

## 2019 Global life sciences outlook

Focus and transform | Accelerating change in life sciences

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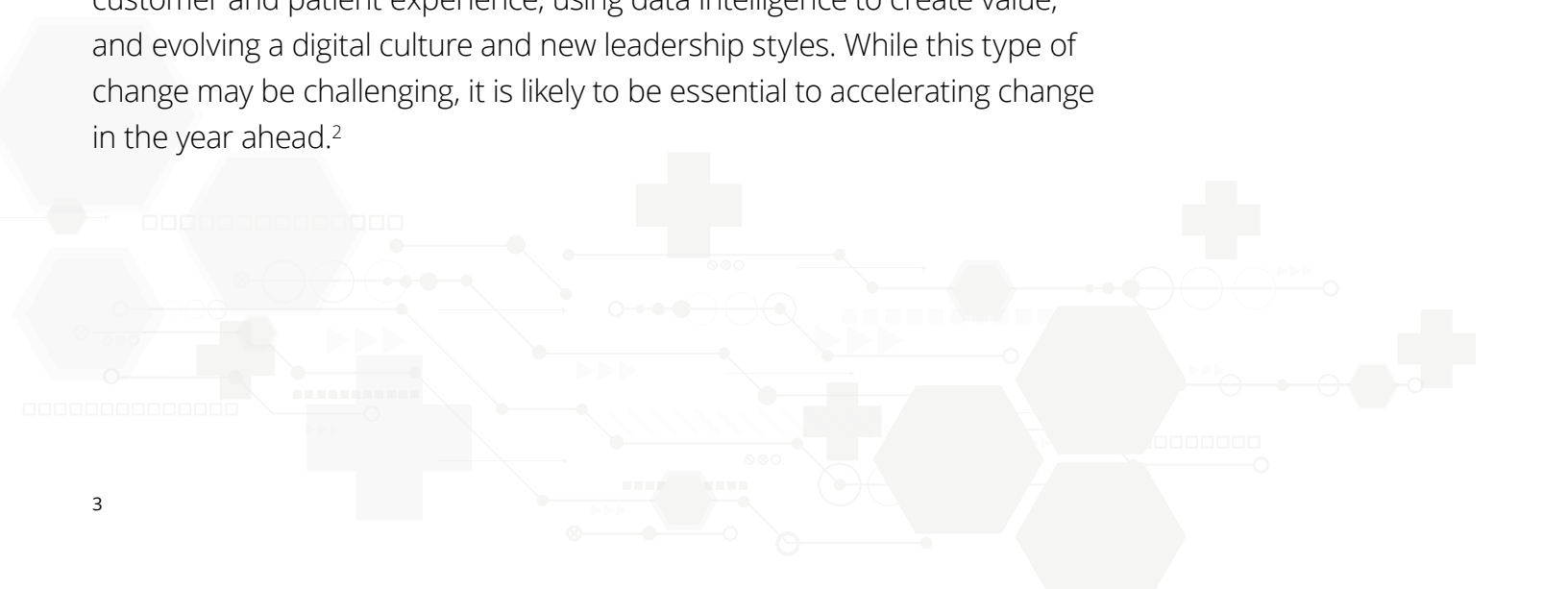
# Outlook

2019 will continue to see a focus on digital transformation in life sciences. This transformation is about using technology symbiotically and strategically, not just adopting a particular technology or device. Data is fast becoming the currency of life sciences, and digital enterprises are building a new business model for the future.<sup>1</sup>

In 2019, how can leaders move forward and accelerate change in life sciences? They should **Focus** and **Transform**.

- Focus on patients and regulators as partners, building partnerships that are strategic and relationship-driven
- Focus on external innovation and expanding a richly networked ecosystem
- Focus on mobilizing data and collaborating with nontraditional partners like startups and tech giants
- Focus on outsourcing for advanced technologies and manufacturing capabilities, and choosing vendors who share similar values and risk profiles

Transforming means aligning the enterprise to deliver an exceptional customer and patient experience, using data intelligence to create value, and evolving a digital culture and new leadership styles. While this type of change may be challenging, it is likely to be essential to accelerating change in the year ahead.<sup>2</sup>



# Economic overview

Global health spending is on the rise. The compound annual growth rate (CAGR) for health care spending across 60 countries is predicted to increase 5.4 percent for the period 2018–2022, compared to just 2.9 percent over 2013–2017. The overall share of Gross Domestic Product (GDP) devoted to health is forecast at 10.5 percent for 2019. Per-person spending varies widely by country—from US\$11,674 in the US to just US\$54 in Pakistan. Except for North America, all regions anticipate spending to accelerate compared to the growth over the period 2013–2017.<sup>3</sup>

## Growth trends

### Life expectancy

Overall, life expectancy at birth is rising rapidly and expected to reach 74.4 years by 2022, up from 73.3 in 2017. Falling infant mortality is contributing to most of the gain.<sup>4</sup> However, the US Centers for Disease Control and Prevention (CDC) reports that life expectancy in the United States fell for the third year in a row, to 78.6 years.<sup>5</sup>

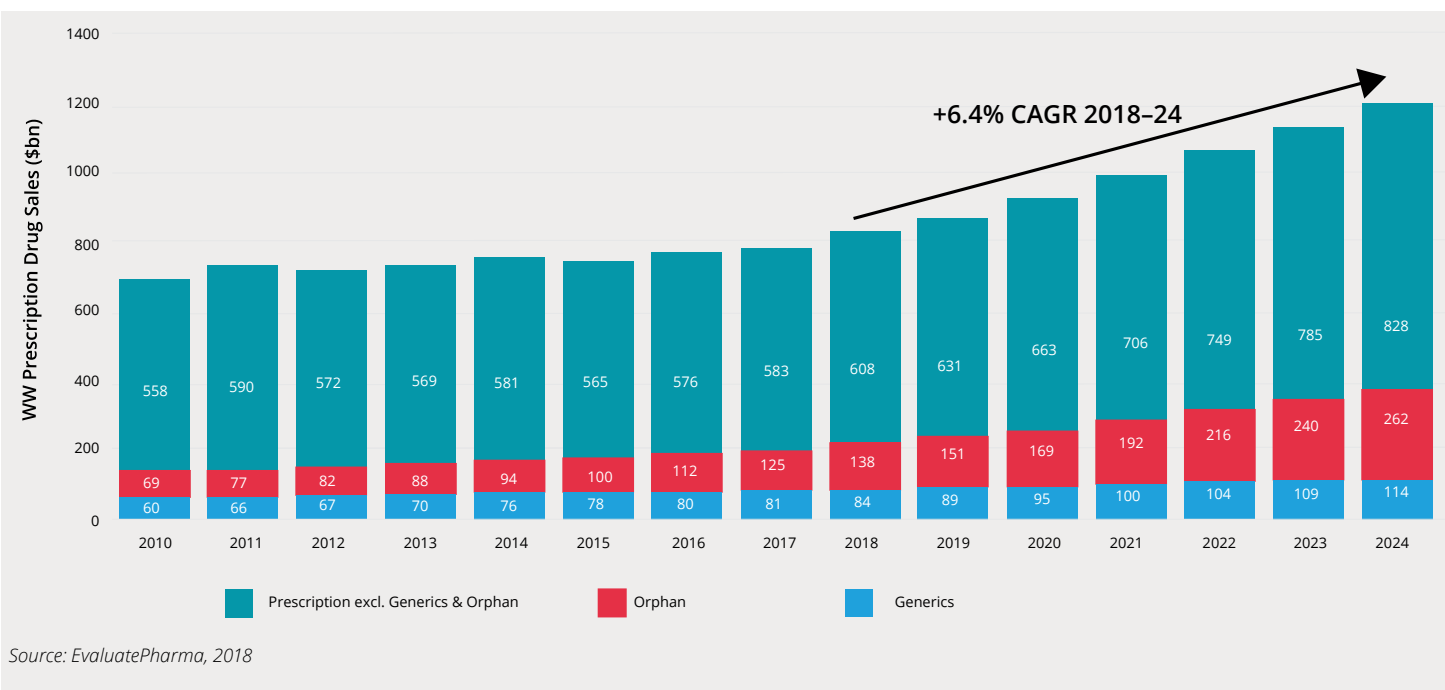
### Pharmaceutical drug and disease trends

