

Introduction

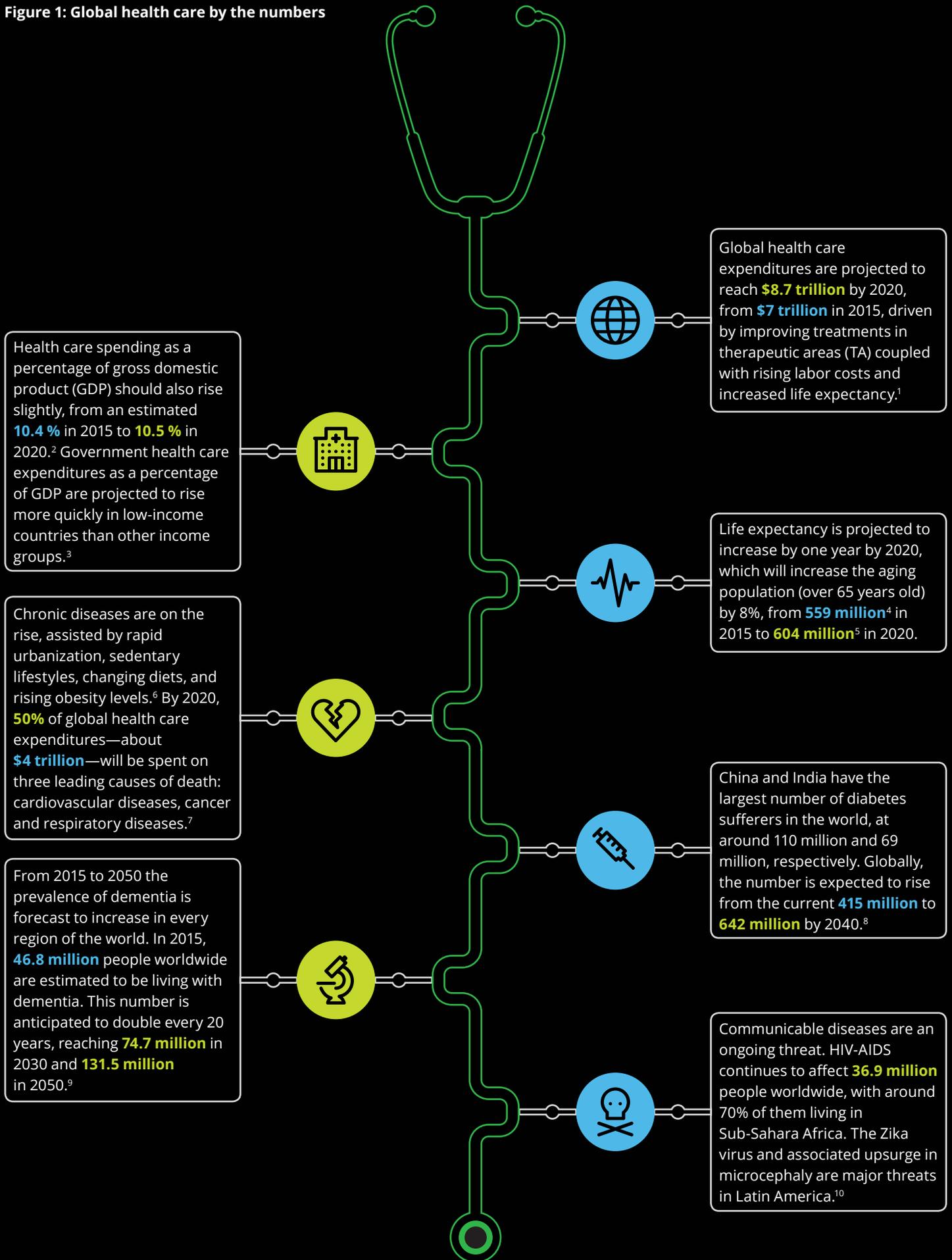
Life sciences companies have always operated in a world of uncertainty. Issues around cost and pricing, clinical and operational innovation, customer and consumer engagement, and regulatory compliance have existed for decades. In addition, new and evolving technology advancements—more sophisticated electronic medical records (EMRs), wearable health care devices, next-generation sequencing, breakthroughs in genomics, immunotherapy, and gene therapy, and use of real-world evidence (RWE) and data analytics—have primed the life sciences sector for disruption. Each year brings changes and challenges, and 2017 is likely to follow suit.

Life sciences sector growth is closely tied to global health care expenditures which, in 2017 and successive years, are expected to be fuelled by increasing demand from an aging population and the prevalence of chronic and communicable diseases (Figure 1, next page). Other potential growth drivers include improved (if uneven) economic activity in key geographies, especially developing nations in the Middle East and Asia; continuing industry consolidation and collaboration; and new business models enabled by scientific and technology advances.

Life sciences companies of all sizes and in all segments—pharmaceuticals, biotechnology, generics and biosimilars, medical technology, and wholesale and distribution—will continue to focus on achieving profitable and sustainable growth in 2017. But this growth won't come easy in an industry heavily influenced by health reform, cost pressures, price- and value-based care models, disintermediation from downstream vertical integration, economic fluidity, and political instability. Looking across a landscape of challenges, the mismatch between increasing R&D expenses and the payer and public demand for lower-cost treatments is a game-changing issue because it will likely affect both the direction and speed of the sector's future development.

How should life sciences companies invest and operate to thrive in today's world of uncertainty? What capabilities do they need to leverage massive (and growing) quantities of electronic health information across the enterprise, from R&D through product commercialization? How can company leaders develop incremental and breakthrough strategies that de-risk clinical, business, and operating models and create added value for patients, payers, and shareholders? This 2017 outlook reviews the current state of the global life sciences sector; explores trends and issues impacting market segments and individual organizations; and suggests considerations for stakeholders as they seek to grow revenue and market share.

Figure 1: Global health care by the numbers



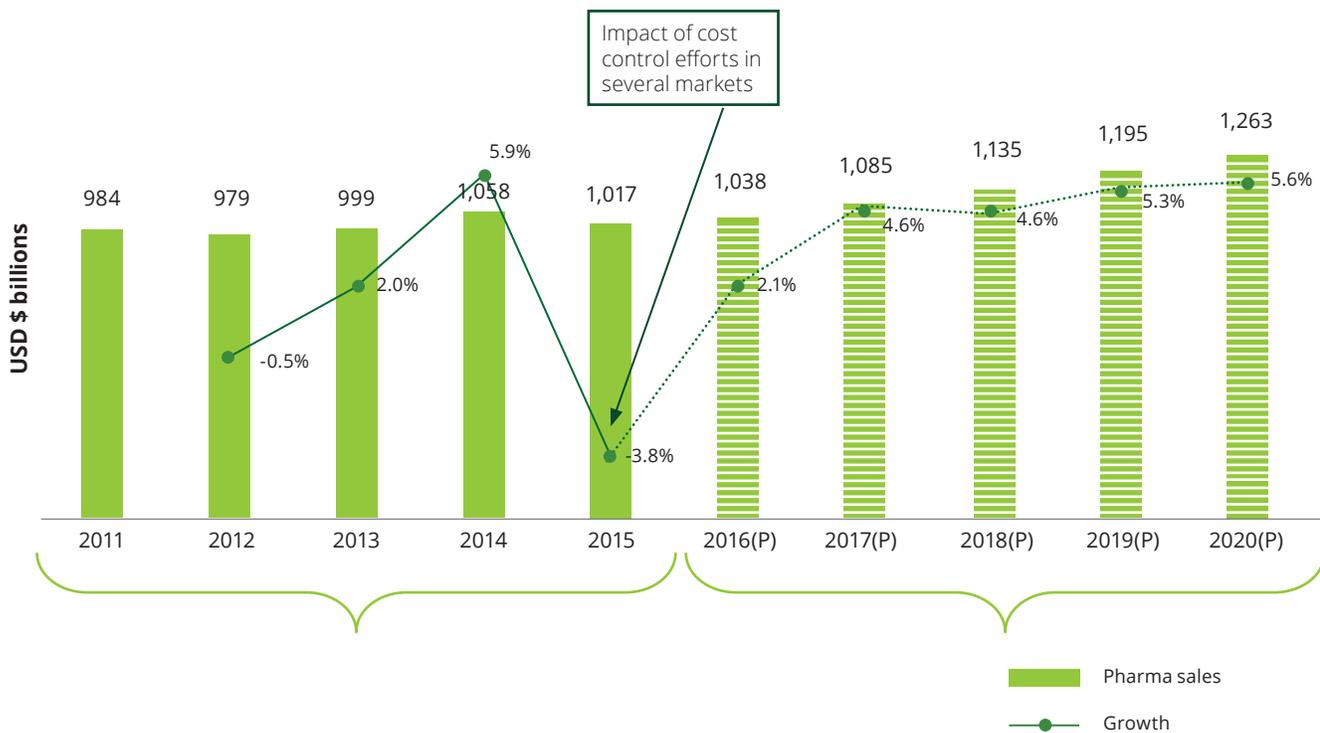
Overview & outlook

Pharmaceuticals segment

Although pharma companies continue to deal with the repercussions of patent expiries and payers' cost control efforts, the growing acceptance of sometimes high-priced innovative orphan drugs and ongoing industry consolidation are expected to drive sales growth for the next several years.

2015 saw a drop in total global pharma sales, in nominal US-dollar terms, due to exchange-rate effect and the impact of cost control efforts in several markets; however, sales are expected to improve over the 2016-2020 period, growing at an average of 4.4 percent annually to total a projected \$1.2 trillion in 2020 (Figure 2).¹¹ Sales from the top 10 pharmaceutical companies accounted for ~35 percent of the 2015 global pharma market.¹²

Figure 2: Worldwide pharmaceutical sales, 2011-2020²¹



Source: *World Industry Outlook, Healthcare and Pharmaceuticals*, The Economic Intelligence Unit, June 2016

Increased pharma spending is projected across all regions: North America and Asia & Australasia, with 46 percent and 23.4 percent shares, respectively, dominate current and projected global pharmaceutical spending. Asia continues to surpass Western Europe (18.8 percent) in terms of projected 2016 global pharma spending. Russia and Latin America's pharma markets should be lifted by the anticipated recovery of their economies by 2017.

- Growth in specialty medicines used in hepatitis and oncology, the ability to detect diseases and diagnose patients earlier, the slower-than-anticipated roll-out of biosimilars, and possible expansions of certain government health programs are some of the factors driving the North America region's pharma sales growth.¹³
- Norway and Sweden are expected to lead improved pharmaceutical spending growth in Western Europe, after Euro devaluation led to a slump in USD terms in 2015.¹⁴ The United Kingdom likely will grow considerably slower than the regional average, at 3.4 percent, due to pressure on its health care budget, wider use of generics, and pricing pressures.¹⁵
- The Latin America region's pharma spending, at a projected 6.3 percent compound annual growth rate (CAGR), is anticipated to improve through 2020; however, economic pressures, currency decline, focus on generics, and restrictions on pharma imports may offset growth.¹⁶
- India and Indonesia are the Asia & Australasia region's fastest-growing countries in pharma sales from 2016 to 2020, at 13 percent¹⁷ and 11 percent¹⁸ CAGR, respectively, due to the rising incidence of chronic diseases and increasing demand from the growing middle class for more advanced medicines. China, meanwhile, is projected to sustain an above-average CAGR of 5.8 percent¹⁹ through 2020.

