When the human body is the biggest data platform, who will capture value?

Progressions 2018

Life Sciences 4.0: Securing value through data-driven platforms

Building a better working world

The better the question. The better the answer. The better the world works.

Life Sciences 4.0

In Life Sciences 4.0: Securing value through data-driven platforms, EY's latest edition of our Progressions series, we explore how health is being reimagined as a result of scientific and technological change and rising customer expectations. We also examine the ramifications for life sciences companies' market offerings, business models and the new capabilities needed as the disciplines of health care and technology merge to become "health technology."

In this fluid environment, every company developing health care products and services is a data company, and therefore a technology company. Likewise, every technology company that has access to health-related, consumer-generated information or other health data is a health care organization.

At the same time, the ubiquity of mobile and peer-to-peer sharing tools are transforming consumers into super consumers. As these super consumers encounter engaging experiences in other areas of their lives, they are now demanding more of the same from their interactions with the health ecosystem. These demands include the contributions from life sciences companies, including experiences with personalized products and services customized to individuals' genomes, microbiomes and metabolomes. Consumers, not organizations, are now at the center of this market paradigm. The rise of super consumers and technologies that deliver data-fueled insights to other health stakeholders (e.g., artificial intelligence and internet of everything) disrupt entrenched relationships and shift power away from life sciences companies. To regain positional power, life sciences companies must invest strategically and differentially in the capabilities that create future value and that can be shared broadly by all stakeholders. This future value will be driven by innovations that not only improve health outcomes but are highly personalized to an individual's health needs. Moreover, to achieve significant improvements in outcomes, companies must unlock the power of diverse data streams that reside outside the traditional health ecosystem.

Framing innovation in terms of outcomes and personalization means products are no longer the central driver of value. Success requires the adoption of flexible business models that allow life sciences companies to develop data-driven improvements to health outcomes. To create future value, life sciences companies must also develop systems that align objectives and share value among stakeholders. That means biopharma and medtech companies must invest in, or acquire, expertise in customer engagement, personalization and other skills more commonly associated with online retailers and social networking sites.

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Embracing Life Sciences 4.0 is both a global urgent need and an opportunity. If companies leverage technology to create platform interfaces and combine their proprietary data with those from other health stakeholders, they can position themselves as powerful leaders and capture sustainable future value.

Life sciences companies have already started to respond to this new demand-driven environment by shifting their business models away from blockbuster and specialty products and toward outcomes-based business models. They must now consider how and when to participate in emerging care platforms that seamlessly collect, combine and share a variety of health data in real time. This will involve the formation of agile, and often short-term, partnerships and collaborations. We call the data-driven, platform-based business models that emerge from such efforts Life Sciences 4.0.

Embracing Life Sciences 4.0 is both an urgent need and a blossoming opportunity that has yet to be realized. If life sciences companies can leverage platforms to combine their proprietary data with environmental, behavioral and financial insights, they can position themselves to capture maximum future value.

In the retail and transportation industries, where data exchange is fast and easy, companies have eliminated long-standing inefficiencies and created benefits for themselves and their customers. Life Sciences 4.0, likewise, can help medtechs and biopharmas unlock and capture value, allowing companies to co-create new solutions that drive improved health outcomes and preserve, or even improve, their position in a rapidly changing health ecosystem.



Pamela Spence EY Global Life Sciences Industry Leader

To seize the upside of disruption in this transformative age, executives should ask themselves the following questions:

- How will your organization transform its business model to create shared value focused on personalized outcomes and fueled by unlocking the power of data?
- How will your organization build new capabilities organically, by acquisition or by flexible partnerships?
- How will your organization ultimately secure value through platform-based businesses?

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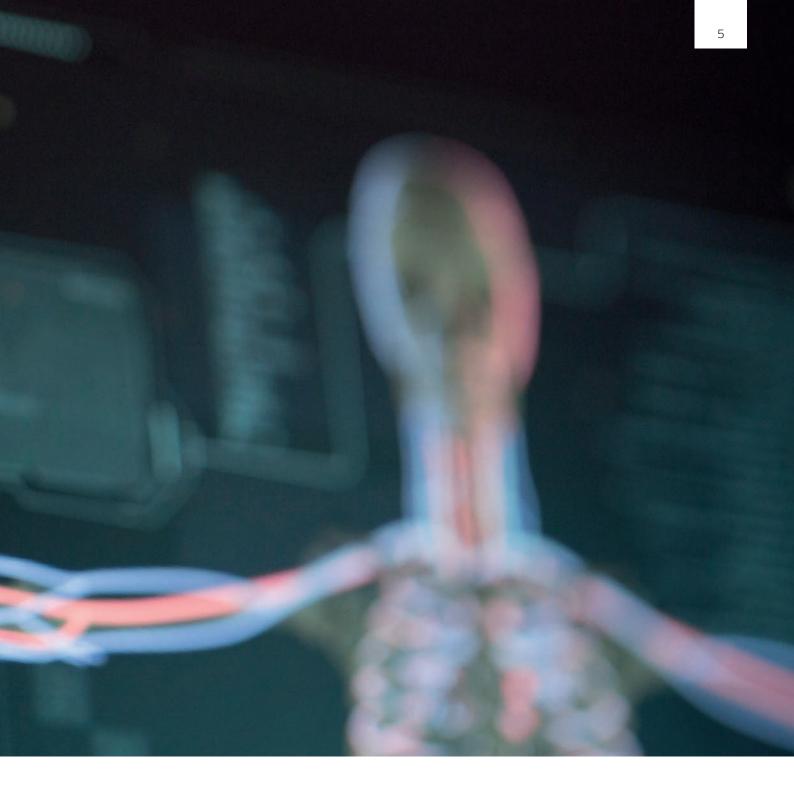
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01

Why are platforms essential to future value creation?

At a time of rapid technological change, markets are becoming superfluid, putting pressure on life sciences companies to change their business models and personalize their products and services. To create value now and in the future, life sciences companies should consider participating in data-centric platforms of care that improve individual health outcomes and reduce costs. In this environment, platforms provide a framework to create future value that is based on individualized outcomes, and is amplified by the ability to connect, combine and share data.

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The Fourth Industrial Revolution

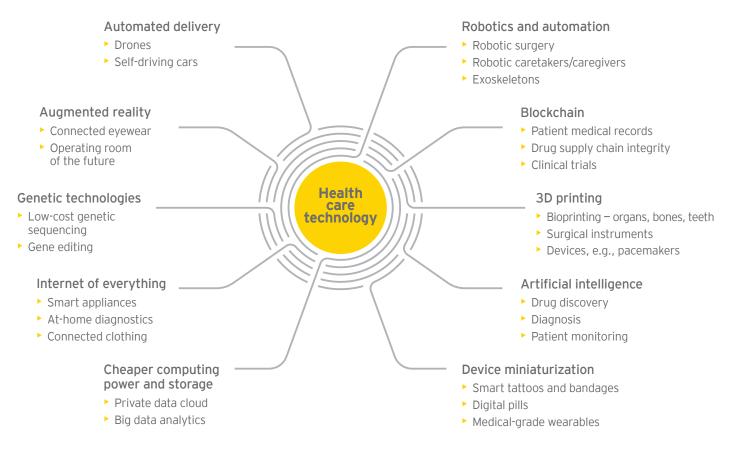
The world is changing.

We are entering what Klaus Schwab, Founder and Executive Chairman of the World Economic Forum, calls the Fourth Industrial Revolution. Cheap storage, increasingly powerful and tiny processors, mobile penetration that approaches ubiquity and emerging technologies such as 3D printing, blockchain and artificial intelligence (AI) have resulted in what Schwab calls "a fusion ... across the physical, digital and biological worlds."¹

Rapid technological advances have made it possible to generate and disseminate data at an unprecedented rate. (See Figure 1 next page.) For consumers, this has created new opportunities to share information, as well as new expectations about what services add value. Indeed, peer-to-peer sharing, widespread mobile access and the democratization of data have transformed today's consumers into super consumers, who demand transparent interactions that are customized to their interests and integrated into their daily lives. It is these super consumers who are driving business changes at scale in the retail, financial and transportation sectors.

Figure 1. Health services will be digitized

Smartphone compatibility and pervasive mobile access are important catalysts to widespread adoption of new health care technologies. Without mobile, their application will be limited.



Source: EY, World Economic Forum.



Increasingly, these super consumers are also making similar demands about their health care, which is dramatically altering the health services landscape (see Figure 2).

Consumers "want to know why the health care industry still requires them to do the same transactions the same way they've been doing them for the last 40 years," says Dr. Minalkumar Patel, the CEO of ABACUS Insights, a data-focused start-up, and formerly Chief Strategy Officer at Horizon Blue Cross Blue Shield.

As new devices and technologies empower individuals to see and share their health data, these consumers are demanding greater say over their lifelong health journey. Those demands are reshaping not only their interactions with physicians and payers, but the products and services consumers use to participate more directly in their own care. Increasingly, consumers will require the integration of existing disease-specific point solutions into more holistic, data-driven platforms of care.

Sensing an opportunity, digital health and technology entrants are already moving aggressively to meet consumers' requests. The explosion of narrow, point solutions are slowly being aggregated into integrated systems that create engaging, high-touch offerings for fitness, aging in place and chronic diseases. In this rapidly converging world, life sciences companies must consider how they will adapt their current business models to create future value. Consumers "want to know why the health care industry still requires them to do the same transactions the same way they've been doing them for the last 40 years." - Dr. Minalkumar Patel, CEO, ABACUS Insights

Figure 2. Data-driven insights are redefining the health services landscape

The health services landscape is in the midst of a massive shift as the seamless sharing of data creates more demanding customers and opportunities for more connected, precise medicine.

Uninformed patients, payers and providers	\rightarrow	Super consumers	Patients, payers and providers empowered by data
Sick care	\rightarrow	Health care	Focusing on prevention and addressing affordability
Blockbuster drugs	\rightarrow	Precision medicine	Mining data to deliver tailored medicine
Disconnected health care	\rightarrow	Connected health care	Integrating health care data; "man and machine" delivering better interventions

At a minimum, that means redefining innovation beyond product-centric attributes tied to mechanism of action to focus on a range of outcomes linked to customer engagement, personalization and data literacy. Tomorrow's blockbusters could well be algorithms that combine scientific, behavioral, economic and financial insights into personalized solutions designed to treat, cure or even prevent disease. Consequently, life sciences companies will need to consider how and when to participate in emerging care platforms that seamlessly collect, combine and share a variety of health data in real time. We call the platform-based business models that emerge from such efforts Life Sciences 4.0 (see Figures 3 and 4). There is an urgent need and a huge opportunity to embrace Life Sciences 4.0. The rapid and easy exchange of data has already transformed the retail and transportation industries. New entrants are using algorithms and analytics to eliminate long-standing inefficiencies and create benefits for themselves and their customers. Life Sciences 4.0, likewise, can help medtechs and biopharmas unlock new value. By co-creating personalized solutions that improve health outcomes with other health stakeholders, life sciences companies can use data to preserve, or improve, their position in a rapidly changing ecosystem.

Figure 3. From blockbuster products to data-driven platforms

As the need to demonstrate product value has grown, companies have altered their business models from blockbuster products and diversified portfolios to health outcomes. In today's environment, where combinations of technologies help create super consumers, companies will need to embrace data-driven platforms.

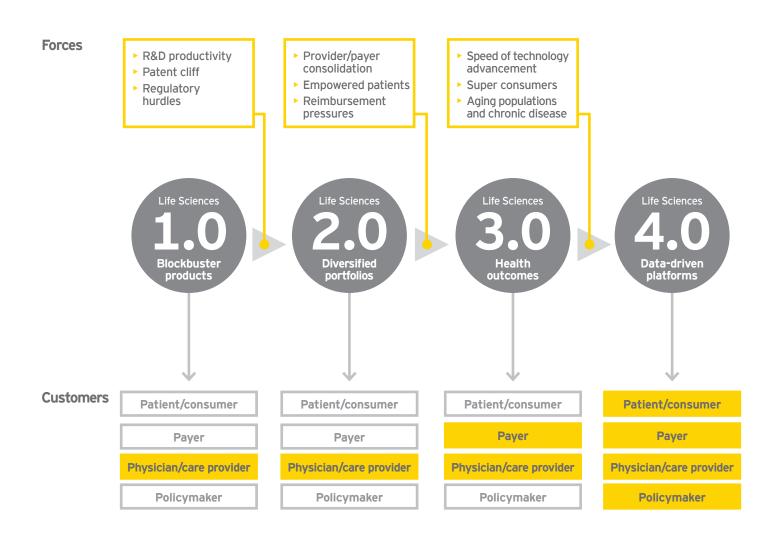


Figure 4. Important definitions

The Fourth Industrial Revolution: A fusion of the physical, digital and biological worlds that redefines innovation and blurs the traditional lines between industries. This advancement is driven by the ability to combine a range of new technologies and the safe and rapid generation and dissemination of data.

Health ecosystem: A number of different stakeholders provide goods or services to super consumers in today's networked health environment. These stakeholders include primary and specialty care physicians, public and private payers, and a range of businesses including technology, retail, telecom, mobility and life sciences companies.

Life Sciences 4.0: A customer-focused, collaborative, data-driven approach to product and service development in which life science companies interact within a network that includes traditional health incumbents and new entrants.

Platform: A mechanism to connect different stakeholders in order to combine and share data easily and securely to deliver a shared goal: improved health outcomes.

Superfluid market: Frictionless markets that eliminate long-standing business inefficiencies and prioritize the customer – not the company – through emerging technologies such as 3D printing, blockchain and artificial intelligence (AI).

The superfluid health market

For centuries, markets have matched buyers and sellers, but as trade and technologies became more complex companies formed. Companies dealt with market frictions, hiring labor and procuring equipment, negotiating and enforcing contracts, delivery logistics and payments.

Market frictions created companies as trading structures between businesses and between countries, and also employment structures between companies and employees. This friction made them untouchable. As a result, traditional markets were often viscous, slow, expensive and opaque. The company, not the consumer, dominated.

With the internet and its widespread adoption, markets that were once viscous became fluid; the frictions that once secured companies now threatened them. The fluidity of the internet started to disrupt these traditional rigid trading structures by democratizing data, shrinking distance, eliminating intermediaries and empowering consumers. For example, companies today can automatically mine customer-generated information for insights about buying habits and behaviors and offer consumers customized buying experiences.

As a result of the Fourth Industrial Revolution and the emergence of increasingly more powerful technologies powered by mobile, there are additional opportunities to empower consumers. As a result, the pace of change is accelerating and fluidity is giving way to superfluidity. Even more market frictions are evaporating. This technological innovation drives the emergence of superfluid markets, which flow without friction and result in the disappearance of entrenched corporate relationships. (See "What makes a company a company when markets are superfluid?")

The health care market has not yet reached this superfluid state. The overall experience remains disjointed, as people are shuffled between multiple caregivers, and regulations and data incompatibilities make it difficult to easily share the information necessary to optimize care. But, as Geoffrey Moore, futurist and author of *Zone to Win: Organizing to Compete in the Age of Disruption* predicts, "the breakthrough will happen when businesses actually genuinely champion the [health] consumer."