Global pharmaceutical spending is predicted to outpace overall health care spending.<sup>6</sup> Worldwide prescription drug sales are expected to rise from

US\$900 billion in 2019 to US\$1.2 trillion by 2024. From 2018 to 2024, CAGR for pharmaceutical drugs is expected to be 6.4 percent, or six times the 1.2 percent over 2011–2017.<sup>7</sup> Drivers of growth are predicted to be novel therapies that address key, unmet needs and increased access to medicines, as a result of new pricing policies around the world.

Challenges to growth include payer scrutiny, sales losses due to genericization, and competition from biosimilars. In 2019, it is estimated that US\$19 billion in prescription sales may be at risk due to patent expiries, with approximately half resulting in lost sales.<sup>8</sup>

Figure 1. Worldwide prescription drug sales, 2018–2024





## Regional and country outlooks, 2018–2022

Regionally, transition economies<sup>9</sup> are expected to be the fastest-growing market, averaging 9.3 percent per year, with the highest growth expected in the Ukraine at 15.2 percent CAGR in US-dollar terms. Latin America is likely to be the slowest at 3.6 percent growth per year. North America is expected to remain the largest regional market, averaging 4.9 percent growth per year, but will see a fall in its share of total pharmaceutical spending to 34.8 percent by 2022.<sup>10</sup>

- United States:** While pharmaceutical spending is expected to rise at a CAGR of 5.4 percent over the forecast period, a sharp deceleration may be expected by 2020 in anticipation of a possible cyclical downturn in the US economy and continued political uncertainty. In 2019, Americans without health insurance will not face a penalty, and private insurers may shift their focus to younger and healthier clients and low-cost policies. It is predicted that the public sector will struggle to cover costly care for the elderly and low-income families.<sup>11</sup> Heart disease and cancer are the leading causes of death in the United States.<sup>12</sup>
- Japan:** The second-largest pharmaceutical market after the United States. Its aging population is expected to continue to drive demand for drugs to treat cancer, diabetes, cardiovascular disease, and other age-related conditions.<sup>13</sup> However, Japan is the only declining market among major countries,<sup>14</sup> despite the launch of health technology assessments (HTAs) aimed at improving cost efficiency.<sup>15</sup> Pharmaceutical sales in Japan are expected to significantly lag<sup>16</sup> behind the 6.3 percent worldwide average over the forecast period.<sup>17</sup>
- United Kingdom:** A major exporter of pharmaceutical products. Pharmaceutical sales are up 5.7 percent annually. However, continued uncertainty around Brexit throughout 2019 may disrupt trade. Pharmaceutical sales in the United Kingdom are expected to rise at a CAGR of 4 percent in nominal local-currency terms.<sup>18</sup> Age-related diseases, including dementia, (especially Alzheimer's), Parkinson's, rheumatism, osteoporosis, and metabolic disorders are on the rise, and the UK's obesity rate is among the highest in Europe. The number of people with diabetes is expected to reach 5.2 million by 2025, from 4.5 million in 2016, with cancer and circulatory system diseases being the leading causes of death in England and Wales.<sup>19</sup>
- China:** Pharmaceutical sales are expected to see a CAGR of 8.7 percent in nominal local-currency terms. Central government reforms represent a maturation of the market,<sup>20</sup> and the recent expansion of drug reimbursement lists is expected to fuel demand. In the next year, there will likely be continued concerns around corruption and safety as a result of recent drug scandals.<sup>21</sup> However, evolving invoicing systems are being designed to streamline distribution channels and prevent corruption.<sup>22</sup> Noncommunicable diseases (NCDs) account for 85 percent of deaths. Other leading causes of death are cerebrovascular disease, ischemic heart disease, chronic obstructive pulmonary disease, lung cancer, and Alzheimer's, according to the latest data from 2016. The share of people over 65 is expected to rise to nearly 14 percent by 2022. A chronic-disease plan, targeting cardiovascular disease, cancer, and chronic respiratory diseases, aims to cut deaths for 30- to 70-year-olds by 10 percent by 2020.<sup>23</sup>
- India:** The world's tenth-largest pharmaceutical market in US-dollar terms. Private expenditure is expected to drive growth. In particular, the increased use of online pharmacies is creating a demand for more advanced, costly medicines among India's growing middle class. NCDs account for 53 percent of deaths, while diabetes accounts for only 2 percent. The leading cause of death is ischemic heart disease followed by chronic obstructive pulmonary, diarrheal, and cerebrovascular diseases.<sup>24</sup>

## Pharmaceutical Research & Development (R&D)

Worldwide pharmaceutical R&D spend is expected to decrease from 4.1 percent CAGR in 2018 to 3.1 percent in 2019. Companies may improve R&D efficiencies by using big data and predictive analytics, or by directing less revenue toward replenishing pipelines. Overall, R&D spend from pharma and biotech companies is expected to be US\$177 billion in 2019, compared to about US\$171 billion in 2018.<sup>25</sup>

According to Deloitte's annual study, *Measuring the returns from pharmaceutical innovation*, projected R&D returns for 12 large cap biopharma companies, have fallen to their lowest level in nine years, at 1.9 percent in 2018, down from 10.1 percent in 2010. The cost to bring an asset to market has increased to record levels in 2018 (to US\$2.168 million) but the forecast peak sales per asset have more than halved since 2010 (from US\$816 million in 2010 to US\$407 million in 2018). In contrast, more specialized biopharma companies are outperforming these large cap companies with projected returns of 9.3 percent in 2018, as despite higher development costs, they have higher projected pipeline values.<sup>26</sup>

## Biotech

Biotechnology products are expected to contribute steadily to sales, rising to 52 percent of the top 100 product sales by

2024, from 49 percent in 2017. In 2019, biotech is forecast to represent 27 percent of the global market, and by 2024, 31 percent.<sup>27</sup>

To date, Japan has fostered a series of licensing deals, contract manufacturing tie-ups, and mergers and acquisitions, and continues to be an attractive place for biotech firms to do business. Japan became the world leader in regenerative medical products with the introduction of the Pharmaceuticals and Medical Devices Act in 2014.<sup>28</sup>

**Orphan drugs, next-generation cell and gene therapies**

By 2024, the orphan drugs sector is expected to almost double and account for 20 percent of prescription sales.<sup>29</sup> In particular, gene and cell therapies are

accelerating growth. The Chimeric Antigen Receptor T-cell (CAR-T) therapy market is projected to increase at an annualized rate of over 51 percent during the time period, 2018–2030.<sup>30</sup>

