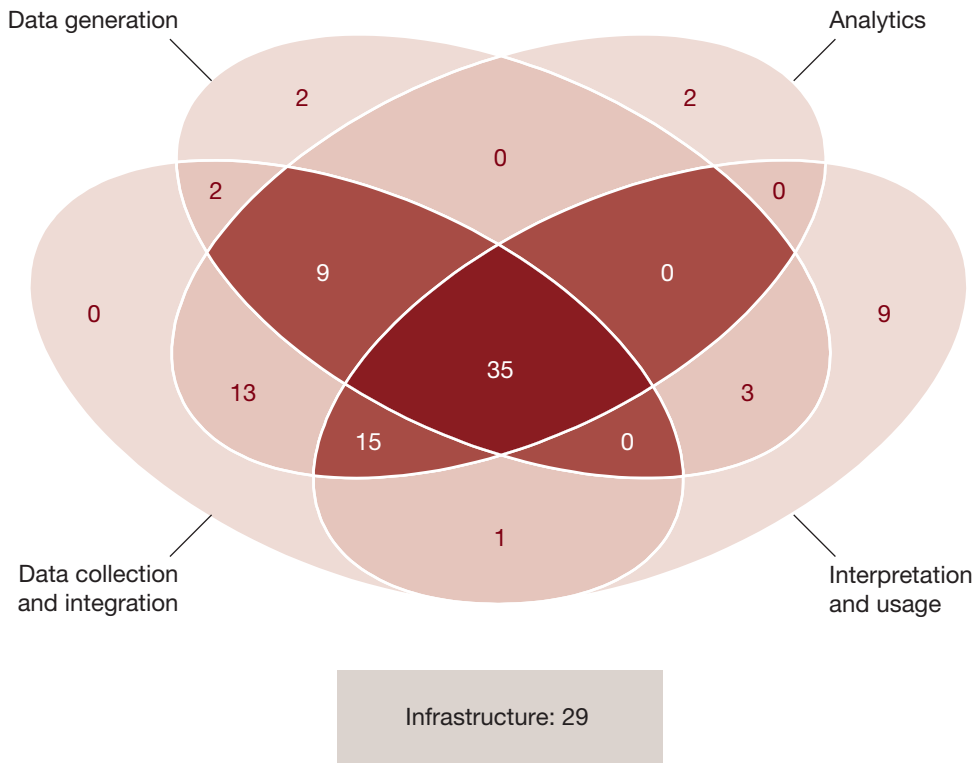


Source: PwC Strategy& Precision Medicine Survey 2017

Exhibit 9

Precision medicine startups and their specialties along the data value chain

Number of companies active in segment



Note: The infrastructure segment excludes companies that are actively involved in data generation, collection, integration, analytics, interpretation, and usage. The sample of companies analyzed is part of a much bigger group of medical data startups. This is meant to be a directional analysis showing the general breakdown of specialty areas.

Source: PwC Strategy& research

One thing is clear — ignoring these new players is a formula for failure. We know that patients are willing to give access to their data to individuals and companies of their choice if it is to their advantage. If startups can gain a first-mover advantage in this market through provision of cheap — or free — wearables or applications, they will gain significant disruptive power. Pharmaceutical companies need to be aware of the players with medical and healthcare data expertise, and they will need to update that market intelligence continuously, to make sure they are working with the best of the best.

The right approach to partnering

How can pharmaceutical companies forge the right partnerships? First, companies must ask themselves, "What gaps in capabilities do we need to fill?" A clear analysis of the company's existing capabilities is an essential first step, before making a determination as to who or what might fill the gaps.

Second, companies must decide which partners are most appropriate to fill those gaps. Because they have limited experience in this new data field, companies will need to understand the landscape before they decide on specific external partners or experts to work with. To be clear, all risks will remain with the pharmaceutical player; regulators will not allow the risk to be transferred elsewhere — all the more reason to ensure the quality of the candidates.

Once a suitable partner (or partners) has been found, the next issue is establishing the right engagement model. Companies will need to trust both their new business partners and the new technologies at the same time, and that will be a tall order. It will require a significant cultural overhaul, particularly given that development cycles in technology are often measured in mere weeks or months. Companies will have to transform their organizational culture and embrace a more agile startup mentality. Among our survey respondents, 72 percent agreed that the right culture in the organization was vital, but only 14 percent said their company had sufficiently transformed its culture to meet the challenges of precision medicine. (More distressing, 39 percent said their company either had not yet started a cultural transformation or had no plans for one.)

The future starts today

We expect the next five years to be crucial in establishing the playing field for precision medicine, the rules of the game, and who the competitors are. Accordingly, pharmaceutical companies need to begin taking action today. Among other imperatives, that means engaging and collaborating with key stakeholders as follows:

- Working with regulators in areas such as laying out the process for precision medicine–informed clinical trials, which will require much smaller patient populations

- Collaborating with payors to cover precision medicine — for example, by establishing real-world evidence of safety and effectiveness and thus determining the actual value of a treatment

- Incentivizing physicians by clarifying the advantages of precision medicine such as better outcomes for their patients at lower cost

- Educating patients on the benefits of this new approach to healthcare: more personalized treatments, reduced side effects, and the ability to prevent diseases more effectively

In sum, precision medicine represents not only a business opportunity but also a clinical opportunity. At a time of greater healthcare challenges, it is a clear means of using emerging technologies to deliver better care to patients. That, in essence, is the responsibility of pharmaceutical leaders. As one respondent in our survey put it, "Precision medicine will happen, and it's better to be one of the shapers than a follower. Pioneering and taking risks to get on the train may afford greater opportunities than resistance or avoidance." In other words, pharmaceutical companies can seize this opportunity — or ignore it and watch their competitors pass them by.

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