Biotechnology segment

Biotech products continue to slowly gain share from conventional drugs. Between 2010 and 2016 the global biotech segment grew at a CAGR of 3.7 percent, from \$263.7 billion to a projected \$293.5 billion, with biotechs comprising seven of the top 10 drugs in global sales in 2015.²¹ Over the five years from 2016 to 2021, global biotech revenue is estimated to rise to \$314.7 billion (Figure 3).²² Greater global investment in biotechnology, particularly in emerging economies, will largely drive this growth, and the industry is expected to undergo further commercialization to cater to an aging population in more developed economies.²³

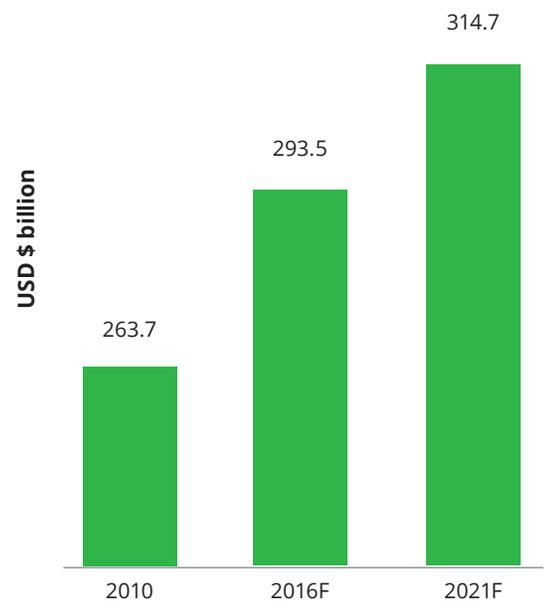
Products from the biotech segment are mainly targeted at oncology, Alzheimer's disease, cardiovascular disease, diabetes, multiple sclerosis, HIV/AIDS and arthritis. Therapeutic areas (TAs) such as obesity offer significant growth opportunity; that market is projected to reach \$8.4 billion by 2022, up from \$407 million in 2012.²⁴

Generics and biosimilars segment

The generic prescription drug market continues to thrive due to pro-generic policies in several regions, including Western Europe. (The increased use of generics has been one of the main reasons for Western Europe's lower pharmaceutical spending over the years.²⁵)

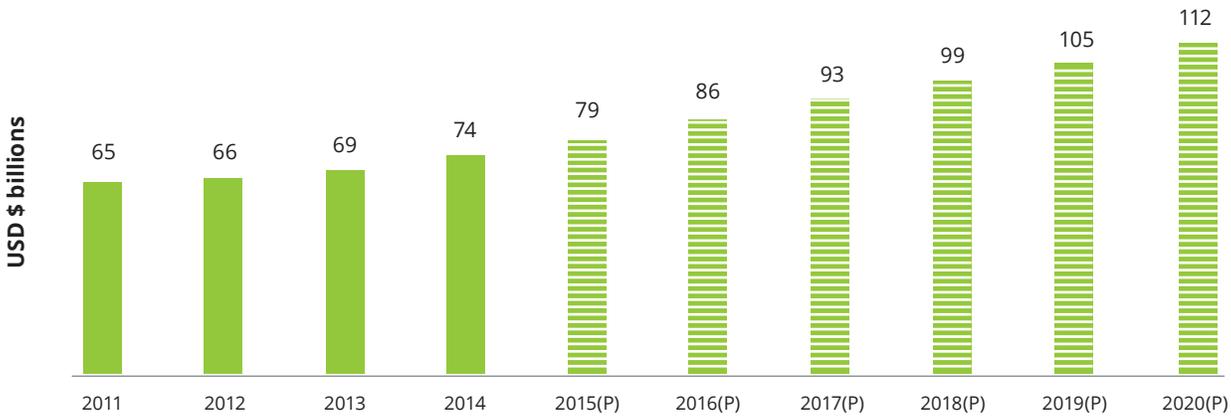
Generic prescription drug sales reached \$79 billion in 2015,²⁶ and are expected to grow to \$112 billion by 2020 (Figure 4, next page).²⁷ The high-volume/low-margin generics market is generally fragmented—among the top 20 companies, only the two leading players had double-digit market share (a combined 23.7 percent) in 2014.²⁹ Analysts expect that the lower price advantage associated with generic drugs may be partially offset by increasing industry consolidation.²⁸

Figure 3: Global biotechnology industry revenue (USD \$ B), 2011-2016³³



Source: IBISWorld Industry Report, "Global Biotechnology," October 2016

Figure 4: Worldwide generic prescription sales, 2011-2020²¹

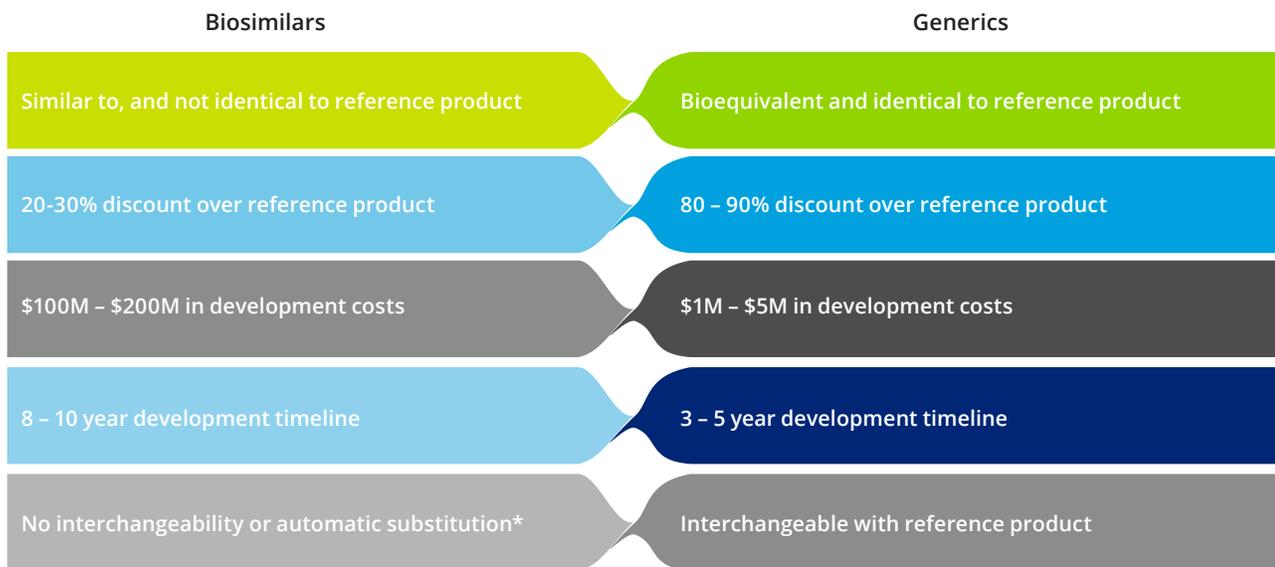


Source: *World Industry Outlook, Healthcare and Pharmaceuticals*, The Economic Intelligence Unit, June 2016

Similar to generics' impact on branded pharmaceuticals, biosimilars threaten to steal market share from more costly biotech drugs. Since the first biosimilar approval in the European Union (EU) in 2006, there are now more than 700 biosimilars approved (~450) or in the pipeline (~250) globally.²⁹ In major markets like the EU, regulators and payers have recognized the potential financial benefit of biosimilars and are driving their uptake. For example, France has initiated automatic substitution of select biosimilars over the reference products.

Analysts expect the biosimilars market to reach \$25 billion-\$35 billion by 2020.³⁰ However, biosimilars' uptake faces several challenges, as illustrated by the key differences between biosimilars and generic medications (Figure 5).³¹

Figure 5: Key differences between biosimilars and generics



*France allows automatic substitution for biosimilars under certain conditions

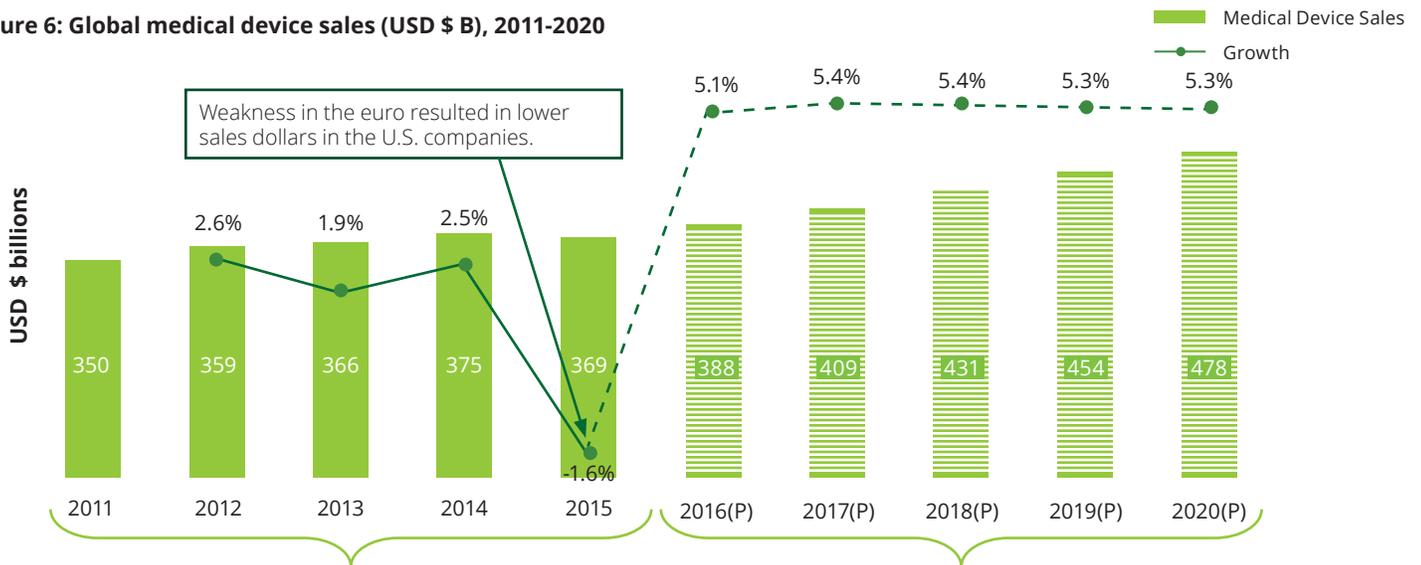
Source: *Winning with biosimilars: Opportunities in global markets*, Deloitte, 2015

Most biosimilars manufacturers have been and remain focused on developed markets—whether it is for their historic and current opportunities (EU) or for their future market potential (United States, Japan). However, a considerable opportunity for long-term growth exists in emerging markets, where biosimilars have little-to-no presence.

Medical technology segment

Global medical device and technology (medtech) market growth was stagnant (CAGR of 1.3 percent) from 2011-2015 due to the lasting impact of the 2009 recession, which resulted in lean financing from investors.³² However, it is projected to gain momentum in 2016, and grow at a CAGR of 5.3 percent from 2016 to 2020 (Figure 6), strengthened by government support for the use of diagnostics to improve clinical outcomes and patient affordability; the rising preference for minimally invasive procedures; dramatic advances in digital health applications; and endorsements for branded devices such as diagnostic imaging and accessories.

Figure 6: Global medical device sales (USD \$ B), 2011-2020



Source: *EvaluatePharma: World Preview 2015, Outlook to 2020*

In vitro diagnostics (IVD) continues to be one of the fastest-growing areas, and is projected to expand at a CAGR of 5.1 percent from 2014 to 2020, to reach \$67.3 billion by 2020.³³ The rise in demand for IVD testing is being driven by the prevalence of chronic diseases, especially among people aged 65 years and above, and new, value-based reimbursement scenarios such as the United States' Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), a payment law intended to drive major health care payment and delivery system reform for clinicians, health systems, Medicare, and other government and commercial payers.³⁴ Advances in genomics, including gene editing and proteomics, are also expected to create new growth opportunities for the IVD market through 2020.³⁵

Medtech manufacturers are also focused on developing minimally invasive devices. For example, increasing adoption of MRI-compatible implantable cardioverter-defibrillators (ICDs), next-generation insertable cardiac monitors, and drug-coated balloons, as a result of increased minimally invasive cardiac procedures, should help drive the cardiology diagnostics market through 2020.