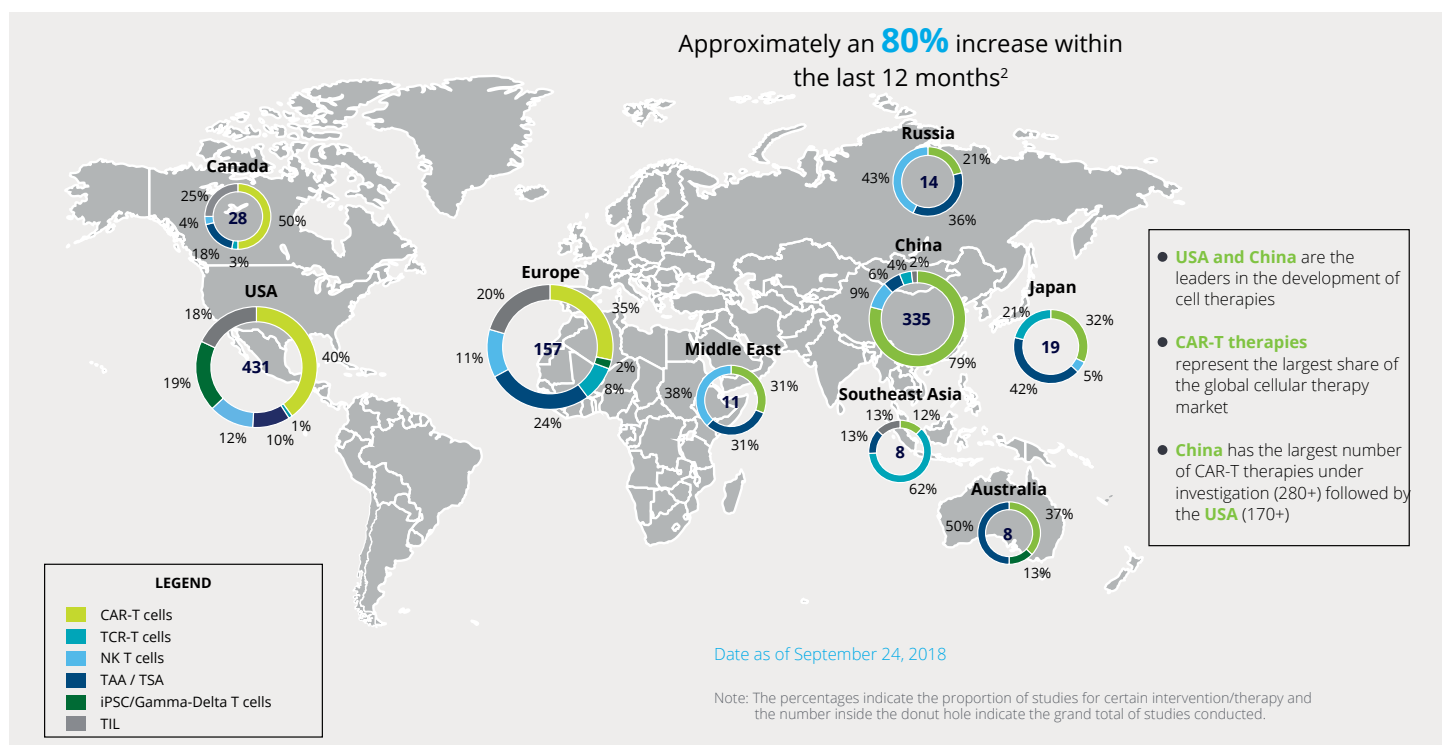
The first two CAR-T immunotherapies, as well as a novel gene therapy targeting a disease caused by mutations in a specific gene, gained US Food & Drug Administration (FDA) approval in 2017.<sup>31</sup> These therapies received Priority Review, Breakthrough Therapy, and Orphan Drug designations, demonstrating the FDA's commitment to expediting the development and review of these groundbreaking treatments.<sup>32</sup> Cellular and gene therapy-related research and development is advancing rapidly in the United States and China, where hundreds of trials are underway.<sup>33</sup>

In 2019, safety, efficacy, and costs will likely continue to be the biggest challenges in this sector.<sup>34</sup> As these drugs comprise substantial shares of payer budgets, they may face a backlash. Payers' decisions to reimburse a drug that may carry a significant price tag will heavily depend on the drug's value, with many ways for value to be determined.<sup>35</sup> The therapy could avert downstream medical costs or be justified by the payer due to low patient numbers. Ten percent of prescription drug spending is on orphan indications, or about 1 percent of approximately US\$3.7 trillion in US health care spending for 2018.<sup>36</sup>

**Biosimilars**

Biosimilars have been on the market in Europe for more than a decade, and India released its first biosimilars guidelines in 2012. But while Europe has approved

**Figure 2. Rapid growth of cell therapies being investigated**



Source: Deloitte analysis

65 biosimilars,<sup>37</sup> and India currently has over 50 approved biosimilars on the market,<sup>38</sup> the United States just made its first approval in 2017.<sup>39</sup> To get biosimilars to market more quickly and help save costs, the FDA is accelerating the approval process through its Biosimilars Action Plan launched in July 2018.<sup>40</sup> The plan was updated in December 2018, to better address anti-competitive practices that abuse current regulations and distribution systems.<sup>41</sup> The new policies and revised guidance aim to prevent companies from gaming exclusivity provisions and ensure that when drugs transition into biologics, they don't receive extra exclusivities they aren't entitled to have.<sup>42</sup> When markets become more competitive, regulators expect prices will fall, and more access will be made available to patients.<sup>43</sup>

The World Health Organization (WHO) is undertaking an effort to harmonize standards for biosimilars worldwide.<sup>44</sup> In 2017, it launched a pilot prequalification program for biosimilars in an effort to make expensive treatments for cancer more widely available in low- and middle-income countries.<sup>45</sup>

### Generics

Governments worldwide are looking to boost patient access to affordable medicines and may increase demand for generic drugs.<sup>46</sup> Over 2018–2024, US\$251 billion in drug revenues are at risk from patent expiries with established pharma giants likely to struggle to compete against generics.<sup>47</sup> While this may create growing pipeline opportunities for generics, the number of companies manufacturing generics is consolidating, and the number of complaints about rising prices for some generics is increasing. Drug shortages may also restrict growth.<sup>48</sup>

- **United States:** The largest generics market in the world. Generic drugs account for the majority of pharmaceutical sales in the

United States.<sup>49</sup> Public and government scrutiny of generics' price increases, along with underperformance, are causing some companies to reevaluate their portfolios, including divestiture of low-margin products.<sup>50</sup> Some companies and hospitals are partnering and manufacturing their own generics in response to shortages and high prices.<sup>51</sup> In 2019, generic drug shortages are likely to continue due to issues with manufacturing quality and capacity, including the impact of the hurricane in Puerto Rico. Disruption in the role of pharmacy benefits managers (PBMs), and other players in the value chain, are expected to be another factor in the future.

