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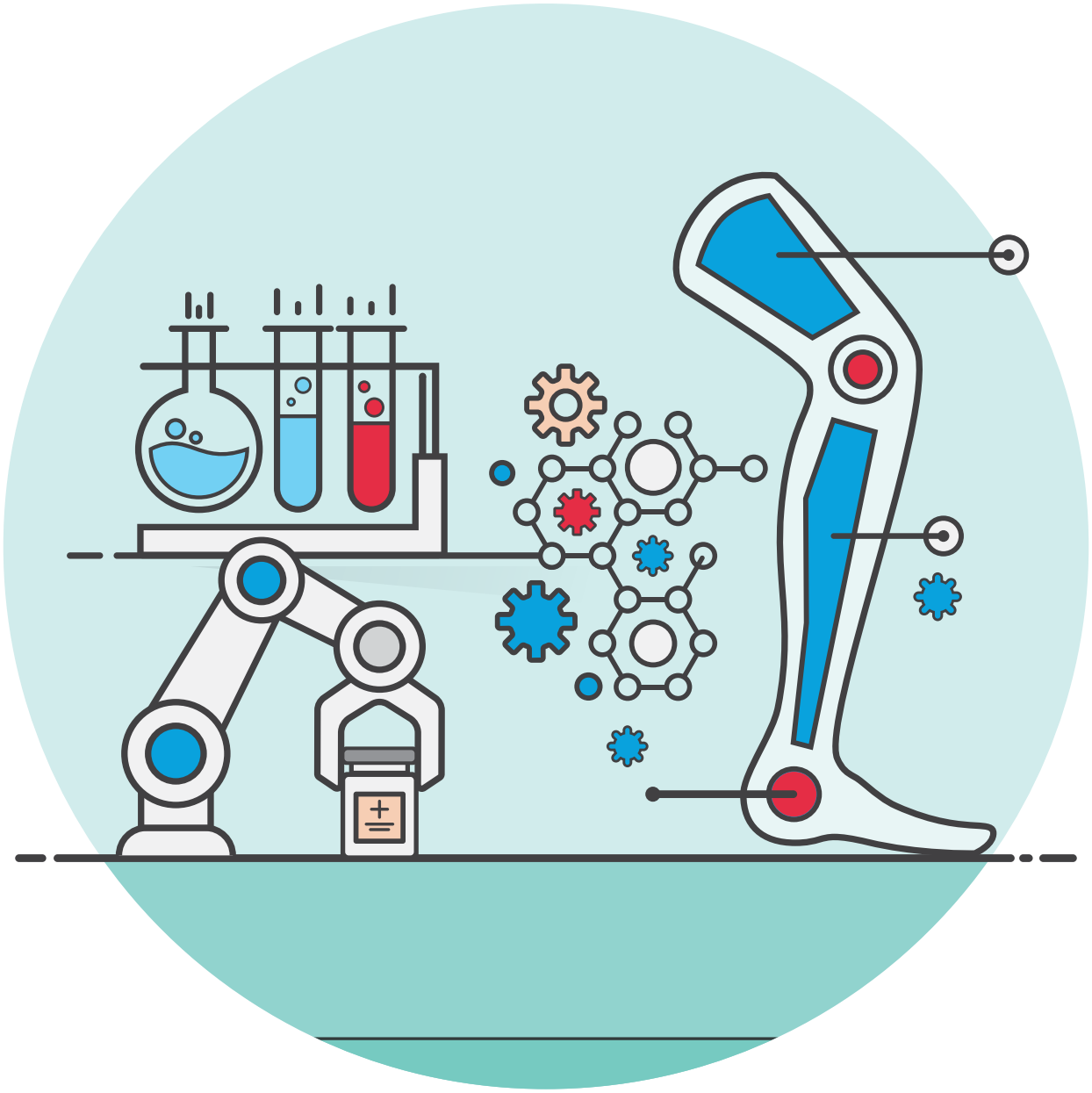

2018 Global life sciences outlook

Innovating life sciences in the fourth industrial revolution: Embrace, build, grow

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Outlook

Emerging technologies are creating a transformative opportunity for life sciences, and scientific achievements are on a record pace. The geopolitical climate is ushering in a new era led by the passage of tax reform in the United States and Brexit in the United Kingdom. In addition to embracing these changes, life sciences companies are looking for ways to meet the opportunities and challenges coming in 2018. Forward-thinking organizations will be:

- Building an adaptable organization for the future of work
- Building a culture of courage to help counter uncertainty
- Building data integrity, maximizing the value of data
- Building patient trust and centricity, across the journey of care
- Building a smart, cross-functional regulatory approach

In order to grow, life sciences companies will need to continue to look for new partnerships and operating models. Alliances and partnerships will be particularly important for accessing external expertise and technology. And technology companies, both large and small, are already poised to disrupt the industry.

Economic overview

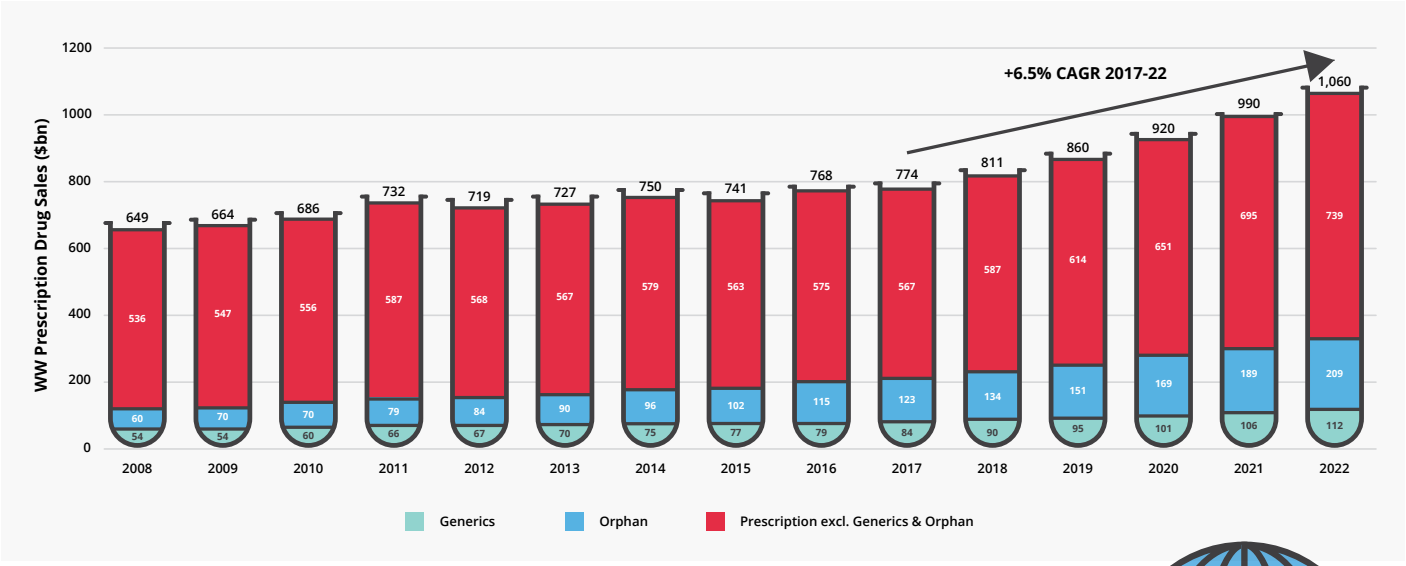
"Health life sciences" refers to the application of biology and technology to improve health care, and includes biopharmaceuticals, medical technology, genomics, diagnostics and digital health. The sector generates a wide range of products including drugs, medical technology, diagnostics and digital tools.[1]

Growth trends

Pharmaceutical drugs

On the heels of a slow recovery, global prescription drug sales are forecast to grow at an impressive annual compound rate of 6.5 percent in the next five years. Worldwide sales are expected to be US$1.06 trillion in 2022 (Figure 1).[2] This growth is in contrast to the 2.2 percent compounded annual growth rate (CAGR) in 2012-2016, but still under the 8.4 percent CAGR before the global financial crisis in 2004-2008.[3] However, this trajectory could be tempered by pricing pressures and a potential second patent cliff.[4]

Figure 1. Worldwide total prescription drug sales, 2008-2022



Source: EvaluatePharma, 2017

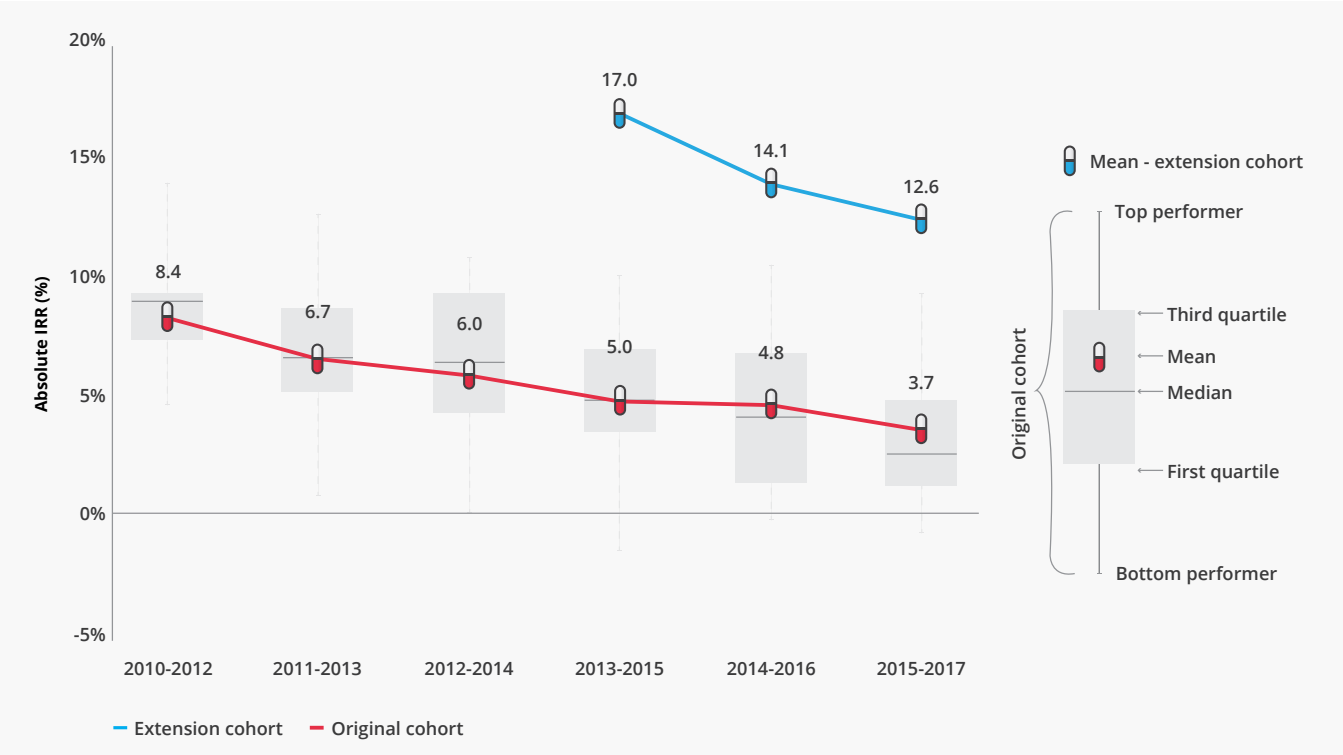
Although not at previous levels, most research-based pharmaceutical companies are reporting an uptick in revenue and profits. Spending on prescription drugs is expected to increase in every market except Venezuela over the next few years. Recovery in spending will be fueled by consolidation in generics markets and increased budgets for high-priced treatments, including orphan drugs. Some companies are still struggling with patent expiries, estimated to be a US$194 billion risk for sales in 2022.[5]

The industry will continue to look to emerging markets for growth, albeit not as aggressively as in the past.[6] Among the top 20 pharmaceutical markets in the world, eight are emerging countries supported by an increasing middle class. China is expected to reach the top three in the near future. However, constraints could come from government incentives that reduce medication reimbursements and health care costs.[7]

Worldwide pharmaceutical and biotech R&D is forecast to grow 2.4 percent per year to 2022, slightly lower than the 2.5 percent annual growth between 2008 and 2016. Total R&D spend is expected to reach US$181 billion in 2022, compared to US$156.7 billion in 2016.[8] Significant innovation is coming from small niche companies focused on discovering new drugs. Less than a quarter of drugs discovered are brought to market by the big pharmaceutical companies.[9]

The industry is expected to continue to face challenges in R&D returns (Figure 2).[10] The cost of bringing an asset to market reached record levels in 2017[11] and many of the largest drug developers will continue to be challenged by losses to generics.[12] With an increase in the number and speed of approvals,[13] a new normal in R&D is triggering competition in pricing, leaving less time for a manufacturer to gain substantially for breakthrough applications.[14] In 2018, the new US administration promises to continue the path towards faster approvals, but the risk in accelerated approvals can be a drug turning into a market disaster.[15]

Figure 2. Three-year rolling average returns on late-stage portfolio, 2010-2017



Source: A new future for R&D? Measuring the return from pharmaceutical innovation, Deloitte Centre for Health Solutions, 2017

Orphan drugs

The orphan drug market is expected to almost double in the next five years, reaching US$209 billion in 2022. It's expected that these high-cost, specialized drugs have and will continue to face pricing scrutiny by policymakers. Of the top 100 drugs in the United States, the average cost per patient per year for an orphan drug was US$140,443 in 2016, compared to US$27,756 for a non-orphan.[16]

According to the US Food & Drug Administration (FDA), 75 orphan drugs were approved in the United States in 2017,[17] compared to a total of 27 in 2016 and 56 in 2015.[18] The 50 highest-selling orphan drugs each averaged approximately US$637 million in sales.[19] While only about 600 treatments are approved, 7,000 conditions are designated as rare in the United States.[20] Major scientific advances will lead to even more rare diseases being identified and even more drugs seeking approval despite pricing pressures.[21]

The passage of the new US tax law reduces the orphan-drug credits that biopharma companies can claim by effectively 40 percent.[22] However, the reduction is not likely to change life sciences companies' strategies. The orphan drug market is a strategic market that solves unmet needs. The key benefits are not just the tax credit, but the other important aspects such as the seven-year market exclusivity, faster FDA review and waived fees, and exception from the ACA branded drug pharma fee for orphan-only drugs.

Biologics and biosimilars

Biologics are predicted to comprise more than a quarter of the pharmaceutical market by 2020.[23] With their success, the industry's biggest biologics face revenue threats from biosimilars and another patent cliff.[24]

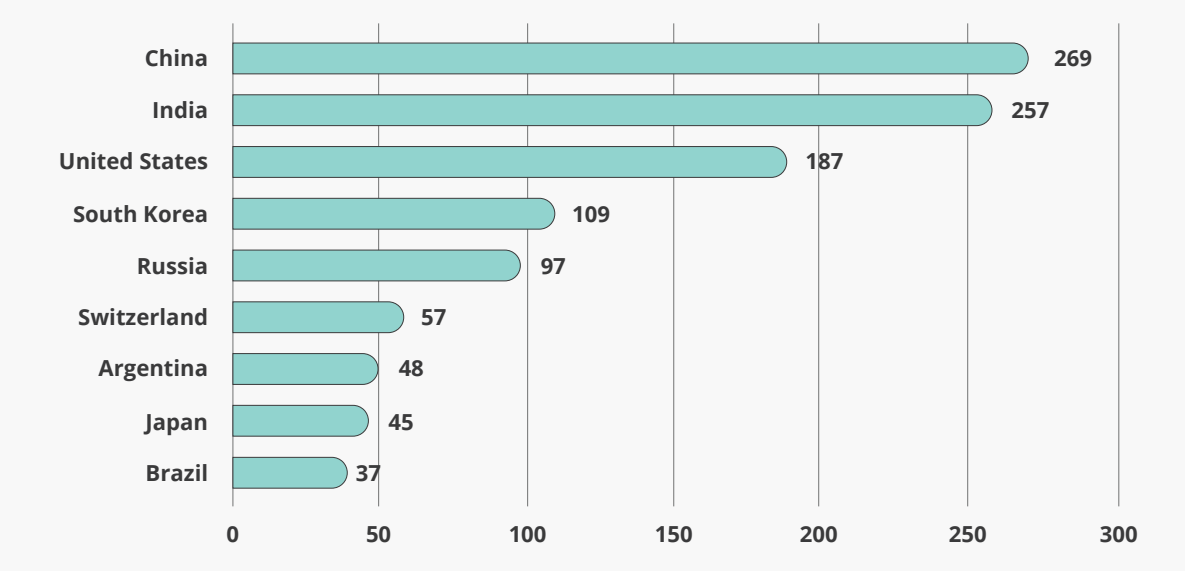
Lack of affordability and access to biologics are driving tailwinds for biosimilars, especially in emerging markets. In the European Union (EU), countries are seeing considerable cost savings with biosimilars, even when market share is low.[25] Typically, biosimilars are around 30 percent less expensive.

The highest impact in US biosimilar sales is expected in the next two years, with an estimated 25 to 35 biosimilars expected to be on the US market by 2020.[26] However, there are headwinds in the United States without a clear regulatory pathway.