Public announcements indicate that breakthrough may come sooner than expected. Starting in 2017, diverse organizations have joined forces to create new health services and products that are more convenient and customer-focused. By offering consumers a wider array of options in how, and where, they receive their medical care, and who has access to this information, these initiatives could redefine the care delivery experience.

In late 2017, for instance, CVS Health, an integrated pharmacy health company, announced its acquisition of Aetna, one of the US's largest commercial insurers. In January 2018, a trio of announcements further demonstrate the convergent forces at work in health care: five US health systems, led by Intermountain Healthcare, publicized plans to create their own not-for-profit generics drug business; Apple, meanwhile, revealed a new feature to make individual health records accessible on the iPhone; and Amazon, Berkshire Hathaway and JPMorgan Chase announced a partnership to tackle rising health care costs for their US employees. Such adaptations are likely only the beginning as the convergence of AI, robotics and 3D printing creates opportunities for consumers and physicians to turn health data into actionable information – especially when linked together via emerging blockchain-enabled infrastructure platforms. As wearables become both more powerful and smaller in the future, they will help nudge consumers to make better health and lifestyle decisions that ultimately result in improved outcomes. When this happens people won't orbit companies. Instead, a constellation of companies will orbit individuals.

Creating future value

The question life sciences companies must address is how to seize the upside of disruption in today's transformative age. The ubiquity of data and analytics continues to blur the traditional boundaries between therapeutics, medical technologies, consumer devices and information technology (IT).

Alex Gorsky, CEO of Johnson & Johnson, reminded investors of the implications of this technological convergence for both traditional health and life sciences leaders at the 2018 J.P. Morgan Healthcare conference. "We won't necessarily be classifying [ourselves] as just a health care or biopharmaceutical industry, but will be a health care and biopharmaceutical technology industry," he said. Technology "will touch everything that we do, whether it's the way we use data to better understand the genome ... or as it applies to things like minimally invasive surgery, even the way we talk to consumer vis-à-vis social media."²

Gorsky's words underscore how technology will help reimagine health care. But technology alone isn't driving the shift. Budgetary constraints and longstanding inefficiencies in care delivery heighten the need for such a reimagining (see Figure 5). Many consumers struggle to afford new medicines or devices. As life spans increase, public and private payers struggle to fund health systems that can provide high-quality care to their oldest and most frail. "We need fundamental, new models of care that challenge the status quo and create opportunities for value-based models that reward the private sector for taking costs out of the system," says Jason Helgerson, Medicaid Director at the State of New York Department of Health.

To regain power and be recognized for their significant contributions to improving health, life sciences companies must invest strategically in capabilities that create future value based on the broader demands of these different stakeholders. Figure 6 suggests one way to do so.

As has been true historically, innovation will continue to be a central component of how life sciences companies create future

Traditional powerFuture powerPower shiftPhysician/care providerBiopharma and medtechPayersPatients/consumersPolicymakersOther sectors'

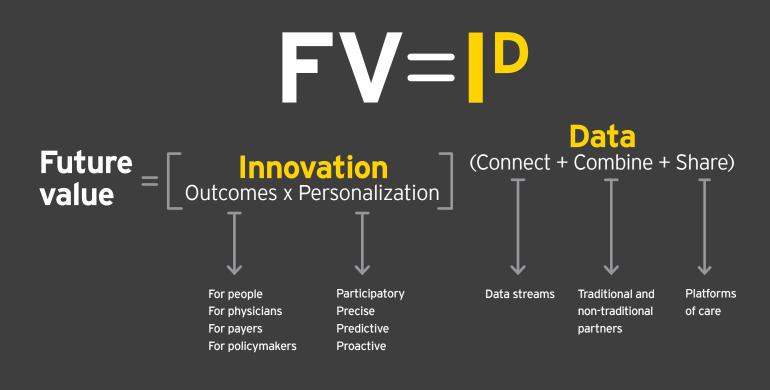
Figure 5. New technologies and cost constraints shift power away from life sciences companies to other health stakeholders Consumers, payers, policymakers and new entrants are gaining power as health budgets tighten and data are democratized.

* "Other sectors" includes retail, technology, manufacturing and industrial products, and consumer products.

² "Johnson & Johnson Management Presents at 36th Annual JPMorgan Healthcare Conference 2018 - Brokers Conference Transcript," Seeking Alpha, January 8, 2018.

Figure 6. A new equation for delivering value

Future value (FV) is driven by innovation (I) that focuses on outcomes with a high degree of personalization and is fueled by unlocking the power of data (D).



We won't necessarily be classifying [ourselves] as just a health care or biopharmaceutical industry, but will be a health care and biopharmaceutical technology industry. Technology will touch everything that we do, whether it's the way we use data to better understand the genome ... or as it applies to things like minimally invasive surgery, even the way we talk to consumer vis-à-vis social media.

- Alex Gorsky, CEO, Johnson & Johnson



value. But these innovations will be valued based on their ability to satisfy a common purpose linked to health quality, cost and outcomes. In other words, to create future value, life sciences companies must develop systems that align objectives and share value among stakeholders.

This definition of value has already emerged in other areas of the economy as investors adopt so-called "prosocial" policies that place the rights of employees and the community on equal footing with the rights of shareholders.³ It's one reason, for instance, there is increasing demand for electric cars, which can cost more than many gas-powered vehicles. In life sciences, where social consequences and profit are deeply intertwined, the need for a broader, shared definition of value is arguably even more important.

The difficulty of defining shared value across health's many stakeholders has always vexed life sciences companies. In all likelihood, companies will have to demonstrate that products improve consumers' quality of life and their health, while also exhibiting a return on spending to cost-conscious governments and commercial payers. At the broadest level, innovations may also need to demonstrate benefits at the population level to satisfy the needs of policymakers. Over the past two decades, life sciences companies have moved away from off-the-shelf blockbusters to the creation of specialized products that are tailored to the individual based on genetic or clinical evidence. This trend will continue as increased personalization begins to account for consumer preferences linked to behavior and risk tolerance and drives stakeholder participation. Success will require borrowing user-centered design principles developed in the technology and consumer industries to develop mechanisms of engagement that are easy to use and naturally fit into daily life.

Framing innovation in terms of outcomes and personalization means the product is no longer the central driver of value. In certain therapeutic areas, especially the treatment of chronic diseases, additional services linked peripherally to care (e.g., transportation services to doctor's appointments), connected consumer-facing devices and digital infrastructure will play increasingly important roles. Indeed, innovation will be powered by an increasingly diverse stream of data that reside outside the confines of the traditional health ecosystem. Life sciences companies need a way to safely and quickly tap into these different data sources to combine and connect them to their deep scientific and clinical data.

Creating agile and data-centric platforms

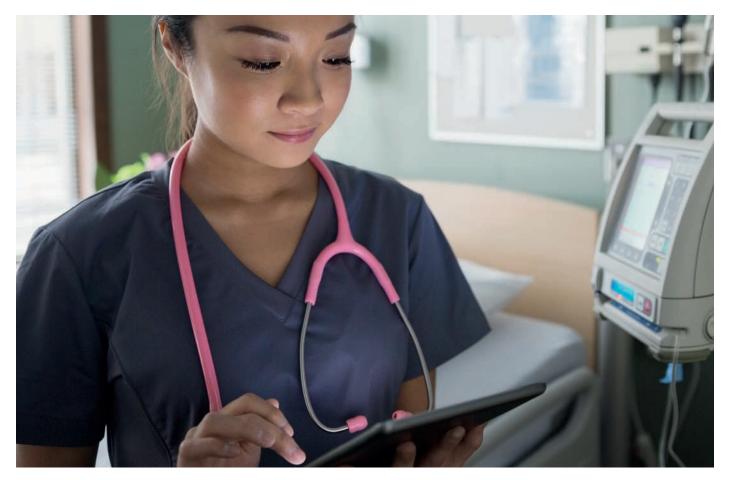
Enter the platform.

Platforms are interfaces (or infrastructure) that allow existing and new stakeholders to connect and share data and insights quickly, while simultaneously deriving benefits from the act of participating. These structures are the backbone of the future sharing economy and have demonstrated enormous value across different industries. Research by the MIT School of Management suggests that in 2013, 14 of the top 30 brands by market capitalization belonged to platform companies.⁴ Amazon, for instance, has transformed the way we shop, including the way we research and decide what to purchase; AirBnB has transformed leisure travel, opening up new experiences for visitors and new revenue streams for homeowners; Uber and Lyft have transformed the transportation industry, divorcing mobility from car ownership or access to taxis.

What do these platforms have in common? All are convenient to use and focused on the user experience. All simplify access to the best products and services and create an opportunity for networks to emerge defined by different resources and capabilities. All drive profitability by eliminating intermediaries. Perhaps most importantly, all combine data in new ways to reveal new business opportunities based on needs that were previously unrecognized. How might platforms unlock similar value in the health care space?

In health care, platforms become a means to connect highly disparate contributors – consumers, physicians, payers, policymakers and product makers. Once connected, these stakeholders can combine capabilities and share data to eliminate the current piecemeal approach to care. In effect, the platform allows the consumer, not products or point solutions, to become companies' central focus. Companies developing technologies to capture or connect the data revolve around the individual, helping the person navigate health-related issues linked to diagnosis, treatment and behavior change.

Of course, a step change in health outcomes will only be possible if these diverse data streams, which are currently stored in incompatible storage systems, can be aggregated and



⁴ "Why Platforms beat products every time," *MIT Sloan Executive Education innovation*@work blog, June 7, 2015. https://executive.mit.edu/blogpost/why-platforms-beat-products-every-time#.WiH_KOqnGuU.

Figure 7. The building blocks to create platforms of care

Health data will be aggregated and structured to create usable insights at the therapeutic-specific level and the supra-platform level.

Point solutions

EVOLVING RAPIDLY

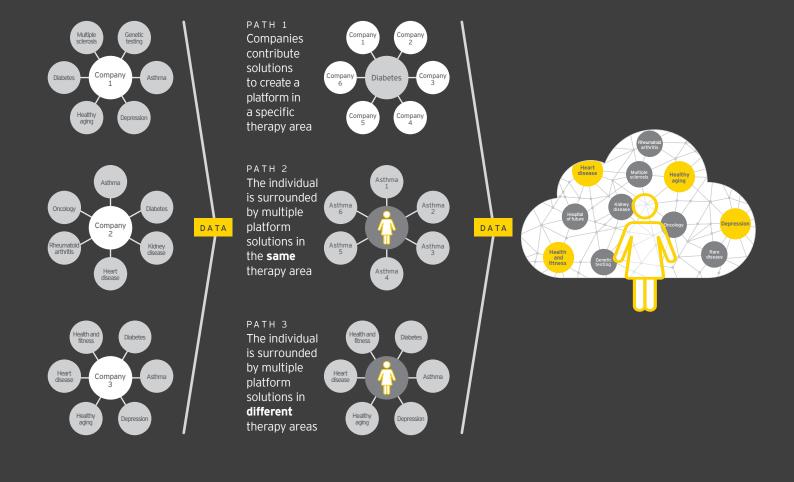
Companies develop solutions or services tied to specific products that operate in isolation.

Therapeutic-specific platforms of care EMERGING

Products, tools and applications from different developers are integrated making it possible to connect, combine and share a variety of data. Three different paths to the formation of therapeutic specific platforms of care are possible.

Supra-platform aggregation FUTURE STATE

Organizations – seamlessly and without friction – connect, combine and share data to establish integrated platforms of care that provide a convenient and easy-to-use interface with the patient/consumer at the center.



structured in ways that allow them to be shared in real time. This aggregation will happen at two different levels. In immediate proximity to consumers, companies developing different applications, products or tools will join forces to create platforms of care that address specific health needs, for instance, aging in place or asthma management. Above these individual platforms of care, global technology, AI and data analytics companies will combine skills to become "platform aggregators," enabling technologies to scale insights gained at the platform of care level (see Figure 7).

Given their data expertise, technology companies are, for now, best placed to drive the integration required at both the platform of care and supra-platform aggregation levels, a topic addressed in Chapter 3. That doesn't mean, however, that life sciences companies can't promote – or participate in – the formation of medically relevant platforms of care either aimed directly at consumers or developed in conjunction with physician or payer stakeholders.

Embracing the health technology opportunity

Although life sciences companies currently house only a small amount of data tied to health outcomes and the total cost of care, the data they do hold are incredibly rich. If life sciences companies combined these clinical data with environmental, behavioral and financial insights, they could position themselves as one of the primary owners of the outcomes data that drive future value. In doing so, life sciences companies could strengthen their position as key health technology providers in a wider ecosystem, where a network of participants connect to exchange information and services that result in better outcomes for individuals, physicians, governments and insurers.

Life sciences companies have a window of opportunity to help shape platforms, embracing the wider definition of value outlined in Figure 6. As business models continue to evolve, they can continue to focus on their core strategy, while building capabilities that help them understand new data-driven platform strategies. In this way, they can manage the complexities associated with operating businesses that still rely on older models, while satisfying evolving customers' needs.

If life sciences companies do not take this step, it's already clear that they may lose the ability to control the direction – and value creation – of future platforms. Indeed, in announcing its new venture with Amazon and JPMorgan Chase to develop innovative health solutions, Berkshire Hathaway's Warren Buffet noted in a prepared statement that this triumvirate does not have all the answers. But he also made clear their refusal to accept the status quo as inevitable. The risk for life sciences companies is that future revenues will be captured by organizations that choose to satisfy that demand.⁵

Questions to consider

- How will platforms help life sciences companies maintain positional power with industry stakeholders?
- How can life sciences companies create future value using data-centric platforms to personalize outcomes?
- How will platforms disrupt care delivery?



How will platforms help life sciences companies capture future value?

By participating in emerging care platforms, life sciences companies can build relationships with health stakeholders that allow them to develop new offerings that meet their customers' demands. If life sciences companies fail to participate in care platforms they could be marginalized by new technology and digital entrants that will fill the void with their own offerings. Succeeding in the emerging platform environment requires new capabilities related to customer engagement, personalization and data literacy.



Technology companies friend or foe?

Digital health start-ups and technology incumbents are already using their engineering skills and data and analytics expertise to create new products and services that satisfy the demands of consumers, physicians and payers. These efforts now go beyond fitness and sleep tracking and cloud-based data storage to include disease management services that historically represented life sciences companies' core offerings.

Many life sciences companies view these developments as an existential threat. In the October 2017 edition of the EY *Global Capital Confidence Barometer* survey, respondents pegged increased competition from companies outside the industry as the top danger to their continued success.⁶ Indeed, the survey results suggest the potential impact of digital technologies on value creation looms larger than almost any other near-term concern for executives in the life sciences C-suite.