Many industry players—both traditional medtech organizations and new market entrants—are capitalizing on recent and emerging technological advancements and providing digitally enabled health care solutions using mobile health applications, sensor technology, data analytics, and artificial intelligence (AI).³⁶ In 20 or even 10 years, the vast majority of devices are anticipated to have imbedded sensors. New handheld diagnostics with built-in AI will revolutionize the way primary care is delivered outside the physician office. Diagnostics and AI will truly usher in the “personalized medicine” era. These new offerings will produce a huge new growth engine with the power to transform clinical care.

Even though medtech companies are focusing considerable attention and resources on IVD, minimally invasive devices, and digital health applications, the biggest challenges many face are not at the product development level; rather, they are on the commercial side and along the supply chain. Questions such as which strategies and tactics should be employed to more efficiently and cost-effectively manage a changing customer base, how best to right-size the organization, where to streamline distribution channels, or how to wrap services around products to differentiate themselves in the marketplace will be key to ongoing market success.

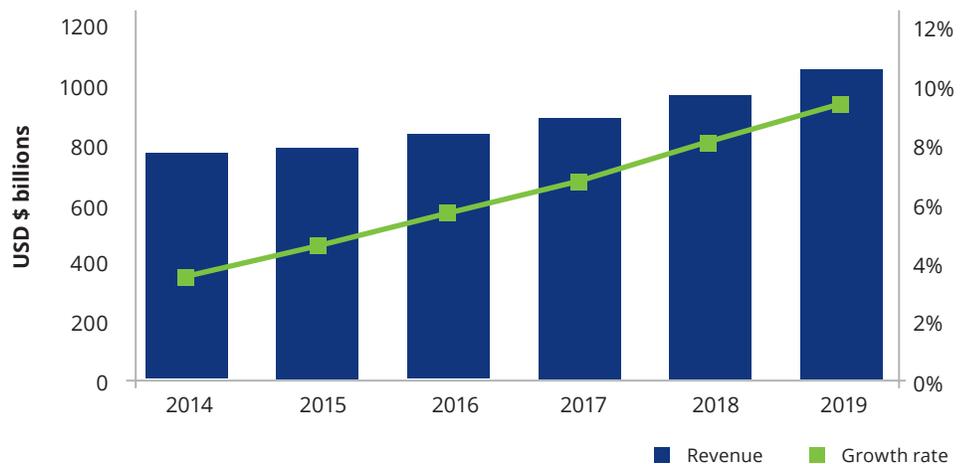
Wholesale & distribution segment

The global life sciences wholesale and distribution market is expected to see steady growth of 6.8 percent annually during 2014-2019 due to increased demand for pharmaceutical products (led by the Americas region) as well as technology advances.³⁷ Revenues are projected to increase from \$752 billion to \$1.04 trillion during the period (Figure 7).³⁸ The U.S. market is expected to have a 37 percent share of the overall market by 2024.³⁹

The life sciences wholesale and distribution process involves the storage and movement of products from manufacturing plants to key customer segments including hospitals and clinics, patients, and specialty/traditional wholesalers.⁴⁰ Two market developments have the potential to disrupt traditional distribution channels and pose challenges for drug manufacturers. The practice of parallel importation, which allows certain countries to import original pharmaceutical products at a lower price,^{41,42} is resulting in the emergence of new and numerous channel intermediaries (e.g., repackaging agents, wholesalers, distributors). This increase in players combined with parallel supply chains' intricacy and lack of transparency, may undermine channel security and increase the opportunity for counterfeits to enter the system. Pharmaceutical companies are concerned that parallel importation could put public health and safety at risk and result in diminished profits that could lead to a reduction in R&D funding for new, innovative drugs.

The second channel-related market development is an increase in online pharmacy operators, which may require manufacturers to change their traditional sales and distribution models. Leading distributors in Southeast Asia and other regions are countering online pharmacy operators, parallel importation, and other channel disruptions by offering more value-added services to pharmaceutical and device companies, such as analytics support, patient assistance program execution, training, and product/device monitoring.

Figure 7: Global pharmaceuticals wholesale and distribution market, 2014-2019



Source: DTTL Life Sciences and Health Care group analysis of TechNavio analysis

Global life sciences sector trends in 2017

Given the number of potential policy and regulatory changes anticipated in 2017, life sciences stakeholders large and small, public and private are expected (and encouraged) to pay close attention to five sector trends that have the potential to help and/or hinder their clinical, financial, and operational plans:

- Managing cost & pricing
- Driving clinical innovation
- Connecting with customers & consumers
- Transforming business & operating models
- Meeting regulatory compliance

Read on to learn about these trends and Deloitte's considerations for sector participants seeking to manage clinical and business risks and sustain growth in today's dynamic life sciences marketplace.

Managing cost & pricing

The pressure to reduce costs and prove value in life sciences is intense.⁴³ Indeed, some assert that it will be the greatest challenge facing life sciences companies in 2017. Uneven regional economic growth, reduced government health care spending in certain areas, and increasing consumer out-of-pocket (OOP) costs for popular treatments are underpinning payer, provider, government, and patient demands for lower-cost drugs and devices; greater use of generic medicines; value- and outcome-based payment models; and more stringent regulatory processes. Increasingly, life sciences companies are expected to justify the cost of their products using improved targeting,⁴⁴ comparative effectiveness (CE) measures, and real-world evidence (RWE) in addition to hard clinical endpoints.

Adding to the pressure, the costs of bringing a new medicine to market have never been higher. Deloitte's analysis of 12 leading biopharmaceutical companies shows that the costs of the traditional, fully integrated pipeline process from idea to R&D to commercialization have increased from \$1.188 billion in 2010 to \$1.539 billion in 2016.⁴⁵ Other cost estimates range both higher and lower, but the expense and complexities of drug development have risen, particularly as researchers focus on challenging disease areas such as cancer. Companies big and small are expending considerable time and effort to reduce the cost side of the equation by right-sizing their organizations, working more cross-functionally, and increasing operational efficiency through digital supply networks (DNS) and other technology advancements (see sidebar).

The rise of life sciences digital supply networks

Forward-thinking life sciences companies are transforming their traditional, linear supply chain into a dynamic, interconnected system that can more readily incorporate ecosystem partners and evolve to a more optimal state over time. This digital supply network (DSN) integrates information from many different sources and locations to drive the physical act of production and distribution.⁴⁶ By leveraging both the traditional and the new, such as sensor-based data sets, DSNs enable integrated views of the supply network and rapid, use-case-appropriate latency responses to changing situations.⁴⁷

Historically, supply chain professionals managed the “four Vs” (volatility, volume, velocity, and visibility)⁴⁸ as they attempted to optimize results across a series of objectives that include total cost, service, quality, and support for innovation. These traditional priorities are not likely to change, but going forward, supply chain decision-makers should be able to achieve higher levels of performance with capabilities developed using new digital technologies. Already, life sciences companies are recognizing the many ways that DSNs can:

- Enable end-to-end supply network visibility
- Improve manufacturing operation efficiency and yield
- Create new options for enabling clinical trial supply.

Many life sciences organizations already on the path to creating DSNs are shifting their focus away from managing and optimizing discrete functions, such as procurement and manufacturing. Instead, they often use DSNs to focus more holistically on how the full supply chain can better achieve business objectives, while informing corporate, business unit, and portfolio strategies. Indeed, DSNs increasingly enable supply chain professional to become an integral part of strategic planning and decision-making, and to help create new sources of revenue by providing faster access to markets and supporting the production of smart products. To this end, organizations can develop and leverage multiple DSNs to complement different facets of their strategy and more effectively target specific needs.⁴⁹

Source: *The rise of the digital supply network: Industry 4.0 enables the digital transformation of supply chains*, Deloitte University Press, 2016

Virtually all countries have or are planning to institute drug price cost-containment measures or value-based pricing and reimbursement models. Initiatives in several countries are posing significant challenges to research-based pharma companies:

- In Japan, two new schemes were implemented in 2016 to strengthen pricing control—Health Technology Assessment (HTA) and “Huge Seller” Re-Pricing. The former requires submission of HTA data for Japan’s National Health Insurance (NHI) price listing if a drug meets certain criteria including sales forecast and level of premium requested by the manufacturer. The latter is designed to cut drug price by up to 50 percent if annual drug sales exceed JPY 100 billion (approx. US \$1 billion) and there is a certain gap between actual sales and the sales forecast presented in NHI price application. As a result, several name-brand drugs got price cuts ranging from 10-31 percent.⁵⁰
- There is a new approach in the way cancer drugs are appraised and funded in the United Kingdom due to the old funding system being financially unsustainable.⁵¹ The “new-look” Cancer Drug Fund (CDF) aims to enable faster patient access to drugs and be more sustainable, while still giving patients access to drugs already supported by the fund, even if the National Institute for Health and Care Excellence (NICE) reappraise the drug. The fund seems to be making a number of positive strides to being more sustainable. It also appears to be offsetting a lot more work to NICE; depending on how many new drugs are being pushed through the pipeline there may be more work for NICE than the agency can handle, potentially resulting in a treatment backlog.

- The United States has liberal drug pricing practices compared to countries like the United Kingdom (which uses 'quality-adjusted life years' to evaluate cost-effectiveness of treatments) and Germany (which uses 'value dossiers' to evaluate clinical, economic and therapeutic value). However, U.S. drug pricing practices are changing, spurred by public interest and new government policies. The U.S. Department of Health and Human Services (HHS) and U.S. Centers for Medicare and Medicaid Services (CMS) have set clear goals and a timeline for shifting all traditional Medicare payments from volume to value—85 percent by 2016 and 90 percent by 2018⁵²—and are testing new models through various payment reform initiatives.⁵³ Pressure is also coming from U.S. commercial/private health plans. Significant consolidation of pharmacy benefits managers (PBMs) and payers is increasing their market power, and they are more aggressively utilizing access-restriction tools (e.g., formulary tiering, formulary exclusions, step edits, prior authorizations) to extract higher discounts and rebates. The growing use of price protection clauses is further limiting the viability of using price as a key lever for driving year-over-year (YoY) revenue growth. Moreover, as specialty medicine budgets continue to grow and these TAs become more competitive, PBMs and payers are increasingly turning their attention to high-priced specialty drugs.
- In an effort to promote drug price reforms and encourage market competition, China's National Development and Reform Commission (NDRC) lifted price controls on most medicines starting June 1, 2016. Cheaper domestic brands should have an advantage under this arrangement. Many provinces have also adjusted their tendering or purchasing process to either give preference to cheaper domestic brands or to enact more complex processes for hospitals to purchase international brands.
- Policies supporting the use of less expensive generic drugs (and, to a lesser extent, biosimilars) continue to be a popular and dependable cost-savings practice in numerous countries. For example, Japan's government aims to achieve an 80 percent generic substitution rate by the end of FY2020, up from around 60 percent at the end of FY2015. To receive the benefit from the government-backed initiative, generic manufacturers are investing in expanding their production capacity. Mexico plans to continue its cost-reduction strategy of using generic drugs, which has produced an average reduction of 55 percent in medicine prices. In the United States, accountable care organizations (ACOs) are being incentivized to increase utilization of generics and Integrated Delivery Networks (IDNs) are using electronic health records (EHRs) to drive compliance with generic use protocols.

Some life sciences companies are making headway in addressing pricing controls, reimbursement model changes, reference pricing systems, and generics by using end-to-end evidence management strategies to demonstrate the efficacy and cost-effectiveness of their products (see sidebar). However, the broad challenge of managing cost and pricing is not expected to subside anytime soon; it should remain a front-burner issue for 2017 and the foreseeable future.

End-to-end evidence strategies strengthen the product value proposition

To thrive in the "facts-beat-marketing-hype" future of value-based, personalized health care, life sciences companies are embracing operating models that are based on end-to-end (E2E) evidence management strategies and capabilities throughout product development, marketing and distribution.

Increasingly, empirical evidence around product efficacy, safety, and economic value as well as patient services "beyond the pill" are at the heart of today's value conversations between life sciences companies and their customers, replacing those based largely on marketing value propositions and unit cost and rebate pricing strategies.