The Asia-Pacific region has more biosimilars in development than anywhere else in the world, led by China (Figure 3). China has the potential to become the frontier market for biosimilar drugs.[27] The growth of biosimilars could push the industry into an innovative phase, even the potential for increased use of biologics.[28]

Figure 3. Country rank by biosimilar pipelines

Number of biosimilars in development by country



Source: Thomson Reuters

Improvements are being made in the manufacturing techniques used to produce biosimilars. We could see biosimilar manufacturing representing 10 percent or more of some companies' global biomanufacturing capacity in the next few years.[29]

Generics

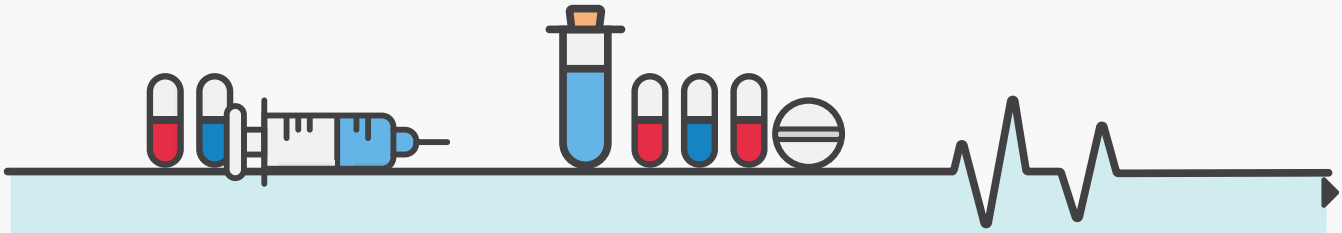
Global generic drug sales are expected to make up 29.2 percent of the total pharmaceutical sales worldwide in 2022, compared to approximately 28 percent in 2017. Emerging markets and the United States will drive demand for generics as they continue to cut health care costs.[30]

Generics now make up more than 80 percent of the volume of drugs dispensed around the world, and that percentage will continue to grow as more drugs lose patent protection. Many of the bigger products coming off patent are biologics.

Therapeutic focus trends

Oncology leads therapy areas in sales (Figure 4) and is likely to account for 17.5 percent of prescription drug and OTC sales by 2022, more than the next three highest therapy areas combined.[31] In addition to oncology, the largest CAGR growth in the top 15 therapy categories will come from immunosuppressants, dermatologicals, and anti-coagulants.[32]

Figure 4. Top 15 prescription drug & OTC therapy categories by worldwide sales, 2016-2022



Therapy area	2016 WW sales (US$B)	Projected WW sales 2022 (US$B)
1. Oncology	93.7	192.2
2. Antidiabetics	43.6	57.9
3. Anti-rheumatics	53.3	55.4
4. Anti-virals	48.5	42.8
5. Vaccines	27.5	35.3
6. Bronchodilators	28.3	30.1
7. Sensory organs	20.2	28.3
8. Immunosuppressants	11.6	26.3
9. Anti-hypertensives	24.8	24.4
10. Anti-coagulants	14.1	23.2
11. MS therapies	21.6	21.7
12. Dermatologicals	10.5	19.9
13. Anti-fibrinolytics	11.6	17.1
14. Anti-hyperlipidaemics	13.8	13.4
15. Anti-bacteria	10.5	12.8
Top 15	434	601
Other	369	500
Total	803	1,100

Source: EvaluatePharma, 2017

Personalized medicine

The global personalized medicine market is forecast to reach $2.4 trillion in 2022 at a CAGR of 11.8 percent, more than double the projected 5.2 percent annual growth for the overall health care sector.[33] Growth will be driven by advancements in technology and targeted therapies that are more efficient, and can provide more value. The focus is on prevention and early intervention, rather than advanced disease.

More than 40 percent of all compounds and 70 percent of oncology compounds have the potential to be personalized medicines.[34] Real-world data and artificial intelligence (AI) technologies are accelerating the development of the most fruitful molecules and compounds.[35]

Medtech

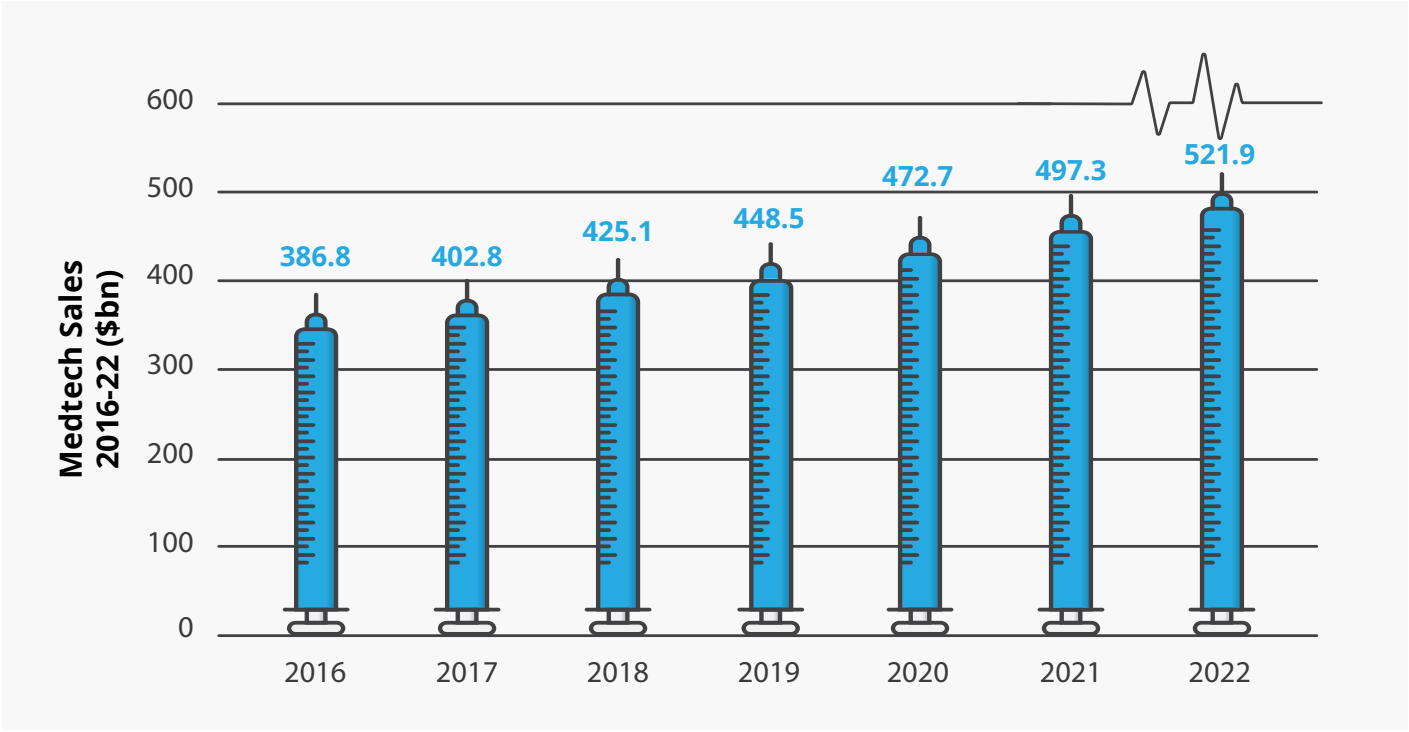
Worldwide medtech sales are forecast to grow at an annual compound growth rate of 5.1 percent, reaching US$521.9 billion by 2022 (Figure 5). In vitro diagnostics is expected to remain the largest medtech segment with annual sales of US$70 billion by 2022.[36]

Ranking second is cardiology, expected to reach US$62 billion in sales by 2022, followed by diagnostic imaging at US$48 billion, and orthopedics, which has been growing slowly at 4 percent per year to US$44 billion. The top 10 companies are expected to make up 37 percent of the medtech market in 2022.

Global medtech R&D spending is expected to grow by 3.7 percent CAGR to US$33.5 billion by 2022 from around US$27 billion in 2017. As a percentage of sales, the R&D investment rate is forecast to decline from 6.9 percent in 2016 to 6.4 percent in 2022.[37]

The repeal of the US medical device excise tax was not included in the recent tax reform and the medtech industry believes the tax has a significant negative impact on medical innovation.[38] However, the industry continues to pursue alternative legislative measures to at least continue the two-year moratorium on the tax that expired 31 December 2017.

Figure 5. Global medtech sales (US$B), 2016-2022



Source: EvaluateMedTech, 2017

M&A investment trends

Life sciences

2017 saw a further decline in deal value from 2016, resulting from global economic and political uncertainty. Large deals that were announced in 2017 tended to be focused on traditional acquisitions that were within the core competencies of the acquirer. According to Thomson Reuters data, the largest deal through Q3 2017 is Becton Dickinson & Co. acquiring CR Bard in April, in a deal worth $24.2 billion. In biotech, Gilead Sciences Inc. acquired Kite Pharma Inc. for $11.1 billion. In pharmaceuticals, Thermo Fisher Scientific, Inc. acquired Patheon NV (99.0066 percent interest) for $7.2 billion.[39]

We believe 2018 will see an uptick in deal volume as well as value, and an increase in mega deals, for a number of reasons:

- The passage of tax reform in the US, the progress of the Brexit negotiations, and the maturation of policy with respect to outbound deal-making from China clears up some of the uncertainty that was constraining M&A in 2017. US tax reform offers some incentives to repatriating monies back to the United States, which could spur additional high value M&A transactions.
- Capital markets remain strong. A weak M&A deal environment across industries in 2016 has resulted in pent-up demand to create value through M&A transactions going forward.
- The life sciences sector remains fragmented. Additional value can be captured via further industry consolidation.

Non-traditional, technology-oriented adjacencies represent an important aspect of M&A strategy for life sciences companies in 2018. The convergence of tech with other sectors has been, to this point, largely driven by tech industry players themselves. However, we are now seeing consumer health, health plan, medical technology, and pharmaceutical sector participants pursuing M&A transactions that either directly or indirectly respond to tech advances and tech investment.

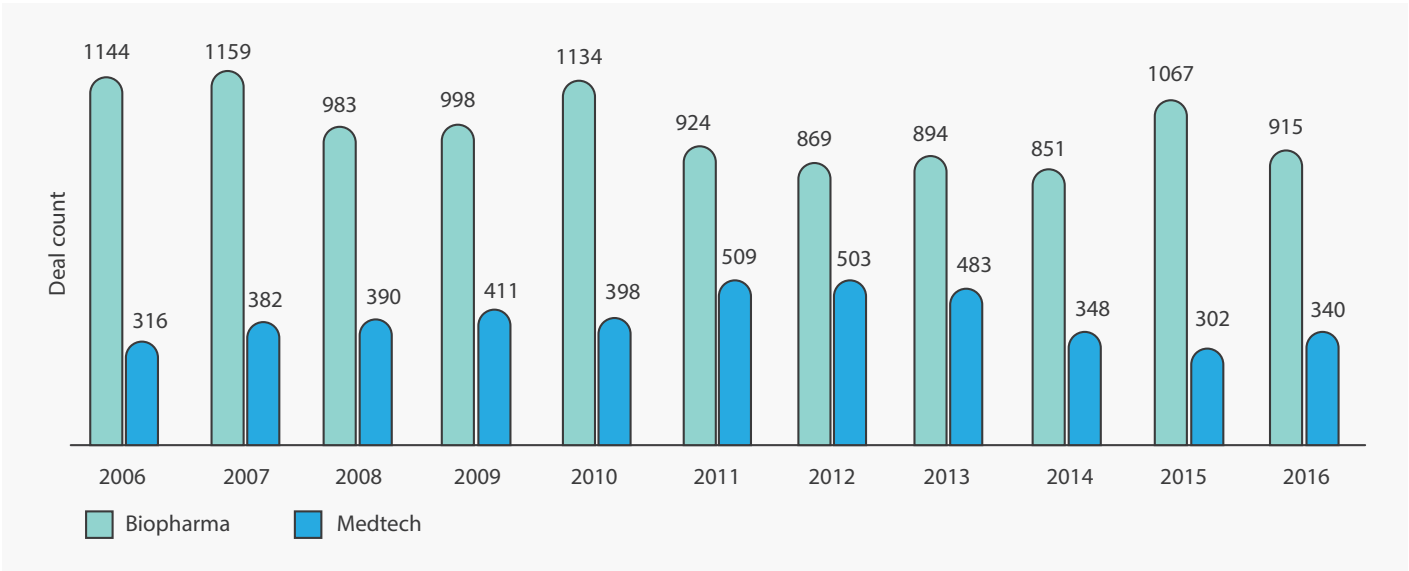
Medtech

In 2017, the total value of medtech venture financing deals rose considerably, despite the number of deals falling.[40] Finding new technologies to fuel future growth could be a challenge for large, established medtech companies.[41]

Exponential advances in technology make medtech ripe for innovation. Sensors, analytics, AI, and other digital health technologies are converging with medtech. Companies have an opportunity to create new business models and pivot from product developers to solution providers. Digital health technologies appear to be attracting more venture capital investment than traditional medtech as well as attracting new types of organizations to invest in the sector.

Large medtech company partnerships are becoming an alternative to traditional venture capital investment. In comparison, biopharma has almost three times the partnership activity as medtech (Figure 6).[42]

Figure 6. Biopharma has almost three times the partnership activity as medtech



Note: Strategic alliances include JV, co-development, co-marketing, and licensing deals
Source: Out of the valley of death: How can entrepreneurs, corporations, and investors reinvigorate early-stage medtech innovation, Deloitte Center for Health Solutions, 2017

Embrace

Embracing exponential changes in technology

The industrialization of life sciences

We are in an era of exponential change – a fourth industrial revolution. Emerging technologies are creating a transformative opportunity for life sciences. Demographic and economic changes, increased patient expectations, and the growth of personalized medicine are disrupting health care worldwide.

AI and cognitive technologies, automation, and computing power are advancing at an accelerating rate. Continuous manufacturing technology and robotic process automation (RPA) are shortening production times and increasing process efficiencies.

Everything is increasingly being connected, and the physical and digital worlds are collecting massive amounts of data. Data from the Internet of Things (IoT) can be continuously accessed in real-time. As data volume grows, the cloud is expected to provide on-demand scale. Blockchain technology pilots are starting to emerge and cybersecurity remains a critical priority.

With advances in science and the growth of new technologies, there is expected to also be a growing demand for people who can drive innovative insights from massive amounts of data – creating new roles in life sciences.

Advances in science and technology

2017 was a breakthrough year in scientific achievements with drug approvals hitting a 21-year high.[43] Since 1950, we have not seen so many breakthroughs in such quick succession.[44] In 2018, the trend will continue, coupled with concerns over the cost of innovation and the affordability of treatment.[45]

3D printing

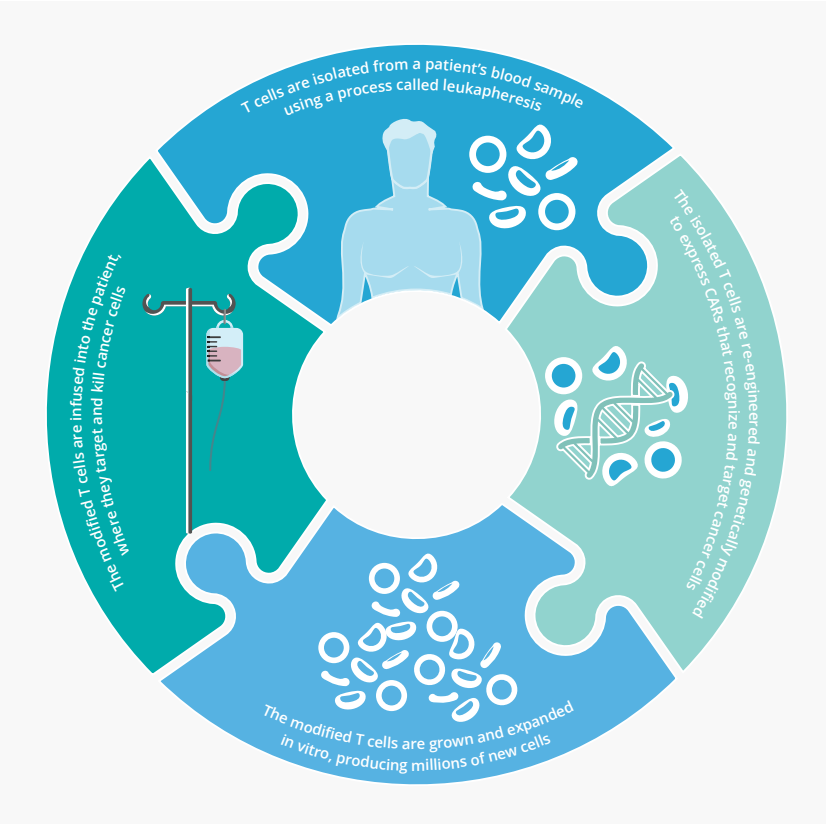
3D printing is another promise of a new global industrial revolution as well as an opportunity to customize patient treatment. For biologics, 3D printing is being explored as a better way to manufacture cell and tissue products. Drugs and disease models can be tested on 3D-printed tissues instead of on animals or humans.[46] In manufacturing, 3D printing has the potential to lower costs, increase production speed and flexibility, minimize distribution borders, and create new markets worldwide.[47]

The FDA says that 3D printing is "a tantalizing step toward changing the manufacturing processes to offer personalized medicines."[48] While only one 3D-printed drug has received FDA approval, 3D printing technology is much farther along for medical devices. About 200 3D-printed devices have been approved in the last decade that can be tailored to fit a patient's anatomy.[49]

Gene therapy

Gene therapy may disrupt the sector by offering customized, targeted patient treatment, including newly approved CAR-T therapies (Figure 7).[50] While adoption is still low due to availability, insights from human genetics and precision medicine have transformed health care, bringing value through innovative biotechnology.