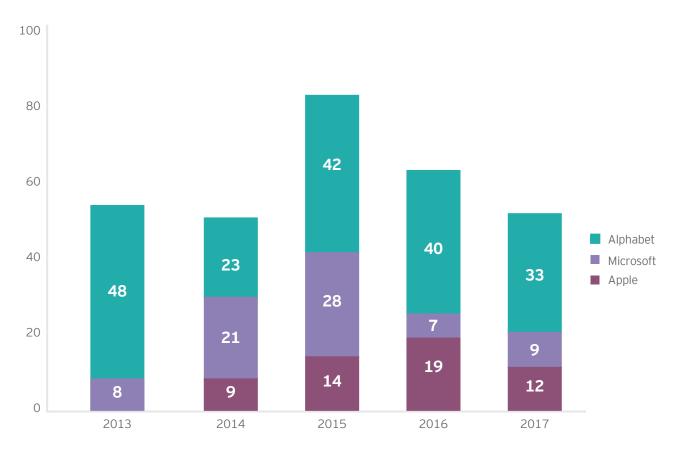


Figure 1. US health care patent applications by technology giants

Source: EY, United States Patent and Trademark Office. Analysis as of 31 January 2018. Analysis is based on year of patent filing filtered by company for select search terms in the patent abstract or claim: health, medical, patient, disease, wellness and physical activity.

It's easy to understand why. EY's analysis of the US health patents filed by major technology players, including Alphabet, Apple and Microsoft, shows the investment technology giants are making in health care (see Figure 1). Alphabet, for instance, has a range of initiatives that span DeepMind and Verily Life Sciences, including joint ventures in diabetes (Onduo), bioelectronics (Galvani Bioelectronics) and smart operating rooms (Verb Surgical).

Apple, meanwhile, has filed patents to turn its phones into medical devices capturing biometric data such as blood pressure and body fat levels; it has also partnered with Stanford University to develop algorithms to predict abnormal heart rhythms.⁷ Based on its filed patents, Microsoft has focused on expanding its AI capabilities and developing monitoring devices for chronic conditions. Although most of its patents are not health care-specific and thus not captured by EY's analysis, Amazon, as discussed in Chapter 1, has taken multiple steps that signal its growing interest in health delivery. In January 2018, Amazon announced its collaboration with Berkshire Hathaway and JPMorgan Chase to create a notfor-profit health care company for the three organizations' US employees. Separately, Amazon's skunkworks health division, 1492, appears to be exploring potential opportunities in drug distribution.⁸ It has also invested in the liquid biopsy start-up Grail, and partnered with Merck on diabetes management solutions.^{9, 10}

Business as usual?

Medtech and biopharma companies have responded with digital partnerships and exploratory programs of their own. In the biopharma space, for instance, we have seen digital innovations

⁷ N. Hughes, "Apple developing advanced EKG heart monitor for future Apple Watch - report," AppleInsider, December 21, 2017.

⁸ E. Kim and C. Farr, "Amazon has a secret health tech team called 1492 working on medical records, virtual doc visits," CNBC, July 26, 2017.

⁹ "Grail Closes Over \$900 Million Initial Investment in Series B Financing to Develop Blood Tests to Detect Cancer Early," Globe Newswire, March 1, 2017.

¹⁰ "Merck Uses Amazon Web Services To Develop Voice-Enabled Solutions To Improve Management of Chronic Disease," Merck website, February 2017.

such as the sensor-enabled version of Abilify (from Proteus Digital Health and Otsuka). In medtech, Philips has developed an automated, internet-connected medication dispensing service aimed at seniors (part of its broader cloud-based HealthSuite Digital Platform). Several companies have also taken significant steps to use AI and other digital tools to improve clinical trial recruitment, drug discovery and to optimize interactions with payers and physicians.

These efforts are important, but don't go far enough to eradicate the risks. Current programs generally focus on developing wrap-around services for key products but don't necessarily position new connective technologies at the heart of their strategic business goals. Moreover, because the present investments are made in isolation from each other across the portfolio, companies are at risk of underinvesting in the technologies that will transform their business models and generate significant future top-line returns. Negative precedents are one reason life sciences companies have been reticent to invest more in digital platforms. Technology companies have tried – and failed – numerous times to reinvent aspects of care delivery, such as personalized health records. For life sciences companies, these historic failures raise legitimate questions about the potential return on investment. And because novel drugs and devices have created tremendous value in the past, many industry executives believe these products will remain the dominant way they create future value.

Undoubtedly that will be true for some companies. Health stakeholders will continue to demand products that offer a step change in health outcomes, but they will also demand that these products be affordable. That's important to note because even major clinical breakthroughs now face the prospect of diminishing returns as cost-conscious payers require proof of real-world value before covering many new medicines or devices. Indeed, since 2005, an increasing proportion of new drugs have failed to reach their prelaunch peak sales projections (see Figure 2).

0

Figure 2. Measuring the return of new drug launches

0%

2002-2005

100% 3 12.5% 38.5% Percentage of successful and unsuccessful drugs Average number of 80% 87.5% 46.3% Percentage of drugs that met the 2 criterion 60% 61.5% Percentage of drugs that did not years to achieve meet the criterion 53.7% Average 40% number of years to achieve 1 peak sales peak sales 20%

The number of drugs achieving at least 50% of analysts' peak sales forecasts is falling as reimbursement pressures increase. This puts more burden on the traditional biopharma Breakthrough innovator business model.

Source: EY, Informa, U.S. Food & Drug Administration (FDA), analyst forecasts, company filings. EY calculated the percentage of drugs approved by the FDA that achieved sales that were at least 50% of analysts' peak sales estimates within five years of launch. Drugs that did not reach at least US\$100 million in sales or for which either sales or forecast data were unavailable were excluded from the analysis. In cases where analysts' sales forecasts diverged widely, the highest sales forecast was used to determine the 50% threshold. There may be small variations in sales figures due to currency conversions.

2006-2008

2009-2011

Biopharma and medtech companies are accustomed to operating in a relatively slow-moving business environment, where product cycles last decades. The reality is portfolios are becoming more commoditized as multiple companies crowd therapeutic areas with competing products that work via similar mechanisms. "Genuine exclusivity in the marketplace is decreasing from eight years to about four years, when me-too competition begins," a senior biopharmaceutical executive told EY in an interview.

Unlocking future value

Most major life sciences companies remain vertically integrated business structures, organized around one of four broad business models:

- 1. Breakthrough innovator: Developer of best-in-class products that command high prices and are primarily paid for by health insurance.
- 2. **Disease manager:** Developer of products and solutions to manage chronic conditions end to end.
- 3. Efficient producer: Developer of lower cost products that perform as well as the competition.
- 4. Lifestyle manager: Developer of products aimed at prevention and overall health maintenance sold directly to the consumer.

For each of these business models, platforms have an important future role to play as life sciences companies respond to the changing demands of their different customers (see Figure 3).

Figure 3. Platforms of care create new opportunities for value creation

Four business models will define the response of life sciences companies and determine which capabilities they should prioritize.

	Breakthrough innovator	Disease manager	Efficient producer	Lifestyle manager			
Strategy	 Develop novel products with pricing flexibility 	 End-to-end management of chronic disease 	 Leverage innovator to create post-patent copies 	 Prevent disease and maintain health status 			
Competitive advantage	 Therapeutic area leadership 	 Creation of seamless customer experience 	 Lowest cost operator Ability to scale Fast-follower execution 	 Deep customer engagement Incentives to drive platform use 			
Value creation	 Leading R&D Real-world value Market dominance via platform 	 Long-term management of longitudinal patient journey Performance-based payment models 	 Business efficiency Focus on volume 	 Owning customer engagement platform Novel payment models 			
	Capabilities required for success						
Customer engagement	 Digital tools improve patient recruitment/ monitoring 	 Simple, robust connected devices/ platforms 	 Low-cost, automated delivery platforms 	 Digital marketing to customers' needs 			
Personalization	 Personalized or individualized treatment solutions 	 Customized services using behavioral and other data 	 Customized ordering/ payment services 	 Tailored lifestyle/health solutions 			
Data literacy	 Real-world data to validate innovations 	 Care algorithms from real-world and clinical data 	 Supply chain and manufacturing analytics 	 Analytics maximize consumers' health status 			

Source: EY. Concept developed from an initial idea first profiled by Prof. Brian D. Smith in his book, The Future of Pharma, published by Gower Publishing in 2011.

Today, consumers are urged to take charge of their care but do not have access to tools that can truly empower them. By offering a medium for the rapid exchange of data, a platform could help consumers to manage and track symptoms, discuss care options and receive education about how to make behavior changes.

"Platforms that utilize information from different stages of the patient journey to inform other stages could create meaningful value," predicts Christopher Bayley, Chief Information Officer, Smith & Nephew. He's seen their benefit in the hotel and leisure industry, where platforms specifically aimed at eliminating frictions in the travel experience have allowed companies such as AirBnb, HomeAway and TripAdvisor to take market share from traditional hotel and vacation incumbents.

Start-ups such as Glooko, Livongo and Onduo are already racing to develop these customer-centric platforms in diabetes. The goal for such "Disease manager" companies is to create holistic offerings that align around a consumer's individual physical and emotional needs, rather than requiring individuals to adopt standard, predetermined solutions that companies think individuals want.

Platforms could also be critical for companies or business units focused on being "Efficient producers" or "Lifestyle managers." In the case of Efficient producers, the goal is to maximize product volumes while maintaining a lowest cost base of operations. By altering the dynamics between demand and supply, platforms can transform manufacturing and distribution practices, creating new efficiencies. At the same time, Lifestyle managers could use AI and other emerging tools to create easy customer-facing interfaces that create future value by engaging consumers in real time while promoting behavioral change.

Platforms even offer potential benefits for the "Breakthrough innovator" business model. Because platforms promote the seamless sharing of data, real-world evidence can be fed back into earlier parts of the life sciences value chain, improving drug and device development processes and optimizing clinical trial design. Platforms can also enable new payment models that have been difficult to scale in the real world, a topic discussed in Chapter 4.

While the life sciences business model built on innovation will endure, the environment in which these companies operate will feel the effects of the 4.0 shift.

As Adam Schechter, Merck Executive Vice President, says, "The core of discovering, developing and delivering medicines and vaccines to improve global health will always be our center at Merck, but many things around this core are changing. That includes competition, the speed at which new products are introduced, and very importantly, the way we can demonstrate the value of these products to payers, patients and health care providers."

Winner takes all? How platforms create a first-mover advantage

The ability of both Facebook and Alibaba to shape dominant positions in key areas or markets demonstrates how platforms create an important first-mover advantage. In 2017, Facebook reported that its user base now numbered more than two billion people. In China, Alibaba dominates online commerce and had more than 450 million annual active buyers at the end of 2017. In each case, the strong initial growth of the platform created a positive feedback loop – a "network effect" – that ultimately resulted in dominance of the market.

How might this network effect play out in the health space? Consider the evolution of two different platforms focused on better diabetes management. Platform A combines a range of services, including cloud-based storage of A1c measurements, real-time message alerts to manage insulin levels and tools to track and analyze activity levels and nutritional intake. Platform B, in contrast, offers fewer services, perhaps only basic resources to monitor compliance and activity. As more and more diabetics congregate on Platform A, its growing popularity will influence other diabetics to sign up. In addition, as the user base expands, service providers are likely to prioritize participation in Platform A because of its greater reach. As additional services are added to Platform A, its functionality increases, due to the depth and breadth of the data that can be amassed from users' experiences. The end result: Platform A continues to grow more powerful, and likely will do so at the expense of Platform B.

Eventually, Platform A may grow so popular that it becomes a standard communal resource for diabetics and their care teams, providing critical communications tools, services and opportunities to accelerate research via clinical trial recruitment. As the aggregator of timely real-world data, Platform A's owner would play a central role within the diabetes health ecosystem and be in a prime position to identify additional unmet needs that could form the basis of new products – or even develop new payment models that are tied directly to improved health outcomes data. In a crowded and competitive market such as diabetes, this would be a powerful differentiator for Platform A's owner. Regardless of the business model, one important feature of platforms is their ability to create a positive feedback loop that encourages continued customer participation. Consider that online retail platforms have won over customers by creating easy-to-use and reliable interfaces to deliver a wide array of goods quickly, while protecting payment information. In the health arena, platforms that combine products and services that flag changing disease symptoms or help people take their medicines correctly could have a built-in advantage relative to standalone drugs or devices.

Because individuals get value from the totality of the offering, they are less likely to switch to a competing product, even when an individual drug or device might present a small advantage. As users engage in higher numbers and with greater frequency, the interface itself becomes more valuable because of the data generated. In essence, says Roger Longman, CEO of the reimbursement analytics focused start-up, Real Endpoints, platforms are "a great way to create incumbency." (See "Winner takes all? How platforms create a first-mover advantage.")

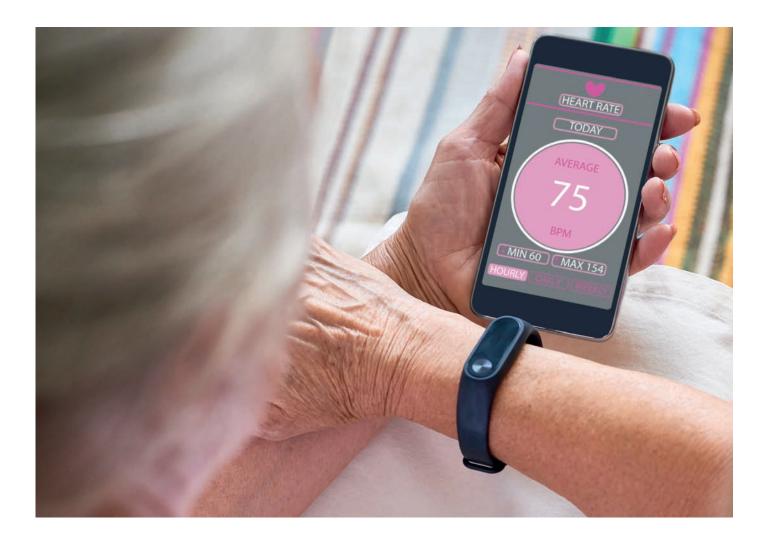
New capabilities

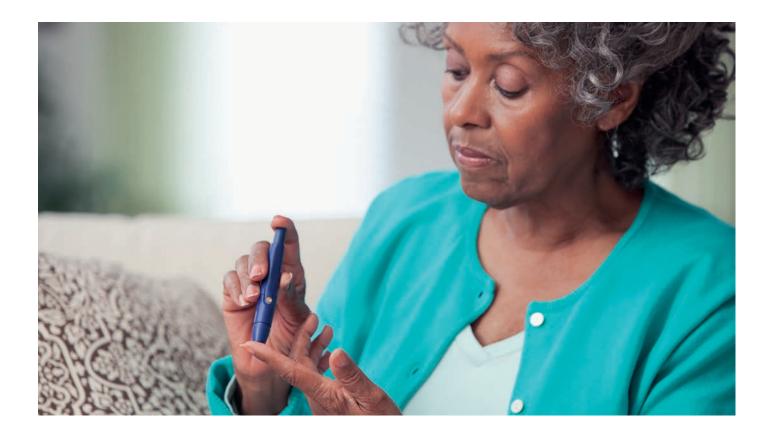
No matter the business model, succeeding in the emerging platform environment will require new capabilities in three distinct areas: customer engagement, personalization and data literacy.