An insights-driven E2E evidence management model is becoming a necessary operating strategy in life sciences today. Advantages include better data transparency; the design of less expensive, targeted clinical trials; the acceleration of product approvals; more on-target market access channels; and the creation of comprehensive and real-world effectiveness analyses. Becoming a true insights-driven company and executing E2E evidence management in daily practice requires alignment across the key components of strategy, people, process, data, and technology.

Ultimately, evidence is at the core of customer decision-making and a strong evidence base will generate more productive conversations with health care stakeholders.

Source: "Pharma's Big Push for Value: A 'How-To' Primer Using End-to-End Evidence Strategies," by R. Terry Hisey and Brett J. Davis, Deloitte, *Pharmaceutical Executive*, May 2016

Stakeholder considerations: Managing cost & pricing

Even as an aging population and proliferating chronic diseases drive increased provider and patient demands for more and better therapies, reform-driven drug price controls and government cost-containment measures continue to challenge the life sciences sector. With public and private payers making increased use of value-based pricing and real-world evidence to provide clinical and commercial insights into the value of products, life sciences companies should balance the pursuit of clinical innovation with improving operational and cost efficiencies via right-sizing, DSN, and other initiatives. For example, to win in emerging markets, biosimilars players should adopt a long-term strategy to provide affordable products and improved access to the large pockets of non-consumption. This will entail growing sales—though at a smaller margin than in developed markets—among an increasingly affluent and health-conscious population. It will also require selecting TAs that offer the largest potential impact for the local population.⁵⁴

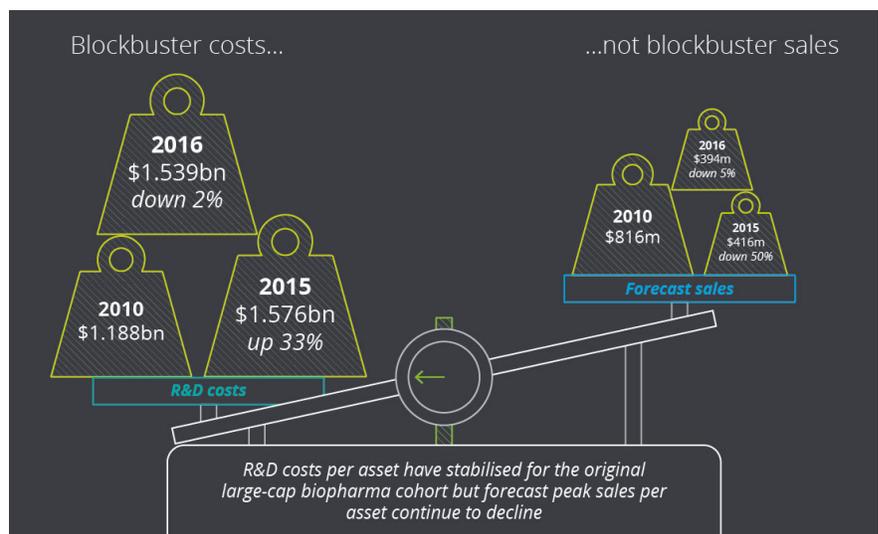
There may be an opportunity for improved cost-justification/rationalization via increased cooperation between life sciences companies and payers based on the push-pull principle. On one hand, regulatory changes and reimbursement incentives will further push payers to reduce health care costs. On the other hand, integrated care contracts may improve care and allow for revenue and profit-sharing between life sciences companies and payers. Also, there is strength in numbers, so life sciences players should engage with other health care stakeholders in markets transitioning to value-based care to make sure that the definition of “value” gives patients access to today's and tomorrow's life-changing innovations⁵⁵ while also enabling organizations to fund future R&D, improve profitability, and meet shareholder expectations.

Driving clinical innovation

Driving and sustaining clinical innovation persists as a life sciences sector priority in 2017, as stiff competition and patent cliffs continue to jeopardize revenue. Soaring R&D costs, increasing pricing pressures, growing market share for generic pharmaceuticals and biosimilars, and heightened scrutiny by regulators are having a dampening effect on clinical innovation. And even though health systems report substantial improvements in outcomes for infectious diseases, heart disease, and stroke—the result of broad use of vaccines and antibiotics, and the prescribing of “blockbuster” drugs such as statins⁵⁶—the demand for new, innovative treatments is unrelenting, driven by the proliferation of age-related diseases such as cancer and dementia, and lifestyle-influenced or behavior-related chronic diseases, such as obesity and diabetes.⁵⁷ Unfortunately for many life sciences companies striving to innovate efficiently and cost-effectively, Deloitte analysis shows that while the costs of taking a blockbuster drug from idea to market have somewhat stabilized after years of increases, forecast peak sales per asset continue to decline (Figure 8).⁵⁸

For the past two decades, the United States was considered the world's leading funder and innovator—providing up to 70 to 80 percent of global life sciences R&D funding.⁵⁹ Yet in recent years, the country has had a major decline in its R&D competitiveness,⁶⁰ with other nations (especially those in Asia) more actively competing and investing in various elements of the value chain.⁶¹ Similarly, the UK life sciences sector has lost some global prominence relative to a number of other markets. Still, there is positive news: The UK's Minister for Life Sciences in November 2014 announced the Accelerated Access Review, with the aim to consider how to speed-up patient access to cost-effective and innovative medicines, devices, and diagnostics. Two years later, the U.S. Government approved the 21st Century Cures Act, a package that includes bills on mental health reform, FDA approval pathways,

Figure 8: Average R&D costs vs. average forecasted sales



Source: *Measuring the return from pharmaceutical innovation 2016: Balancing the R&D equation*, Deloitte UK Centre for Health Solutions, 2016

and biomedical innovation funding.⁶² The 21st Century Cures Act has broad industry, advocate, and stakeholder support, but concerns remain. Some advocates say that the act does not go far enough in addressing prescription drug prices. Others say that the act's funding is not stable since it is not mandatory and would have to be re-appropriated every year.⁶³

Companies and governments are expected to continue to increase funding into new product development:

- Worldwide pharmaceutical R&D spending totaled \$149.8 billion in 2015, and is expected to grow by 2.8 percent annually to \$182 billion in 2022 (compared with CAGR of 1.7 percent between 2008 and 2015).⁶⁴
- Overall medical device R&D spending is expected to grow at a CAGR of 4.3 percent from 2015 to 2020. R&D spend among leading medical device manufacturers has grown by 38 percent YoY, from \$1.6 billion in 2014 to \$2.2 billion in 2015, driven by investments in less-invasive devices, such as the innovative leadless pacemaker.⁶⁵
- Currently, more than 7,000 drugs and treatments are in development globally.⁶⁶

Blockchain technology could improve life sciences innovation, security, and accountability

Blockchain technology has the potential to drive life sciences innovation, strengthen security efforts, and increase company and industry accountability.ⁱ Blockchain, the technology underlying the crypto currency bitcoin, is a distributed ledger where multiple parties can see and add information transparently and securely.ⁱⁱ Data is exchanged, verified, and stored in fixed structures called blocks, and each copy of the blockchain independently validates new blocks before adding them to the chain.ⁱⁱⁱ

Although blockchain was originally proposed to revolutionize the financial industry, experts have turned their attention to pharmaceutical applications. As drugs are manufactured, patents filed, and clinical trials carried out, blockchain technology could be used across the product lifecycle and provide visibility among pharmaceutical companies, CROs, regulators, distributors, and patients. Blockchain could be used to validate user information, proof of work, and smart contracts (decentralized applications that automatically execute actions based on blockchain activity),^{iv} thus changing how the industry manages and records data, and improving stakeholder collaboration and transparency.

Blockchain also could provide enhanced visibility and data-tracking at various points along the pharmaceutical and medical device supply chain, combatting the ongoing problem of counterfeit medications.^{v,vi} The idea is to track the medication by using an immutable time stamp showing where and when it was produced. Blockchain also could supplement the pharma product serialization system by monitoring the national drug code, the unique serial number or the active pharmaceutical ingredient.^{vii} Finally, blockchain applications could help life sciences companies provide faster and more accurate reports to regulatory authorities by automating portions of the compliance process that draw on immutable data sources.

i. <http://dcebrief.com/applications-for-blockchain-pharmaceutical-industry/>

ii. David Schatsky and Craig Muraskin, "Beyond bitcoin: Blockchain is coming to disrupt your industry," Deloitte University Press, December 7, 2015, <http://dupress.deloitte.com/dup-us-en/focus/signals-for-strategists/trends-blockchain-bitcoin-security-transparency.html>, accessed October 6, 2016

iii. Blockchain in insurance: Turning a buzzword into a breakthrough for health and life insurers, Deloitte Center for Health Solutions, 2016

iv. Ibid

v. <http://www.ibtimes.com/blockchain-technology-could-help-solve-75-billion-counterfeit-drug-problem-2355984>

vi. <http://dcebrief.com/applications-for-blockchain-pharmaceutical-industry/>

vii. Ibid

However, according to the Deloitte UK Centre for Health Solutions' 2016 pharmaceutical innovation study,⁶⁷ its seventh-annual review of 12 leading biopharma companies' estimated returns, R&D productivity remains hit-or-miss:

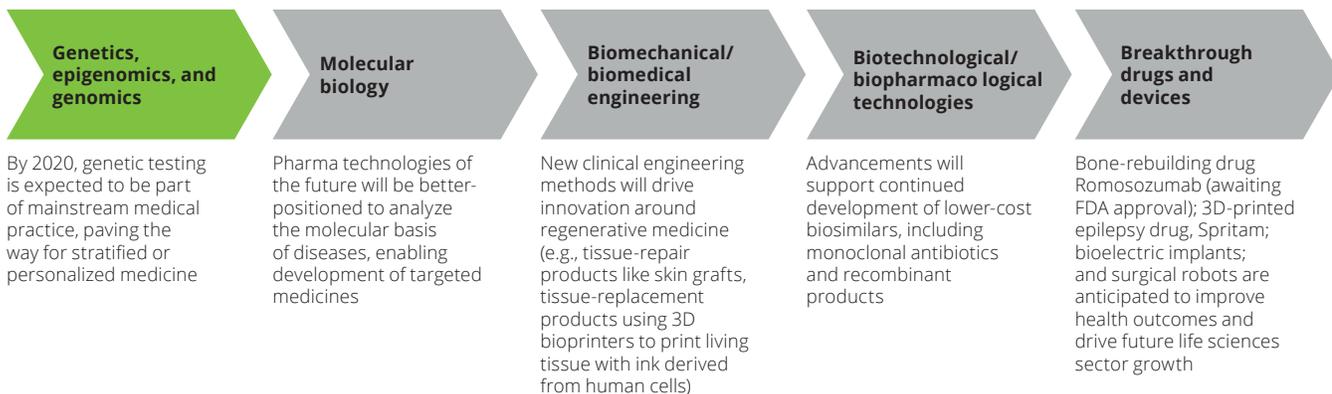
- Annual projected pharma R&D returns have continued to decline, from 10.1 percent in 2010 to 4.2 percent in 2015 to 3.7 percent in 2016.⁶⁸
- Peak sales per asset have fallen 11.4 percent year-on-year since 2010.⁶⁹
- Costs to bring a product to market have stabilized, from \$1.57 billion in 2015 to \$1.53 billion in 2016.⁷⁰
- Smaller pharma companies have seen a decline in overall performance, but on average they continue to outperform their larger counterparts, generating returns up to three times higher.⁷¹

Even with less-than-stellar productivity gains, more treatments are moving swiftly through the R&D pipeline:

- Fifty-six products were approved in 2015, a record high—although 2016 may yield less stellar results.⁷²
- The number of orphan drugs (i.e., drugs that treat very rare diseases that are often life-limiting) approved in both the United States and Europe has increased significantly over the last five years.^{73, 74}

A number of vertical and horizontal clinical trends are expected to drive life sciences innovation; have significant, transformative impacts on the products and services offered to patients; and improve how companies operate in terms of the efficiency and security of their product supply (Figure 9):

Figure 9: Trends in clinical innovation



Translational medicine. A translational approach to life sciences R&D connects the traditionally discrete steps of discovery, development, and delivery to facilitate a continuous process improvement cycle and accelerate time to market.³ Big pharma and other life sciences companies are using translational medicine to develop novel therapies for cancer and chronic diseases, focusing on gene sequencing, unlocking nanoparticles' potential and evaluating biomarkers.