- **Europe:** The European Medicines Agency (EMA), which, as a result of Brexit, is moving from London to Amsterdam in 2019, is showing an upward trend in marketing approvals for innovative drugs and generics.<sup>52</sup>
- **Japan:** The government has a target of achieving an 80 percent market share for generics by September 2020, and it is encouraging Japanese companies to develop generic drug production facilities in lower-cost Asian countries. Not only would this likely reduce drug prices in Japan, but it is expected to also strengthen Japanese pharmaceutical sales across Asia.<sup>53</sup>
- **India:** Accounts for approximately 20 percent of global generics output, and generic drugs account for three-quarters of the Indian market by volume. Local production of generic drugs and vaccines keeps prices low, while local companies are taking advantage of low labor and research costs to export generics.<sup>54</sup>
- **Latin America:** Governments are not only expected to focus spending on generics, but also restrict imports of more expensive medicines.<sup>55</sup>

## Not-for profit generics: Civica Rx

**A new business model disrupting the generics segment.** In 2018, Civica Rx, a not-for-profit generic drug company formed by a consortium of hospitals, launched in the United States with the aim of addressing shortages and high prices of lifesaving medications. Attracting the interest of 120 health organizations, including the US Department of Veterans Affairs (VA), its initial focus will be 14 hospital-administered generic drugs.<sup>56</sup> Civica Rx presents a new business model—a non profit, non stock-bearing company with transparent pricing. It will own the right to manufacture all products and be backed by the FDA.<sup>57</sup>

### Personalized medicine

The global personalized medicine market is expected to increase over 11 percent CAGR for the period 2017–2024, with the help of advances in health care analytics, artificial intelligence (AI), and blockchain.<sup>58</sup> In 2019, the shift to value-based, personalized health care will likely require new platforms to support the patient and many stakeholders needed to deliver targeted breakthroughs to patients.<sup>59</sup> The most pressing challenges

for personalized medicine are anticipated to be reimbursement, clinical utility, data connectivity, and access.<sup>60</sup> About 30 percent of personalized medicine is focused on oncology.<sup>61</sup>

The FDA is planning a new 52-person Office of Drug Evaluation Science (ODES) to improve the review of new medicines and standardizing the approach for using personalized medicine, digital data, and patient reporting.<sup>62</sup>

### Personalized medicine: LinkDoc

Digital health startups are enjoying robust funding, especially in China.<sup>63</sup> LinkDoc is a Chinese medical data solution company that provides clinical, structured data and personalized information to government bodies, insurers, pharmaceutical companies, and research organizations. It serves China's oncology hospitals, as well as 500 hospitals in over 30 provinces.<sup>64</sup>

LinkDoc's tools work to provide better decision making, by standardizing health care data and personalizing information, using AI and Big Data. Millions of clinical electronic medical record (EMR) data can be converted into research-grade data. Its image-intelligent diagnosis system is designed to increase efficiencies, while reducing rates of misdiagnosis or inaccuracy.<sup>65</sup>

### Therapeutic focus

Oncology is expected to remain the dominant therapy segment, growing US\$129 billion in projected worldwide sales over 2017–2024, and reaching US\$233 billion by 2024. Immunosuppressants are expected to have the highest CAGR gain in the period, 2017–2024, at 15.7 percent, followed by Dermatologicals (13 percent), Oncology (12.2 percent), and Anti-anemics (11 percent).<sup>66</sup>

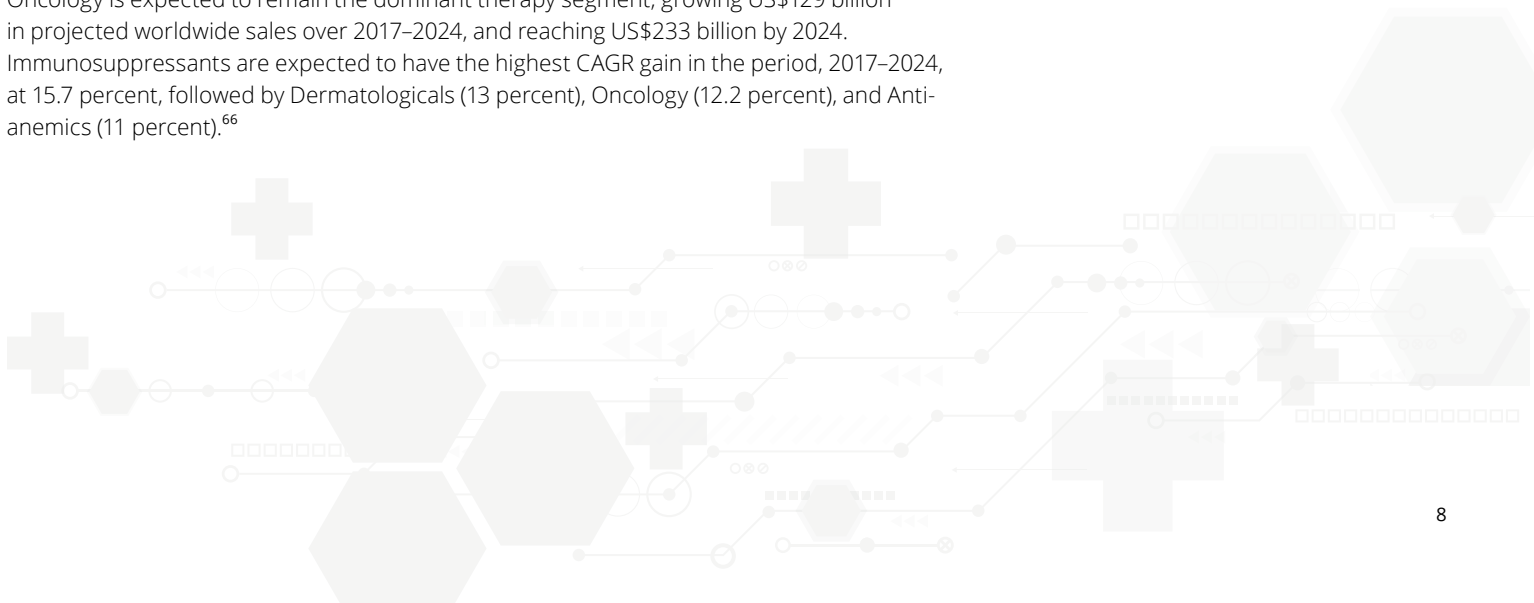




Figure 3. Top 15 prescription drug & OTC therapy categories by worldwide sales, 2016–2022

	Therapy Areas	WW Sales 2017 (US\$B)	Projected WW Sales 2024 (US\$B)
1.	Oncology	104.0	233.0
2.	Anti-diabetics	46.0	59.5
3.	Anti-rheumatics	55.7	56.7
4.	Vaccines	22.7	44.6
5.	Anti-virals	42.4	39.9
6.	Immunosuppressants	3.7	38.1
7.	Bronchodilators	27.2	32.3
8.	Dermatologicals	12.9	30.3
9.	Sensory organs	21.6	26.9
10.	Anti-hypertensives	23.0	24.4
11.	Anti-coagulants	16.8	22.9
12.	MS Therapies	22.7	21.5
13.	Anti-fibrinolytics	12.7	20.4
14.	Anti-hyperlipidemics	11.3	16.4
15.	Anti-anemics	7.6	15.7
	Top 15	445.0	683.0
	Other	379.0	567.0
	<b>Total WW Prescription &amp; OTC</b>	<b>825.0</b>	<b>1247.0</b>

Source: EvaluatePharma, 2018

## Medtech

Medtech is projected to grow at a 5.6 percent CAGR over the forecast period 2017–2024. In 2019, worldwide medtech sales are predicted to be US\$475 billion, growing to US\$595 billion by 2024. The fastest-growing device areas by CAGR are predicted to be Neurology (9.1 percent), Diabetic Care (7.8 percent), and General and Plastic Surgery/Dental (tied at 6.5 percent).<sup>67</sup>

By 2024, In Vitro Diagnostics is expected to be the largest medtech segment with annual sales of US\$79.6 billion, followed by Cardiology and Diagnostic Imaging. Medtech R&D spend is estimated at US\$39 billion by 2024.<sup>68</sup>

Software-as-a-Medical Device (SaMD) is a rapidly growing area of innovation that regulators across the globe are working to de-risk and make more agile.<sup>69</sup>