Customer engagement: creating high-touch, high-information relationships

Leading platforms in other sectors establish direct linkages with customers via cloud- and mobile-based tools. That direct relationship remains a distant dream in the life sciences, in part due to regulations that limit direct to consumer interactions. But as companies working in the rare diseases space have shown, there are opportunities to cultivate high-touch, high-data relationships with consumers that improve health outcomes.

There's an appetite for such engagement on the individual's side, too. Apps such as the cancer-focused Belong have taken the established concept of the patient support network online, linking people to oncologists and other medical professionals,



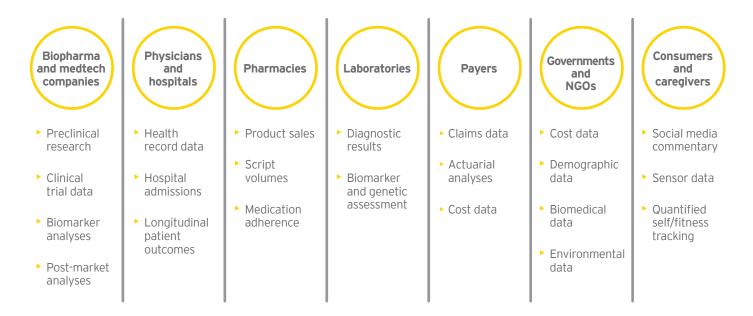


and providing a platform for securely storing and sharing personal data and documents. PatientsLikeMe, meanwhile, which launched as an online community in 2006 and now has more than 600,000 members, combines patient support with scientific rigor in its collection of robust, structured data. In this way, PatientsLikeMe signals the dividends platforms can yield for research, including clinical trial recruitment.

As in the consumer products world, the number of users matters; so do retention and scale. For life sciences companies, developing offerings that make people want to stay involved in their care will be essential. As life sciences companies forge stronger links with the end-users they serve, they can incorporate additional activities guiding the care journey, including remote monitoring and clinical decision support. While those services might first be focused on managing a specific condition, expanding services to promote the holistic management of health would make them even more valuable. For life sciences companies, developing offerings that make people want to stay involved in their care will be essential. As life sciences companies forge stronger links with the end-users they serve, they can incorporate additional activities guiding the care journey.

Figure 4. Health data are siloed across many different organizations

One key challenge for life sciences companies: accessing and integrating different data, which are stored in multiple locations in the health ecosystem.



Personalization: moving beyond clinical biomarkers

Personalization is one of the key opportunities emerging from the wealth of data generated via direct customer engagement. A number of studies indicate that billions of dollars are wasted annually in the US alone because of wasted or inappropriate care. People diagnosed with rheumatoid arthritis (RA), for instance, are prescribed one therapy, and then step through alternatives depending on their response and side effects. Despite having a range of therapeutic options to treat RA, treatment decisions are made via trial and error.

In the future, new tools such as machine learning will generate new patterns of evidence based on statistically significant responses observed in individuals with one set of risk factors and not another. As a result, physicians can more quickly determine which RA drug is right for a given person.

To transform business models, life sciences companies must also begin to define personalization more broadly than clinical data. Precision should incorporate an understanding of individual behavior, engagement style and tolerance for risk and uncertainty. Certain nudges or incentives are more likely to work for some people than others. The recent partnership between Merck KGaA and Blue Mesa to build a behavioral change program in diabetes hints at the potential of behavioral science to help improve clinical outcomes in many therapeutic areas.

"Behavioral data is going to be a very important aspect of these kinds of health care platform models," says Jennifer Lovejoy, Chief Translational Science Officer of the scientific wellness company, Arivale. Companies' ability to track behavioral data in real time and customize services accordingly will drive greater use of their products, she says.

In addition to Arivale, a number of new health ventures are beginning to offer more customized consumer services. The Chinese start-up iCarbonX, for instance, is building a Digital Life Alliance that incorporates offerings from at least six other health technology companies. Its goal is to build tools for personalized health management based on genomic, metabolomic, microbiomic and lifestyle data.

Data literacy: extracting value from data

There has been an explosion in the amount of health data now available, from clinical results to payers' claims data to genetic data to real-time data generated by mobile sensors. Whether life sciences companies can extract full value from these data depends on their ability to make the information usable. Currently, many life sciences companies lack access to data scientists, a highly prized resource in the modern economy. That isn't the only data-related challenge life sciences companies face. Health data are isolated in databases dispersed across the ecosystem (see Figure 4). Because of the way these databases are structured, it's difficult to interpret and use the data to improve health outcomes. Even when companies have significant reservoirs of health information within their own organizations, a significant proportion of it goes unused. A senior pharmaceutical executive quantified this dilemma at the 2018 J.P. Morgan Healthcare Conference, estimating his company currently uses less than 40% of the data it collects.

The path forward

Intuitively, it's not difficult to imagine the gains companies could realize from building or participating in platforms that achieve scale in a given disease area. Some life sciences companies might choose to develop and own their own platforms. Others will find ways of using or contributing to digital platforms built by other companies. In the next chapter we address where, and how, life sciences companies are partnering with other organizations to create platforms of care. To transform business models, life sciences companies must also begin to define personalization more broadly than clinical data. Precision should incorporate an understanding of individual behavior, engagement style and tolerance for risk and uncertainty.

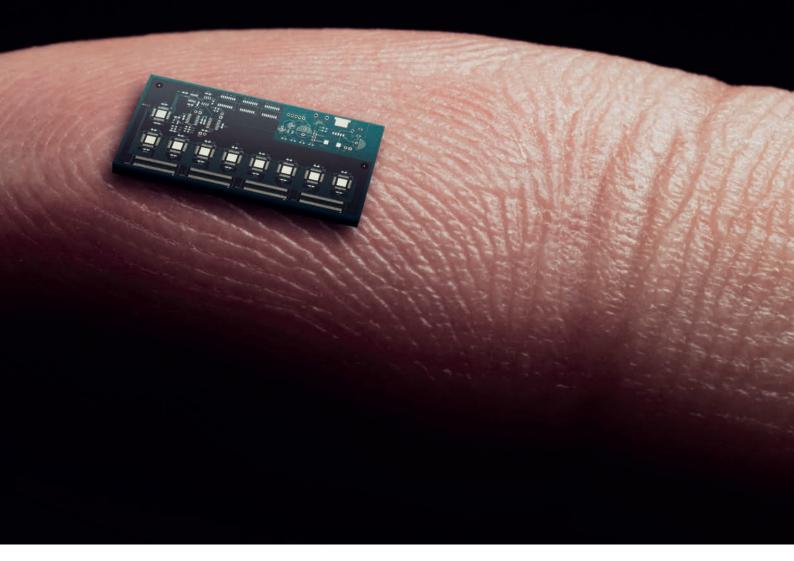
Questions to consider

- How will life sciences companies connect, combine and share currently siloed data to create value?
- How will platforms of care demand new customer engagement, personalization and data literacy skills?
- How do platforms of care create a first-mover advantage for early adopters?

03

How can life sciences companies participate in new platforms of care?

Platforms are emerging organically to manage certain chronic diseases and maintain wellness, but early efforts are modest. Most life sciences companies do not have the in-house capabilities or desire to build comprehensive platforms of care from scratch, so dealmaking will be essential. EY's analysis shows companies are using dealmaking to create new – or enhance existing – products and services, and to collect and structure real-world data.



The partnering imperative

Wellness-focused platforms of care linked to the development of fitness and nutrition solutions have already emerged. But we are only beginning to see the emergence of platforms for managing chronic diseases, particularly in diabetes and asthma (see Figure 1 next page). Outside these indications, there has been a proliferation of interesting, but ad hoc, point solutions. The result is often a confusing array of well-meaning, but siloed technologies that don't integrate seamlessly with each other or into someone's life.

When platforms start to achieve the scale needed to transform health delivery, we'll see a significant shift in value generation. That's because they provide the necessary tools for rapid and fluid connection, driving more effective and profitable interactions between stakeholders, as well as improving outcomes for consumers. Practices developed in the consumer genomics and end-stage renal disease spaces provide important sign posts for how platforms of care might evolve. (See "Helix: creating a consumer genomics platform" and "Fresenius Medical Care: providing differentiated care across the continuum.") The reality is many of the skills required to succeed in a platform-driven world, especially those tied to customer engagement, personalization and data literacy, are not core competencies for a majority of life sciences companies. Separately, very few, if any, life sciences companies have the financial wherewithal to build bespoke platforms of care from scratch on a timeline that is competitive with well-capitalized technology players.

However, the complexity of developing solutions that are engaging, data-rich and medically relevant also means technology companies don't have all the skills and medical knowledge required to create compelling offerings either. One reason technology companies have struggled in the health space is that they have created solutions that don't solve the most relevant health problems end-customers care about. Because life sciences companies understand consumers' unmet medical needs and how to develop products within today's existing regulatory framework, they have an opportunity – if they choose to seize it – to take a leading role in shaping embryonic platforms of care. Because life sciences companies understand consumers' unmet medical needs and how to develop products within today's existing regulatory framework, they have an opportunity – if they choose to seize it – to take a leading role in shaping embryonic platforms of care.

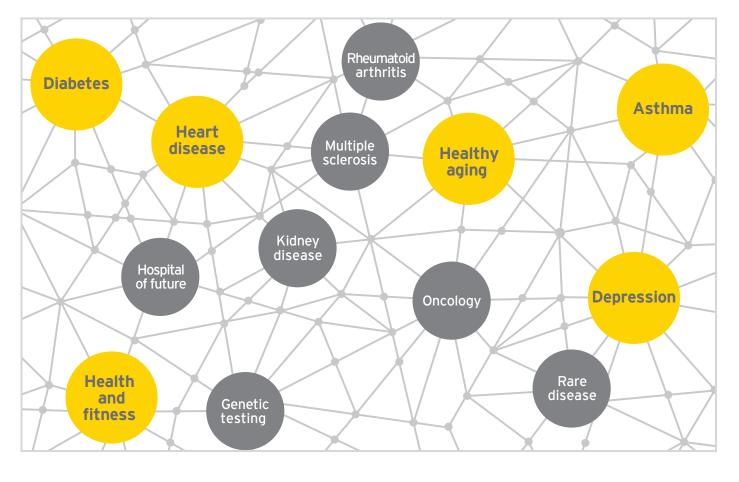


Figure 1. Platforms of care are emerging first to manage fitness and certain chronic diseases

Laying the foundation

At least initially, multiple care platforms for the same disease area or health purpose will be created and orbit around the individual. Over time, however, leading platforms in specific disease categories will likely emerge as users gravitate to one platform or another depending on where customers find greater value. In addition, as global technology players build data and analytics capabilities, these organizations will drive the emergence of supra-platform aggregators operating one layer above individual platforms of care. These aggregators will connect data generated from discrete disease-specific platforms to help individuals and health systems address larger health goals that might be linked to wellness and prevention, as well as the improved management of populations.

For the greatest impact, platforms of care require the participation of multiple stakeholders united in their definition of delivering future value. To achieve this goal, collaborations must span public and private entities across a number of industries, including health care, consumer products, technology and life sciences. That's because stakeholders in each of these industries bring unique skills or resources that, when combined, empower individuals to become super consumers. This fluidity of interaction ultimately drives a deeper bond between individuals, care providers, payers and life sciences companies.

> Initially, multiple care platforms for the same disease area or health purpose will be created and orbit around the individual. Over time, however, leading platforms in specific disease categories will likely emerge.

Helix: creating a consumer genomics platform

Helix was formed in 2015 as a spin-out of the next-generation sequencing company Illumina. Helix is a personal genomics platform that enables every person to get sequenced once, and query their data longitudinally. Helix also hosts a store of applications that offer interpretations of one's genome in various categories: ancestry, entertainment, family, fitness, health and nutrition. Helix's partners can develop new products on the platform by leveraging APIs, thus greatly reducing the capital and workforce requirements to utilize genomic data in their applications or products. Products launched on Helix must pass its internal Scientific Evidence Evaluation (SEE).

As Dr. James Lu, Co-founder and Senior Vice President of Applied Genomics at Helix describes it, "We have built a platform around longitudinal use of one's genomic information. This platform includes laboratory and data services, all enabled through microservices architecture. Interpretation products built by partners can be purchased by individuals."

National Geographic's Geno 2.0 ancestry test was the first product to debut on the Helix platform. Users are sent Helix DNA collection kits, which are returned to Helix's CLIA- and CAP-accredited lab. All tests are run on Helix's custom Exome+ assay. Helix then performs all the relevant bioinformatics and provides just the portion of genomic information necessary for their ancestry product to National Geographic. National Geographic then runs its own interpretation and returns that analysis directly to users through the Geno 2.0 experience.

There are now over 35 products available at Helix's marketplace and the company expects that to double this year. By providing standardized genomic services, Helix is leveraging technology from other well-known platforms that enable their partners to build more complex offerings in a variety of ways.

Fresenius Medical Care: providing differentiated care across the continuum

Fresenius Medical Care has a footprint in more than 120 countries and operates more than 3,400 dialysis clinics worldwide. The company is noted for its focus on providing integrated care solutions tailored to the needs and preferences of its patients, including where the individual receives care (e.g., at home, in the clinic or at the hospital).

In North America, Fresenius Medical Care's push to integrate care around the patient has been driven at least partially by the use of capitation, a style of reimbursement that pays a single bundled rate for treatment to pay for end-stage renal disease. This reimbursement shift has given the company incentives to collect data that enable more proactive management of dialysis patients, including comorbidities that might affect outcomes but aren't strictly related to chronic kidney disease. "We don't look like the traditional dialysis company today," observes Frank Maddux, MD, FACP, Chief Medical Officer and Executive Vice President of Clinical and Scientific Affairs for Fresenius Medical Care North America (FMCNA).

As FMCNA has developed richer seams of data, the company has also expanded its expertise in analytics. Not only does the company have a better understanding of the medical risks associated with its patient population, but it is using this knowledge to develop algorithms that improve treatment protocols. "Our goal," says Maddux, "is to use analytics to help change clinical practice and create new, better standards of care."

FMCNA's decision to focus on a single therapy area, chronic kidney disease, makes it easier for the company to provide a continuum of care and proactively manage treatment risks. As a result, it is more deeply embedded in the health ecosystem than other traditional life sciences companies. Still, the capabilities it has built are harbinger of what's to come as platforms of care emerge in other disease areas. These resources can be grouped in the following categories:

- Innovative technologies: Companies in the technology and medical device space are creating connected devices that can generate the real-world data required to better understand the consumer's health journey. As those connected devices are bundled with other products and services, biopharma and medtech companies have a role to play in developing solutions that are powerful enough to provide a step change in health outcomes.
- Data and analytics: Enabling technologies, including AI, offer the promise of making it easier to connect, interpret and share diverse data streams. As these technologies mature, global technology players can partner with life sciences companies to develop offerings that interweave insights from currently distinct care platforms. AstraZeneca, for instance, has partnered with the Chinese e-commerce giant Alibaba to use the tech company's AI capabilities to safeguard the medical supply chain and improve disease education and chronic disease management. In addition to global technology players, governments have a role to play in developing regulations that promote the safe and appropriate sharing of data.
- User design: As noted in Chapter 2, the ability to create engaging easy-to-use solutions that naturally fit into the daily routines of customers will be essential if platforms of care are to achieve widespread use. Any strategy that adds complexity or makes participation more difficult is counter-productive because it detracts from the experience. Just look at the thousands of health care apps and fitness trackers that are used briefly but then abandoned. As technologies converge to create platforms of care, working with sophisticated retailers to improve the overall health experience could be a differentiating factor.
- Health relevance: For platforms to demonstrate value, they must eliminate discontinuities in the health journey to improve outcomes or lower costs (or preferably both). To make sure emerging solutions are fit for purpose, physicians and payers need to play a role in pressure-testing their development. There is an opportunity for these two stakeholder groups to drive individuals to the most robust, medically relevant care platforms by creating incentives for platform participation.