Figure 7. First CAR-T therapies approved



Source: A new future for R&D? Measuring the return from pharmaceutical innovation, Deloitte Centre for Health Solutions, 2017

Gene therapy will continue to play a significant role in the rare diseases market. Since approximately 80 percent of rare diseases are of genetic origin, gene therapy is a rapidly emerging treatment, with several pharmaceutical and biotech companies testing gene therapies to treat various orphan diseases. Different approaches are being explored, such as the replacement of a defective gene with a healthy one, inactivation of a mutated gene, and introduction of a new gene in the patient's body to fight a disease. According to the Alliance for Regenerative Medicine, currently 34 gene therapies are in the final US FDA approval stage and 470 are in initial clinical trials.[51]

AI in drug discovery

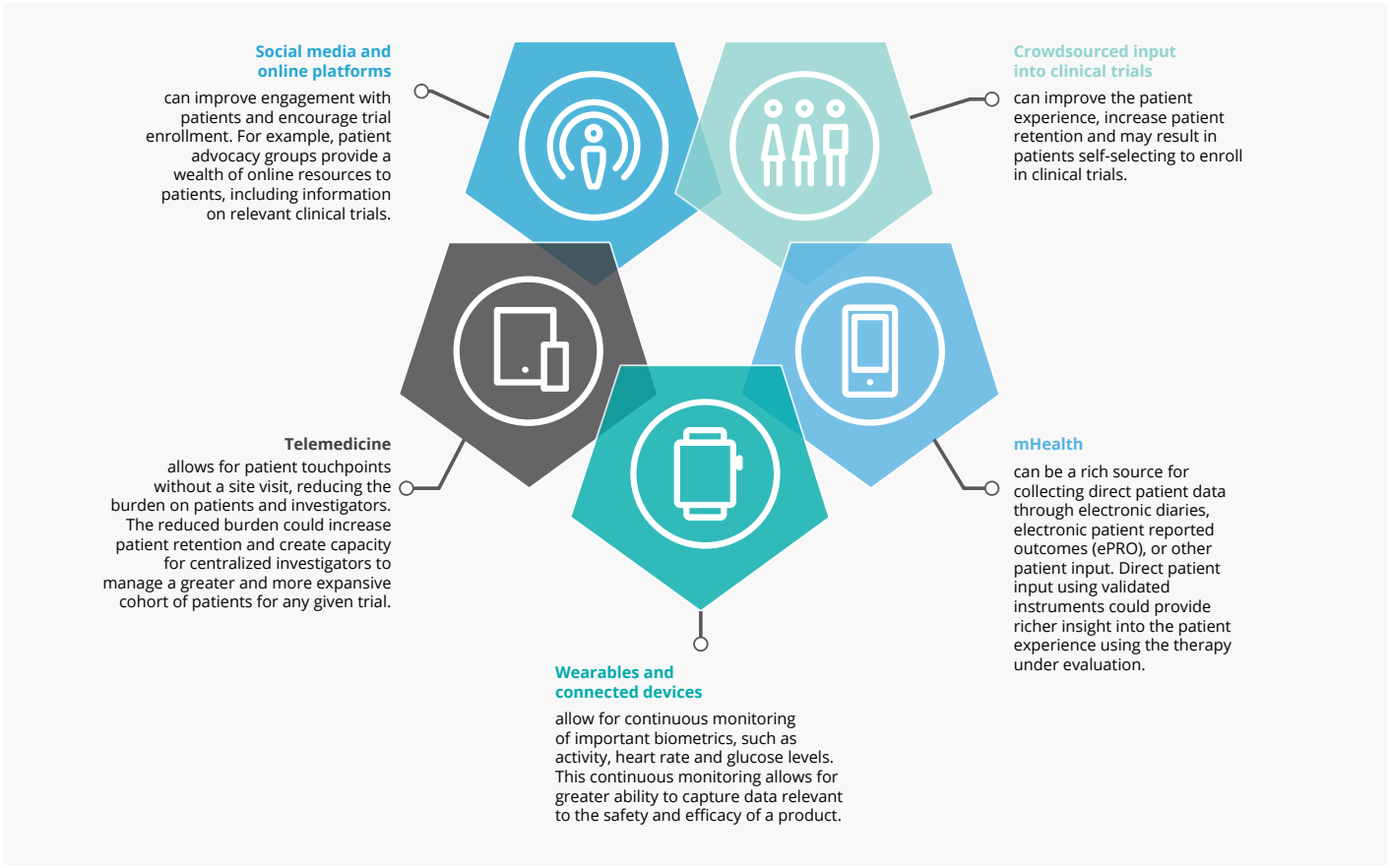
A growing number of global biopharma companies are using AI to streamline the drug discovery process. AI algorithms can analyze large data sets from clinical trials, health records, genetic profiles, and pre-clinical studies. Patterns and trends within this data can help develop hypotheses at a much faster rate than researchers alone and deliver new insights more quickly.[52]

Technologies in the connected journey of care

Cognitive computing is also being used to improve patient outcomes. Companies are partnering with large and small technology companies to derive insights from the high volumes of data generated from EHRs, claims, clinical trials, and other sources.

Many inpatient health care services can now be delivered more effectively at home or in outpatient ambulatory facilities. Clinical roles have been optimized and providers can use cognitive technologies to deliver more seamless, integrated care, designed around patient needs.[53] Social media, mHealth, wearables, connected devices, and telemedicine all have the potential to transform how patients engage in clinical trials (Figure 8).[54]

Figure 8. Technologies that can benefit patient engagement and clinical trial productivity



Source: A new future for R&D? Measuring the return from pharmaceutical innovation, Deloitte Centre for Health Solutions, 2017

Speed, scale, complexity, and security

Cloud computing

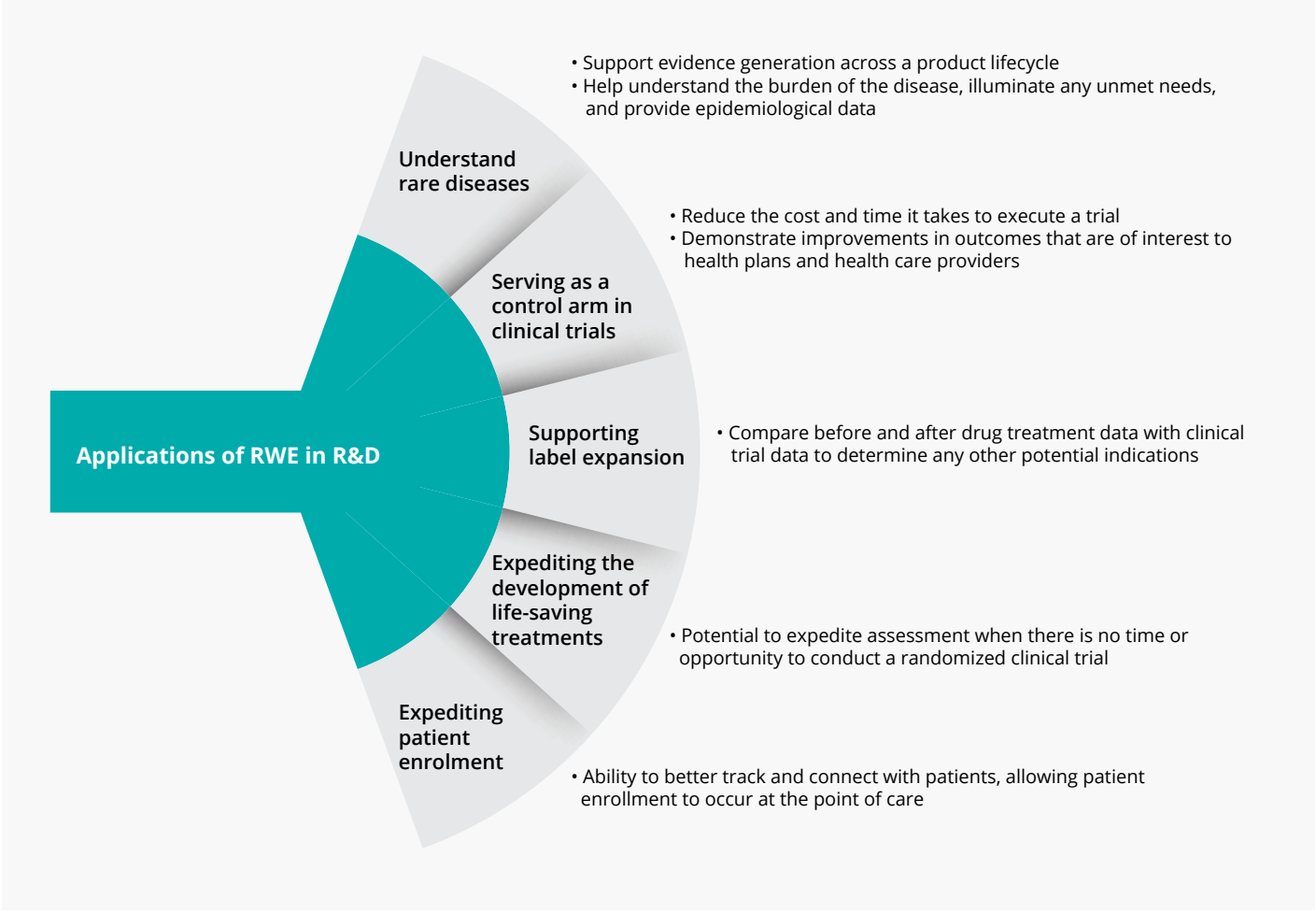
Another trend is the adoption of cloud technologies for the speed, scalability, flexibility, and security they provide. More than 60 percent of life science leaders surveyed by Deloitte said having a scalable environment was "most important." As data volume grows, the cloud can provide on-demand scale, allowing users to access computing and storage resources when needed. Combined with newer big data technologies, using the cloud can improve analytical systems' overall performance to manage real-world data.[55]

Technology accelerating R&D

The use of big data for evidence generation could vastly improve the speed and outcomes of clinical development. AI, real-world evidence (RWE), and robotic and cognitive automation are expected to bring transformational change to R&D (Figure 9).[56]

These emerging technologies can improve study design, physician and patient recruitment, and in-trial decision making as well as increase efficiency and accuracy in repetitive tasks all the way through to regulatory filing.[57]

Figure 9. Applications of real-world evidence (RWE) in R&D



Source: A new future for R&D? Measuring the return from pharmaceutical innovation 2017, Deloitte Centre for Health Solutions, 2017

In the future, a "virtual control room" could provide real-time insights for continuous improvement in a data-driven R&D operation, including site-less virtual clinical trials. But R&D leaders surveyed say a paperless R&D world is still a distant prospect.[58]

Technology optimizing the supply chain

Accelerating technologies are also bringing dramatic transformation to the pharma supply chain. Traditional linear and siloed supply chain processes will be transformed into connected "digital supply networks" – harnessing the power between the physical and digital worlds, including visibility of third parties.

Because many of the supply chain compliance processes are routine, they can be optimized through a scalable, flexible solution that leverages advanced data analytics, cognitive computing, and RPA.[59] This will not only reduce costs, but also improve accuracy and reliability.[60]

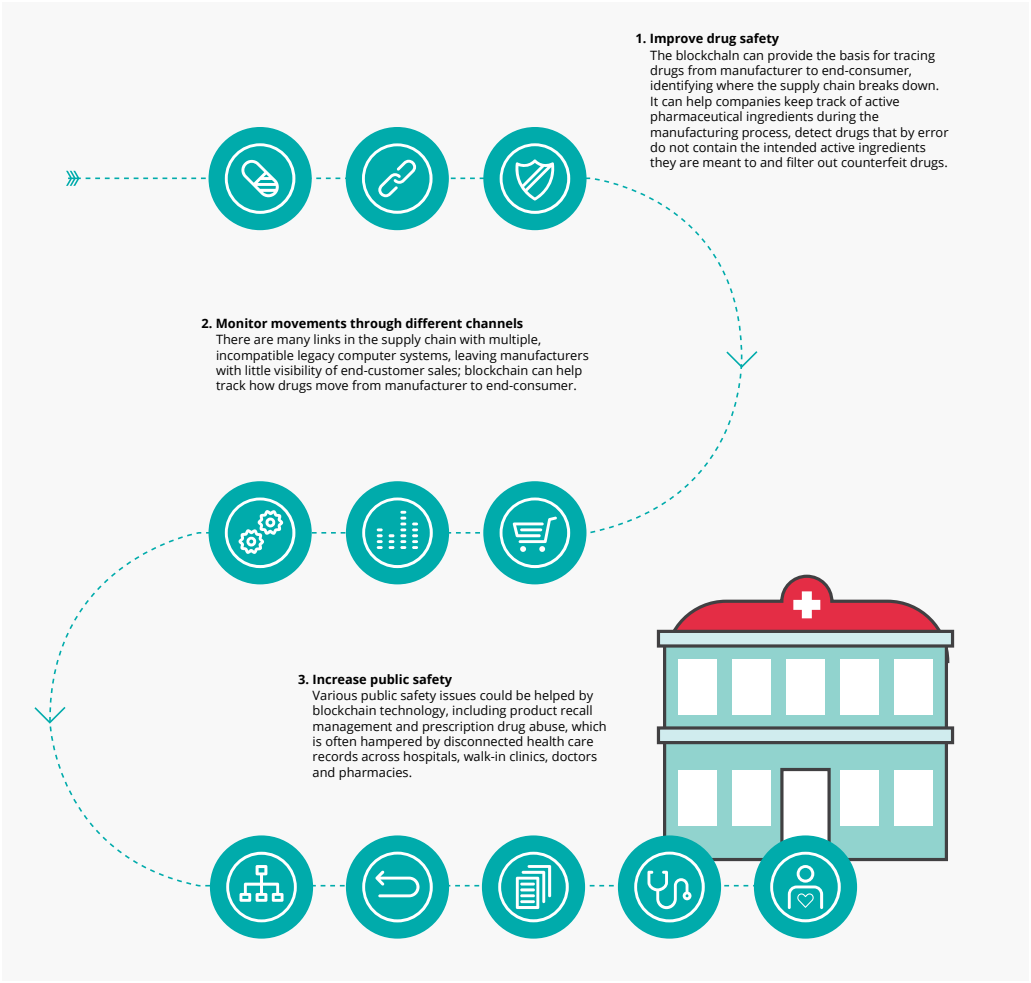
Blockchain technology

Pharma companies are starting to explore blockchain technology. The blockchain is a shared, immutable record of peer-to-peer transactions built from linked transaction blocks stored in a digital ledger. The blockchain allows each patient data source to be a "block" of a complete, unalterable patient data profile that can then be shared securely with health care providers or research organizations.

For pharma, the blockchain can record irrefutable evidence on the performance of a medicine and demonstrate adherence to a prescribed regimen, issues that continue to be a priority for the sector (Figure 10).[61] Other use cases include smart contracts and evidence sharing between regulators and collaborators in R&D. In the future, blockchain solutions from different companies or even industries will be able to communicate and share digital assets with each other seamlessly.[62]

Even though pilots abound, the adoption of this technology as an integral platform is still in a nascent phase.

Figure 10. Blockchain can benefit pharma supply chain



Source: A new future for R&D? Measuring the return from pharmaceutical innovation, Deloitte Center for Health Solutions, 2017

Scale and complexity of cyber threats

The scale and complexity of cyber threats will require organizations to elevate cybersecurity to a constant, critical priority. In the next year, 70 percent of all enterprise cybersecurity environments are expected to use cognitive/AI technologies to assist humans in dealing with cyber threats. IT architectures are increasingly being secured through cloud, hosted, or software as a service (SaaS) security services. Another growing trend is biometric authentication, expected to be used in half of all online transactions by 2021.[63]

Demand for data, analytical, and AI talent

New technologies are creating new roles in life sciences, including the addition of a chief data officer to the C-suite in many organizations. While demand for data, analytical, and AI expertise is increasing, there is a scarcity of talent.

Life sciences companies compete for the majority of data scientists and graduates with other technology companies or payers and providers. Only one-fifth of companies recruit data scientists from other life sciences companies, looking for talent already familiar with RWE. The rest are training in-house statisticians from other departments.[64]

Hiring from other industries is seen as an opportunity to get new insights. However, life sciences companies are challenged to retain this talent due to a lack of operating models and talent structures conducive to new work paradigms. For example, data scientists need to be integrated across the organization, not in IT silos, to deliver actionable insights and a holistic view of data.

If big pharmaceutical companies do not provide this talent with opportunities to maximize their skillsets and provide upward mobility, they can expect to lose them to smaller startups and other industries.