Health care digitalization. The collection and electronic exchange of vital biological and clinical data (e.g., disease statistics, patient population statistics, electronic patient dossiers) among life sciences companies, providers, health plans, and patients can improve drug and device R&D, manufacturing, distribution, adoption, and use.

Artificial intelligence (AI). Technical advances by collaborating robotics and medtech companies are enabling semi-autonomous patient care and robot-assisted surgeries.

Big data and analytics. Sophisticated data sharing, processing, and mining techniques can support the development of personalized medicines, increase speed to market for new drugs and devices, and create a competitive advantage.

Sources: Deloitte's path to 21st century cures: A call to action, Deloitte, 2014
<http://www.delivering-tomorrow.de/wp-content/uploads/2015/08/dhl-white-paper-lsh.pdf>;
<http://whoswholegal.com/news/analysis/article/32977/trends-life-sciences-legal-market-2016>.

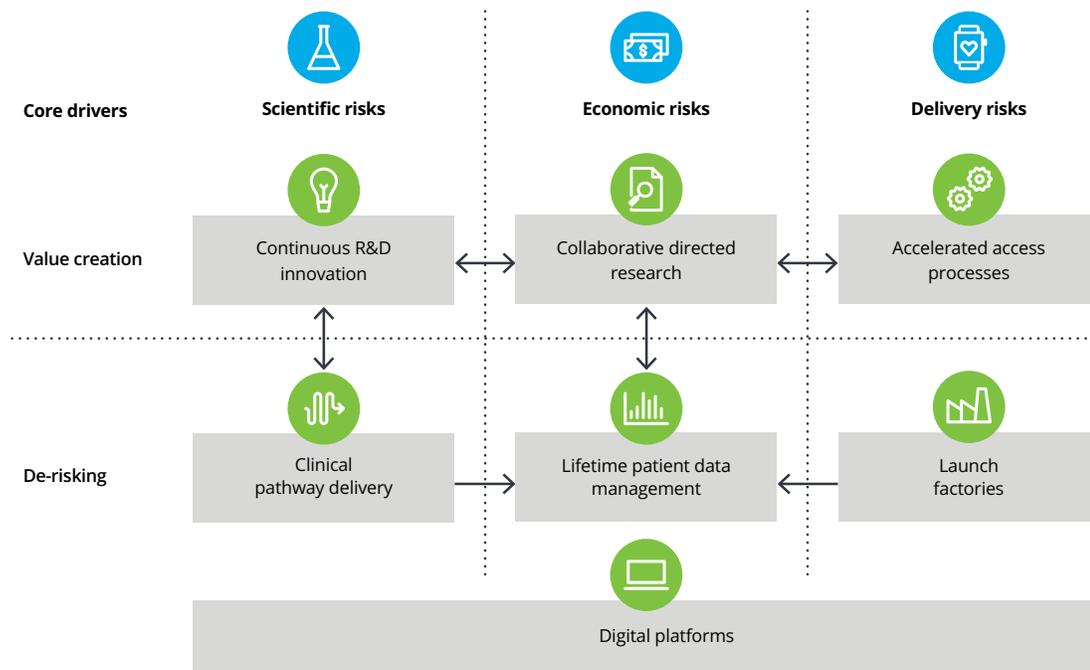
Stakeholder considerations: Driving clinical innovation

Aligning R&D capabilities around a few, stable TAs may add to scientific, regulatory, and commercial value propositions. In addition, reducing development complexity, through streamlining functions and addressing unproductive infrastructure, should materially improve returns.⁷⁵ Other suggestions to foster life sciences innovation include:

- Using real-world data to identify unmet needs and/or populations that benefit from existing therapies (based on ethnicity, genotype, comorbidities, etc.)
- Using big data (i.e., “omics”) to develop new therapies targeting specific patient populations
- Investing in companion diagnostics to guide research to the most likely targets, shorten R&D lead times, and support higher probabilities of success in subpopulations
- “Institutionalizing” innovation by sponsoring academic research and providing local job opportunities in exchange for steady access to a highly educated and well-trained workforce
- Expanding collaboration with high-tech companies to develop/provide more patient-centric care solutions (e.g., wearable technologies) that address unmet needs
- Replacing traditional organizational structures and processes to improve collaboration among geographically dispersed employees and partners
- Moving “beyond the pill” to consider broad solutions around prevention rather than simply treatment.

Concurrent with driving clinical innovation, pharmaceutical and other life sciences companies need to minimize the accompanying scientific, economic, and delivery risks that can diminish product value. Deloitte has identified seven options for “de-risking” and creating value in the life sciences business model (Figure 10):⁷⁶

Figure 10: Seven options for developing the pharma business model



Source: *Facing the tidal wave: De-risking pharma and creating value for patients*, Deloitte UK Centre for Health Solutions, 2016

Continuous R&D innovation. New innovation models can help improve the operational effectiveness of research organizations. The continuous R&D innovation model incorporates balancing skills, teamwork, a 'manifesto', partnerships, destructive creativity and multidisciplinary staff.⁷⁷

Lifetime patient data management. Lifetime patient datasets are used to develop an integrated understanding of patients and help de-risk the process of discovery through a better focus on unmet needs; improve selection of biomarkers/sub-populations; and support earlier/faster identification of trial patients.⁷⁸

Clinical pathway delivery. Following a patient's disease and treatments increases the probability of improved outcomes and increased productivity. Also, joint development of clinical pathways offers the opportunity to reduce delivery risks by improving pathway design and optimizing the division of work between pharma companies and the health care system.⁷⁹

Digital platforms. Digital platforms can create a step change in the cost of engaging with patients and physicians, both delivering significant new value and helping to lower costs.

Collaborative directed research. This approach shifts the balance of economic and scientific risk radically, and includes governments or other funders directing the research. Collaborative directed research was used successfully in the development of vaccines for Zika and Ebola.⁸⁰

Accelerated access processes. Working with regulators to redesign access processes could accelerate the availability of new drugs, increase adoption rates and redesign reimbursement and contacting models.⁸¹

Launch factories. Launch factories help improve launch efficiency, reliability and compliance. This makes them deliverable across different countries and products over time. A launch factory industrializes tools, methodologies, data sources, people/talent and processes.⁸²

Connecting with customers & consumers

Increasingly engaged and empowered health care consumers are demanding services and solutions that are coordinated, convenient, customized, and accessible. This trend is being driven by factors including patients' ability to change their own outcomes based on behavior; financial scrutiny due to cost-sharing models that push more costs onto the patient; the industry's shift towards evaluating outcomes to determine value delivered to the patient; and the availability of technology solutions providing patients with more information and the ability to play an active role in managing their well-being.⁸³

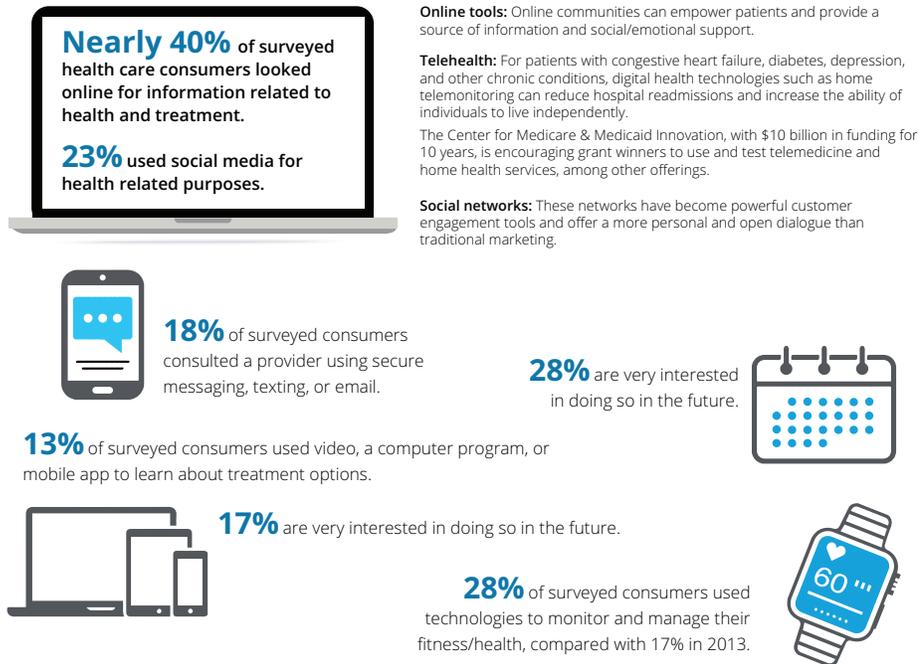
Large pharmaceutical companies focused on traditional markets have lagged in responding to the industry's changing focus towards holistic patient management—for example, many supply chain functions are struggling to wrap necessary services around their products to supply the expanding home health care market. Companies have a small window of time to frame their engagement strategies for operating in a new, customer-centered, digital ecosystem or risk being disintermediated by fast-moving entrants that are developing digitally enabled products and programs to cater to changing patient expectations.⁸⁴

According to findings from the *Deloitte 2016 Survey of US Health Care Consumers*, there is growing consumer appetite for using technology-enabled care:

- Seven in ten consumers are likely to use at least one of the technologies presented in the survey (e.g., telemedicine, remote patient monitoring, drones).
- Telemedicine, in which half of the respondents show interest, is the most popular technology. Respondents are most interested in using it for post-surgical care and chronic disease monitoring.⁸⁵
- Particular subgroups are especially keen on these technologies, especially those with chronic diseases, Millennials using telemedicine, and Seniors using remote monitoring.⁸⁶
- Caregivers are a key population. Consumers who are caregivers say they are most likely to use sensor technology when caring for others rather than for themselves. Experienced caregivers are more likely to use telemedicine and remote monitoring technology than non-caregivers.⁸⁷
- Consumers demand high-quality, personalized care. They also want assurance that their personal information will be safe.⁸⁸

The increase in data and information access, mobile applications, and personal health devices is accelerating the pace of consumer engagement in health care⁸⁹ (Figure 11). Today's consumers are posing pointed questions about the value of medicines, medical procedures, treatment regimens, and claims of medical superiority. These actions are putting pressure on life sciences companies to shift their focus from traditional product development and marketing models to more patient-centric ones.⁹⁰ They can begin by leveraging their digital and analytics capabilities to gather data and monitor outcomes, improve treatment regimen compliance, and increase product utilization.

Figure 11: Technology is powering consumer health care engagement



capabilities to gather data and monitor outcomes, improve treatment regimen compliance, and increase product utilization.

Social networks have become powerful customer engagement tools and offer a more personal and open dialogue than traditional marketing channels like commercials or advertisements. These networks allow patients and life sciences companies to interact in new ways, including collecting and sharing information on the efficacy of treatments. Patients have been a driving force for sharing and disseminating information regarding treatments and patient experiences through sites such as PatientsLikeMe, DiabetesMine.com, and TheCancerForums. Content is created within the blogs, online support groups, and resource tools for effective disease management. This allows patients to connect and interact with other patients to discuss treatment options and real user experiences.⁹¹

Source: *Convergence of health care trends: Innovation strategies for emerging opportunities*, Deloitte US Center for Health Solutions, 2015

medication safety data. Proper design of these instruments can help to increase the size of the population being monitored (thus increasing the likelihood of identifying rare events) and for tailoring the populations being evaluated that were not well studied during the trials needed for regulatory approval.⁹²

One of the most interesting consumer engagement challenges facing life sciences companies is how to increase consumer trust and improve the overall reputational perception of the sector. Historically, the pharmaceutical companies that manufacture prescribed medicines have not been trusted go-to sources—for information, support, or counseling—compared to a physician, nurse, or community group. But these companies are increasingly seeking to step in and answer questions and to help patients navigate the complexities involved in receiving a diagnosis, deciding on treatment, securing financial assistance, connecting with other patients and community experts, and supplementing clinical education.⁹³

Although trust in life sciences companies has grown recently, it's still lower than for other health care stakeholders and other industries. And recent public and political outcries over price increases for several widely used older drugs have done little to improve the industry's image. Creating greater awareness of a drug or device's role in the context of comprehensive treatment regimen costs is one way that companies can continue to engender consumer confidence and gain permission to participate in customer engagement—which in turn can go a long way towards building trust and impacting market opportunities.