31

It might seem counterintuitive to see a big push to develop platforms of care in oncology. A number of conditions make the cancer arena ripe for a platform-based approach.

Likewise in diabetes, all three major insulin providers have formed partnerships to better empower and engage consumers in their care. Sanofi and Alphabet's Verily Life Sciences have created the joint venture Onduo, a "virtual diabetes clinic;" Eli Lilly, meanwhile, has partnered with Livongo to conduct real-world trials aimed at better understanding consumers' health behaviors and how to more actively engage diabetics in their own care; and Novo Nordisk has partnered with Glooko to launch a free mobile app for diabetes management. At the same time, Roche took a step forward in building a patient-centered digital health services platform via its 2017 acquisition of mySugr, and Johnson & Johnson continued to extend its capabilities via agreements with Qualcomm and WellDoc.

Given the pricing flexibility and exclusivity many cancer therapeutics currently enjoy, it might seem counterintuitive to see a big push to develop platforms of care in oncology. However, a number of conditions make the cancer arena ripe for a platform-based approach. First, certain cancers (e.g., multiple myeloma) are no longer acute diseases but chronic conditions that must be managed over a period of years. Second, as the desire to combine and customize therapeutics based on molecular or other clinical tests grows, there are opportunities for holistic platforms of care that optimize individual treatment pathways. Third, as more biopharmas compete to bring therapeutics to market and competition from biosimilars grows, the perceived differentiation for any one product can be harder to demonstrate to payer and physician stakeholders. Platforms can help first movers distinguish themselves in this crowded marketplace.

Oncology-focused platforms of care could also improve R&D activities. That's one reason why Novartis in 2017 signed a multi-year partnership with Cota Healthcare, a data visualization and analysis company. The two groups will use Cota's web-based analytical tools to identify likely responders to new breast cancer treatments.

Capital: Scaling platforms of care will require capital to mitigate the financial risks associated with their creation and deployment. A range of companies, including strategic investors from technology or life sciences companies, can play a role here. Biopharmas or medtechs interested in differentiating their products from the competition via a platform might choose to participate in platforms first as financial backers as a mechanism to gain greater familiarity with how they operate.

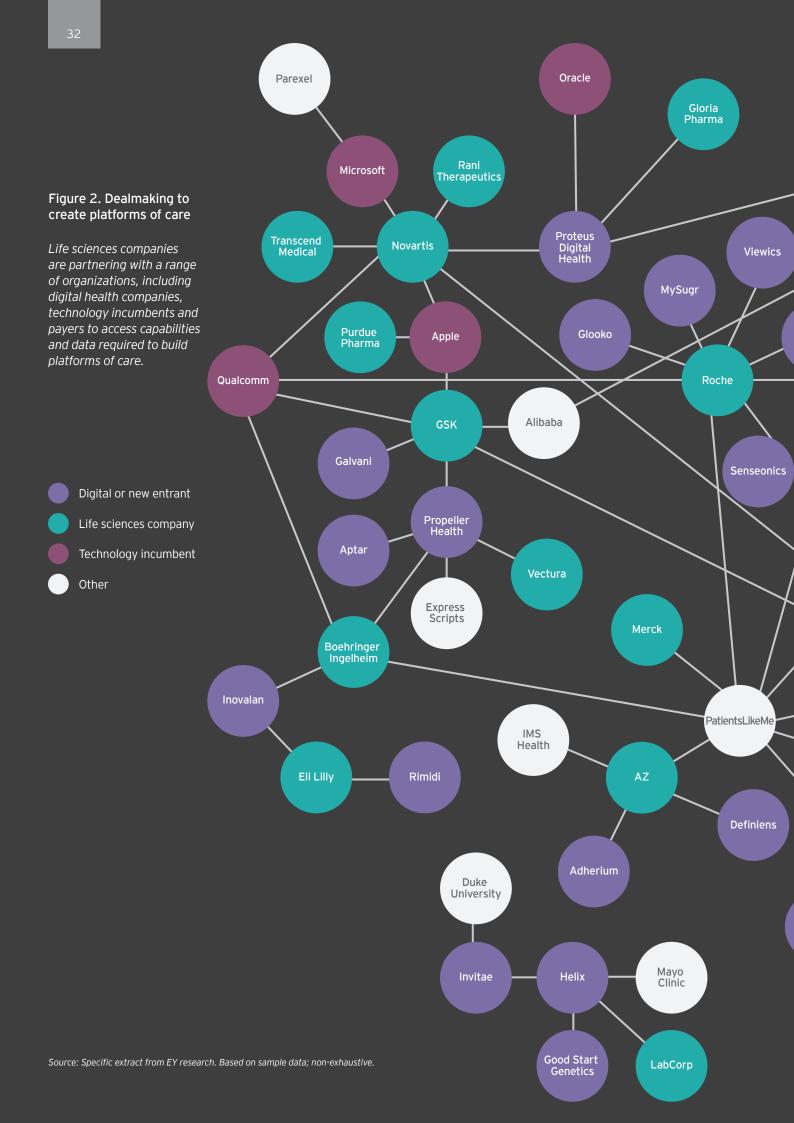
Creating tomorrow's care platforms

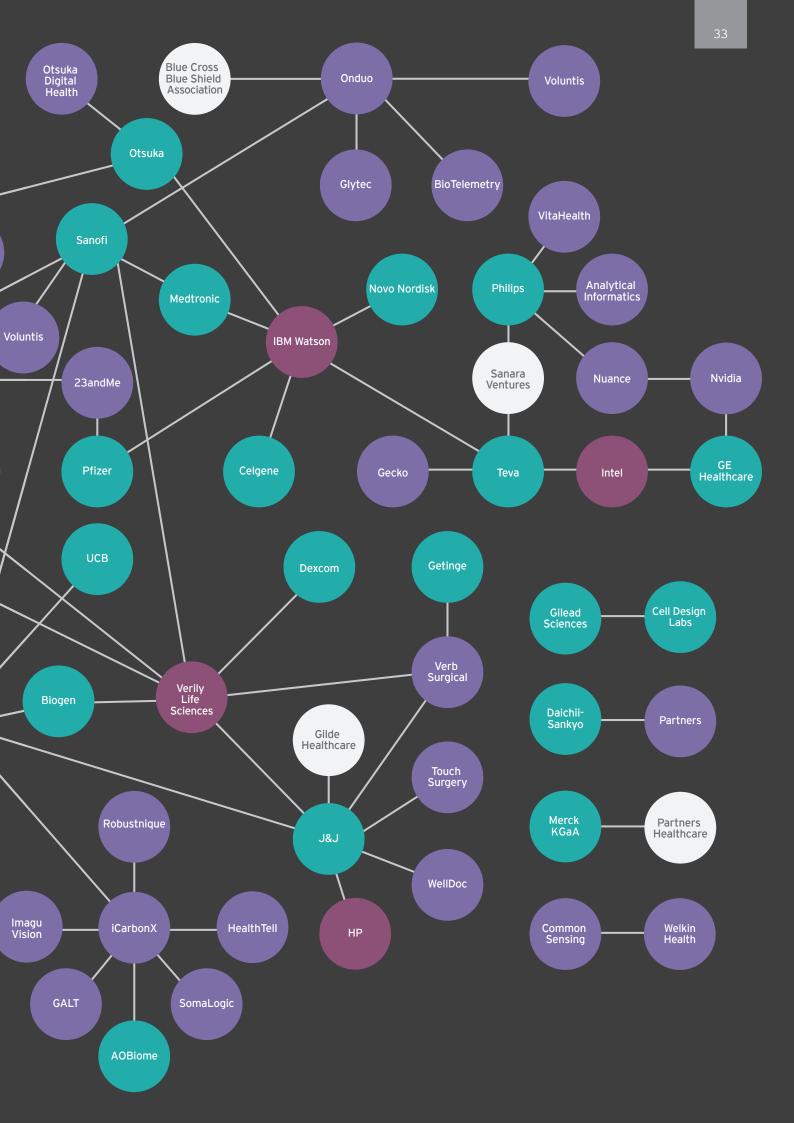
To better understand where life sciences companies are partnering to build capabilities or access resources, EY spoke with more than 25 life sciences leaders from October 2017 to January 2018 and analyzed more than 150 digitally focused partnerships announced between life sciences companies and other stakeholders since 2014. These efforts build on the EY 2018 *Digital Deal Economy* study, which tabulated responses from more than 900 senior executives across all industries to understand how dealmaking can accelerate the formation of digital platforms.¹¹

No single external database tracks partnerships of a digital nature, so EY created its own digital deals database, searching company reports, news releases and third-party analyst reports for relevant partnerships, as described in the 2017 paper *Digital deals: spotlight on life sciences*. Our study reveals a complicated web of relationships emerging between biopharma, medtech, digital health start-ups and technology companies (see Figure 2 next page).

We also analyzed the findings to understand the growth in partnerships over time, the therapeutic areas commanding the greatest interest and the types of capabilities being accessed. (See "Partnering to create platforms: dealmaking trends.") Of the nearly 90 partnerships with a clear therapeutic area of focus, 50% of them involve platform capabilities in the diabetes or respiratory arenas, while 14% involve oncology-focused products or services.

The emphasis on new platforms in respiratory care and diabetes is unsurprising. In both cases, the competitive landscape is fierce – many products are either already generic or soon will be – and advances in sensors have created opportunities for smart, connected devices to capture user-generated data to inform care management. In 2018, for instance, every major biopharma with a significant respiratory franchise has now partnered with, or invested in, companies developing connected inhaler technology.





Partnering to create platforms: dealmaking trends

EY's research suggests there are three main reasons life sciences companies seek partnerships to build platform capabilities (see Figure 3). They are:

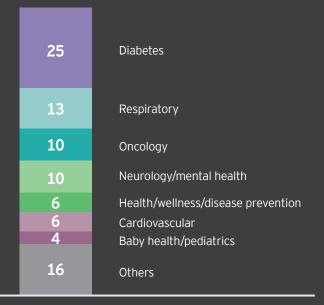
1. **Create a new product or service:** Many life sciences companies are partnering to create new products or services that provide end-to-end solutions. Indeed, 51% of the platform partnering deals EY reviewed belong in this category. Notable examples include Novo Nordisk's alliance with Glooko to create a diabetes management app and UCB's partnership with Garmin to build a wearable pilot program tied to the drug Cimzia.

2. Improve an existing product or service:

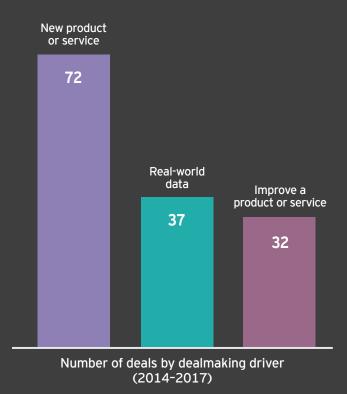
Of the partnerships we analyzed, 23% are designed to improve a current product or service offering by adding capabilities linked to real-time data capture or improved consumer engagement. Partnerships to improve management of respiratory conditions and diabetes figured prominently.

3. Collect real-world data: Another 26% of partnerships are driven primarily by product developers' need to marry clinical data with real-world data to inform R&D and commercial activities. Companies are aware that data streams from wearables and sensors allow real-time feedback, creating an opportunity for continuous learning in clinical trials via analytics. Many of the first efforts are clustered in neurological indications where measuring product efficacy and disease progression have historically depended on subjective survey data. Teva Pharmaceutical Industries, for instance, partnered with Intel in September 2016 to incorporate data from wearable devices into a Phase II trial monitoring disease progression in Huntington disease; that same year, Novartis and Microsoft launched Assess MS, to better evaluate how individuals perform on MS tests using Xbox's Kinect technology.

Figure 3. Partnering to create care platforms: where the deals are



Number of platform deals by therapeutic area (2014-2017)



Source: EY research. Based on sample of non-exhaustive data from 2014 to 2017.

The importance of being brand-agnostic

Currently, product developers interested in accelerating customer-centric care platforms face challenges in identifying who to partner with to create the most natural and engaging solutions. For the near term, the focus will be on consolidating capabilities in given disease areas to further extend market reach and know-how. That has already begun to happen in the diabetes and respiratory spaces. As product developers join forces with innovators, payers and physicians to develop more integrated solutions, the emphasis will shift to the creation of more holistic care platforms that manage complicated disease conditions across the care continuum.

In practice, not every company will be able, or want, to take ownership of the entire continuum of care. Strategies will vary depending on how confident a company feels about its ability to provide a range of products and offerings. As Fresenius Medical Care's Maddux says, "Some will try to take on that whole continuum and some will incorporate pieces of it. The companies that become platform players will be more driven to owning a substantive portion of the continuum."

To be most successful, however, these holistic platforms must be brand-agnostic. In other words, they shouldn't be designed to drive sales of certain therapeutics or devices. There are regulatory, ethical and practical reasons why such an approach would be counter-productive. From a consumer perspective, for instance, a care platform tied specifically to one brand of insulin or glucose meter would have limited functionality, perhaps providing drug dosing information but not necessarily addressing wider issues related to the customer's day-to-day experience with diabetes. Such a product-centric approach would also do little to repair the current trust deficit associated with many life sciences companies, particular big pharmaceutical manufacturers. Product developers interested in accelerating customer-centric care platforms face challenges in identifying who to partner with to create the most natural and engaging solutions. For the near term, the focus will be on consolidating capabilities in given disease areas to further extend market reach and know-how.

First mover or first responder?

There are many ways for life sciences companies to participate in a platform-based economy and create value. For instance, life sciences could be "first movers" or "first responders." First movers will invest in the creation of platforms themselves either financially or through the development of infrastructure and offerings, while first responders contribute relevant products and services to the platform and its participants.

The form those products and services take will almost certainly need to be different than it is today; it will be less about the specificity of a brand and more about the ease with which a product or service can connect to an existing platform. The good news is there is room within the same organization to be both a first mover and a first responder. The specific approach a company, or business unit, chooses to take will depend on a number of factors, including the therapeutic area of interest, the competitive landscape and partnering opportunities.