Embracing geopolitical change

Pricing pressures and value-based contracting

Pricing pressures and portfolio strategies

Pricing, along with securing market access, are expected to continue to be a top priority for life sciences companies in 2018. Changes in the payer and pricing environments in the United States and Europe have meant that larger companies are re-balancing portfolios to ensure that high price products are not over-represented, and that broad access to markets is maintained.[65] Several countries are focused on cutting pharmaceutical pricing, including Australia, France and Germany.[66]

Balancing the value and volume parts of the business is seen as a key to a successful R&D portfolio strategy.[67] Companies focused on consistent therapeutic areas (TAs) and few classes of high value products are seeing the highest returns in the sector. However, activity in some areas of R&D serving the smaller markets – particularly rare diseases – remains important.[68] Companies focused on immunotherapy and oncology are more often pursuing portfolio combinations of new molecular entities (NMEs).

Precision medicine is emerging as an answer for the growing demand from payers for more personalized therapies that have more chances of treatment success and incur less overall health care cost as compared to traditional therapies.[69]

Value-based contracting

Value in the eyes of patients and payers is expected to increasingly drive pricing, not simply cover R&D expenses.[70] Payers in the United States, the National Health Service (NHS) in the United Kingdom, among others, are signing value-based contracts with pharmaceutical companies.

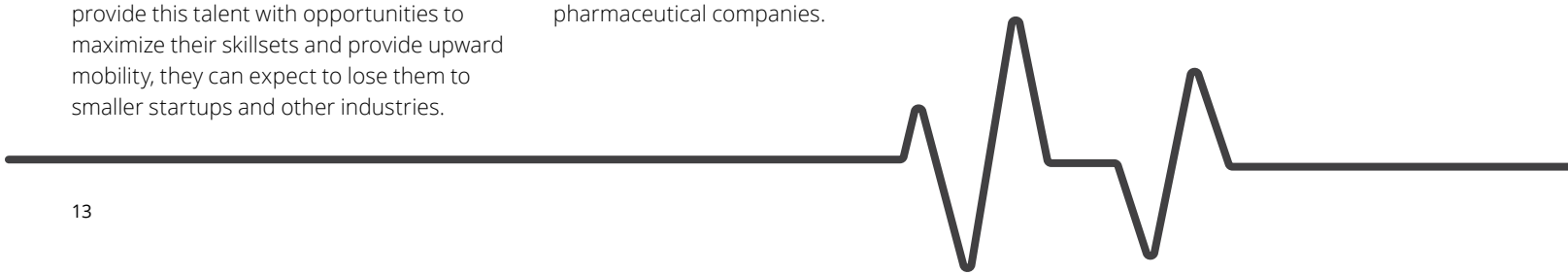
Understanding the need for a good value proposition is vital. Value-based contracts are contingent upon proving better patient outcomes over peer products to receive reimbursement.[71] For some high-value, high-cost treatments, like curative therapies, value-based contracting models could amortize costs over a longer timeline. Medtech companies are also in the early stages of value-based contracting.[72]

New geopolitical climate

Tax reforms worldwide will create incentives and disincentives for the life sciences sector and impact future investments. The United States passed a major overhaul of its tax law at the end of 2017, and most provisions are already in effect for 2018. A lower corporate tax rate of 21 percent from 35 percent could make the US market more competitive.[73]

Under the new tax law, US-based multinationals are required to pay US tax on all previously untaxed accumulated offshore earnings. This one-time transition tax will be levied at 15.5 percent on cash and equivalents, and an 8 percent tax on non-cash earnings. This provision will incentivize many to bring overseas cash back to the United States.

While extra capital may now be available to fund additional research, business expansion, job growth and capital expenditures, some companies may approach domestic expansion conservatively, given that certain capital allocation decisions are long-term in nature and the permanence of US tax reform may be in doubt. Those making acquisitions can expect potential limits on the ability to deduct interest expense, but opportunities to expense the purchase of new or used fixed assets, even if part of an asset acquisition of a business.



Companies that outsource manufacturing activity offshore or have earnings from foreign customers may enjoy an incentive from the new law which could further reduce the 21 percent corporate tax rate. However, two provisions on global business operations may increase the US tax burden. First, US multinationals that have low taxed earnings offshore will be required to pay additional US tax on those earnings. Second, a new alternative minimum tax, called the Base Erosion and Anti-Abuse Tax, could negatively impact US subsidiaries of foreign-based companies as well as US-based multinationals who procure certain goods or services from their foreign parents or affiliates.

In 2018, the US administration is expected to continue to advocate for policy changes to reduce drug prices,[74] and the medtech segment is expected to continue to battle against the 2.3 percent medical device excise tax.[75]

In the United Kingdom, policies on patents, data protection, clinical trials, and marketing authorizations are among Brexit's key implications for pharma. The UK government recently secured commitments from 25 organizations to ensure the country remains a pharma hub after it leaves the European Union.[76]

US regulatory highlights

Regulators have found the pace and rate of change challenging and continue to modify their policies and regulatory procedures to keep pace with the widening use of digital products in health care.[77]

The FDA is working on a new framework for a comprehensive, science-based policy for proven regenerative cell therapies.[78] It stays committed to helping patients maintain access to innovative new therapies. The agency is also committed to digital innovation. In 2018, nine companies are taking part in the FDA's Pre-Cert program that shifts approval of a product to the software or digital health technology developers.[79] New implementation guidance for legislation related to digital health innovation and greater clarity on the 21st Century Cures Act software provision are planned for 2018.[80]

To learn more, please refer to the *US Life Sciences Regulatory Outlook for 2018*.

EU regulatory highlights

Regulatory changes occurring across the European Union will impact companies selling product into the European Economic Area (EEA) region. The effects of the United Kingdom leaving the European Union will not only be felt in these regions but globally. Significant implications are expected for supply chains, regulatory, clinical trials, and tax compliance.

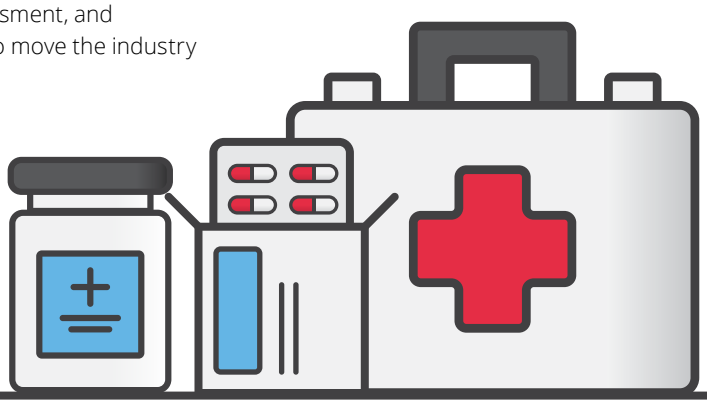
Currently, many life science organizations are planning for maximum change should negotiations not provide more favorable conditions on a timely basis.[81] In a report to the UK government, Professor Sir John Bell states that regulatory and technology changes are an opportunity for the United Kingdom, and believes investments in innovation must be adopted post-Brexit. The same innovation that drives global economic growth could be used to improve outcomes in the NHS and reduce costs. He recommends establishing a new regulatory, Health Technology Assessment, and commercial framework to move the industry forward.[82]

It was announced that the European Medicines Agency (EMA) will also be relocating its operations to Amsterdam in the next 16 months, resulting in a loss of approximately 1,000 jobs in the United Kingdom. The change will potentially disrupt the EMA's work as well as drug approval processing and monitoring in the European Union.[83]

The Identification of Medicinal Products (IDMP) regulation is driving change to pharmaceutical companies' product-related processes and systems – ushering in a new era of cross-functional collaboration. Also in 2018, proper (meta) data management will be essential as the General Data Protection Regulation (GDPR) will be enforced starting 25 May 2018.[84] In Europe alone, 28,000 new data protection officers (DPOs) will be required to lead compliance. Organizations who are non-compliant face heavy fines and proactive and robust privacy governance will be required.[85]

Currently, there is still uncertainty as to how regulators will respond to the growing use of innovative digital technologies. Pharma, alongside other health app developers, will need to engage directly with key regulatory bodies to clarify compliance requirements. The legal and financial ramifications of non-compliance could be significant.[86]

To learn more, please refer to the *Impact of EU regulatory change on the global life sciences industry*.



Build

Building an adaptable organization for the future of work

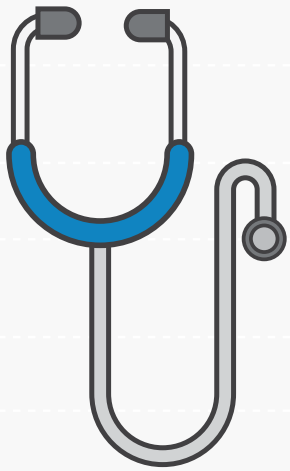
Old rules vs. new rules

Building an organization of the future is the most important challenge of life science and health care human resource (HR) leaders responding to Deloitte's latest Global Human Capital survey.[87] Technology is transforming the workplace. The new world is augmented, and rules have changed (Figure 11).[88] The future of work will be more networked, devolved, mobile, collaborative, team-based, project-based, and fluid. Organizations will need to adapt to emerging trends:

- New leadership mindsets, networked and inclusive
- Work built around technology, for greater efficiency
- A skills-based economy, where talent will be the differentiator
- Augmented Intelligence, combining machine intelligence with human insight
- Organizations and talent connecting on mission, values, and ethics

Figure 11. The future of work: The augmented workforce

Old rules	New rules
Machines and artificial intelligence are taking over jobs (replacement)	Jobs and tasks are being redesigned to use more essential human skills, and are augemented by technology (augmentation)
Full-time employees are the main source of talent	A continuum of talent is available, including contractors, gig employees, crowds, and competitions
Workforce planning focuses on full-time workforce and skill requirements	The focus in workforce planning shifts to start with work and analyzing options across multiple workforces and technologies
Jobs are relatively static with fixed skill requirements	The half-life of skills continues to decrease rapidly, and work is being constantly reinvented
Jobs and career ladders are the foundation of work and the workforce	Projects, assignments, and tours of duty are building blocks for work; careers are portfolios of projects and experiences
Robotics and cognitive technologies are IT projects	Integrating people and technology is a multidisciplinary task
HR's job in automation is to focus on change management and workforce transition	HR has a strategic role to facilitate and orchestrate the redesign of jobs and train the augmented workforce
The fundamental elements of work are "jobs," with formally developed "job descriptions"	The fundamental elements of work are "tasks," which are aggregated into jobs and roles



Source: The future of work: The augmented workforce, Deloitte Insights, February 2017

The challenge for many life sciences and health care organizations is the slow rate of adopting new technologies. Many still work on systems or hierarchical processes that are 20 to 30 years old, and change will come more slowly.

New leadership mindsets, networked and inclusive

The leaders of the future will be network architects, able to connect work and resources through broad networks. In a world where markets, customers, ideas, and talent are all diverse, leaders will need to have an inclusive mindset.[89] Work will be redesigned around technology and learning, and leaders embracing digital technologies will see knowledge flow through networks. Leaders must be role models for new ways of working.[90]

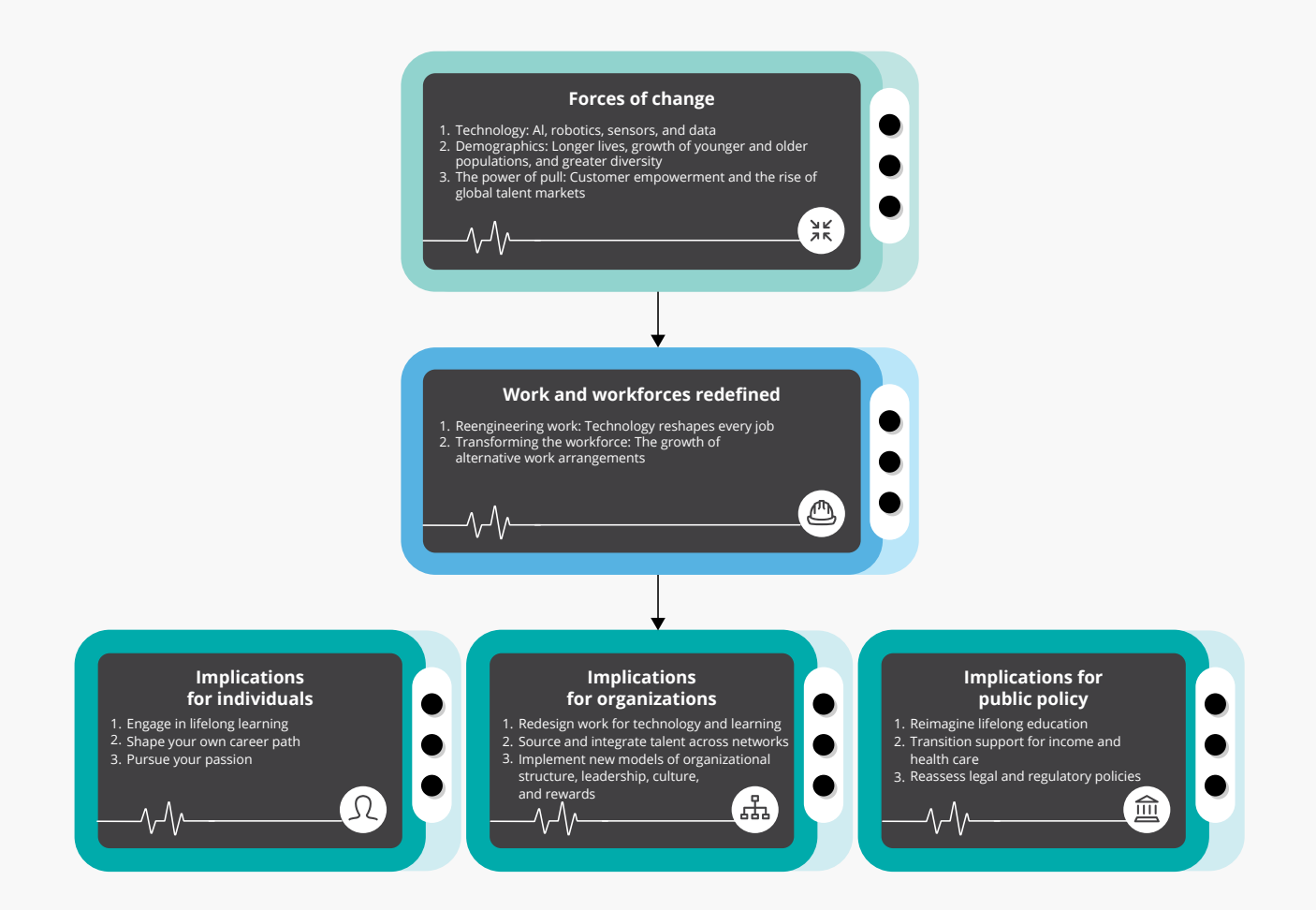
A major threat to life science organizations is that too few leaders and board members understand the impact advanced technologies have, or will have in the future, without seeing these applications at work. For this reason, many organizations are looking outside the sector for talent. But without an informed, forward-thinking mindset, the life sciences sector could remain at a disadvantage in competing with tech companies for this talent.

In a survey conducted by Deloitte, more than 40 percent of C-level leaders expect to put more focus on facilitating the exchange of ideas. By 2021, most of these executives expect to move away from email in favor of more collaborative digital platforms. These technologies will provide greater transparency, resulting in more personal accountability, and changes will be able to be made in real-time.[91]

New models of organizational structure, culture, and rewards will emerge.[92] Organizations will be less hierarchical in the future, and leaders will need to provide greater autonomy at team and individual levels. They need to be able to step back and see the full picture, ask the right questions, then trust that teams will come up with the right strategies.[93] Big picture leaders are often generalists, who have more than one specialization, and will be better skilled at breaking down silos and bridging knowledge across an organization.[94]

Informed leaders of the future will recognize these forces of change, how work is being redefined, and the implications for individuals, organizations and public policy (Figure 12).[95]

Figure 12. Navigating the future of work



Source: Navigating the future of work, Deloitte Review, July 2017

In a skills-based economy, talent will be a differentiator

The future is a skills-based economy. Talent is already being curated around specific projects and tasks on demand, and organizations will become more agile. It is easier than ever before to find and connect with specialized talent through an array of digital tools.[96]

Work environments are increasingly fluid and dynamic. In the United States, 40 percent of the workforce is already contingent,[97] and more than half of millennials are freelancers.[98] Deep specialization can be accessed, wherever it is located, and deployed, wherever it is needed, anywhere in the world.[99]

Individuals who work in a "gig economy" may have a variety of employers, and control their own time and terms. Seventy percent of the time, they provide services remotely. This talent will choose to work with those who support their values and work styles.[100]

The challenge for organizations will be the fierce competition across industries for the most desirable talent and in-demand skills. In addition to new digital and analytical skills, there will be a demand for skills that are "essentially human," such as curiosity, imagination, creativity, and social and emotional intelligence. Thirty percent of high-paying new jobs are predicted to require these social, human skills.

As work is constantly reinvented by technology, individuals will need to continually add new skills and adapt to new teams and work environments.[101] It will be the job of companies to consistently train people to be prepared for a job that may not even have been invented yet. Micro-learning is one way companies can maximize learning in a minimum amount of time[102] along with embedding learning opportunities into work processes.

According to Tom Friedman, author of *Thank You for Being Late: An Optimist's Guide to Thriving in the Age of Accelerations*, if a company is not providing both the resources and the opportunity for lifelong learning, they're doomed.[103]

Augmented intelligence, combining machine intelligence with human insight

Technological advances are remaking every sector of the economy and society. Robotics, AI, sensors and cognitive computing will result in the redesign of almost every job. The World Bank suggests that 57 percent of people will lose their jobs to automation in the next ten years.[104] However, in many cases historically, where technological progress replaced some jobs, it also created new roles and opportunities.