Stakeholder considerations: Connecting with customers and consumers

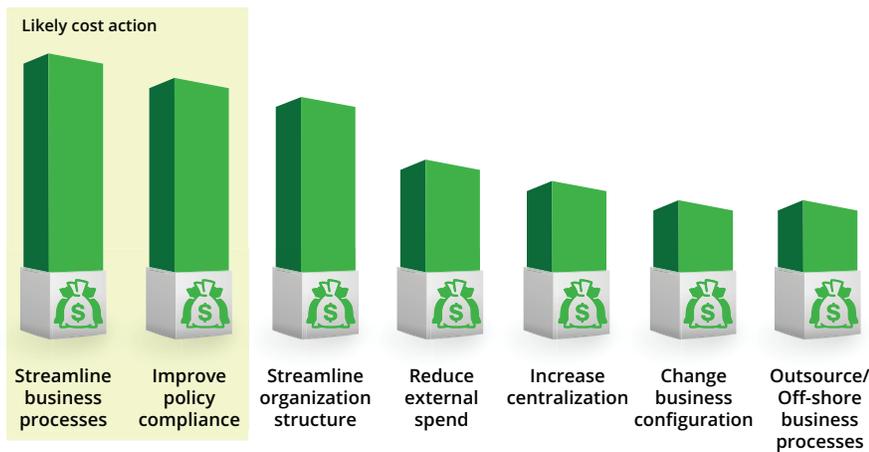
The increasing number and diversity of customer segments calls for life sciences companies to shift from “one-size-fits-all” engagement approaches to a more cross-functional, collaborative model that provides touchpoint opportunities throughout the product lifecycle. Organizations that understand how consumers like to use online resources and health technologies may be better-positioned to develop more effective engagement strategies. By doing so, companies can help to improve effectiveness, efficiency, and value in health care service and product delivery; excel on quality measures that reflect the consumer experience; and outflank their competition by attracting and retaining actively engaged customers.⁹⁴

Life sciences companies should strengthen consumer connections by developing online information resources, mobile applications, and personal health devices to help individuals in their patient populations and customer bases become more engaged.⁹⁵ In addition, they will need to streamline/harmonize all of their digital channels to provide a consistent customer experience and reduce costs. Using advanced analytics may provide pharma companies with a view across all customer types (prescriber, patient, and payer) to better understand the appropriate mix of messages and channels to help increase product utilization of products. However, solely offering technology tools may not be enough to move the needle. Marketing, customer service, and technical support will be critical for raising consumers' levels of awareness, comfort, and trust.⁹⁶ In addition, changing corporate culture is an important step in the evolution towards more customer- and patient-centric business models. One leading pharmaceutical company, for example, appointed a Chief Patient Officer in 2014 who implemented a patient-centric strategy into the organization.

Transforming business & operating models

Many life sciences companies are looking at how they can transform their current business and operating models to counter rising cost pressures and pursue excellence across their organizations—not only in R&D and global operations, but also in areas such as finance, sales, and distribution. According to *Thriving in uncertainty, Deloitte's fourth biennial cost survey: Cost improvement practices and trends in the Fortune 1000*, focus areas for life sciences and health care cost-management actions in the coming year include streamlining business processes and improving policy compliance with a focus on reducing administration and operational costs (Figure 12).⁹⁷

Figure 12: Life sciences company likely cost-management actions



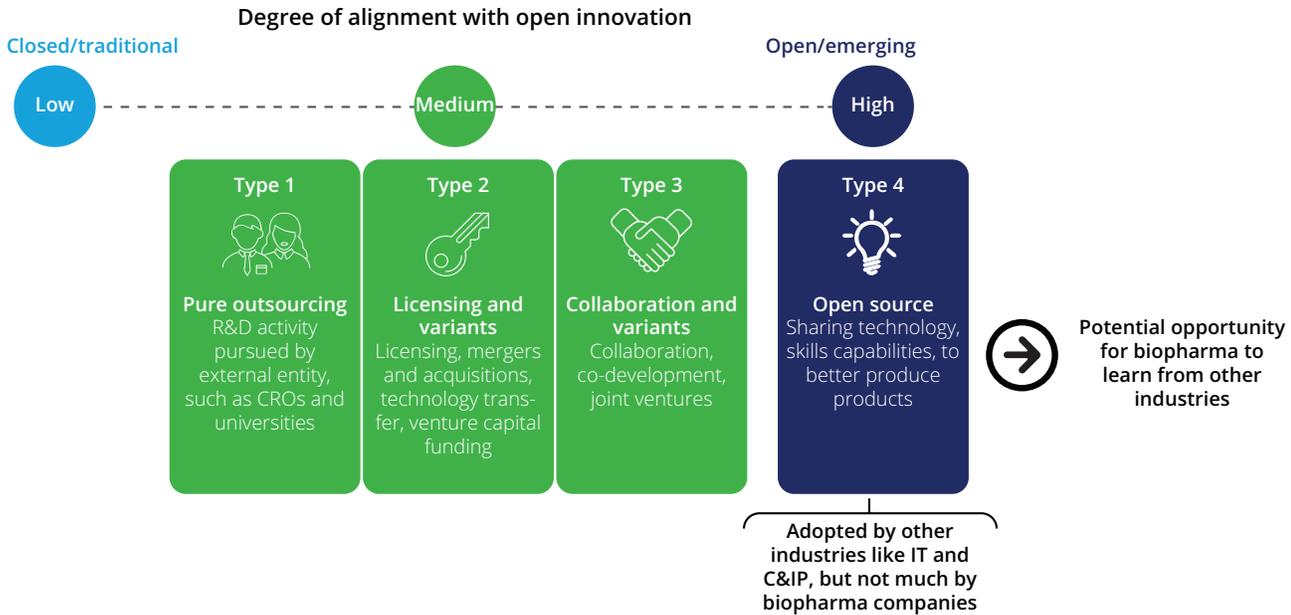
Because cost-management and transformation opportunities vary across geographies, customers and products, companies are taking multiple paths to achieve their quality, cost, and efficiency goals.

Collaborative product development—Life sciences is joining other industries in which companies have turned to open innovation (OI) and other collaborative models as a way to fill in-house capability gaps and overcome R&D and marketplace challenges by externally sourcing innovative ideas, knowledge, skills, and technologies.⁹⁸ Indeed, collaborating throughout the product development lifecycle is becoming an increasingly common and effective way for biopharma and medtech companies to offset mounting R&D costs, funding shortfalls, increasing disease complexity, and rapid-fire technology advances.⁹⁹ Collaborations can span the spectrum of openness (Figure 13, next page)

Source: *Thriving in uncertainty: Deloitte's fourth biennial cost survey: Cost improvement practices and trends in the Fortune 1000*, Deloitte, April 2016

and potential partners may be found in government, academia, traditional biopharma, and new industry entrants. According to a Deloitte analysis, there is a three-fold probability of success when drugs are sourced via OI.¹⁰⁰

Figure 13: Mapping the major types of open innovation along the spectrum of openness



Source: Titles for Type 1, Pure Outsourcing, And Type 2, Licensing And Variants, from Waldron RF, "Open Innovation in Pharma: Defining the Dialogue," Pharmaceutical Executive, September 1, 2012. Titles for Type 3, Collaboration and Variants, and Type 4, Open Source; the figure itself; and all definitions/details associated with all four types were developed by Deloitte Services LP.

Among current examples of collaborative life sciences product development is the United States' Accelerating Medicines Partnership (AMP), a \$230 million venture between the National Institutes of Health (NIH), 10 biopharmaceutical companies, and several non-profit organizations. The initiative aims to transform diagnostic and treatment development by jointly identifying and comparing biological targets of disease.¹⁰¹ Japan's top three pharmaceutical companies have announced that they will collaborate on building a biomarker database on healthy adults in a bid to optimize and speed up the development of innovative medicines—the first deal of its kind among those drug companies. In addition, 22 pharmaceutical companies are offering a total of roughly 200,000 compounds to a project led by the Japan Agency for Medical Research and Development (AMED) to match up drug makers' compound libraries and academic institutions' drug seeds.¹⁰²

In the United States, the 21st Century Cures bill became law in December 2016, providing \$4.8 billion in funding for the NIH and key initiatives focused on precision medicine, cancer, and Alzheimer's research. The regulation facilitates collaborative research and extends the National Center for Advancing Translational Science (NCATS) ability to support clinical trials through Phase IIb (previously IIa). The regulation also calls for innovation to the drug and development process—directing the FDA to establish a review pathway for biomarkers, provide guidance on the use of patient-generated data in drug development, evaluate RWE for the approval of new indications, create a breakthrough pathway for devices, and allow accelerated approval for regenerative medicine products.¹⁰³

Universities are a willing partner in efforts by life sciences companies to decrease the risks associated with early-phase product development. According to a Tufts Center study, many large life sciences companies have established collaborations with at least one academic medical center (AMC). These arrangements enable the training of a steady pipeline of scientists who can take on the big challenges present in health care. Regional innovation clusters, often found around major research universities, are also important to innovation.¹⁰⁴

Collaboration opportunities also extend beyond early-stage R&D. For instance, multinational corporations (MNCs) may partner with local enterprises to facilitate in-country product marketing and distribution. In addition, there is a growing trend of pharma MNCs teaming with insurance companies and regulatory bodies to improve coverage of expensive therapies or provide patient payment-assistance programs.

Portfolio and operational restructuring—Some biopharma and medtech companies are pursuing revenue and market growth by expanding their product portfolios via investments in new technologies such as regenerative medicine. Others are transitioning from being a short-term treatment provider to a long-term solutions provider offering products and services throughout a disease's lifecycle, from diagnosis to chronic-condition maintenance.

Numerous companies are streamlining offerings and/or operations by consolidating research centers or transferring non-core functions to contract research or manufacturing organizations (CROs or CMOs); swapping products with other players to build critical mass in a specialty area such as oncology or diabetes care; and divesting under-performing products or those in a certain lifecycle stage (i.e., off-patented drugs) to concentrate on specific geographic and/or therapeutic areas (e.g., drugs or drug delivery mechanisms that target complex disease areas with high unmet needs). It appears that medtech companies want to be seen as a master of a few products or therapies rather than a jack-of-all trades, as evidenced by ongoing streamlining of their product portfolios. Most of the big life sciences sector players in the United Kingdom continue to attempt to offload non-performing or uneconomic assets in their portfolios. It seems that many of these carve-outs are being picked up by small, locally-based providers. In the medium to long term this may provide an opportunity for greater innovation in the UK life sciences industry, provided these smaller operators can remain going concerns.

The Southeast Asia region is seeing changes in go-to-market models, where some MNCs partner or out-license their products to smaller pharma companies to perform marketing, sales and distribution activities. The tendency to outsource certain operations is moving closer to the core of supply chains, especially for mature products, for which filling and finishing is increasingly being shifted to contract manufacturers. Third- and fourth- party logistics providers cover tactical and administrative logistical activities as well as specialist services; for example, temperature management, emergency or courier shipments, recall management and patient assistance programs.