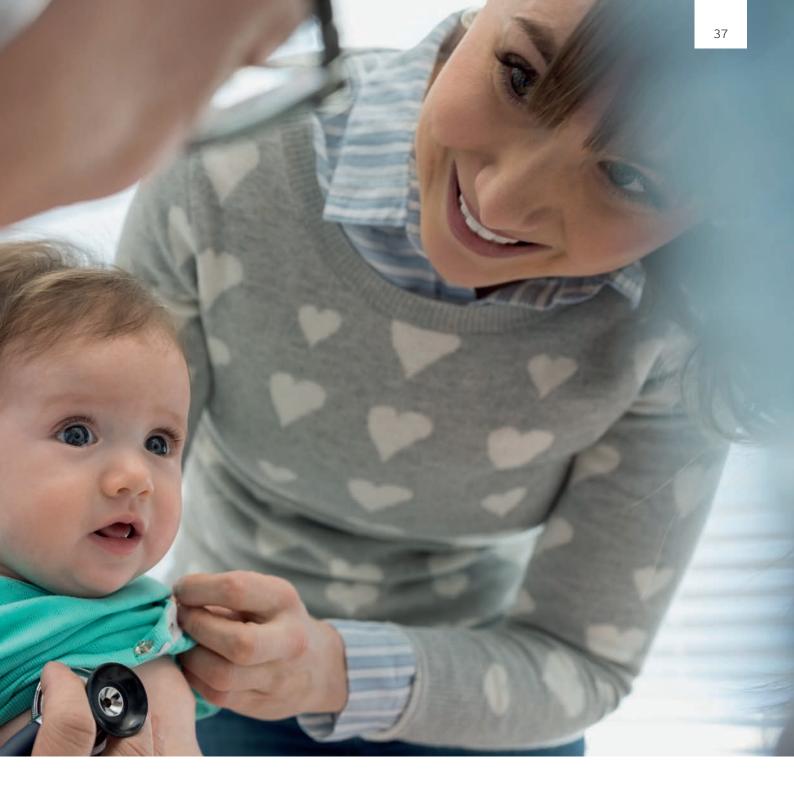
Questions to consider

- Where are platforms emerging and why?
- Create platforms or contribute to them what role should your organization play?
- Who should you partner with to create winning platforms of care?



How will platforms accelerate value-based health care?

Because of global cost constraints, tweaking payment models is not enough to achieve value-based health care; more radical revision is required. Life sciences companies must move beyond product-centric definitions of value and create sophisticated datadriven partnerships that share value with other health stakeholders. Platforms that support the easy and transparent collection, combination and sharing of data will be essential to the success of these partnerships.



Achieving a shared vision

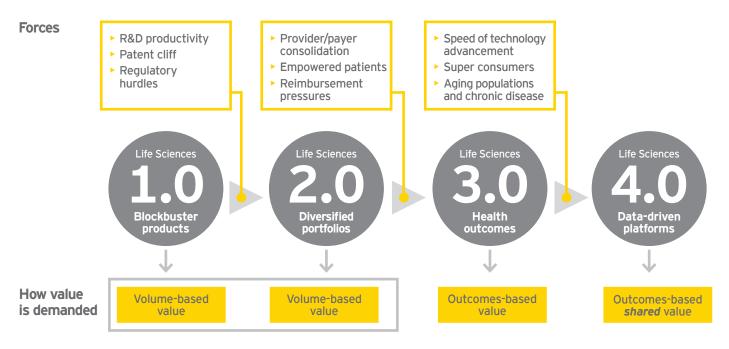
While life sciences companies have begun to sign deals that integrate digital services and tools with traditional products, robust platforms of care won't become a reality unless partnerships with other stakeholders in the ecosystem accelerate. The success of those partnerships – and the ability to move to new value-based models of care – depends on the ability to create a common vision of future value that moves from volume to outcomes to outcomes-based shared value. "It's time," says Jason Helgerson, Medicaid Director at the State of New York Department of Health, "to create new relationships between manufacturers and other health stakeholders that aren't just about buying a drug or device. These relationships should be about buying a whole care model of which the product is just one part."

Central to achieving this vision is an ability to define, and then deliver, the

outcomes that are most meaningful to individual stakeholders (see Figure 1 next page). That is challenging because stakeholders are not only starting from different objectives but also have different time horizons for when those outcomes must be achieved. This misalignment makes it more difficult to identify definitions of shared value that extend beyond those needed to pass regulatory hurdles.

Figure 1. In Life Sciences 4.0, value will be shared across multiple stakeholders in the ecosystem

To be rewarded in the future, life sciences companies must adopt business models that share outcomes-based value with payers, physicians and consumers.



Indeed, as we move to a more integrated system in which value is shared by multiple stakeholders, the outcomes that matter to each will continue to evolve. For the payer or policymaker, the most desired near-term outcomes relate to cost-effectiveness or the elimination of wasteful care. As aging populations become more prevalent, broader, more humanistic goals linked to social welfare and productivity may grow in importance.

For the physician or care provider, the outcomes of greatest priority today center on reducing care inefficiencies or improving care delivery for the sickest, frailest individuals. In the future, as these providers adapt to market forces by creating new models of care delivery, economic- and population-based outcomes could be more significant. Finally, as patients become super consumers and take on a greater share of the cost of their own treatments, they will begin to define value using economic metrics, as well as clinical and quality of life parameters (see Figures 2 and 3).

To be successful, systems need to be flexible enough to meet these changing definitions of shared value. In addition agility and the ability to understand and then deliver specific outcomes to specific customers will become increasingly important in the future. Robust platforms of care won't become a reality unless partnerships with other stakeholders in the ecosystem accelerate. The success of those partnerships – and the ability to move to new value-based models of care – depends on the ability to create a common vision of future value that moves from volume to outcomes to outcomes-based shared value. Figure 2. Creating future shared value is about aligning stakeholder objectives

Different health stakeholders have their own priorities. In the future, success will be measured by the ability to find common ground to meet these demands.

As a patient/consumer	How can I get the right, affordable treatment and support to be healthy?
As a physician/care provider	How can I deliver the most cost-effective treatment to achieve health improvement?
As a payer	How can I provide the most cost-effective health solutions to get impact, and transition to them?
As a policymaker	How can I have a transparent market with a balance of health improvement versus cost?
As a biopharma or medtech	How can I get appropriately paid for providing the right treatment solution?

Figure 3. Platforms allow life sciences companies to create future shared value with multiple health stakeholders

Health outcomes can be defined across three different dimensions – clinical, economic and humanistic. To be successful in the future, life sciences companies must be agile enough to deliver the right outcome quickly and reliably to the right stakeholder.



Technology platforms do not eliminate challenges related to misaligned incentives that favor fee-for-service providers and the hoarding of data. However platforms, by making data sharing easier and more secure, can ease friction and create opportunities for shared economic growth.

When shared interests can be identified – for instance, medication adherence – platforms can enable multiple stakeholders to benefit. Fundamentally, says James Lu, Co-founder and Senior Vice President of Applied Genomics at Helix, "It's about creating a model that allows different stakeholders to benefit from shared incentives."

Building a bridge, not a wedge with data

In recent years, life sciences companies have taken steps to develop patient education and awareness programs, bolstering their position within the wider health ecosystem. Still, a significant trust gap still exists (see "Breaking the trust barrier").

As care platforms become a more important part of capturing future value, life sciences companies can deepen existing relationships using data. They can help stakeholders achieve value-based care goals that include increasing the quality of care delivery, lowering the total cost of care, and most importantly, improving overall long-term health outcomes.

Data-driven stakeholder engagement

Physicians: Studies suggest high-prescribing physicians are contacted by drug makers nearly 3,000 times a year, but most of these interactions are not tailored to the physicians' priorities and may seem unwelcome at a time when they are struggling to deliver higher quality care in shorter appointment times. Life sciences companies are now developing physician-directed digital tools that are more tailored and personal. There is more work to do, however, to create systems that leverage real-time data and analytics to help physician groups manage their patient populations more efficiently and effectively.

Consumers: As manufacturers develop their analytics capabilities, they can further enhance the consumer experience by providing tailored interactions to promote medication adherence or healthy behaviors such as better sleep hygiene. Data analytics could also be a valuable tool for providing disease education. Mining metadata from social media (e.g., Twitter, Facebook and YouTube), biopharmas and medtechs could help develop clinical descriptions of disease that are consistent with how individuals themselves discuss their symptoms. This terminology could then be used to develop more meaningful consumer-based education portals, as well as inform R&D activities.

All of these approaches offer considerable potential, though companies will need to tread carefully. Guidance spelling out how companies can interact with consumers safely and legally continues to evolve (see *"Partnering with regulators"*). There is also clear evidence that people want brand-agnostic information, not materials linked to a specific therapy. Success will depend partly on establishing a new social contract that makes individuals more willing to share their personal data with non-provider stakeholders in the health space.

Payers: A small number of life sciences companies have begun to work directly with payers on performance-based agreements that link product reimbursement to improved health outcomes. The current crop of outcomes-based contracts are still too limited in scope to drive a meaningful shift in reimbursement on their own, however. Many contracts have focused on the reimbursement of diabetes or cardiovascular products, where outcomes are easy to agree upon and measure, and the time to generate results is just weeks or months. Now the advent of more complicated, more expensive curative cellular and genetic therapies is driving renewed attempts from both life sciences companies and payers to embrace new value-based models (see Figure 4).

Policymakers: Across all geographies, governments want to digitize health care and shift delivery to lower cost settings. Efforts to date have focused on creating necessary infrastructure, including electronic health records (EHRs), online systems for procurement and regulatory submissions, and systems to trace the movement of products through the supply chain. Delivering care via digital platforms gives life science companies multiple opportunities to align their offerings with policymakers' current priorities. The groups can collaborate to accelerate value-based health care by co-developing frameworks for sharing and standardizing data, for instance.

"It's about creating a model that allows different stakeholders to benefit from shared incentives."

> – James Lu, Co-founder and SVP of Applied Genomics, Helix

Year	Company	Payer (country)	Product (therapeutic area)	Summary	
2011	AstraZeneca	AMNOG (Germany)	Brilique (acute coronary syndrome)	In one of the first early-benefit assessments now conducted as standard in Germany, Brilique was shown to have considerable benefit versus alternatives in non ST-elevation myocardial infarction/unstable angina patients.	
2014	Gilead Sciences	TLV (Sweden)	Sovaldi (hepatitis C)	Sweden's TLV, which has overseen pricing and reimbursement since 2002, established a risk-sharing agreement for Sovaldi, with refunds paid to local councils.	
2015	Celgene	CEPS (France)	Imnovid (oncology)	Celgene agreed to one of the first outcomes-based pricing agreements in France, undertaking to repay the cost of the initial 21-day treatment period if ineffective.	
2016	GlaxoSmithKline	Italian Medicines Agency (AIFA)	Strimvelis (ADA-SCID)	AIFA will pay for the Strimvelis gene therapy, indicated for pediatric ADA-SCID, only if it successfully demonstrates a cure.	
2016	Eli Lilly	Harvard Pilgrim (US)	Trulicity (diabetes)	Deal mandates enlarged rebate to payer if fewer Trulicity patients reach A1c target compared to other GLP-1 drugs.	
2016	Novartis	Aetna (US)	Entresto (heart failure)	Payment for Entresto is linked to the number of hospitalizations due to heart failure occurring in the treated population.	
2017	Merck KGaA	NHS England (UK)	Mavenclad (multiple sclerosis)	A first-of-its-kind outcomes-based deal for the NHS allowed patients early access to the drug, with a NICE appraisal to be conducted concurrently.	
2017	Medtronic	Aetna (US)	Insulin pumps, including MiniMed 670G system (diabetes)	Value-based agreement partially ties Medtronic's reimbursement to successfully meeting clinical improvement thresholds.	
2017	Myriad Genetics	UnitedHealthcare (US)	Various	Collaboration establishes pricing for diagnostic tests in multiple therapeutic areas including breast cancer, prostate cancer, rheumatoid arthritis and neuropsychiatry.	
2017	Novartis	Centers for Medicare and Medicaid Services (US)	Kymriah (oncology)	CMS will only pay for Kymriah if patients respond within one month of inititating treatment.	

Source: EY research, company filings, and the following country-specific health technology assessment organizations: France – Economic Committee on Health Care Products (CEPS); Germany – Institute for Quality and Efficiency in Health Care (IQWiG); Italy – Italian Medicines Agency (AIFA); Sweden – Swedish Agency For Health Technology Assessment and Assessment of Social Services (SBU); United Kingdom – National Health Service.

Breaking the trust barrier

Life sciences companies struggle to build trusted relationships with their stakeholders, despite creating innovations that contribute to human health. In a 2016 Gallup poll assessing corporate reputations, for instance, 50% of more than 1000 randomly selected adults gave the pharmaceutical industry a negative ranking, making it the second least popular business sector. That is the pharmaceutical industry's worst showing in the survey's 16-year history.¹²

These negative perceptions arise for a simple, but fundamental, reason: the industry has failed to define innovation in ways that are consistent with stakeholders' definition of shared value. High-profile instances of predatory product pricing, deals to stifle competition and the withholding of negative clinical trial data tarnish the entire industry – even if the actions are practiced by a minority of companies. More broadly, the high upfront price tags of new therapeutics or devices have made it easier to advocate for pricing and intellectual property reforms that exacerbate the power shift away from life sciences companies toward more informed and connected payers, physicians and consumers.

Life sciences companies have already responded to these reforms by moving to specialty arenas tied to oncology and rare diseases, where there is a greater chance of market exclusivity and pricing flexibility.

¹² L. Saad, "Restaurants Again Voted Most Popular US Industry," Gallup, August 2016. Available from: http://news.gallup.com/poll/194570/ restaurants-again-voted-popular-industry.aspx.

Future models

Ultimately, to accelerate the shift to value-based health care, new models are required that engage stakeholders and share risk more broadly. These new models are outlined in Figure 5 on the next page.

Subscription-based models

Consumers are increasingly comfortable with models in which they lease access to a product or service (e.g., music, books, mobile phone usage, internet access or even cars), pay a regular membership fee to participate (Netflix or Amazon Prime) or commit to buying products at regular intervals for discounts (e.g., cleaning supplies or toilet paper). Why not pay for health care products in a similar way?

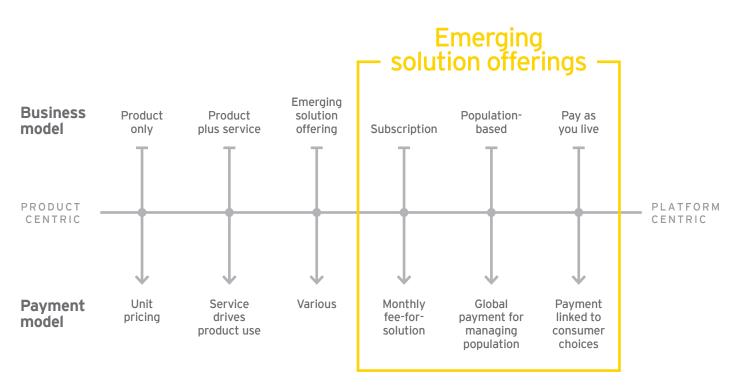
Subscription-based businesses that charge a regular fee for personalized solutions are not that different from how many pharmacies approach prescription refills or evolving models linked to concierge medicine. In the latter case, consumers pay a retainer to gain access to a number of enhanced and more convenient services such as same-day appointments or increased access to the care team via phone, email and video channels. On the health care delivery side, these recurring revenue arrangements, which are still a minority, foster long-term, deeper relationships between physicians and consumers.