### Medical device and SaMD regulations

- **United States:** In 2019, the FDA will launch its software precertification (Pre-Cert) program for Software-as-a-Medical Device<sup>70</sup> and recently released a new working model: *Developing a Software Precertification Program*.<sup>71</sup> The agency will review previous software approvals and also test its model on some new software submissions, applying the standards it uses for medical devices classed as medium-risk. Data-sharing between developers and reviewers will also be tested.<sup>72</sup> The FDA is updating its Medical Device De Novo Classification process, amending the definition of a medical device (excluding certain medical software functions). This process aligns medical device quality systems with international standards and finalizes the FDA's proposed rule for procedures and time frames for requesting internal agency supervisory review.<sup>73</sup> Digital health companies contributed to 38 De Novo authorizations

in 2018, up from 31 in 2017.<sup>74</sup> In a new *Report on Non-Device Software Functions: Impact to Health and Best Practices*, the agency addresses medical software functions not part of SaMD.<sup>75</sup> As more devices become connected in the Internet of Medical Things (IoMT), the FDA's medical device cybersecurity program is being strengthened to protect patients,<sup>76</sup> as part of the *Medical Device Safety Action Plan*.<sup>77</sup>

- **United Kingdom:** The National Institute for Health and Care Excellence (NICE) set new standards for digital health technology development in 2018. The new guidance outlines what evidence is needed when innovators submit health care apps and wearable devices to National Health Service (NHS) commissioners.<sup>78</sup>

- **European Union:** The EU is preparing for a new regulatory framework in 2019—the Medical Devices Regulations (MDR)<sup>79</sup> and In Vitro Diagnostics Directive (IVDR).<sup>80</sup> The MDR provides a three-year transition period to 26 May 2022, and the IVDR, a five-year transition to 26 May 2022.<sup>81</sup> Once in place, the new regulations will be stricter than those imposed by the FDA, particularly with the depth and breadth of clinical evidence required and post-market product monitoring.<sup>82</sup> The regulatory change will result in product reclassification and recertification for many of the medical devices and in vitro diagnostics on the market today. Notified bodies and industry are expected to struggle to meet the tight timelines required.

- **Australia:** The Therapeutic Goods Administration (TGA) released guidance on SaMD regulation in late 2018. However, the TGA is concerned that its current regulations underestimate the risks posed by many SaMDs and its advice is likely to change in the near future.<sup>83</sup>

- **China:** The National Medical Products Administration (NMPA) is targeting data integrity in a new checklist to guide on-site inspections of medical device clinical trials released in late 2018.<sup>84</sup>

### Navigating geopolitical uncertainty

Disputes over US health care policies are expected to continue, causing uncertainty for all market players in the next few years. There is also considerable uncertainty for Western Europe, where Brexit has raised risks for some economies and health care systems across the region.<sup>85</sup> If no deal is reached by 29 March 2019, the United Kingdom has a contingency plan to remain part of the EU medicines and medical devices regulatory networks. Medicines and medical devices have been prioritized on alternative routes to maintain access to these supplies for UK patients.<sup>86</sup> On 4 January 2019, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) issued "Further guidance note on the regulation of medicines, medical devices, and clinical trials if there's no Brexit deal," whereby UK Marketing Authorizations, which are currently Centrally Authorized Products in the EU, will be grandfathered in on exit day.<sup>87</sup>

### Pricing pressures

Pricing pressures on the pharmaceutical segment are predicted to continue, driven by governments, patent losses, and increased promotion of generics and biosimilars.<sup>88</sup> To deal with these pressures, some pharmaceutical companies are buying rivals to streamline marketing staff or buying unique treatments that do not have lower-cost alternatives.<sup>89</sup> Many will continue to look for ways to increase efficiencies, enhance trial savings, and demonstrate value.<sup>90</sup>

- United States:** Rising health care costs are driving greater scrutiny of the economic value of new treatments by government and private payers.<sup>91</sup> The US administration is looking to test lower drug prices and raise pricing transparency.<sup>92</sup> The aim is to align US prices more closely to those abroad, but some believe this could dampen innovation.<sup>93</sup> The potential *International Pricing Index Model for Medicare Part B Drugs*<sup>94</sup> would affect certain pharmaceutical companies more than others.<sup>95</sup> Also proposed is giving Medicare Advantage plans the option of applying step therapy for physician-administered and other Part B drugs<sup>96</sup> as well as overhauling how physicians are reimbursed for prescription drugs through Medicare Part B.<sup>97</sup> In addition, legislation is under review to eliminate rebates on prescription drug purchases.<sup>98</sup> Rebates are negotiated by PMB managers and used by large health plans and employers to lower prices for their clients.<sup>99</sup> New alternatives are likely to emerge, and drug manufacturers will need to rethink their market-access approach and pricing strategies. Some believe lower prices overall could be more beneficial to consumers.<sup>100</sup> Should the PBM model be disrupted in 2019, new investments in technology, processes, and organizational capacity will likely be required.<sup>101</sup>

- United Kingdom:** The Health Service Medical Supplies Act grants public authorities more power to regulate medicine prices.<sup>102</sup> For 2019, the Association of the British Pharmaceutical Industry (ABPI) and the NHS have agreed to a new voluntary scheme regarding

*Branded Medicines Pricing and Access.* The scheme places a 2 percent cap on the growth in sales of branded medicines to the NHS, potentially saving approximately £930 million in 2019. Pharmaceutical companies are expected to repay the NHS for spending above the cap but will benefit from faster NICE appraisals, and patients are likely to get access to new medicines up to six months earlier than today.<sup>103</sup>

- France:** The government has an agreement with the Federation of Medicines Enterprises to regulate the price of medicines from 2017 to 2019.<sup>104</sup>
- Germany:** The government approved the German Drug Law (AM-VSG) in 2017, aimed at ensuring Social Health Insurance financial stability and extending the price moratorium for all patent-free drugs until 2022.<sup>105</sup>
- Japan:** The government is seeking to constrain pharmaceutical prices, while promoting innovations to improve treatment. A full HTA for drugs is being put in place to ensure that only the most cost-effective treatments are used. The ministry is also increasing the frequency of its price reviews.<sup>106</sup>
- India:** The Drug Price Control Order (DPCO) regulates the prices of 384 drugs on its National List of Essential Medicines. In the second half of 2018, it announced plans to expand the list to include more medical devices and consumables and was preparing new rules to cap distribution margins for pharmaceuticals amidst complaints of some margins increasing

500 percent. The Central Drugs Standard Control Organization is launching a digital database that will list information on pharmaceutical producers and medicines.<sup>107</sup>

### Expanding access to drugs, cell and gene therapies

In 2019, life sciences companies should align their commercial models with changing market dynamics. If physicians are no longer the key decision makers, and clinical programs are no longer sufficient to gain market access and product differentiation, life sciences companies may want to demonstrate the economic and humanistic value that their products provide to all stakeholders, not just the clinical benefits.<sup>108</sup> Market access becomes a priority, before field force, calls, samples, details, and Direct-to-Consumer (DTC).