For example, when automated teller machines (ATMs) were first introduced, many feared they would replace bank tellers. While ATMs did take over many of the tasks formerly performed by tellers, an opportunity opened up to make banking more personal. Jobs became more varied as tellers became liaisons for the marketing of new financial products. There are now more than 400,000 ATMs in the United States but also more than 550,000 tellers.[105]

The difference today is that a wide array of jobs across the life sciences workforce are expected to be augmented, combining machine intelligence with human insight.[106] The world will demand more people who can operate at the highest levels of thinking and, more regularly, make difficult, complicated decisions.[107]

Life sciences is just starting to identify the work and workforce segments that will become early adopters of rapid process automation. While information technology (IT) and finance have seen the most activity, RPA is also poised to improve the accuracy and quality of processes in R&D, pharmacovigilance, and supply chain.

Connecting on mission, ethics, and values

Culture is critical, and grows in importance at scale. In a Deloitte survey of C-level executives, almost 70 percent agree that realizing an organization's mission and values depends on culture (Figure 13).[108]

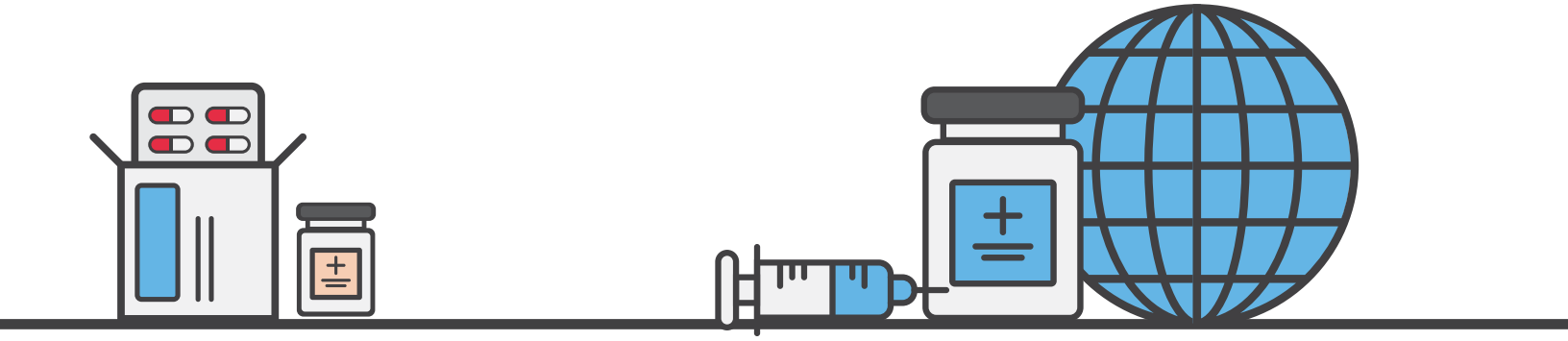
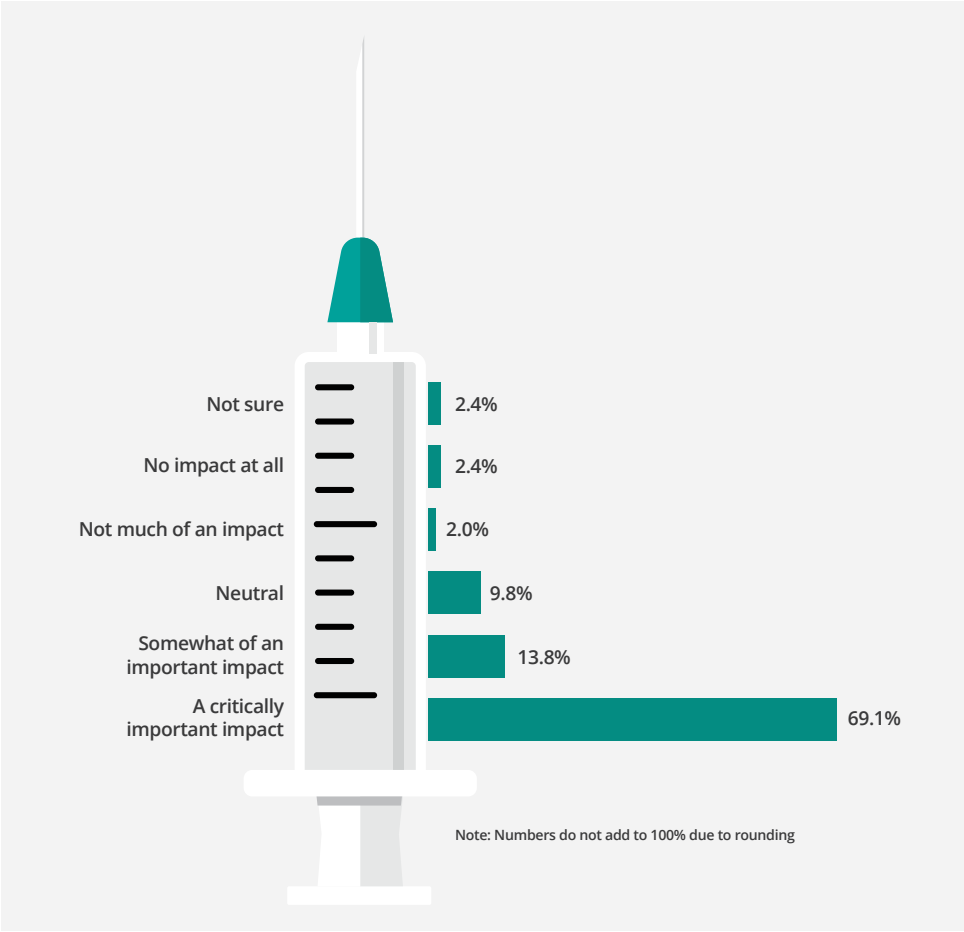
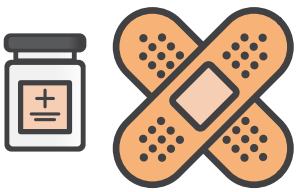


Figure 13. Degree of impact an organization's culture has on the ability to realize its mission and values



Source: Transitioning to the Future of Work and the workplace, Deloitte, 2016

Being able to manage across generations is more important than ever with five generations now in the workforce. By 2020, millennials will constitute 50 percent of the workforce and will drive the pace of change.[109] More collaborative and socially responsible, this generation will increasingly seek out organizations that share their values.[110]



In life sciences, almost every organization places "serving the patient" at the center of their mission. The differentiator will be how this mission defines expectations for employees and their interactions with each other and the outside world.

Strong organizational cultures align on values. But not all cultures encourage good or ethical behaviors. Building a culture of integrity is also expected to become increasingly important and will fortify an organization against risk.[111]

Building a culture of courage to help counter uncertainty

Proactive vs. reactive leadership and governance

An ethics-driven culture will be a massive focus of regulators in the next few years. Regulators expect the life science sector to be proactive, rather than just react to inquiries or defend themselves. Life science leaders can be proactive by developing a clear roadmap for how behaviors should align with values.[112]

In an ethics-driven culture, decisions are made based on both what is right for compliance and right for the business. In the next year, leaders should not only emphasize the right "tone at the top" but also the right "tone in the middle" and throughout an organization to insure ethical decision making.[113] Only then, can people be empowered, and organizations can build a culture of courage.

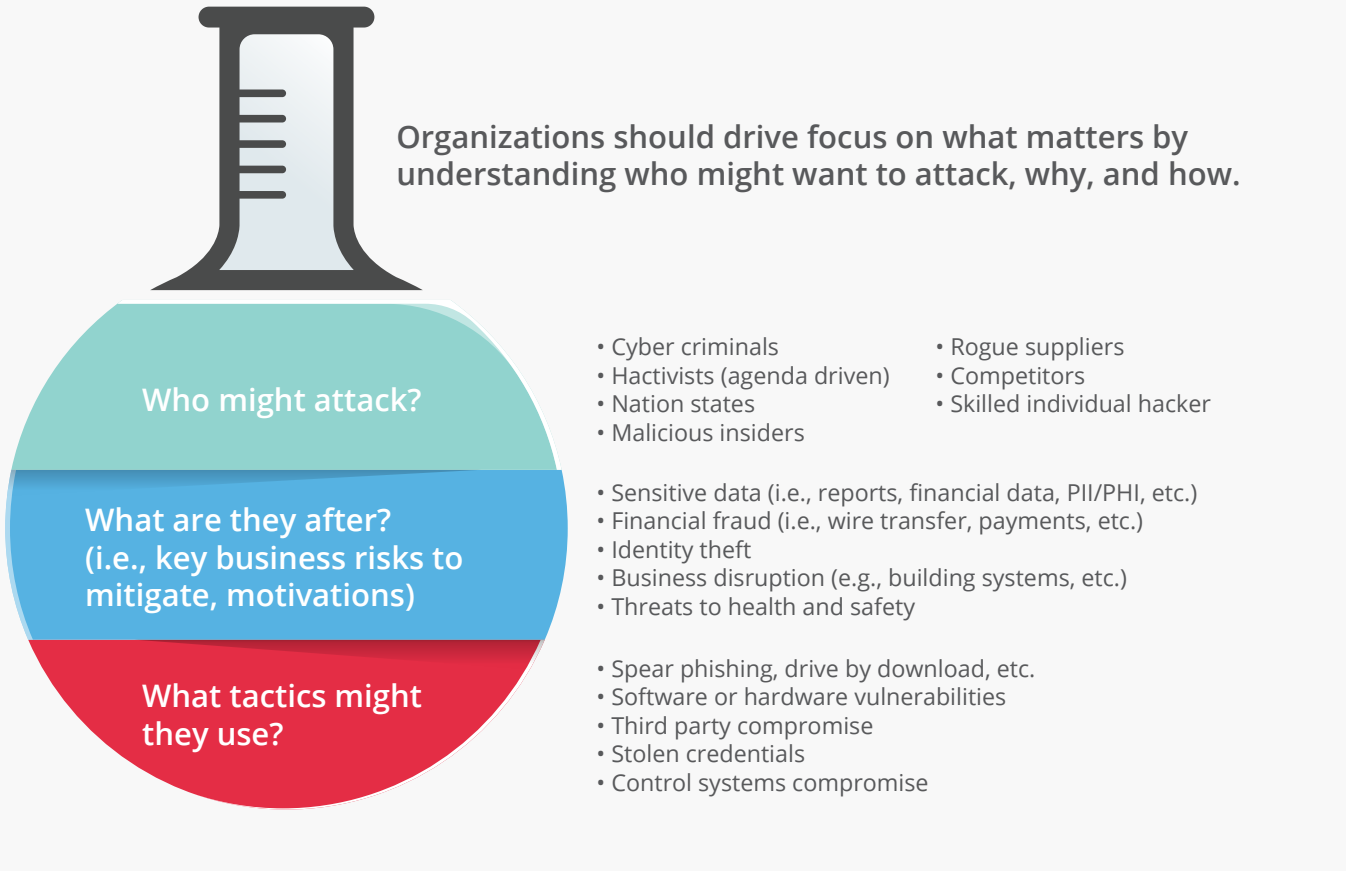
Ethical decision making in a machine-run world

Who will determine ethics in a machine-run world? The discussion is nascent on how human values will be reflected in the algorithms and autonomous systems that will be responsible for more and more decision making in the future. Forward-thinkers will need to anticipate potential ethical challenges and build the kind of AI-infused world we want to live in.[114]

Proactive cybersecurity, minimizing risk

Innovations driving rapid growth create complex cyber risks. Every year, the financial impacts of security breaches to life sciences organizations increase with significant physical impacts and added liabilities. Cyberattacks result from malware, phishing and social engineering (SE), web-based attacks, or malicious code (Figure 14).[115] These attacks exploit the weaknesses in increasingly complex and interconnected systems. They can cause real-world security incidents that have the potential to impact patient care and safety, organizational assets, reputation, intellectual property, relationships with customers, shareholder value, and regulatory compliance.[116]

Figure 14. Components of a cyberattack



Source: Deloitte analysis

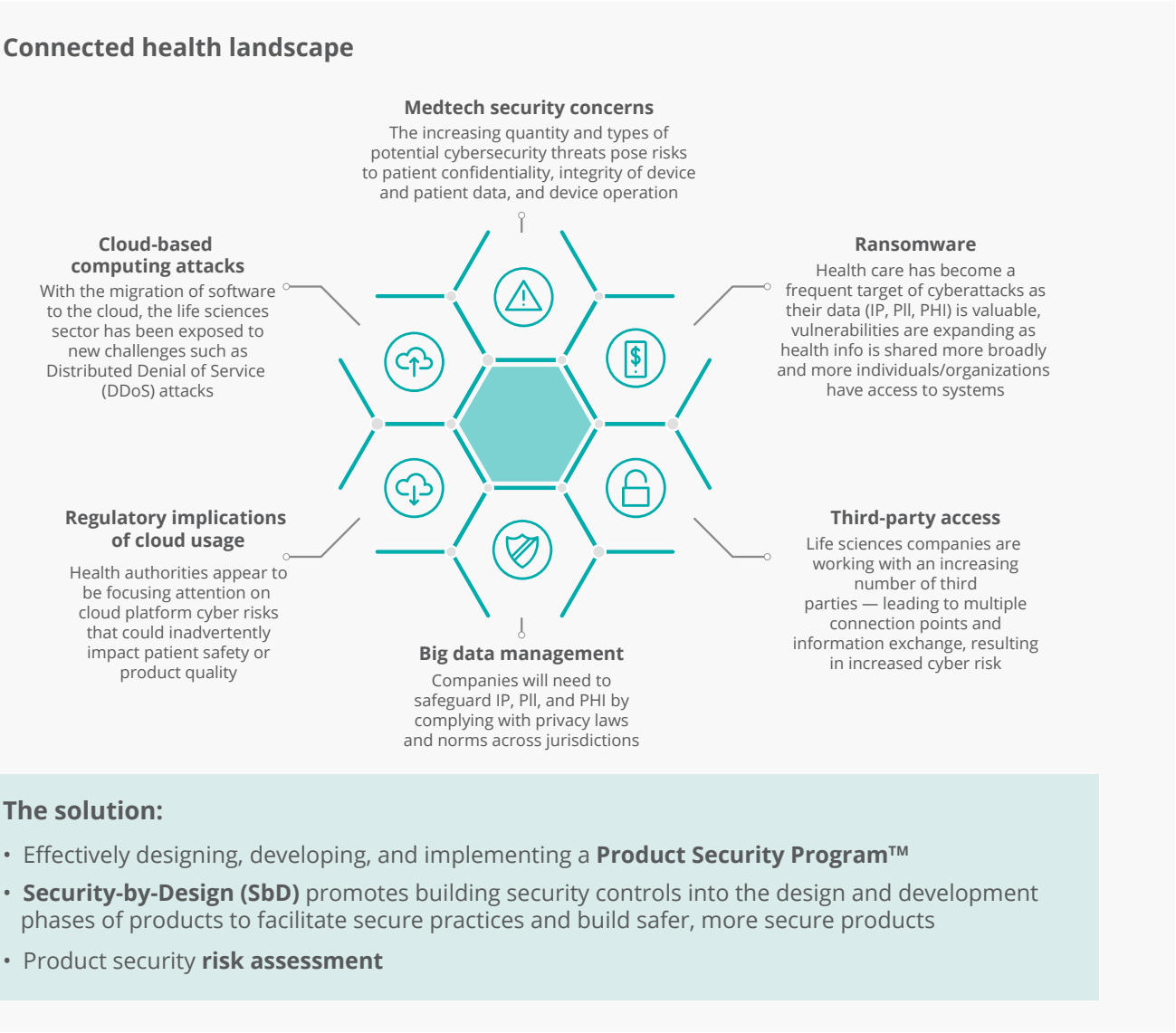
Life sciences leaders need to be more vigilant in deploying "critical" issue patches from software vendors, be more aware of high profile, vulnerability disclosures, and make sure there are valid business reasons for exposing services to any public/untrusted network.