Subscription models allow consumers to pay for higher touch care in increments, making the service more affordable. For physicians, these models allow them to spend more time with individuals with more complicated medical needs than in today's volume-focused system.

Consumers are increasingly comfortable with models in which they lease access to a product or service, pay a regular membership fee to participate or commit to buying products at regular intervals for discounts. Why not pay for health care products in a similar way?

Figure 5. New payment models will emerge with the formation of data-driven platforms of care and will accelerate value-based health care

Platforms can help accelerate alternative payment models that share risk differently with payers, physicians and consumers.



For life sciences companies, subscription models provide opportunities to engage directly with other health stakeholders to promote medication adherence or long-term behavioral change.

Population-based models

Population-based models, also known as capitated or bundled care models, pay a physician or group of physicians a set amount for each enrolled individual assigned to them during a defined period, whether or not that person seeks care. The idea is to divorce physician reimbursement from service volume, and create incentives that standardize treatment protocols to provide the most cost-effective care to the greatest number of people.

In most cases, life sciences products and services have yet to be fully included in population-based payment models. One notable exception is end-stage renal disease, where reimbursement in the US has been driven by global payments since 2011 (see "Fresenius Medical Care: providing differentiated care across the continuum").

Outside end-stage renal disease, diabetes is another area ripe for population-based payment models. Indeed, in June 2017, Medtronic and Aetna announced an outcomes-based payment model that links reimbursement of Medtronic's self-adjusting insulin pump and support services to its ability to help type 1 and type 2 diabetics meet certain pre-agreed upon clinical thresholds.

The complexities of defining which products and services are included in the payment model have limited the number of stakeholders willing to follow Medtronic's lead. Time-bound bundles that define the scope of services and products provided during a discrete period (also known as an "episode of care") are another solution for life sciences companies to consider as they look for opportunities to engage with payer and physician stakeholders.

Pay as you live models

A recent trend in the insurance market is the rise of "pay as you live" (PAYL) models that reward customers for adopting healthy behaviors such as maintaining a healthy body weight or not smoking. In exchange for providing data to the insurer via wearables or mobile phones, consumers are encouraged – in the form of lower premiums and personalized solutions – to make long-term changes that reduce the risk of chronic illness.

Partnering with regulators

Life sciences companies must work with regulators to shape policies that make expanded volumes of clinical and real-world data more accessible. On both sides, historically protective attitudes toward data have hindered collaboration.

But sharing data is a prerequisite for value based health care. As a paper from the World Economic Forum notes, value based approaches can only work if regulators overcome their historically "too-stringent tack on data privacy," while life sciences companies, providers and other institutions renounce their tendency to "hoard data for reasons of self-interest or perceived competitive advantage."¹³

Close cooperation between companies and regulators will also be needed to validate the use of digital technologies that will generate future clinical data. The U.S. Food & Drug Administration has taken some steps toward putting the regulation of digital devices on a formal footing, beginning with the 2016 measures announced in the 21st Century Cures Act. The European Medicines Agency has been less explicit about its planned approach.

In the future, agencies may have to create an entirely bespoke validation framework to regulate and certify digital products entering the market. Such a framework would lessen the risk that consumers would be exposed to what James Madara, CEO and EVP of the American Medical Association, calls "the digital snake oil of the early 21st century": direct-to-consumer tools based on limited evidence or apps of mixed quality.¹⁴

¹³ "Value in Healthcare: Laying the Foundations with Health System Transformation," World Economic Forum paper, (April 2017), p.28. Available at: http://www3.weforum.org/docs/WEF_Insight_Report_Value_Healthcare_ Laying_Foundation.pdf

¹⁴ "AMA CEO Outlines Digital Challenges, Opportunities Facing Medicine," American Medical Association, June 11, 2016. Available at: https://www.amaassn.org/ama-ceo-outlines-digital-challenges-opportunities-facing-medicine



While most current PAYL models are linked to wellness, they could be adapted to the treatment of diseases, especially chronic conditions, and involve not just insurers but life sciences companies as well. A biopharma company that develops a medication adherence solution to support consumers with heart disease, for instance, could take that solution directly to consumers, developing a strategy that ties the cost of the service (or the product) to the individual's ability to remain compliant with the therapeutic regimen. Alternatively, it could form a consortium with insurers and providers that links payment for the beyond the product solution to some pre-agreed adherence metric.

A catalyst for change

The most appropriate value-based model will depend on a number of factors, including the therapeutic area. Regardless, the massive increase in health data offers unprecedented opportunities to create value for different stakeholders. Life sciences companies can unlock value for themselves and other stakeholders by helping shape platforms of care that connect, combine and share data.

As David Redfern, Chief Strategy Officer of GlaxoSmithKline, predicts, "Some form of platform that uses data analytics will be the catalyst for change in health care. What if Google becomes a major insurance company and drives more precise outcomes measurements based on data?"

That's a question that should give all life sciences companies pause.

Some form of platform that uses data analytics will be the catalyst for change in health care. What if Google becomes a major insurance company and drives more precise outcomes measurements based on data?

- David Redfern, Chief Strategy Officer, GlaxoSmithKline

Questions to consider

- How can platforms accelerate new value-based payment models?
- How do platforms help align stakeholders around a shared goal?
- How will platforms create new opportunities for moving from volume to shared value?

05



New digital technologies, especially the ubiquity of mobile, have radically altered customers' expectations, putting power in the hands of more informed health stakeholders. To create future value, life sciences companies must satisfy stakeholders' increased expectations by delivering personalized and improved health outcomes amplified by the power of data. To achieve this goal, life sciences companies must transform their business models using data to create shared value for themselves and health stakeholders.



Reimagining health care

In November 2017, Flemming Ornskov, CEO of Shire Pharmaceuticals, opened his keynote address at the FT Global Pharmaceutical and Biotechnology Conference with a provocative statement: "You have to have some kind of platform."

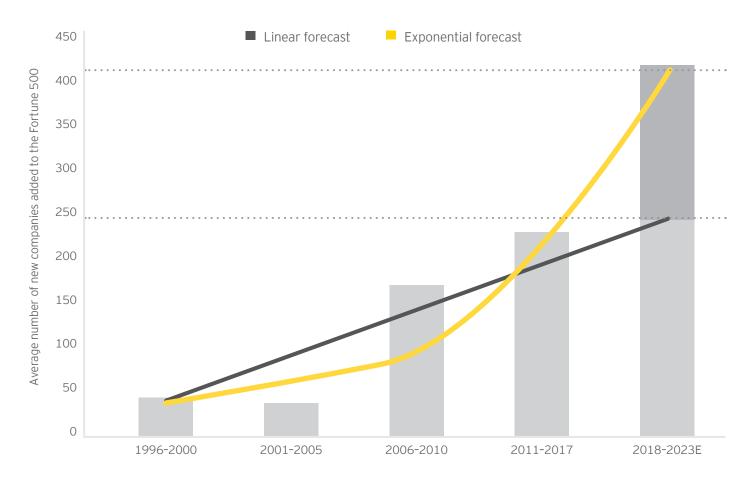
Challenging audience members to take a hard look at how their organizations will create future value, he highlighted an important advantage that platforms provide: the ability to give life sciences companies real-time, market-based feedback on product usage. "I think this is the medicine model of the future," Ornskov said.

One reason why is that the technological convergence sparked by the Fourth Industrial Revolution will push life sciences companies to change their business models to meet rising customer expectations. These changing expectations create a disruptive shift toward a more participatory health system. In this system, super consumers will define value in terms of the ability to deliver affordable, personalized health outcomes that advance lifelong health goals. To create future value, life sciences companies must develop the products, services and business models that satisfy this new brand of health consumerism. As noted in earlier chapters, because life sciences companies understand how to use scientific methods to develop innovations that treat clearly defined medical needs, they can play a critical role in shaping platforms of care into robust, evidence-driven interfaces that exponentially improve health outcomes. Given current data access and regulatory challenges, many life science leaders may believe it is reckless to push too far or too fast into the untested waters of platform-based models. However, the current pace of technological change and the rise of new health entrants means there is a limited window of opportunity to make the necessary business model shifts required.

Across all industries, disruption has accelerated the turnover rate for companies earning a place on the Fortune 500. For the 18 life sciences incumbents that are currently listed on the Fortune 500, the implications are significant. If the rate of the Fortune 500 turnover is linear, the data suggest that, on average, 47% of the companies will be new to the list in 2023. If, as a result of disruption, the rate of turnover is actually exponential and not linear, up to 81% of the companies occupying the Fortune 500 in 2023 could be new. That means it is possible that only four of today's current life sciences cohort would merit a Fortune 500 designation (see Figure 1).

EY believes participating in evolving platforms of care focused on outcomes-based measures will allow companies to seize the upside of disruption in a transformative age. As such, platform participation is both an offensive and defensive strategy. By providing meaningful, easy-to-use and affordable solutions to consumers, platforms of care allow life sciences companies to create a competitive advantage for their products and services and rebuild consumer trust by directly satisfying health needs. As relationships with consumers deepen, life sciences companies move from being simply vendors selling into a system to a trusted part of the health delivery process.

Figure 1. In the age of disruption, the volatility of the Fortune 500 has increased



Source: EY; Fortune 500. The Fortune 500 is an annual list published by Fortune that ranks companies by total revenues for their respective fiscal years. Companies included in the directory are incorporated in the US, operate in the US, and file financial statements with a government agency. The 2018-2023 estimate is determined by extrapolating linear or exponential trend lines in Microsoft Excel.

Living in a platform of care world

Ongoing industry convergence will enable the formation of health-focused platforms of care. There are a number of milestones that signal their approach (see Figure 2). These include:

Seamless sharing of data: In a fully digital future, the ability to connect, combine and share health data in real time will exponentially increase, while the marginal costs of doing so will continue to plummet. Stakeholders, including life sciences companies, will move from managing data – currently a key challenge – to actually using it to improve care. Future innovations will be linked to the ability to create a personalized outcomes-focused "data-ome" for each individual based on genetic, medical, behavioral, environmental and financial

information. These data will provide a more informed understanding of disease risk and promote preventive interventions before signs of disease become visible.

Already, advances in cloud computing promote easy access to information regardless of where the data are generated or their format. In the future, private decentralized databases built on blockchain technology could revamp medical records, giving consumers more direct control of their health records. In a step in this direction, in January 2018, Apple announced a new feature that allows consumers to automatically download and share portions of their medical records to their iPhones.¹⁵ In early February, the start-up Nebula Genomics announced a program to sequence consumers' genomes and then add the data to the blockchain via the purchase of "Nebula tokens."¹⁶

Figure 2. Signposts to data-driven business models

A number of signposts show the acceleration of data-centric business models enabled by platforms of care.

	Near-term		Future-state		
Seamless data sharing	 Widespread adoption of electronic health records 	 Analytics enables combination of traditional and m-health data 	 Blockchain-enabled patient records 	 Data transactions between patients and platforms 	
Regulatory adaptation	 First digital product approved 	 Standards defined for digital biomarkers 	 Behavioral analytics incorporated into regulatory assessments 	 Disease algorithm approved as therapy 	
Health care everywhere	 Primary care via telehealth 	 Proactive patient monitoring, including home diagnostics 	 Smart operating rooms 	 Drone and 3D printing create on-demand product distribution 	
Hyper- personalized care	 App and wearable data increasingly used to monitor health 	 Genomic, microbiomic and other biological profiling becoming standard 	 Al-enabled predictive analytics routinely applied to patient data 	 Personalized outcomes-focused "data-ome" for each individual 	
Evolving payment models	 Payment models linked to real-world data 	 Value determination driven by behavioral and social data 	 New payment models emerge (e.g., subscription, pay as you live) 	 Focus on prevention, earlier disease interception 	

¹⁵ N. Singer, "Apple, in Sign of Health Ambitions, Adds Medical Records Feature for iPhone," The New York Times, January 24, 2018.

¹⁶ D. Grishin, K. Obbad, P. Estep, M. Cifric, Y. Zhao and G. Chruch, "Nebula Genomics: Blockchained-enabled genomic data sharing and analysis platform," February 7, 2018. Available from: https://www.nebulagenomics.io/assets/documents/NEBULA_whitepaper_v4.51.pdf



Regulatory adaptations: New categories of regulated health solutions are beginning to emerge as a result of guidance set forth by the 2016 21st Century Cures Act and the UK's Medicines and Healthcare products Regulatory Agency (MHRA), among others. These regulations open up a market dominated by traditional biopharma and medtech products to innovations from new entrants. Regulators continue to grapple with the implications of self-learning algorithms that can optimize or improve health outcomes, and the development of policies that appropriately determine efficacy while safeguarding consumer safety and privacy. To that end, the U.S. Food & Drug Administration's Software Precertification Pilot Program, which brings together technology and life sciences constituents, is just the latest initiative to create regulations that are more in line with the digital health revolution. In the future, consumer preference, behavioral and social data could do more than inform new product approvals; such data might also affect how health technology assessment bodies calculate value in many countries.

Distributed health: Recent dealmaking between payers, pharmacies and new entrants demonstrates how stakeholder demands are driving changes to care delivery and the creation of future value. As technological advances support more consumer-friendly, medical-grade monitoring devices, experiments like Mercy Virtual Care Center, a virtual hospital that connects medical professionals to consumers in their homes, or telehealth services from companies such as Teladoc and Babylon Health will become the norm not the exception. So will smart operating rooms and the incorporation of drones and 3D printing. As care becomes divorced from traditional settings (e.g., the physician office or hospital), life sciences companies must be prepared to take advantage of connected devices to design innovations that deliver personalized outcomes anytime, anywhere.

Hyper-personalized care: Truly personalized care that is tailored to an individual based on medical history as well as specific patterns of behavior and risk has long been medicine's goal. Technologies that deepen the connections between individuals and their care teams will be critical to realizing this vision. In the future, powerful AI systems will make connections that were impossible based on limited historical data. Multidimensional diagnostic systems will not only drive decisions about what drugs and supportive care are the best choices for a loved one with breast cancer or heart failure, but will be used to capture data in real time to inform the future health choices of others. There is a real opportunity for life

sciences companies to deliver tremendous value as platform partners by developing tools and analytics that support care decisions that deliver significantly better health outcomes based on individualized disease risk profiles.

Evolving models of value: As discussed in Chapter 4, data will underpin new value-based care models that share risk differently between life sciences companies, payers, physicians and consumers. Importantly, real-world data linked to consumer behaviors or preferences will be combined with outcomes data to drive reimbursement decisions. In addition, shareable infrastructure will make it possible for life sciences companies to replicate pay-for-performance deals quickly across many payers and geographies. Forward-thinking life sciences companies could help ease budgetary pressures for both payers and consumers by developing more sophisticated subscription-based models that bundle products and services into holistic offerings. As these models allow life sciences companies to share value with their stakeholders in new ways, biopharma and medtech companies can forge deeper relationships with users that create disincentives to switching to other products.