Growth through M&A—Merger, acquisition, and divestiture activity plays a significant role in life sciences companies' strategies to gain scale and to add new markets, new drugs, and novel technologies. In 2015, 236 pharma mergers and acquisitions were closed worldwide, worth over \$403 billion combined. The medtech segment saw 51 deals worth over \$1 billion.¹⁰⁵ M&A activity advanced in the first half of 2016,¹⁰⁶ although through November, global life sciences deal volume and value were down from the previous year.¹⁰⁷ Emerging markets performance was mixed but remains important. 2016 was also notable for the deals that did not happen.¹⁰⁸ The biggest transaction announced was eventually called off after the United States implemented tax inversion rules.¹⁰⁹

MNCs contemplating M&A are also preparing for international tax reform now that the OECD G20 Base Erosion and Profit Shifting (BEPS) initiative will fundamentally change the global tax landscape.¹¹⁰ BEPS is expected to alter the transfer pricing outcomes in many situations and to require multinational enterprises to undertake additional analysis and documentation.¹¹¹ BEPS and other tax changes may compel life sciences organizations to alter supply chains, move IP, and restructure certain businesses.

The general consensus is for continued life sciences sector consolidation in 2017. However, in light of some failed deals, analysts anticipate that big pharma will focus on acquiring smaller companies to strengthen businesses and portfolios. Medtech companies should also keep active in M&A, particularly with acquisitions of data analytics firms. As mentioned earlier, asset swaps in big pharma are likely as companies become de-diversified by choosing to only focus on one or two key TAs. Also, life sciences companies are expected to continue to divest assets and businesses in order to free-up cash and management attention to focus on core businesses and next-generation innovations. Regional M&A activity in 2017 could be variable: China expects to see increased outbound M&A as domestic pharmaceutical companies grow bigger and more eager to acquire advanced technologies and products overseas. Also, there are likely to be more attempts to form joint ventures (JVs) between MNCs and local firms. This gives MNCs enhanced local capabilities and market access and local firms more opportunities to learn advanced management skills. Conversely, disconcertion caused by BREXIT and continued political unrest in Ukraine may slow M&A activity in Europe.

M&A in emerging markets should continue to offer growth opportunities in 2017. Although results over the past few years have been mixed, life sciences companies should still look for openings in markets with significant access constraints and unmet needs—within Latin America, Southeast Asia and Africa, for example. Yet there are considerable barriers to acquiring, partnering, and operating in emerging markets. Apart from political instability and regulatory inefficiencies, many underdeveloped nations have poor transport and logistics systems, and the provision of intermediate goods to fuel production may become problematic. Even though cheaper labor may be available, the lack of adequate skills embodied by the labor force may require manufacturers to expend considerable resources on training and development, or, alternatively, to outsource labor. In addition to meeting good manufacturing practices as established by the World Health Organization (WHO), the aforementioned bottlenecks would require ongoing risk management on time and cost overruns. Governments in emerging markets such as China, Russia, and Southeast Asia also can make it difficult for MNCs to increase their global footprint by instituting policies that promote locally produced drugs and encourage domestic companies to invest in pharmaceutical manufacturing.

Talent transformation—Achieving operational excellence, measurable cost savings, and sustained innovation requires that life sciences companies leverage advancements in talent acquisition, management, and development as well as advances in technology because the two are intrinsically linked.

A confluence of factors is changing the way that companies and their employees operate. Often, clinical and technical employees work on global innovation teams that operate 24/7, aided by cloud-based computing, robotics, AI, and other technologies. More companies are using part-time and contract employees and partnering arrangements. Some are considering employing a contingent workforce, even with the legal and regulatory challenges that come with it, to temporarily fill skills gaps on demand and introduce more fluidity in recruitment. Crowdsourcing platforms are also gaining steam. These developments and others call for new workforce management models that recognize the advantages and challenges of an open talent economy and the need to develop and retain employees with critical clinical, business and technology skill sets.

Persistent talent shortages will continue to challenge global life sciences companies, especially in developing markets. Government efforts to boost domestic innovation and localized manufacturing in nations like Singapore and Russia are frequently stymied by a lack of qualified in-country talent. Singapore, for example, is tightening the approval process for work visas and companies may need to revisit their operations in Singapore if appropriate staff cannot be employed. Other Southeast Asian governments are working to ease restrictions on the movement of labor but it remains to be seen if and how quickly those efforts will meet the region's talent needs.¹¹²

Stakeholder considerations: Transforming business and operating models

Transforming customer needs and patient demands should compel pharma, biotech, and medtech companies to take a more holistic approach to manage operational complexities and business risk and drive greater integration and collaboration across their R&D, manufacturing, and commercial functions—especially if they work with CROs, CMOs, or other external partners. For example, companies can identify and analyze operational efficiencies as a way to develop innovative offerings while holding down R&D costs. Such an all-inclusive perspective could yield a different value model as opposed to the more traditional way of funding programs and controlling costs. Consideration should also be given to alternative private funding sources, especially public-private partnerships (PPPs).¹¹³

Life sciences companies should examine their supply chain strategies and seek to eliminate inefficiencies along the value chain. Using differentiated and specialized manufacturing and distribution systems—differentiating supply chains by product, for instance—could improve overall operational efficiency. In this case, third- and fourth-party logistics providers could cover tactical and administrative logistical activities as well as specialist services on behalf of pharmaceutical companies. Such activities could include temperature management, emergency or courier shipments, recall management and patient assistance programs.

Finally, M&A deal-making will continue in 2017 but transactions are likely to be smaller, especially compared with 2015's impressive tally. One area to watch is deals that combine life sciences with technology. While such transactions to date have been relatively small and more focused on alliances, life sciences companies can benefit greatly from analytics and digital investments, especially as these capabilities are not generally developed in-house. Also, if life sciences organizations don't use M&A and strategic partnering to join this community, they risk being leapfrogged by the technology companies.

Meeting regulatory compliance

The life sciences sector operates in one of the world's most regulated environments. Companies face particular compliance challenges as they seek to push the boundaries of innovation, developing and launching new products which address unmet patient needs but for which there is often little or no regulation.¹¹⁴ In 2017, organizations of all sizes will need to deal with a highly complex, changing set of global, regional, country, and industry-specific laws and directives that span a drug or device's developmental and commercial lifecycle. Primary regulatory focus areas include cybersecurity, drug and device safety, counterfeit drugs, intellectual property (IP) protection, and corruption.

- Cybersecurity**—Cyber-theft and cyber-espionage continue to endanger sensitive R&D and patient information and diminish life sciences sector profits. Developed markets, including the United States and United Kingdom, have suffered economic losses of more than \$279 billion due to cybercrime.¹¹⁵ Cyber security measures including implementing frameworks, integrated systems management programs, and security patch applications to identify data breaches have strengthened companies' ability to respond to threatened and actual cyber incidents. However, the security infrastructure needs to be even more robust, as life sciences and health care companies experience 340 percent⁵⁹ more security incidents than the average industry.¹¹⁶
- Drug and device safety**—In the past several decades there has been a rapid globalization in the manufacturing, distribution, and marketing of medicine and medical devices. Gradually more and more biomedical companies are conducting research in emerging countries that have nascent and expanding research regulations. Furthermore, pharmaceutical manufacturers are seeking to expand their market and need to submit applications for products to be approved and enter countries with requirements discordant to that of their own; this may result in additional costs, studies, and clinical trials and potentially slow down patient access to medicine. Global harmonization for the evaluation of quality, safety, and efficacy of drugs and medical devices could substantially reduce cost, encourage sharing of knowledge and resources, and result in fewer clinical trials. Identification of Medicinal Products (IDMP), for example, is a set of five data standards from the International Organization for Standardization (ISO) that allow for the definition, characterization, and unique identification of regulated pharmaceutical and biotech products across their lifecycle.¹¹⁷ The potential benefits of meeting evolving IDMP requirements extend far beyond regulatory compliance. Through IDMP implementation, pharmaceutical companies can unlock the power of product data to transform their business and improve patient health.¹¹⁸
- Counterfeit drugs**—According to the World Health Organization (WHO), 100,000 deaths annually are linked to the counterfeit drug trade.¹¹⁹ These fake medicines threaten human safety, affect consumer perceptions of drugs and drug companies, infringe on IP rights, and act as a barrier to pharmaceutical industry growth.¹²⁰ Legitimate drug manufacturers and distributors should continuously invest in countermeasures such as product traceability and authentication technologies. These efforts, however, can pose both financial and strategic challenges for pharmaceutical manufacturers, as they need to continuously update technologies and security along their distribution channels.
- IP protection**—Safeguarding valuable IP is a growing challenge, especially in Russia, Southeast Asia, and other emerging economies due to increasing prices for innovative drugs and protectionist policies favoring national market players. Some emerging countries already implement or have plans to implement compulsory licensing measures whereby patent-protected drugs are produced and sold without any consent of patent holders. Another concern is leakage of sensitive commercial information¹²¹ amid the operational shift towards collaborations with outside companies, suppliers, and scientists to spread R&D costs and risks. The loss of information may damage business prospects and help competitors. Furthermore, leakage of information surrounding clinical trials could introduce bias and potentially halt the development of life-saving drugs. Pharmaceutical manufacturers will need to implement costly security measures to protect their IP.
- Corruption**—Compliance failures such as payments to doctors/consultants and supply chain breaches carry the risk of fines and, more importantly, reputational damage. The United States continues to aggressively pursue and prosecute pharmaceutical industry violations: Over a 24-year period (1991 to 2015), U.S. federal and state governments made 373 settlements with pharmaceutical companies totaling \$36 billion.¹²² In addition, pharmaceutical companies are under significant scrutiny and have been receiving considerable negative press in respect to perceived exorbitant drug pricing and what areas of R&D and drug development they focus on and make available to patients. China's anti-corruption campaign continues and compliance remains a critical focus for companies, especially how companies should put appropriate controls on operations and how they should reorganize the sales force and optimize sales resources.

The regulatory environment is becoming more demanding and detailed which, in turn, will require businesses to implement stricter compliance policies, increase cross-functional collaboration, and improve data management and data integrity. For example, recent and ongoing regulatory changes in the EU are anticipated to be among the most significant yet. Every pharmaceutical, biotechnology or medical technology (medtech) company that currently sells or sponsors products in the EU will be impacted by IDMP, an enhanced EudraVigilance System,¹²³ the EU Medical Devices Regulation,¹²⁴ a new Clinical Trials Regulation,¹²⁵ the Falsified Medicines Directive,¹²⁶ and other changes

At a country level, many of Germany's legal and regulatory changes expected for 2017 are based on discussions identified at "Pharma Dialog 2016" between the German health and research ministries, the German pharmaceuticals industry, the academic community, and the respective trade union (IG BCE). Key discussion areas included continuously guaranteeing companies' ability to supply drugs prone to shortages, and protection against fortified medicines (suggesting the need for expanding the "securPharm" platform).