### Trade wars and supply chains

Global pharmaceutical companies depend on stable supply chains, and uncertainty about trade policy could cause disarray in supply chains. Scores of biopharma materials and medical devices from China are targeted in the US\$100-billion trade war between the United States and China.<sup>109</sup> About half of the goods the United States imports from China could be subject to tariffs.<sup>110</sup>

Uncertainty also makes it very difficult for companies to make investment decisions. For global pharmaceutical companies, major decisions on strategic investment can have a time horizon of at least 10 years. In 2019, a lack of a clearly foreseeable end to the US-China trade war could put future investments at risk.<sup>111</sup>

# Focus

## Strategic focus on deal-making and external innovation

The continuous search for the next generation of market-leading medicines and decreasing returns in R&D make external deals attractive sources of innovation for biopharma companies, either through licensing, mergers and acquisitions (M&A), and/or joint ventures.<sup>112</sup>

In 2019, external innovation is likely to continue to be a strategic focus for pharma companies that may face patent expiries, competition from and biosimilars, weak new drug pipelines, and growing technology needs.<sup>113</sup> But many factors can determine the optimal deal structure. Below are some of the most successful strategic reasons buyers and sellers might consider for each type of deal.<sup>114</sup>

## Licensing

According to Deloitte research, licensing leads biopharma deal-making activities, constituting 93 percent of deals in the data set.<sup>115</sup> The first three months of 2018 resulted in almost 20 percent more licensing deals compared to the same period in 2017.<sup>116</sup>

**Figure 4. Deal types and potential strategic rationale, advantages, and disadvantages**

Deal type	Rationale-buyer/ licensee	Rationale-seller/ licensor	Advantages	Disadvantages
<b>Licensing</b>	<ul style="list-style-type: none"> <li>Access to talent and expertise</li> <li>Traditional contingent payment structure allows risk sharing</li> <li>Economically viable option budgets, especially when M&amp;A valuations are high</li> </ul>	<ul style="list-style-type: none"> <li>Access to capital and capabilities to help get to the next value inflection point</li> <li>Upside associated with the asset is retained</li> <li>Company investors may be seeking an IPO</li> </ul>	<ul style="list-style-type: none"> <li>Access to new capabilities or technology</li> <li>Access to new geographic regions</li> </ul>	<ul style="list-style-type: none"> <li>Shared decision making can complicate or delay operational progress</li> <li>Each party is dependent on the other to achieve key milestones or goals</li> </ul>
<b>Merger &amp; acquisition (single-asset companies or deals)</b>	<ul style="list-style-type: none"> <li>Ownership of new product(s)</li> <li>Redundant capabilities are reduced, thus lowering costs</li> </ul>	<ul style="list-style-type: none"> <li>High valuations could be lucrative for current investors and employees</li> <li>An exit option for private investors</li> </ul>	<ul style="list-style-type: none"> <li>Streamlined decision making after transition of ownership</li> <li>Contingent M&amp;A deals could allow for additional payments tied to value creation</li> <li>Potential tax benefits for the buyer</li> </ul>	<ul style="list-style-type: none"> <li>Alignment on valuation for public companies may be difficult</li> <li>Tend to be more disruptive in nature; may result in loss of key personnel and tacit knowledge</li> <li>Consolidation of assets could have a negative accounting impact</li> </ul>
<b>Joint venture</b>	<ul style="list-style-type: none"> <li>Able to align on goals with little definition of specific products or technology</li> <li>Complementary capabilities are maximized</li> </ul>		<ul style="list-style-type: none"> <li>Ideal for areas where scientific mechanisms are not well known</li> <li>Entry into new or unknown markets</li> </ul>	<ul style="list-style-type: none"> <li>Complex financial structure</li> </ul>

Source: External Innovation – How biopharma companies are bolstering R&D pipelines through deal-making, Deloitte Center for Health Solutions, 2017

## M&A

Over the last ten years, the top 10 pharma companies with the highest return on investment (ROI) spent an average of 35 percent on M&A from their total R&D and M&A investment.<sup>117</sup> The biotech segment is seen as one of the most active in M&A.<sup>118</sup> However, as trade tensions between the United States and China escalated in the third quarter of 2018, biotech M&A experienced the slowest quarter since 2013.<sup>119</sup> High-risk sectors like biotech are challenged in volatile times, and 2019 is likely to continue to be volatile for pharma and biotech.<sup>120</sup>

While expectations around immunology have been tempered, cell and gene therapies are expected to remain popular with investors in 2019.<sup>121</sup> A new era of deal-making is accelerating among biopharmaceutical and genomics companies looking for a leadership position in next-generation therapies.<sup>122</sup> In particular, China is in a race with the United States for "bio-intelligence," investing over US\$9 billion in expanding AI and biotech capabilities to commodify biological and genomic data.<sup>123</sup>

Large, transformative acquisitions in the US\$60–70 billion range defined 2018 and the beginning of 2019. This year, companies may be rearranging portfolios based on the coming pricing controls, and acquisitions are expected to be very strategic, with a focus on core therapies or specialties. As a result, a lot of activity is expected in divestitures. Some companies are being creative about divestitures and using alternative financing models, like alliances and joint ventures, to keep a pulse on new therapies.<sup>124</sup>

## Joint ventures

Large companies are expected to pool resources and create more innovative joint ventures and partnerships to look at parts of their business that might be non-core, but enable them to divest, monetize, or gain value.

The trend of different types of structures is likely to accelerate, but we'll likely see less of the traditional framework of just buying a company outright. Instead, we can expect more complicated, innovative structuring with use of options, milestones, and partnerships.

## Focus on new entrants

As the world continues to digitize, life sciences incumbents may see next-generation or technology startups and large tech companies continue to threaten the status quo. Some new entrants are diversifying from other industries, while others are innovating with new capabilities.<sup>125</sup> Traditional pharma and medtech companies can take advantage of these opportunities and drive innovation or find themselves increasingly on the outside and in a reactive mode.

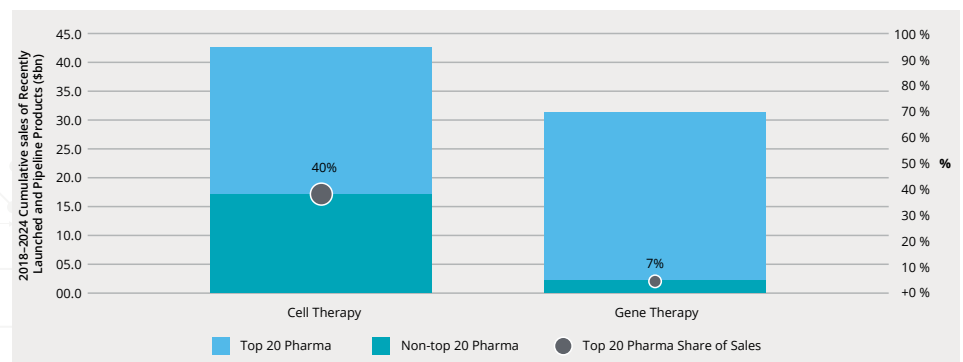
## Startups: Key drivers in the disruption of next-generation therapies

While only a few big pharma companies are developing next-generation therapies, more than 250 startups are focused on gene-based therapeutic solutions.<sup>126</sup> As these startups mature, pharma companies who may be looking to buy these companies can expect a hard time acquiring this innovation. Startups bring a whole new mind-set and tech culture that appears to be dramatically

opposite to pharma's traditional, legacy culture. In the future, next-generation therapy startups are more likely to mesh into their own mergers and could form a new breed of company with a very different culture around innovation and life sciences. Among the challenges is pharma's value chain, which is built around traditional products, while next-generation therapies are being built around the patient. The cost of goods sold is also much greater than the 20–25 percent average that exists in life sciences today, as is the revenue required to maintain return on innovation. While costs are expected to go down, they will still likely be significantly higher than most other therapies in the marketplace.

Smaller companies, often with one asset, are increasingly trying to control that asset throughout its life cycle—or for a bigger portion of the life cycle. The digital world is making it possible for smaller companies, without the infrastructure of Big Pharma, to acquire capabilities that could put them on par with larger companies.