Creating value in the convergent age

In 2018, simple platforms of care that streamline the management of chronic diseases already exist. Moreover, there is the imminent prospect that a technology player will make a major move in the consumer health space. As industry convergence continues to accelerate, the bright lines between health care and technology continue to diminish. Every company developing health care products and services is a data company, and therefore a technology company; every technology company that has access to health-related, consumer-generated information or other health data is likewise a health care organization.

As discussed in Chapter 2, four business models explain how life sciences companies create value: **Breakthrough innovators** develop best in class products that command high prices; **Disease managers** offer products and solutions that seamlessly manage chronic conditions; **Efficient producers** create affordable, reliable products and services; **Lifestyle managers** focus on building consumer-focused products and services that maintain overall health.



No matter the business model, life sciences companies must respond to the evolving demands of super consumers if they want to create future value. That means medtechs and biopharmas must proactively identify and find ways to capture what consumers value. That will result in a shift in the types of products and services under development and the prioritization of innovations that are engaging, personalized, affordable and improve health outcomes.

As companies respond to evolving customer demands, their share of total market value will shift in ways that depend on their chosen business models. For instance, the total value Breakthrough innovators may be able to capture is most likely to come from a small share of wealthy individuals or institutional health systems that prioritize their higher cost products. Meantime, as platforms enable Disease managers to network with a wider universe of users, adoption in the mass market will drive greater market share and thus, higher revenues (see Figure 3).

In the future, life sciences companies will be better able to use data to understand the shifting market landscape. As a result they will have a greater understanding of how changing customer needs directly affect the future value they can create – e.g., what kinds of products and services maximize revenues. They will be able to adapt to the changing environment by aligning with other stakeholders through partnerships or acquisitions. Those deals will allow them to acquire the key capabilities requires to design new innovations that meet evolving definitions of success.

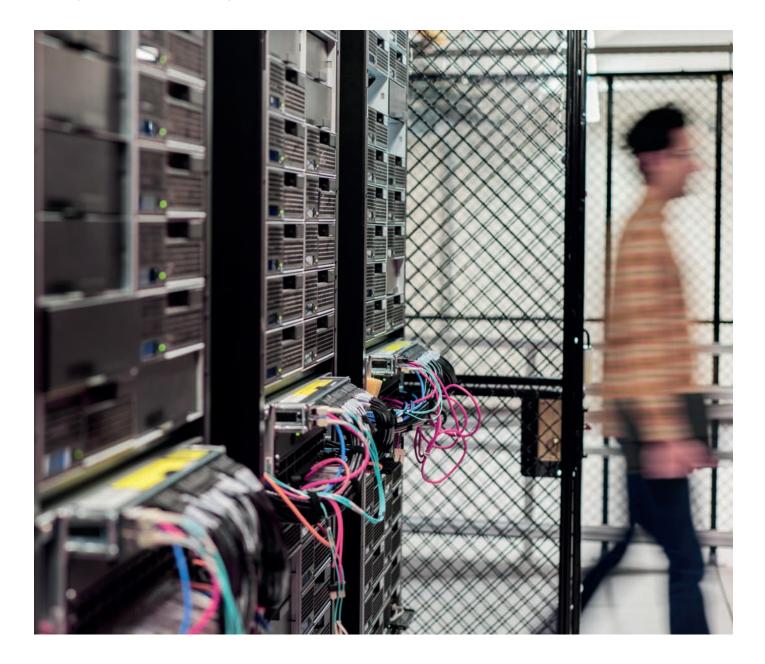
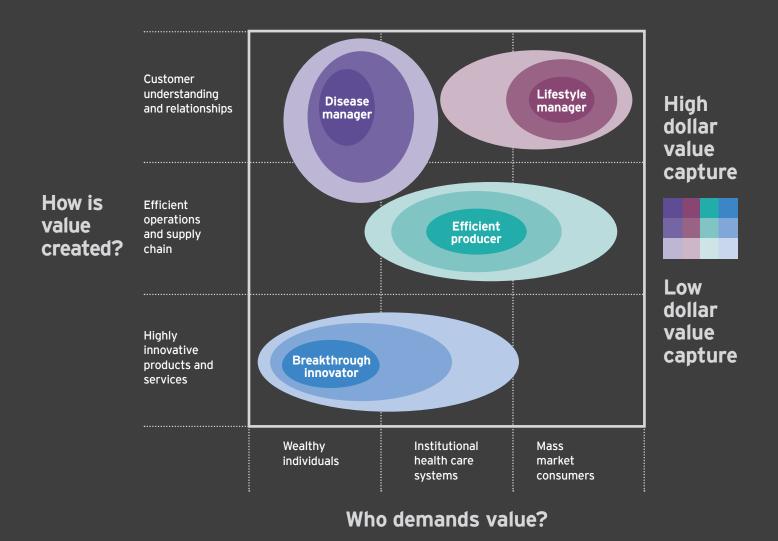


Figure 3. Optimal value will come when life sciences companies create products and services to match demands from different customer segments

As companies respond to evolving customer demands their total market value will shift in ways that depend on their chosen business models. They will increasingly need to use data to predict future customer demands so they can adapt to the dynamic health care landscape.



Source: EY. Concept developed from an initial idea first profiled by Prof. Brian D. Smith in his book, The Future of Pharma, published by Gower Publishing in 2011.

Three different parameters define value creation (y-axis): innovative products, efficient operations and customer understanding. The x-axis corresponds to which health stakeholders are defining the value: wealthy individuals, health care systems and mass market consumers. The area of the ellipse corresponds to dollar value of the total addressable health services market captured by companies employing a particular business model. The color gradient correlates with the increased opportunity for value capture (US\$). The darker the color, the greater the opportunity for value capture.

Future-proofing the business

A necessary precursor if a medtech or biopharma is to future-proof itself, however, is to make sure that the company's business model aligns with the kinds of products and services it actually sells. That self-definition is critical as it helps determine a company's essential purpose. As Simon Sinek reminded us in his 2009 TED Talk, most executives know what their companies do and how they do it. But they struggle to explain "the why" that defines their organizations' existence.¹⁷ Life sciences companies have always emphasized a "why" rooted in new innovations that deliver better, safer care to individuals.

A life sciences company's strategic focus determines how – and how much – value it can capture. This focus drives investment in capabilities, as well as differentiating gains in intellectual property and institutional knowledge. Should companies decide their purpose demands a shift in business model, for instance, from Disease manager to Breakthrough innovator, companies must understand the investment in time, money and talent required to make the switch and plan accordingly.

It is important to note that as disruption creates new business models, and new opportunities for value capture, these categories may shift, meld or completely disappear. The amount of value captured may also fluctuate in response to stakeholder interests and capital outlays. Depending on the business model, here's how companies will capture future value.

Breakthrough innovators: The successful innovators will be those that develop novel products and services in areas where they have deep therapeutic area expertise. Establishing therapeutic area leadership has been a strategic driver for many of the industry's incumbents, influencing both bolt-on acquisitions and divestitures. Going forward, innovators need to assess how they create scale in digital capabilities. Depending on the therapeutic area, they will need to establish external collaborations to access emerging science as well as services that provide consumer support, engagement and/or integrated data capture across the value chain.

Disease managers: For Disease managers, especially those developing diabetes and respiratory offerings, the ability to personalize consumer-facing solutions based on individual preferences and needs will be vital if they want to capture future value. An understanding of behavioral science and how cognitive biases affect compliance and adherence will also be critical if companies are to develop offerings that nudge consumers at the right times and in the right ways. Combining these capabilities with a deeper understanding of disease risk will allow companies to develop data-driven tools that help busy physicians and stretched payers optimize the care of the consumers at greatest risk for serious and costly health events.



¹⁷ Simon Sinek, "How great leaders inspire action," TEDx Puget Sound, September 2009. Available from: https://www.ted.com/talks/simon_sinek_how_great_leaders_inspire_action

Efficient producers: Efficient producers strive to maximize efficiencies in the supply chain to maximize the sales of their offerings while minimizing the costs. Personalization is less important than data literacy, since this business model is grounded on affordability. To provide additional value, however, these companies will want to bolster predictive analytic capabilities to improve inventory management, smooth distribution and better forecast demand for offerings.

Lifestyle managers: Technology companies' interest in health puts the greatest pressure on this group of companies to adapt most quickly to the new environment. Like Disease managers, the ability to drive behavior change will be an important and needed skill. Other capabilities that will differentiate successful Lifestyle managers include systems that promote frictionless (superfluid) customer engagement, make the payment process transparent and use algorithms to anticipate consumers' needs.

See the future, build the future, operate in the future

In January 2018, Larry Fink, CEO of BlackRock, an investment fund with more than US\$6 trillion under management, electrified the business community. In his open letter to CEOs and their boards, Fink urged executives to look beyond short-term shareholder gains to the wellbeing of the general citizenry. "Society is demanding that companies, both public and private, serve a social purpose. To prosper over time, every company must not only deliver financial performance, but also show how it makes a positive contribution to society," he wrote.¹⁸

Fink's appeal is a stark reminder that investors care deeply about how companies generate value, and for whom, and that narrow definitions built solely around shareholder returns are no longer sufficient. While Fink's words were not explicitly aimed at life sciences companies, biopharmas and medtechs would do well to pay attention. In today's changing health care climate, life sciences companies will continue to cede power to other health stakeholders – unless they find ways to align their stakeholders' different objectives and actually build a shared vision of value.

At the time when access to data alters the definition of innovation approaches, life sciences companies have an opportunity to embrace their "why" more fully. They can play a leading role in shaping the platform-enabled economies that are – and continue – to emerge. By participating in platform development, life sciences companies not only gain direct access to health care customers, but also build needed trust by working alongside payers and physicians to improve the health care experience. In doing so, companies will not only create new and increased revenue opportunities, but solidify their place as rightful contributors to the overall health ecosystem.

Questions to consider

- Are you investing in the capabilities that will drive future value from platforms in this transformative age?
- Does your business model give others confidence that you are focused on generating shared value to the wider ecosystem?
- Is your organization ready to seize the platform opportunity? What first steps will you take?

Unlocking the power of data in intelligent ways is both exciting and necessary to fuel innovation and deliver highly personalized health care. This is what consumers increasingly will demand. Higher degrees of personalization will also generate efficiencies and increase effectiveness, aspects welcomed by all health care systems globally.

– Pamela Spence, EY Global Life Sciences Industry Leader

FV=D



Innovation Outcomes x Personalization

> For people For physicians For payers For policymakers

Participatory Precise Predictive Proactive Data streams

Traditional and non-traditional partners

Data (Connect + Combine + Share)

> Platforms of care

Conclusions

- To create future value, life sciences companies must determine how they can seize the upside of disruption in today's transformative age.
- The ubiquity of data and analytics creates new opportunities for life sciences companies to rethink innovation and create personalized health outcomes that the wider ecosystem of health stakeholders are now demanding.
- Platforms that connect, combine and share data will be a central enabler of this future value creation.
- These platforms create a mechanism for companies to quickly and safely tap into diverse data streams and link them to scientific and clinical data.
- Companies will also need to consider developing new capabilities linked to customer engagement, personalization and data literacy that are central to emerging platforms of care.
- Life sciences companies can access these capabilities by building them organically or through flexible partnerships or acquisitions.
- These customer-focused capabilities will help life sciences companies transform their business models using data to create shared value for themselves and health stakeholders across the ecosystem.

Looking ahead

- How will your organization transform its business model to create shared value focused on personalized outcomes fueled by unlocking the power of data?
- Will your organization build new capabilities organically, by acquisition or by flexible partnerships?
- How will your organization ultimately secure value through platform-based businesses?

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EY Global Life Sciences contacts

GLOBAL LIFE SCIENCES INDUSTRY LEADER

Pamela Spence

Ernst & Young LLP Email: pspence2@uk.ey.com Phone: +44 207 951 3523 Twitter: @PamelaSpence_EY

AUTHORS

Ellen Licking

Senior Analyst, Life Sciences and lead author Ernst & Young LLP Email: ellen.licking@ey.com Phone: +1 650 521 7238 Twitter: @EllenLicking

James Evans

Senior Analyst, Life Sciences Ernst & Young LLP Email: james.evans@uk.ey.com Phone: +44 207 951 3751

Aaron Bean

UK Advisory, Life Sciences Ernst & Young LLP Email: abean1@uk.ey.com Phone: +44 207 951 9731



EY Global Life Sciences executive team

AMERICAS TRANSACTIONS ADVISORY SERVICES

Ambar Boodhoo Email: ambar.boodhoo@ey.com Phone: +1 212 773 9567

US INNOVATION

Orlan Boston Email: orlan.boston@ey.com Phone: +1 212 773 2269 Twitter: @OrlanBoston

GLOBAL TAX SERVICES

Mitch Cohen Email: mitchell.cohen@ey.com Phone: +1 203 674 3244

US CENTRAL REGION

Jerry DeVault Email: jerry.devault@ey.com Phone: +1 312 879 6518 Twitter: @jdevault

GLOBAL TALENT

Caroline Dhir Email: cdhir@uk.ey.com Phone: +44 20 7951 2580

JAPAN

Patrick Flochel Email: patrick.flochel@jp.ey.com Phone: +41 793 102 887 Twitter: @patrickflochel

GLOBAL TRANSACTIONS ADVISORY SERVICES

Jeffrey Greene Email: jeffrey.greene@ey.com Phone: +1 212 773 6500 Twitter: @JeffreyRGreene

US NORTHEAST REGION

Diana Hoff Email: diana.hoff@ey.com Phone: +1 215 448 5590

EUROPE INNOVATION

Daniel Mathews Email: dmathews1@uk.ey.com Phone: +44 20 7197 9375

UK AND IRELAND

Andrew Monro Email: amonro@uk.ey.com Phone: +44 207 951 2125

US WEST REGION

Chris Nolet Email: chris.nolet@ey.com Phone: +1 650 802 4504

GLOBAL ADVISORY SERVICES

Matt Ringelheim Email: matthew.ringelheim@nl.ey.com Phone: +31 88 40 79066

AMERICAS ADVISORY SERVICES

Andy Rusnak Email: Andy.Rusnak@ey.com Phone: +1 215 448 5029

GLOBAL ASSURANCE SERVICES

Tobias Schlebusch Email: tobias.schlebusch@de.ey.com Phone: +49 211 9352 10351

GLOBAL GENERICS

Sriram Shrinivasan Email: sriram.shrinivasan@in.ey.com Phone: +91 22 619 20000

GERMANY, SWITZERLAND AND AUSTRIA

Gerd Stuerz Email: gerd.w.stuerz@de.ey.com Phone: +49 211 9352 18622

JAPAN

Hironao Yazaki Email: hironao.yazaki@jp.ey.com Phone: +81 335 031110

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As populations age and chronic diseases become commonplace, health care will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of 15,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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