Security by design

Incorporating cybersecurity practices into the product development life cycle is often referred to as "security by design." Manufacturers are taking steps to secure devices prior to deploying them, and are conducting technical security testing and security-risk assessment on devices while in development (Figure 15).[117]

This approach helps manufacturers design a device from the ground up to be secure, versus adding security features after the device has been delivered to market. However, security by design is not enough. Staying ahead of adversaries in the evolving, connected medical device landscape requires continuous identification, assessment, and remediation of risks.[118]

Figure 15. Security in the connected health landscape



Source: Deloitte analysis

To mitigate cybersecurity risks, organizations need to be proactive with real-time and near real-time monitoring, threat pattern collection, cyber threat modeling and analysis, threat mitigation and remediation, incident management, and threat intelligence reporting (Figure 16).[119]

Cloud and security are not an "either-or" proposition; data in the cloud is a high value target. While cloud vendors are responsible for the security "of" their cloud, security "in" that cloud is the enterprise's responsibility. Organizations will need to avoid disconnected governance and misaligned security strategies.[120]

Building data integrity, maximizing the value of data

The biggest drawback to future innovation is everyone tends to work in a very siloed manner. Currently, companies, and even departments within companies, might collect data in different ways and use different terminology and definitions. This can make it difficult to identify and compare quality issues between functional groups.[121]

High expectations for data quality

Companies need to create a working environment that values data integrity. Data integrity is data that is complete, consistent, and accurate throughout the data lifecycle.[122]

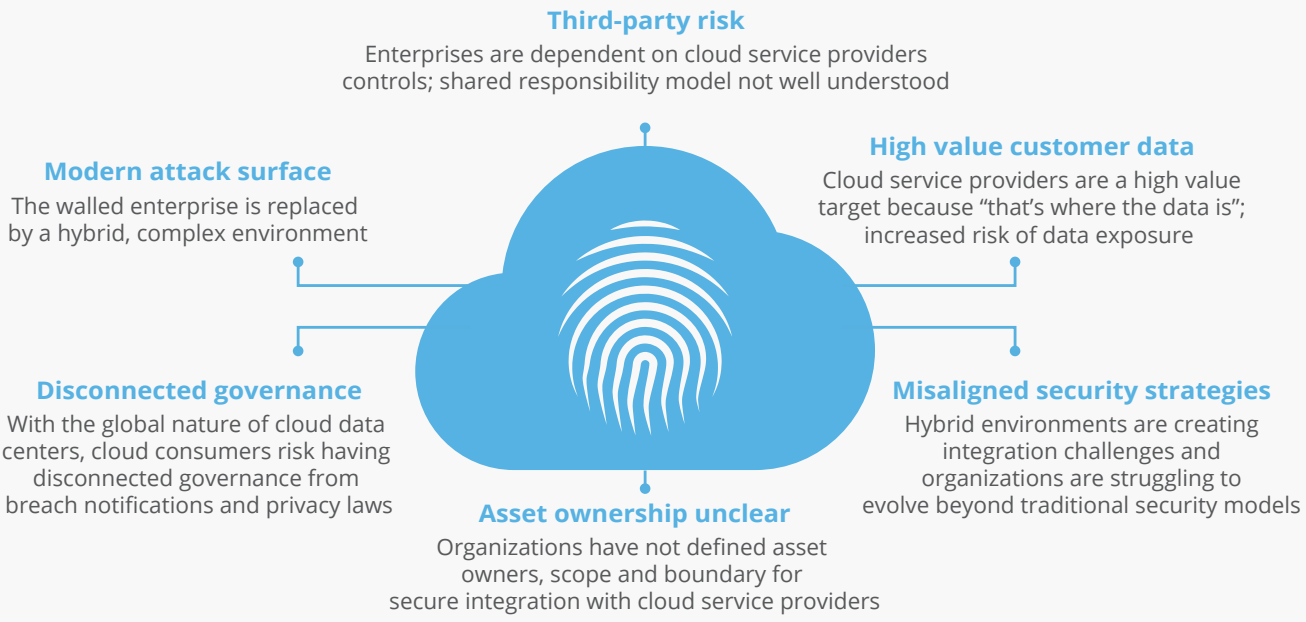
In the next year, regulatory bodies will have high expectations for data integrity due to the adoption of automated systems and advanced technologies, including storage of data in the cloud.[123] Data integrity can help deliver insights for value-based pricing and market access.[124]

Linking data and teams across silos

In addition to creating greater efficiencies over the next year, life sciences companies will be creating a more collaborative, not competitive, culture. One way they can break down silos is to form cross-functional teams – stressing the importance of sharing knowledge between departments and therapeutic areas.

For example, some pharma companies have multiple groups in regulatory – corporate regulatory, R&D regulatory, supply chain regulatory. Data across these departments will need to be unified, accessible, and reusable to create value for these cross-functional teams.[125]

Figure 16. Cloud security risks



Source: Deloitte analysis

Maximizing data value

As companies move away from silos and start to achieve data integrity, big data and analytics could help unlock the potential of disparate sources of data. Increasingly, data will better serve decision making at the enterprise level and provide a better understanding of emerging risks. (Figure 17).[126]

Life sciences companies can expect to maximize the value of data is by implementing end-to-end evidence (E2E) management – unifying data across research and clinical development, through to commercialization.

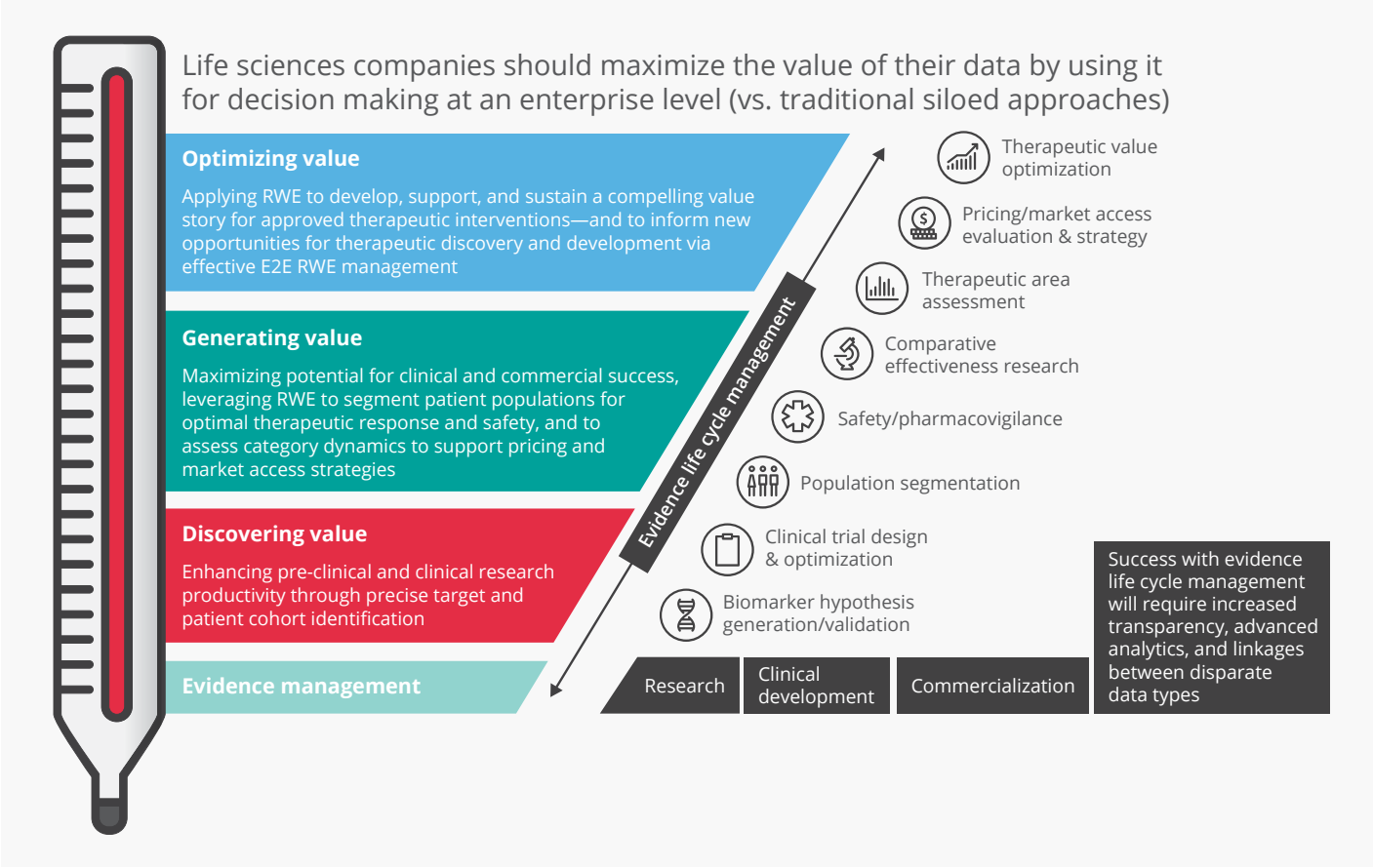
Lack of access to data is a big challenge for RWE programs, underscoring the importance of new collaborations with health systems, patient advocacy groups, and other digital health constituents.

As the volume of real-world data grows and accessing it improves, companies will have an opportunity to leverage RWE earlier in the product life cycle, streamlining development and driving down costs and leveraging opportunities in market access and R&D.[127]

Building patient trust and centricity

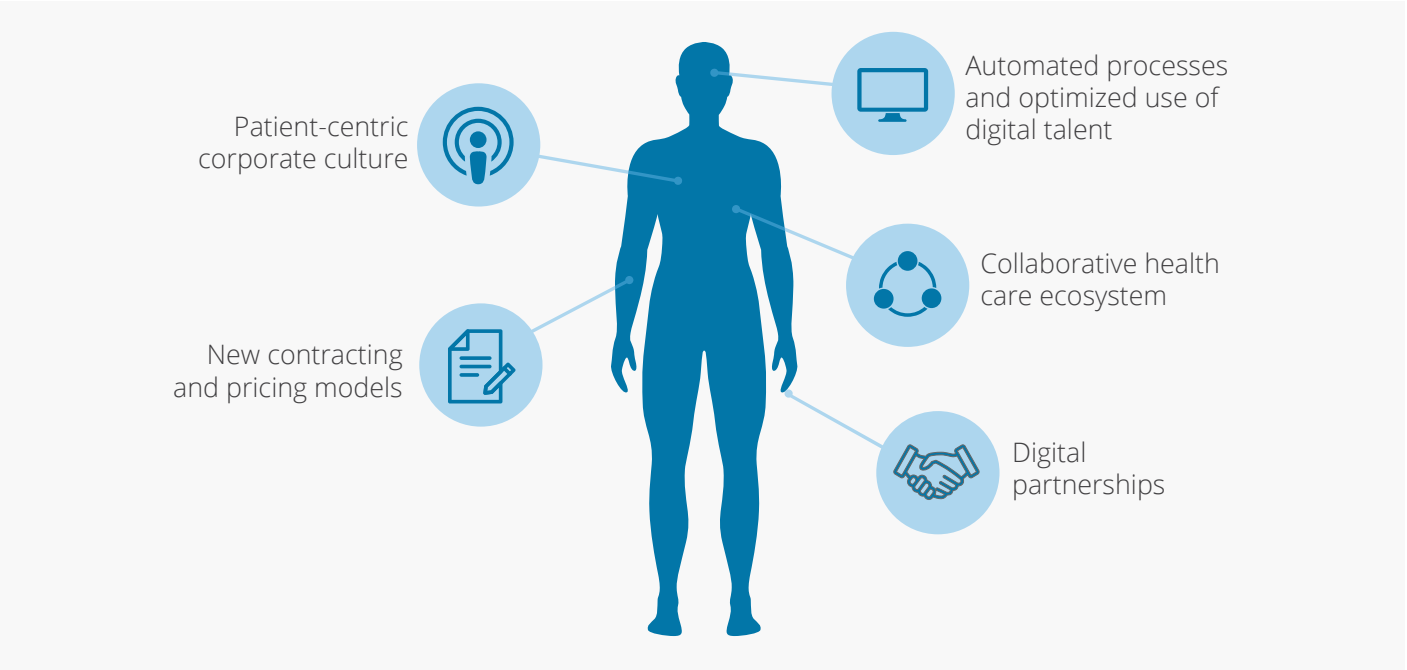
Investing in the development, manufacture, and distribution of products aimed to deliver improved health and quality-of-life outcomes builds trust. These investments could potentially offset some of the reputational issues facing the pharmaceutical segment and enhance a company's brand value.[128]

Figure 17. A new paradigm of E2E evidence management



Source: Innovating to survive, 2017 Pharmaceutical R&D leader survey, Deloitte Centre for Health Solutions, 2017

Figure 18. Strategies to improve patient centricity



Source: Pharma and the connected patient: How digital technology is enabling patient centricity, Deloitte Centre for Health Solutions, 2017

Strategies to improve patient centricity

Life sciences companies are embracing digital technology's potential for advancing patient centricity. Pharma is developing new, more personalized, drugs for smaller groups of patients and monitoring and managing patient adherence and health outcomes. To become more digitally-enabled and patient-centric, pharma companies are using a number of key strategies (Figure 18).[129]

Organizations are increasingly engaging with patients earlier to better understand unmet needs, inform trial design, patient recruitment and resilience. Current data suggests that products and services that better meet patient needs and improve treatment regimens will receive higher acceptance by payers, providers, and regulators.[130]

Clinical trials

Focusing on the patient is increasingly seen as essential to enhance the speed of patient recruitment, improve patient resilience, reduce patient burden, and raise awareness of patient issues. Systematic interactions with patients and patient organizations can facilitate the identification of new areas of unmet need, and knowledge gained will improve the design and conduct of clinical trials.[131]

New clinical trials are starting to actively involve patient representatives in the development program. This approach aims to increase acceptance by payers and providers through improved demonstration of value directly to patient groups.[132]

Personalized treatment optimization

An increasing level of engagement with patients, patient organizations, and advocacy groups is seen as necessary not only to support the development of products that meet patient needs and improve treatment regimens, but also improve acceptance of new products or services by payers and regulators.[133]

Patients receiving treatment will benefit from an increased focus on patient centricity. Companion diagnostics or supporting digital technologies will help patients and providers determine the best treatment and correct dosing as well as improve adherence.[134]

One pharma company held a workshop on gamification that led to the development of web-based services to collect patient data. The data was translated into personalized regimens, reminding patients to take an active role in managing their treatment.[135]

Corporate reputation can undermine patient engagement with pharma

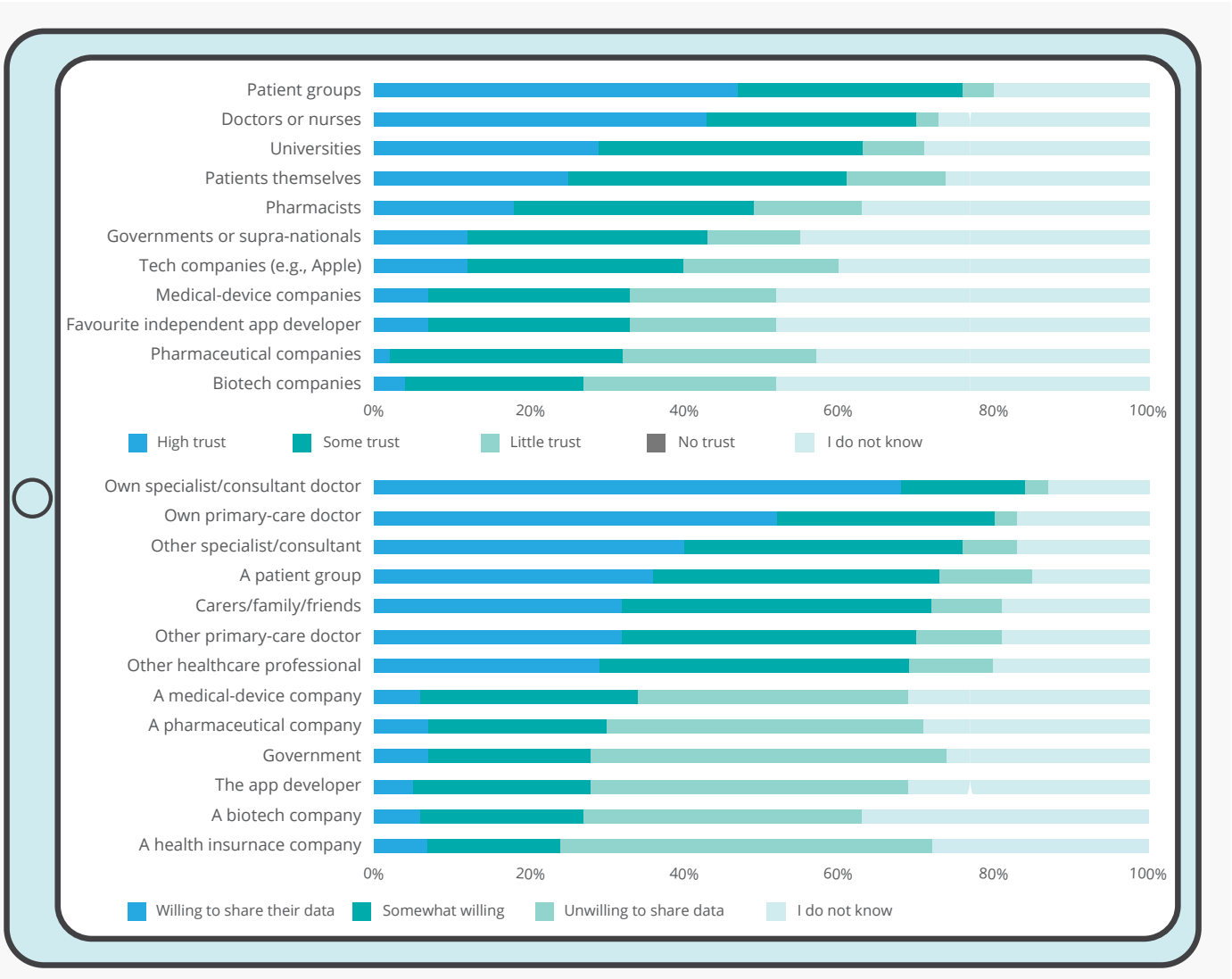
To what degree, do patient groups trust developers and producers of health apps? Deloitte research, in conjunction with PatientView, found 76 percent of patient group respondents stating that members have "high" or "some" trust in health apps developed by patient groups, but only 32 percent could say the same for apps produced by pharma (Figure 19).[136]

Similarly, 83 percent of patient groups said their members would be "willing" or "somewhat willing" to share the personal data from their health app with their own specialist/consultant or primary doctor, but only 30 percent would be willing to share the data with a pharma company.[137]

This lack of trust among patient groups, especially surrounding data sharing, stems from a fear of negative personal consequences (e.g., loss of insurance), a lack of trust in data gatherers, the need to protect privacy, and a lack of confidence in the ability to guarantee the security of personal data.[138]

Despite these concerns, patient groups highlighted a willingness to collaborate in the creation of apps with pharma. However, only 15.1 percent of the patient groups surveyed had been involved in co-creating a pharma health app.[139] These figures demonstrate the continued need for increased involvement with patients and patient advocacy groups.