Figure 5. Value creation of cell and gene therapies



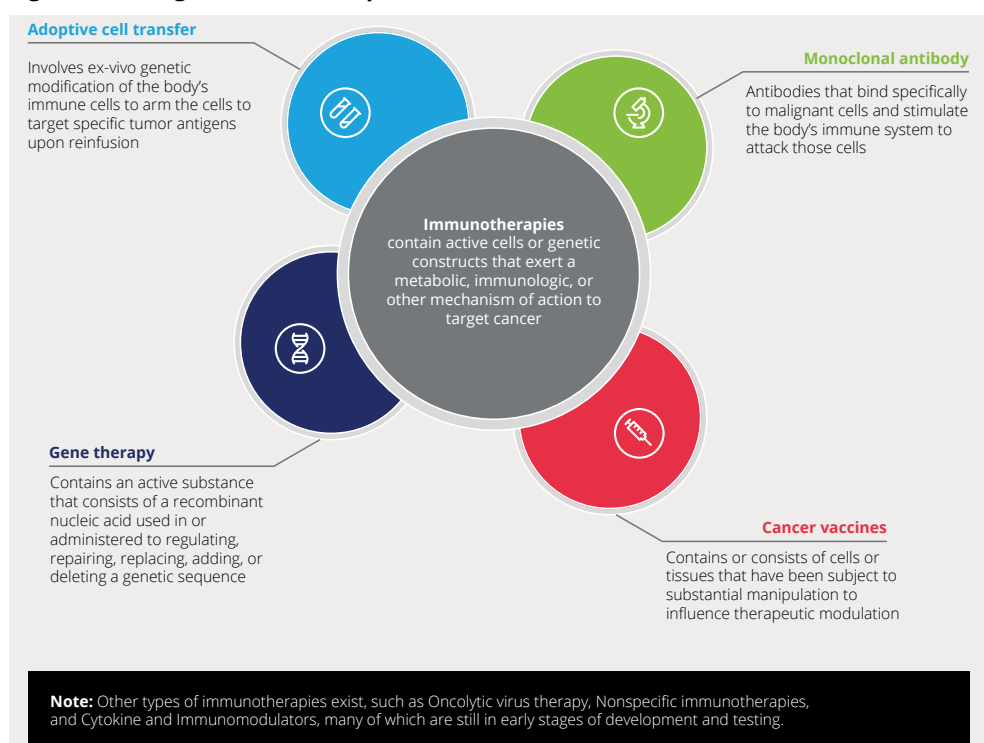
Source: Evaluate Pharma, May 2018



## CAR-T therapy: Nanjing Legend Biotech

More than 200 CAR-T therapies are being investigated in China.<sup>127</sup> CAR-T cells have become a major source of cellular immunotherapy in China, and the number of clinical trials in progress in China continues to grow.<sup>128</sup> In March 2018, Nanjing Legend Biotech received approval from the Chinese FDA (CFDA) for the first cellular therapy to officially enter the clinical trial stage in China. In 2017, Nanjing Legend reported remarkable data to the oncology field for its experimental anti-BCMA CAR-T treatment on 35 relapsed multiple myeloma patients. The data showed that a total 94 percent, or all but two patients, had shown clinical remissions (complete response or very good partial response) in two months after receiving the treatment.<sup>129</sup> However, CAR-T therapy competition in China is intense, and in late 2018, Nanjing Legend was facing scrutiny over its data.<sup>130</sup>

Figure 6. Next-generation therapies



In 2019, lack of manufacturing capacity is expected to continue to present a significant challenge for next-generation therapies. Many startups are not vertically integrated and do not have the necessary manufacturing capability, e.g., to produce vectors. As a result of hundreds of ongoing clinical trials and projected drug launches, the contract manufacturing capacity is already being taxed. Wait times can be 12–24 months. In 2019, companies should continue to develop, or contract, manufacturing capability, without compromising quality and safety.

Source: Deloitte analysis

### Tech giants: Partners, competitors, or chaos

Six of the top ten tech giants are diversifying into health care and life sciences. They have a cumulative value estimated at almost US\$4 trillion<sup>131</sup> and are investing in startups. Alphabet's venture arm, Google Ventures (GV), allocates a third of its funding to 60 health care and life sciences companies from genetics to telemedicine.<sup>132</sup>

About a third of the world's data is generated from health care, and technology companies specialize in data.<sup>133</sup> In health care, tech giants are using Big Data and AI for prediction and prevention.<sup>134</sup> For example, AI shapes every aspect of Amazon's business,<sup>135</sup> and it recently launched Amazon Comprehend Medical to mine and decode unstructured data in medical records using machine learning.<sup>136</sup> For Alphabet, the future is structured data and AI,<sup>137</sup> including its deep learning platform DeepMind Health.<sup>138</sup>

Tech giants are developing medical-grade consumer technology focused on both diagnostics (e.g., Amazon Echo) and therapeutics (e.g., Alphabet's Calico and Verily), and using their deep understanding of the consumer to enhance and simplify the patient experience.<sup>139</sup>

For life sciences, tech giants can be:

- An opportunity as potential partners,
- A threat as competitors, or
- An opportunity and a threat by disrupting a specific area and creating chaos.

In the future, a tech giant, or one of the larger data companies, may begin to push so far into R&D that they come up with their own hypotheses or even seek out a different type of compensation. As a result, they could have a real impact on R&D spend in the future, although this is not evident yet. In 2019, we may see more "coopetition," collaboration between

### Obsessed with customer experience: Amazon

Amazon's deep knowledge of the customer experience is one of biggest threats to traditional players in life sciences and health care. In 2018, Amazon reportedly paid almost US\$1 billion for PillPack,<sup>140</sup> an online full-service pharmacy, in one of the most transformative deals in health care by a tech giant. Licensed to operate in all 50 US states, PillPack is dedicated to simplifying customers' lives and reducing costs with its technology. Customers receive a personalized bi-weekly package containing prescribed medications, a recyclable dispenser, and any other medications that cannot be placed into packets, such as liquids and inhalers. A medication label explaining each pill and how it should be taken is included in every shipment.<sup>141</sup>

Amazon says it selected PillPack because the company is well run and matches its obsession for a highly differentiated customer experience.<sup>142</sup> News of the acquisition reduced market cap by US\$11 billion off major US pharmacy/drugstore companies.<sup>143</sup> Delivery giants are also rattled by the threat of Amazon Air.<sup>144</sup> Is it a sign punishing incumbents for not already being where Amazon appears to be going?<sup>145</sup> Amazon is poised to control every mile of the customer experience.<sup>146</sup>

business competitors, in the hope of mutually beneficial results.

A survey by Deloitte and AdvaMed also found medtech R&D leaders looking to nontraditional partners for help to drive innovation. Over the next two years, 82 percent of those surveyed plan to collaborate with organizations outside of medtech-like technology and health care companies—almost double the percentage today.<sup>147</sup>

### Regulatory disruption

Pharma and medtech companies are witnessing regulatory disruption as a result of tech companies. A common tech archetype is the company who sees beyond traditional regulatory approaches when entering a market, disrupting the status quo and building consumer buy-in quickly. Once behind a product or service, consumers may exert public pressure on lawmakers, and ultimately, regulators. The trend could make the process less burdensome.

We've already seen the accelerated push in approvals for CAR-T and next-generation therapies as well the FDA's Pre-Cert program to expedite standards for SaMD.<sup>148</sup> The ECG app for Apple Watch<sup>149</sup> was one of the most high-profile clearances receiving de novo classification from the FDA.<sup>150</sup> While this is a signal the agency is helping them to innovate,<sup>151</sup> it may also be a threat to traditional medtech companies and the way they currently operate.