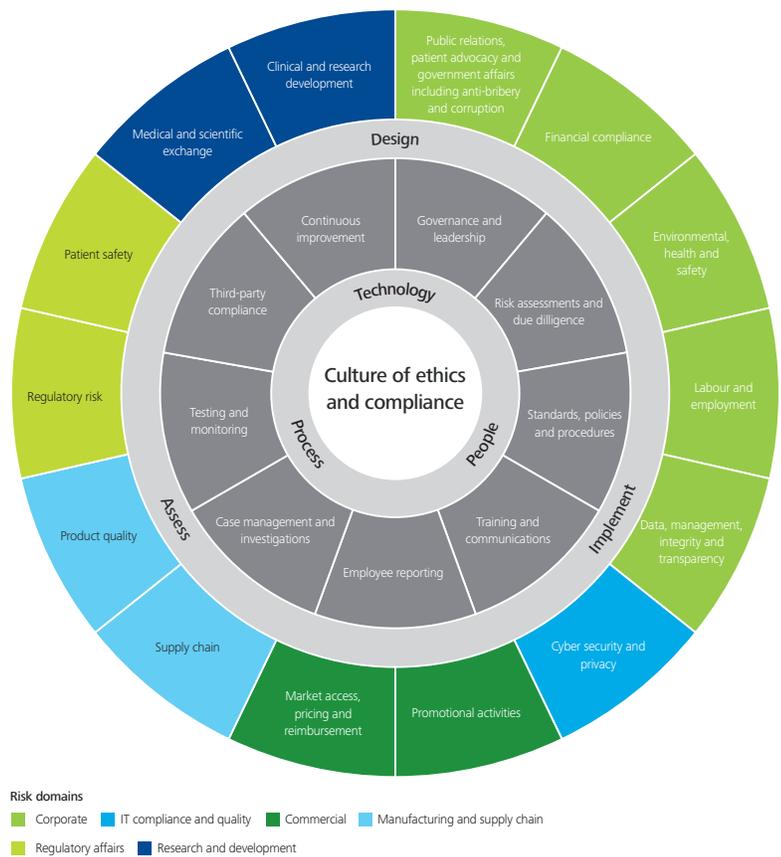
In China, regulatory complexities have a large impact on MNCs wanting to introduce innovative products there; companies may need to make changes to global R&D models to adapt to local policies. Mexico's Ministry of Health, through COFEPRIS (Federal Commission for the Protection against Sanitary Risk), is seeking to strengthen and align the country's life sciences manufacturing best practices with international standards including "PICS" (Pharmaceutical Inspection Cooperation Scheme). PICS includes 48 major health agencies that aim to exchange information, streamline, standardize, and reduce the time and costs of procedures related to drugs and active ingredients. And while most African countries do not have well-developed frameworks or bodies for regulating pharmaceutical and/or medical devices, South Africa is developing the South African Health Products Regulatory Authority (SAHPRA) to replace the Medicines Control Council (MCC), to give the government a wider mandate to regulate medical devices and complementary medicines. The entrance of SAHPRA, if it is approved in South Africa by 2017, should ease entry of drugs and medical devices into the country.

Managing operating models along with evolving regulatory requirements will test companies' abilities to respond in a coordinated, cost-efficient, and timely way. MNCs, regional, and local life sciences companies in 2017 should consider basing their efforts on a compliance risk framework that identifies and addresses their overall risk architecture (Figure 14).

Stakeholder considerations: Meeting regulatory compliance

Compliance failures can be costly in terms of fines, remediation costs, and reputational damage. Identifying, analyzing, and mitigating compliance risks are, therefore, essential in developing an effective compliance program.¹²⁷ Based on Deloitte's experience in helping companies manage regulatory change, we estimate that each large pharmaceutical company will need to invest in multi-million dollar programs over the next few years to implement the changes necessary for full compliance.¹²⁸ In considering their response, companies should look well beyond addressing basic, functional-level compliance requirements. Ultimately, the goal should be mitigating the most intrinsic industry risks, such as safety concerns and drug supply interruptions. By taking a proactive approach to tracking and monitoring the regulatory developments and understanding their independent and combined impacts to the business, companies can be well-equipped to comply in a timely manner, differentiate themselves in the marketplace, and be part of defining tomorrow's regulatory platform.¹²⁹

Figure 14: Deloitte compliance risk framework



Source: *The challenge of compliance in life sciences: Moving from cost to value*, Deloitte UK Centre for Health Solutions, 2015

Thriving amid uncertainty

"Sustainable growth" has evolved from catchphrase to mantra for companies operating in today's increasingly competitive, regulated, and cost-constrained life sciences sector. Incentivizing behaviors that will help enable organizations to tackle 2017's challenges and opportunities can pay off in increasing nimbleness, competitiveness, and growth. However, embedding the necessary corporate culture changes across functions, business lines, and locations requires consistent, top-down efforts – especially in large, geographically dispersed organizations. And although changes can be slow and uneven, they are taking place, as seen by expanding cultures of:

- **Partnering prowess**—Functional networks of academic, industry, and regulatory partners with shared values and a collective commitment to improve population health are becoming key competitive assets.
- **Shared accountability**—Defining ownership of projects and processes instills a sense of personal and collective achievement and responsibility.
- **Lifelong learning**—Continuous learning and experimenting at all employee levels helps a company maintain the necessary plasticity and enthusiasm to drive innovation.
- **Purposeful action**—Fostering employee confidence to continually move forward and align actions to a common set of values and objectives creates a purposeful work environment.
- **Nimble adaptability**—Acknowledging the reality of "survival of the fittest" imparts a sense of urgency and willingness to embrace and adapt to dynamic market conditions.

As mentioned at the beginning of this outlook, life sciences companies have always operated in a world of uncertainty, and they will continue to do so in 2017. Issues around cost and pricing, clinical and operational innovation, customer and consumer engagement, and regulatory compliance are not going away – in fact, these issues will continue to evolve and disrupt even the best strategic business models. Life sciences leaders who understand this reality, plan accordingly, and embrace change should be well-positioned to thrive amid uncertainty.



Appendix

Explore additional Deloitte life sciences insights

Explore the latest life sciences sector research from Deloitte member firms or visit:

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Are physicians ready for MACRA and its changes? Perspectives from the Deloitte Center for Health Solutions 2016 Survey of US Physicians

The Deloitte Center for Health Solutions 2016 Survey of US Physicians sheds light on physicians' awareness of MACRA, their perspectives on its implications, and their readiness for change. The survey is a nationally representative sample of 600 primary care and specialty physicians who were asked about a range of topics on value-based payment models, consolidation, and health information technology (HIT).

Measuring the return from pharmaceutical innovation 2016: Balancing the R&D equation

The pharmaceutical industry continues to face regulatory and reimbursement hurdles weighing on the research and development returns of pharmaceutical firms this year. The seventh annual pharmaceutical innovation study by the Deloitte UK Centre for Health Solutions looks at the challenges the industry faces in generating returns from its R&D investments while highlighting the key strategies to help increase pipeline value while reduce R&D costs to generate sustainable R&D returns.

Blockchain in insurance: Turning a buzzword into a breakthrough for health and life insurers

Health and life insurers are among the many players scrambling to determine how blockchain could be adapted to improve the way they maintain records, execute transactions, and interact with stakeholders. Key questions center on whether blockchain's unique attributes could help insurers cut costs, manage risk, improve customer service, grow their business, and, ultimately, bolster the bottom line. How can a cryptocurrency technology like blockchain potentially solve these problems and more?

Convergence of health care trends: Innovation strategies for emerging opportunities

The convergence of powerful trends—new technologies, the demand for value, a growing health economy, and the government as an influencer—is transforming the traditional US health care market. While this convergence is creating substantial challenges for health care stakeholders, it is also creating opportunities for innovation in four major areas.

Delivering medical innovation in a value-based world: Summary of the meeting between the Deloitte Center for Health Solutions and the Network for Excellence in Health Education

Discover the implications for medical innovation as the health care industry transitions to value-based care. Biopharma, medtech, health plans, and provider executives suggest four changes that could encourage innovation as value-based care takes root and evolves.

Deloitte's path to 21st century cures: A call to action

The United States has had a strong commitment to life sciences research and development (R&D) for new treatments and cures. A translational approach to the R&D value chain removes discrete steps and connects the discovery, development, and delivery processes. New learnings inform this value chain, and additional discoveries and developments lead to a continuous process improvement cycle. This could accelerate U.S. life sciences R&D and bolster global competitiveness.

Executing an open innovation model: Cooperation is key to competition for biopharmaceutical companies

Biopharma companies' reliance on a traditional, closed R&D model might stifle true innovation. However, companies that adopt a cooperative, open innovation framework are likely to spur product development, speed time to market, reduce costs, and increase competitiveness.

Facing the tidal wave: De-risking pharma and creating value for patients

The pharmaceutical industry is facing a 'tidal wave' of complex age and behavior related diseases creating increased economic, scientific and delivery risks. How can pharma companies evolve to overcome these obstacles? Report looks at the changing pattern of diseases and its implications for the industry whilst highlighting a series of bold choices on de-risking and delivering greater value to healthcare systems

Health care consumer engagement: No "one-size-fits-all" approach: Trends in consumers' use of online resources and health technologies from the Deloitte Center for Health Solutions 2015 Survey of US Health Care Consumers

Findings from the Deloitte Center for Health Solutions 2015 Survey of US Health Care Consumers provide evidence that consumer engagement is trending upward in three important areas — partnering with providers, tapping online resources, and relying on technology.

Measuring the return from pharmaceutical innovation 2015: Transforming R&D returns in uncertain times

Deloitte UK's Centre for Health Solutions sixth annual pharmaceutical innovation study looks at the challenges the industry faces in generating returns from its R&D investments.

No regulation is an island: EU regulatory changes and their impact on the global life sciences industry

The life sciences industry operates in one of the world's most regulated environments. Recent and ongoing European regulatory changes are anticipated to be among the most significant yet for the global life sciences industry. The new and updated EU legislation is expected to drive enterprise-wide changes for life sciences companies, impacting current organisational structures, governance, processes, and technology.

Patient engagement strategies in a digital environment: Life sciences companies respond to changing patient expectations

In a shifting health care landscape, patients are demanding care and solutions that are coordinated, convenient, customized, and accessible. In response, nontraditional players – pharma companies in particular – are coming forward to address these emerging expectations and establish their brands for patient engagement services.

The building blocks of IDMP implementation: Unlock the power of data to transform business and improve patient health

The potential benefits of meeting evolving Identification of Medicinal Product (IDMP) requirements extend far beyond regulatory compliance. Through IDMP implementation, pharmaceutical companies can unlock the power of product data to transform their business and improve patient health.

The challenge of compliance in life sciences: Moving from cost to value

How well does the life sciences industry understand the totality of its compliance risks? How is compliance managed and implemented? What does the future hold for compliance functions? The Deloitte UK Centre for Health Solutions' research provides a unique view of the enterprise-wide compliance functions of major life sciences companies.

The new transfer pricing landscape: A practical guide to the BEPS changes,

The new BEPS guidance has been hailed as a game changer intended to alter the transfer pricing outcomes in many situations and require multinational enterprises to undertake additional analysis and documentation. But how will the new BEPS guidance impact your company?

The rise of the digital supply network: Industry 4.0 enables the digital transformation of supply chains

SUPPLY chains traditionally are linear in nature, with a discrete progression of design, plan, source, make, and deliver. Today, however, many supply chains are transforming from a staid sequence to a dynamic, interconnected system that can more readily incorporate ecosystem partners and evolve to a more optimal state over time. This shift from linear, sequential supply chain operations to an interconnected, open system of supply operations could lay the foundation for how companies compete in the future.

Thriving in uncertainty: Deloitte's fourth biennial cost survey: Cost improvement practices and trends in the Fortune 1000

Global macroeconomic factors are having a major impact on cost management efforts at large US companies. Deloitte's fourth biennial survey of cost management and cost improvement trends explores how companies are managing costs in this challenging environment.

Unlocking the potential of value-based care in Medicare Advantage

Are health plans effectively engaging providers in testing value-based care (VBC) arrangements in Medicare Advantage (MA)? Results from Deloitte's 2015 Study of MA Health Plans and Providers suggest that there is great – and unrealized – potential. As yet, the business case for VBC in MA is not evident to all stakeholders.

Will patients and caregivers embrace technology-enabled health care? Findings from the Deloitte 2016 Survey of US Health Care Consumers

MOST everyone who has set foot in a hospital or clinic in recent years has seen changes in everything from ICU equipment to billing practices, primarily based on technology advances. And now technology is actually making care outside of traditional settings both possible and desirable. But it turns out that consumers—both patients and caregivers—can also be amenable to technology-enabled care.

Winning with biosimilars: Opportunities in global markets

Biosimilars are gaining traction across the globe. While developed markets will remain important for biosimilars manufacturers, Deloitte analysis indicates that long-term growth may be fueled by emerging markets. To win in these markets, biosimilars players will need to adopt a long-term strategy to provide affordable products and improved access to the large pockets of non-consumption.

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