Figure 19. Patient group trust in health apps (top) and willingness to share data with pharma and other groups (bottom)



Source: Pharma and the connected patient: How digital technology is enabling patient centricity, Deloitte Center for Health Solutions, 2017

The future of patient centricity, a connected journey of care

Some challenges to the future of patient centricity include attracting talent with the skills to support a patient-centric ecosystem and low levels of health and digital literacy, which will impact patients' ability to engage effectively.[140] Future enablers of patient centricity include:

- Embedded blockchain technology to improve efficiency, safety, and traceability.
- Adopting gamification to enhance patient engagement, health literacy, and medication adherence.
- Optimizing the potential of the connected patient to develop new outcome-based propositions.[141]

Envisioning the future of a connected patient journey of care

New technologies will continue to transform the patient's journey of care. We might envision a future where:

- Comprehensive software platforms support multiple modes of health care communication (voice calls, secure text messages, alarm and alert notifications), improving the efficiency and safety of caregiver communication.
- E-visits are supported by portable point-of-care diagnostic tools, facilitating remote physical examinations.
- Telemedicine has improved health care productivity by improving access and reducing traveling, wait times and inconvenience.
- Bio-telemetry monitors patients in their own homes providing objective insights to clinicians and helping individuals understand their own vital signs.
- Patients have greater control of their health and data, and the quantified self makes data more actionable for patients.
- Web-based portals enable regulatory compliant video-chat interactions between patient and clinician.
- The design of the hospital supports the well-being of patients and staff, emphasizing the experience of care.
- RPA and AI initiate and coordinate concurrent activities, allowing caregivers to spend more time providing care, less time documenting.
- Gamification is used to encourage compliance with treatments.
- Radio frequency identification (RFID) technology tracks staff and equipment, helping to optimize use of resources.[142]
- Using 3D printing to transform all stages of the pharma value chain.

Building a smart, cross-functional regulatory approach

Taking a proactive approach to the regulatory environment

As regulation timelines fluctuate, all stakeholders will need to continually evaluate the individual and collective impacts of new regulations and take a proactive approach to managing regulatory change (Figure 20).[143]

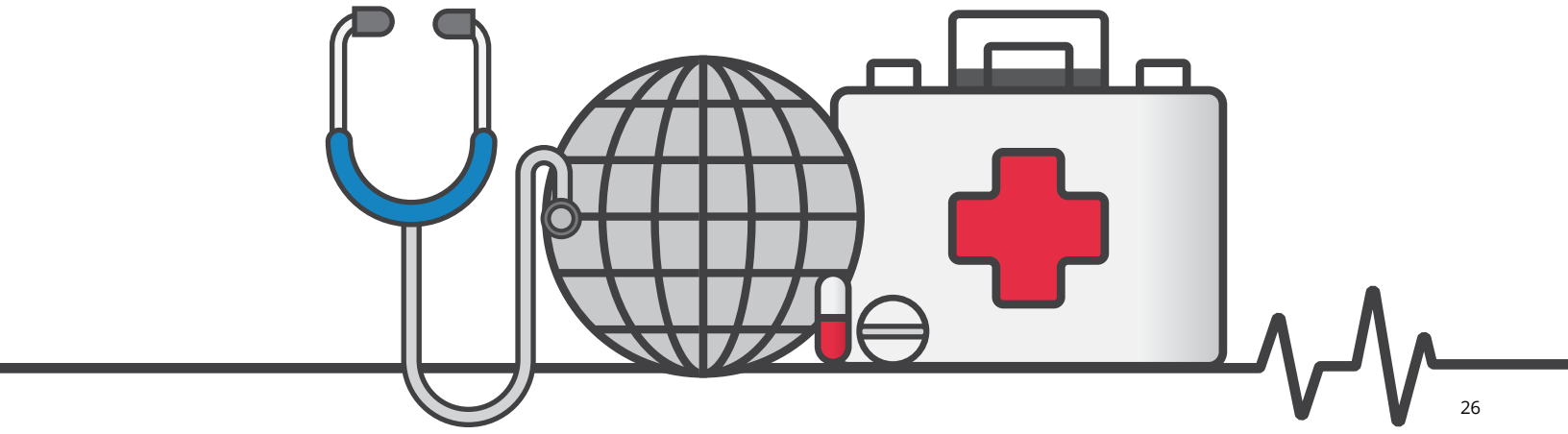
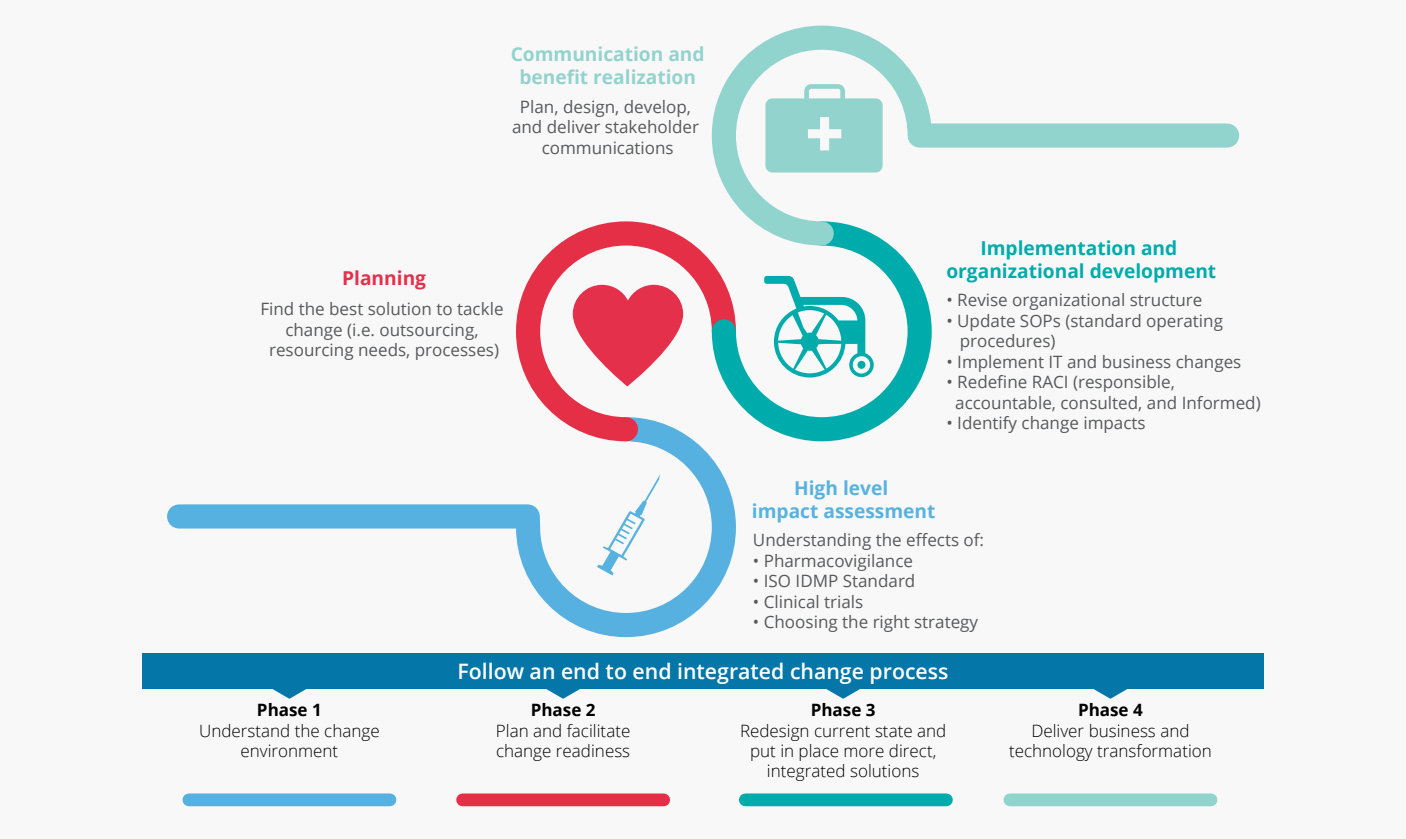


Figure 20. Taking charge of the regulatory environment



Source: The bigger picture, Impact of EU regulatory change on the global life sciences industry, Deloitte, 2017

Moving towards self-regulation and a culture of quality

Regulations are becoming more global. In the future, it's expected there will be a joint agreement between US and EU regulators to openly share inspection results. If one regulator inspects a company, that information will be able to be shared with other regulators. Transparency will accelerate innovation.

In the United States, the FDA is challenged for time and resources to continually inspect sites, and the trend is moving towards a self-regulatory model. In the future, companies could be expected to provide their own metrics on internal processes and outcomes, and the FDA may mandate and evaluate those metrics to decide which companies pose the highest risk and warrant inspection. To date, many of the inspection site warnings have been associated with data integrity and human error.

Regulators are currently evaluating ways to measure a "culture and quality index" for a company. If a company establishes a culture where quality and 'doing the right thing' is part of the culture, they will see the effect in all parts of the organization.

A holistic ecosystem

With connected devices, products, and services, regulatory groups will be compelled to better coordinate the ecosystem. As efficiency initiatives drive processes to become simpler, companies are beginning to align their regulatory groups to accelerate the process.

Another trend towards a holistic approach can be seen in the synergies between regulations. Many of the regulations and mandates for which more granular guidance has or is being developed are expected to feed into the broader IDMP regulations (Figure 21).[144]

One example is the alignment of the CDISC Global Clinical Trial Registry with the IDMP regulatory compliance, first in Europe and then beyond. This alignment will bring data integrity from R&D through to the supply chain, further highlighting the importance of data reusability.[145]

Life sciences companies who make investments in unifying data, resources, departments, and technology are expected to realize benefits throughout the organization – not just for compliance purposes. Investments to reach full compliance could be significant, but companies will then create business-building synergies across industry segments and product life cycle stages.[146]

Figure 21. Synergies between IDMP and other regulations

Source: Unravelling Complexity, The challenge of compliance in the life sciences supply chain, Deloitte Centre for Health Solutions, 2017

Grow

Growing through partnerships and new operating models

Partnership trends

Strategic alliances enable companies to acquire new knowledge about technologies, processes, products, and business models. Over the next few years, alliances and partnerships will become more important for accessing external expertise and technology. New collaborations and partnerships should be established where the best scientific or technological fit can be achieved.[147]

Non-traditional players are disrupting the health care landscape using their brand, engineering expertise, and knowledge of customers. Many of the top technology companies have health care initiatives and are partnering with pharmaceutical companies. New capabilities can be gained from technology giants, start-ups, and players from other industries through investments, joint ventures, acquisitions, product innovation, and licensing of software.[148]

Digital, IT, or data analysis collaborations

Collaborations with technology partners will become increasingly important for pharmaceutical and medical device companies. Technology partnerships can provide competitive advantage and allow companies to become more patient-centric and digitally-enabled across both their commercial and clinical spaces (see sidebar).[149]

Life sciences companies need to increase technical capabilities for the development of innovative products and devices which will enable:

- Optimized patient treatment regimens
- Management and analysis of increasing amounts of data
- Improved internal data accessibility to drive better informed decision making[150]

Solutions will be able to be tested and implemented faster and at reduced risk, especially when key digital skills are lacking in larger pharma organizations.[151]

Scientific partnerships

There is a major shift underway as life sciences stakeholders move from traditional asset-based partnerships to collaborative, non-asset based R&D partnerships. These new biopharmaceutical collaborations often include a mix of ecosystem stakeholders including life sciences companies, academia, non-profits, and government entities.[152]

To access new talent and technologies, significant investment is being made by life sciences companies in building relationships with academia. By supporting doctoral and post-doctoral research at leading universities worldwide, pharma is likely to drive recruitment of core scientific, bioinformatics, and analytical talent.[153] In addition to partnering with pharma, AI-based startups are also partnering with university researchers or developing their own new drugs based on extensive clinical data analysis.[154]

Increasing collaboration among pharmaceutical companies is expected to lead to consolidation in certain areas of the sector. These collaborations will provide some risk sharing and better protect companies against the cost of attrition.[155]

Partnerships between pharma and technology companies

PatientslikeMe - an online portal and mobile application that allows people with health conditions to share information and data relating to health and clinical trials with other patients and researchers with the aim to improve patient outcomes and involvement in research.[64] Currently, the platform has a network of over 500,000+ patients who have collectively contributed 40 million points of data about disease.[65] PatientslikeMe has collaborated on a number of projects with pharma companies in an endeavor to be closer to what concerns patients most, including with UCB to create a patient community around epilepsy,[66] and Shire Pharmaceuticals to track and share experiences for patients and their caregivers living with rare diseases.[67]

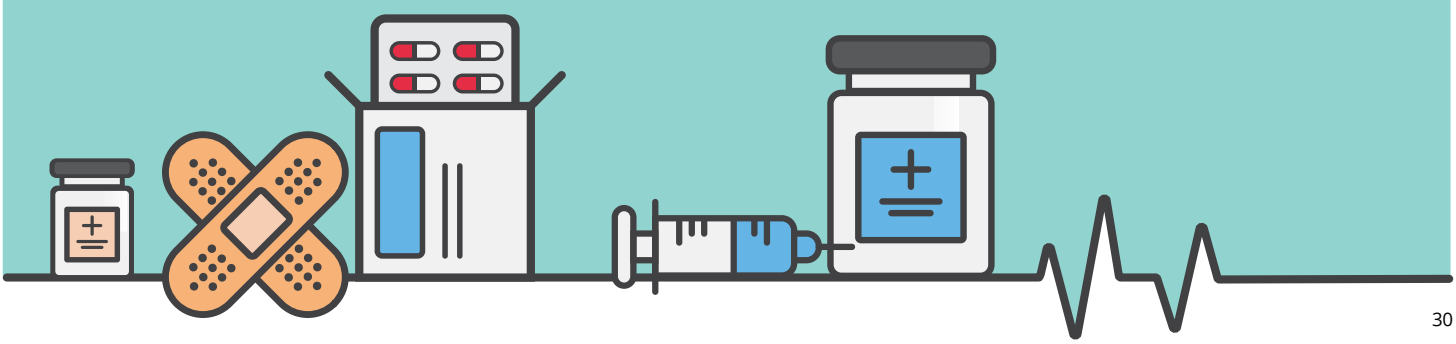
u-Motif- a collection of tools, including an easy to use mobile app and an online platform that has been validated for use in clinical trials, which enables patients, health care providers and life sciences companies to capture and analyze data surrounding health conditions.[68] Its patient-centric approach was honed through working with IDEO, experts in embedding human-centered design processes. In the past year, the tools have captured 64 million data points from over 18,000 patients who have chosen to take part in research studies.[69] The company has worked with several large organizations within health care and life sciences. In 2016, the mobile application was used in a clinical trial to assess the impact of using a smartphone-based Parkinson's tracker app to promote patient self-management, as well as enhance treatment adherence and the quality of clinical consultation.

After 16 weeks, 72 percent of participants continued to use the application, elucidating that smart-phone apps may be an effective way for patients to manage complex chronic conditions.[70] In 2017, uMotif announced a partnership with AstraZeneca, which will use the companies' technology in order to develop a more patient-centric, real world evaluation based approach for future clinical trials.[71]

Voluntis - a technology developer that has created a range of Conformite Europeenne (CE) and FDA-approved mobile apps in collaboration with big pharma.[72] These include:

- **Sanofi:** Diabeo is a mobile application which aims to better treat patients suffering with type 1 and type 2 diabetes. The application provides patients with decision-making support through algorithms that help calculate personalized doses of insulin and remote management of patients' conditions through connections via telemedicine with health care providers.[73] Clinical evidence has shown that the technology significantly improves HbA1c in poorly controlled type 1 diabetic patients.[74] As a result of further clinical evaluation the application was approved CE certification in 2013.[75]
- **Roche:** This is a partnership that aims to develop an application for women afflicted with breast cancer. The application will require the patient to manually enter their symptoms into the application which then analyzes the data and relays it back to the patients' medical teams to encourage personalized follow-up. The application will then facilitate tailored notifications and treatments to be pushed to the patients' smartphones in order to facilitate better care.[76]

Source: Pharma and the connected patient: How digital technology is enabling patient centricity, Deloitte Centre for Health Solutions, 2017



Clinical partnerships

Some R&D leaders acknowledge that gaining and maintaining expertise in designing clinical trials is becoming increasingly important as a knowledge base for future value creation. Becoming less dependent on contract research organizations (CROs) for the design and conduct of clinical trials is believed to support a more patient centric trial design and subsequent value creation.[156]

In an era of precision medicine and more expensive trials, the trend is to answer more questions more efficiently and in less time. Instead of investigating a single disease, coordinated research efforts are being introduced through master protocols, evaluating more than one or two treatments in more than one patient type or disease within the same overall trial structure.[157]

Regulatory partnerships

Strong partnerships with regulators are fundamental to creating sustainable innovation, ensuring new products progress efficiently through the pipeline.[158] For the past decade, most life sciences and health care companies have highlighted that a risk averse approach to regulation has impeded adoption of innovation.[159]

The evidence today and predictions for tomorrow illustrate that this is changing. For example, the FDA's new early approval process for CAR-T cancer treatments reflects efforts by the new cross-cutting Oncology Center for Excellence to implement a more collaborative review model for innovative medicines.[160] The FDA's 21st Century Cures Act offers another opportunity to be proactive and take advantage of the agency's flexibility by discussing novel approaches to drug development and medical device innovation.[161]

Greater harmonization between regulators is increasingly seen as a key enabler in maintaining compliance while securing supply to markets. By building engagement with regulators into their innovation models, new regulations for innovative treatments, such as 3D printing of drugs or gene editing, can be developed contemporaneously rather than retrospectively using enhanced regulatory pathways.[162]

New operating models

Establishing collaborative ways of working is high on the agenda for life science organizations and will require breaking the constraints of the current system.[163] New operating models will welcome diverse and collaborative efforts from a cross-sector of industries, public and private collaborations, and partnerships between nonprofit and for-profit organizations.[164]

One trend upending business and operational models is Everything-as-a-Service (XaaS). XaaS envisions business capabilities, products, and processes, not as discreet vertical offerings operating individually in silos, but as a collection of horizontal services that can be accessed and leveraged across organizational boundaries.[165]

Companies will want to adopt new capabilities to support external partnerships and collaborations with health systems, patient advocacy groups, and other data aggregators.[166] Internally, several companies have established cross-functional steering committees to integrate R&D functions with commercial, medical affairs, clinical, market access, and key areas of external partners.[167]

A new type of leader will be needed to think outside the usual silos and chains of command. The chief innovation officer will become one of the more important executives in the pharma C-suite and key to leading fast, focused innovation.[168]

R&D

R&D leaders listed a broad range of strategies in the top three initiatives transforming the current operating model in their companies (Figure 22). The most frequently mentioned initiatives were those that were related to developing internal technical and data capabilities, with companies looking to grow their internal capabilities in order to harness growing volumes of data.[169]

Companies are also upgrading internal systems in order to make better use of existing data. Other common initiatives were ones aimed at boosting operational efficiency, either through the modification or overhaul of existing operational processes and systems.[170]

The increasing pressure to provide value for money requires R&D organizations to revisit their operating models. New approaches will see a shift in focus from primarily delivering a commercially successful product to delivering a patient-centered service rewarded on outcomes.

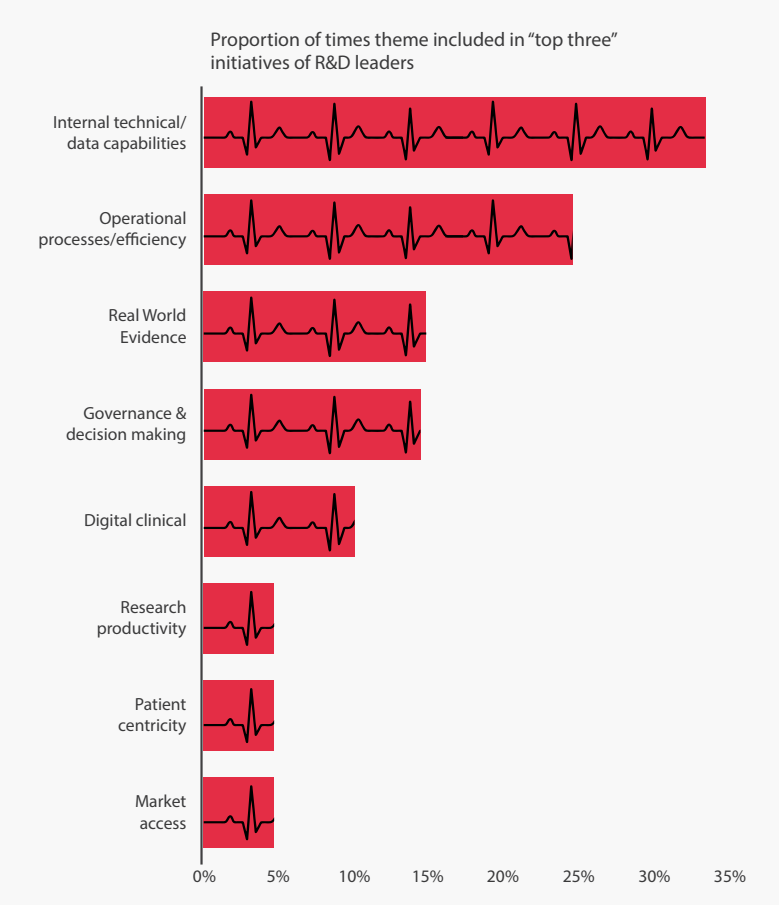
Under the new model, the patient moves from being a passive recipient of treatment to becoming a central part of the R&D process for new therapies. Successful adoption of this approach is expected to deliver products that better meet patient needs, satisfy payer and provider expectations, and are commercially rewarding.[171]

Supply chain

Routes to market or distribution models are often overlooked as a source of competitive advantage in life sciences. Trends such as patients acting as health care consumers, the dramatic shift towards biotechnology products, and stretched health care budgets are all forcing manufacturing leaders to relook at their distribution models and consider new and innovative routes to market.[172]

Organizations that adopt direct to patient distribution models could reduce distribution spend by 15 to 20 percent and improve patient experience. Challenges will be the scale and complexity of change required across functions, departments, and geographies.[173]

Figure 22. Top 3 initiatives transforming the operating model



Source: Innovating to survive, 2017 Pharmaceutical R&D leader survey, Deloitte Centre for Health Solutions, 2017

Pharmaceutical companies are beginning to engage with the idea of a single command center for visibility, decision making, and action, based on real-time data. Real-time dashboards enable more effective decision making and control, and advanced analytics can be applied to enable supply chain insights. Simple systems focus on visibility while advanced setups are predictive and can highlight issues before they become problems.[174]

Commercial

The traditional biopharma business model is being disrupted by biopharma companies bringing potentially curative treatments to market. Advances in new gene and cell therapies are paving the way for a paradigm shift – from managing a disease to curing it. The payment model needed to finance the development of these innovations has generally not kept pace with the biopharma industry, and there is little precedent on how to commercialize cures successfully – especially highly complex ones.

For future success in the market, biopharma companies are likely to reimagine their organizations and lead payment-model innovation that rewards effective and cost-efficient cures.[175]

What's next: Actions for 2018

1. **Work collaboratively, manage risk strategically**
   In 2018, organizations that effectively manage strategic risk should be better prepared to deal with uncertainty. People across the organization – in regulatory affairs, business development, product development, R&D, and manufacturing – all need to work together and share information. Being aware of legislative, technological, scientific, or regulatory risks is not enough. Successful organizations should prepare to respond to them.[176]

2. **Use scenario planning for trends and uncertainties**
   Scenario planning could help organizations deal with uncertainty and prepare for the future. For example, companies in the United States may need to consider:
   - How insurance coverage might change by payer
   - The financial impact of changes to the corporate tax rate and potential strategies to ramp up manufacturing quickly in the United States
   - Re-envisioning drug or device development plans to incorporate some of the flexibility allowed by new provisions under 21st Century Cures
   - Participating in the shift to value-based care by generating evidence and developing solutions to effectively compete on value as defined by health plans, providers, and patients[177]

   Value-based competition is likely the new reality regardless of policy. Transitioning from volume to value changes the way stakeholders evaluate new drug treatments and adopt them into clinical practice. Biopharma and Medtech companies could benefit from addressing the evolving needs of stakeholders to demonstrate value by:
   - Understanding care delivery models
   - Identifying appropriate and meaningful metrics to measure outcomes
   - Understanding the value of portfolio offerings to support the patient journey
   - Capturing real-world evidence[178]

3. **Evaluate your "culture and quality" index**
   Culture influences decision making from all levels of leadership, the quality of talent a company attracts, and the regulatory and security risks a company faces. Focusing on ethics, mission, and values can bring an organization into alignment.

4. **Recruit for new leadership and data roles**
   Some of the new life sciences leadership and data roles growing in importance include: chief data officer, chief innovation officer, chief patient officer, and data protection officer.

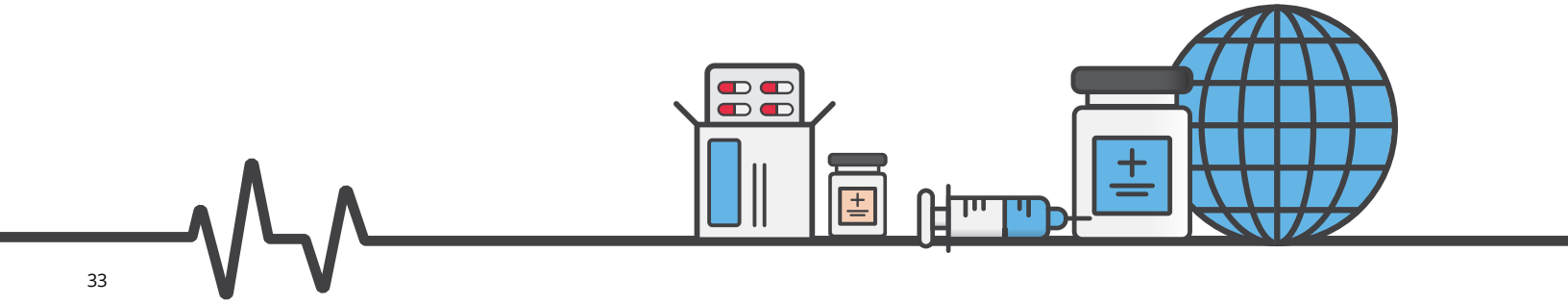
   Look across industries to attract data, analytical, and AI talent to drive new insights. Competition will be fierce and communicating a company's mission is critical to attracting the right talent.

5. **Improve profitability in an era of patent expiries**
   In addition to cutting costs and improving efficiencies, strategies for life sciences to increase profitability include:
   - Increasing productivity in R&D
   - Acquiring smaller players to fill gaps
   - Selling non-core assets to focus on therapeutic areas[179]
   - Continue looking for growth in emerging markets

6. **Be strategic in deal-making and explore non-traditional types of deals** The best deals are likely to bring synergies in therapeutic areas and build on a life sciences company's strengths. Divestures, in areas where a life sciences company is weak or where an acquisition is not performing, are likely opportunities for growth.

   Opportunities for innovation are more likely in therapeutic areas, like oncology, that are seeing major advancements in science.

   Technology acquisition and XaaS are two ways life sciences companies can stay on pace with innovation. Acquiring small companies for data, analytical, and AI talent could also fill gaps.



7. **Experiment with emerging technologies**
   Real-world engagement is the best way to understand the opportunities and challenges of emerging technologies. Organizations can set up pilots for technologies that support collaboration and knowledge sharing throughout the organization and with external partners. Some of the best results may come by focusing on possibilities, not limitations.

   Life sciences companies can benefit from strategic alliances for technology. While large and small tech companies can be symbiotic partners, they can also be competitors. All of the top tech giants are preparing to disrupt life sciences and health care and are experts in the consumer experience. Tech giants are also making big moves in medical research.[180] Smaller tech companies spend more time getting domain expertise and are prepared to disrupt with their willingness to partner and collaborate across industries.

8. **Make data actionable**
   New legislation and complex contract structures will continue to present ongoing operational challenges. A foundation of reliable data and technology can help life sciences analyze, predict, and create actionable insights for strategic and operational decision making.[181]

   One of the most effective analytical tools for life sciences is an integrated and strategic gross-to-net model. Not only can this model help detect potential compliance and pricing risks, but also provide better forecasting for fast-changing markets and guide the company toward new areas of profitability.

   Companies that fail to develop and implement suitable data standards risk falling behind global regulatory requirements and may face consequences ranging from recalls and plant shutdowns to criminal charges, in addition to losing the competitive advantage of valuable data insights.[182]

9. **Explore patient, clinical, regulatory, and scientific partnerships**
   Patient groups are growing in influence. Precision medicine is driving clinical innovation and research on multiple diseases in trials. Innovative treatments are increasingly being accelerated as a result of early engagement with regulators. A mix of ecosystem stakeholders – life sciences companies, academia, non-profits, and government entities – are increasingly collaborating.

   To thrive in today's technology-enabled, value-focused health care market, companies should consider embracing a new operating model based on end-to-end (E2E) evidence management from R&D through commercialization. This includes establishing an effective governance strategy and leveraging technologies such as the cloud and self-service analytics.

   An organization also needs the ability to integrate data sets and understand the appropriate resources for the necessary analytics as well as tactical issues around data access and quality.[183]

10. **Be cognizant of the potential for a reconfigured value chain**
    Pharma is likely to be disrupted by no longer owning parts of the value chain, and reconfigured value chains will likely give rise to new business models. The data governance of internal and external data is a huge gap right now, and companies need to explore a central data governance strategy.

Appendix

Explore the latest life sciences sector research from Deloitte or visit:
www.deloitte.com/us/healthsolutions
www.deloitte.co.uk/centreforhealthsolutions
www.deloitte.com/lifesciences

Return on pharmaceutical innovation 2017
Deloitte UK's Centre for Health Solutions eighth annual pharmaceutical innovation study looks at the challenges the industry faces in generating returns from its R&D investments.

The future awakens: Life sciences and health care predictions 2022
The year is 2022. The quantified self is alive and well, digital technologies have transformed the culture of health care and new entrants have disrupted delivery models. We offer some predictions that, if they come true, will shake up the life sciences and health care industry in the next five years.

Pharma and the connected patient: How digital technology is enabling patient centricity
With over 260,000 health apps worldwide and 70% of patient groups using at least one app to manage their condition, it's clear that a digital ecosystem has developed within health care. New research released by the Deloitte UK Centre for Health Solutions explores how digital technology can help pharma embrace patient centricity to remain relevant, profitable, and to deliver better health outcomes.

How biopharma companies are bolstering R&D pipelines through deal-making
Sourcing research externally seems to be the preferred path for biopharma companies to strengthen their R&D pipeline. But when choosing from the three main options open to them—licensing, mergers and acquisitions, and joint ventures—what factors should they examine, and do deal types differ in the ways they accelerate development and deliver long-term value?

Reinvigorating medtech innovation: How can stakeholders address the capital and commercialization risk challenges?
Venture capital investment in medtech has declined over the past several years, placing medtech innovation at risk. This report examines strategies and solutions—gleaned from interviews and discussions with more than 20 medtech leaders—that could help reverse this trend.

How biopharmaceutical collaborations are fueling biomedical innovation: Life sciences partnering for progress
Deloitte was contracted by the Pharmaceutical Research and Manufacturers of America (PhRMA) to analyze the various types and number of biopharmaceutical partnerships created over the past several decades, which resulted in a comprehensive database of partnerships formed between 1980 and 2014. From this effort, we found that R&D-focused partnerships—most notably, non-asset based models—have grown substantially over the last decade.

The bigger picture: Impact of EU regulatory change on the global life sciences industry
Recent and ongoing European regulatory changes will impact every pharmaceutical, biotechnology or medical technology (medtech) company that currently sells or sponsors products in the European Union (EU). Companies can be well-equipped by taking a proactive approach to tracking and monitoring the regulatory developments and understanding their independent and combined impact on the business.

Unravelling complexity: The challenge of compliance in the life sciences supply chain
In an environment driven by increasing complexity, product diversity and regulatory scrutiny, what are the major compliance risks impacting the entirety of the life sciences supply chain? What opportunities exist to transform compliance from a burden to a source of competitive advantage?

Identification of Medicinal Products: Connecting the parts
Identification of Medicinal Products (IDMP) is one the biggest regulatory challenges for all pharmaceutical companies operating in Europe. How can companies navigate this journey towards increased patient safety and use it as an opportunity for business transformation?

Preparing for the future: The new European Union medical devices regulation
New regulations will impact all device manufacturers. What steps do manufacturers need to take to mitigate this impact? Given the scale and complexity associated with implementing the EU MDR changes it is important for manufacturers to adopt a structured enterprise wide cross-functional approach.

2017 Pharmaceutical R&D leader survey: Innovating to survive, collaborating to thrive
In an environment driven by scientific, regulatory and economic pressure, Deloitte UK's Centre for Health Solutions' first annual pharmaceutical R&D leader survey gauges the current sentiment of R&D executives. Based on interviews with R&D leaders across a sample of big pharma organizations, the report identifies current priorities, future investment plans and key factors that are driving operational excellence.

Master data management for pharma product data and information: Building readiness for global regulations
In addition to achieving compliance, master data management (MDM) can bring many benefits to pharmaceutical companies. Learn how MDM can help your organization improve speed and efficiency across the product life cycle.

Under the spotlight: Data integrity in life sciences
Regulatory bodies now have high expectations with regard to data quality and integrity owing to the life sciences sector's growth, globalization and adoption of advanced technology, such as highly automated systems and storage of data in 'The Cloud'. Good data practices will enrich the quality of data, allowing life sciences companies to make strategic decisions backed by analytics and data-driven insights.

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