### Focus on expanding a richly networked ecosystem

Digital technologies and massive connectivity are creating rich networks of connection, collaboration, and interdependence. As companies can more easily deploy and activate assets they neither own nor control, opportunities and risks are expected to grow exponentially. Rich networked ecosystems could create new value, provide a competitive advantage, and accelerate learning. It appears the need for companies to translate learning into innovation has never been greater.<sup>158</sup>

### Managing third-party risk

A growing, networked ecosystem, however, may also carry risk. There could be the traditional risk of adapting to an increasingly complex environment, but there could also be a broader-based and extended enterprise risk. Organizations may lack the necessary visibility and monitoring of third-party activities and platforms.<sup>159</sup> In life sciences, this is seen as a possible risk because companies are ultimately responsible for any regulatory mishaps and security breaches by vendors and contracted partners.

New data partners and the Internet of Things (IoT) are already dictating a need to better manage "cyber everywhere." In 2019, management frameworks are

## Regulatory disruption: Apple Watch<sup>152</sup> ECG Tech giant receives its first FDA clearance.<sup>153</sup>

The ECG app on Apple Watch<sup>154</sup> Series 4 generates an ECG similar to a single-lead ECG. It can provide information about heart rate and heart rhythm and enables classification of atrial fibrillation (AFib). However, the app cannot be used to identify heart attacks and other heart-related conditions, blood clots, or stroke. In a clinical trial of approximately 600 subjects, the ECG app could accurately classify an ECG with 99.6 percent specificity with respect to sinus rhythm classification and 98.3 percent sensitivity for AFib classification for the classifiable results. The clinical validation results reflect use in a controlled environment.<sup>155</sup>

Apple<sup>156</sup> says the tool is not a diagnostic device, and patients should consult their doctor for health advice. But with easy access to an ECG, patients are starting to inundate their doctors with data. Some doctors are concerned their time is being pulled from those who are actually sick. But better-informed patients are changing the culture of medicine, and the future is likely to continue to be a balancing act. Patient support organizations could play a pivotal role.<sup>157</sup>

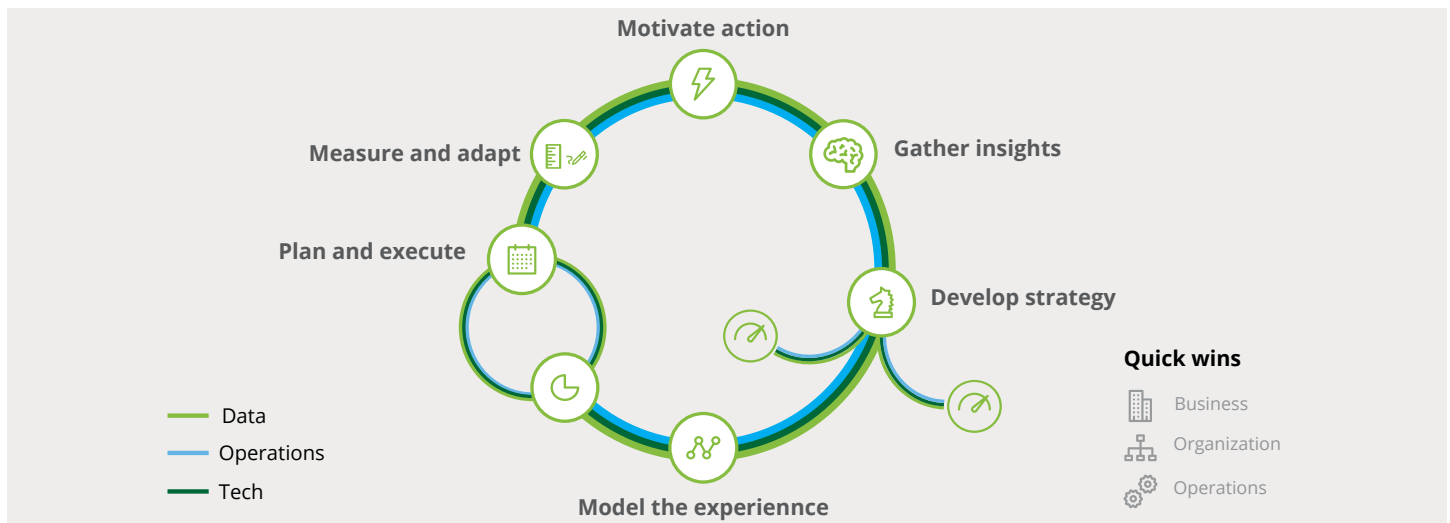
expected to be critical, and leaders should look for partners that match their own risk profiles.<sup>160</sup> Smart companies will want to be proactive in understanding the risks associated with "cyber everywhere."<sup>161</sup>

### Keeping patients at the core

As an increasing number of processes and tools become digitized and more patient-centric, patient expectations grow. In order to gain a better understanding

of the customer experience, life sciences companies should keep patients at the core, and start thinking "outside in" when designing value chains. They should create coherent and meaningful experiences through the entire chain of patient interactions—from R&D to product launch and commercialization phases.<sup>162</sup> When patient-centricity is engrained into a company's culture, a lot of new creative ideas may be uncovered to create value.<sup>163</sup>

Figure 7. Patient experience feedback loop



Source: *Elevate the patient experience*, Deloitte Patient Connect, 2018

## Design thinking: Big Pharma

**The human aspect is critical. Design thinking brings empathy to innovation.** The first step is to gain an empathic understanding of the problem you are trying to solve. When coming up with solutions, refocus back to the end user, the people you are trying to benefit.<sup>164</sup>

A patient with systemic sclerosis was invited to meet with the team designing a clinical trial. The patient explained, “I’m not sure if you realize, but with the disease, I am in a wheelchair now. If you want me to come to your meeting at eight or nine o’clock, I need to wake up at three o’clock in the morning. I need to get dressed, I need to style my hair and do my makeup.” She lost part of the skin on her chin and wanted to look her best. She added that she also needed assistance from her husband, and the whole ordeal was a nightmare.<sup>165</sup>

In lieu of an in-person meeting, the team met via Skype with the patient, and soon realized, that to enroll this patient in the clinical trial, or any patients with this disease, in no way could they be asked to travel, possibly take public transportation, and have a 20-minute visit every week. Patients may drop out of the trial and not be compliant—not because they don’t want to, but because they simply can’t as a result of this disease. This is not something readily understood within study teams. Even with highly qualified people, MDs and PhDs, they tend to look at the scientific needs and aspects, and not the human ones as much. This experience changed that mentality and the approach, as well as the business.<sup>166</sup>

## Focus on outsourcing

Over the next few years, major pharmaceutical companies are expected to shift from transactional outsourcing relationships to more strategic, relationship-based models for biologics, data-driven clinical innovation, and manufacturing capacity.<sup>167</sup> Also, more companies will likely be outsourcing expertise in advanced technologies, such as AI, robotic and cognitive automation, and cloud computing. Outsourcing technology providers could increase efficiencies, lower costs, and decrease clinical timelines.<sup>168</sup>

### Outsourcing for biologics

In 2019, biopharmaceutical outsourcing will likely continue to drive sector growth as third-party contractors provide more external expertise, technology, and capacity that is unavailable in-house. Companies are increasingly partnering with academia and contract research organizations (CROs) for R&D capabilities.<sup>169</sup> Biopharmaceutical delivery devices, such as prefilled syringes, could be another outsourcing opportunity as drug companies look to make products that are easier for physicians and patients to use.<sup>170</sup>

### Outsourcing for data-driven clinical innovation

Patient-centricity, risk-based monitoring, digitization of clinical trials, adaptive trials, and analytics are all having an impact on clinical outsourcing. In the future, outsourcing decisions will likely be influenced by patients' experiences with vendors and CROs. Vendors that provide platforms to effectively integrate data from multiple systems into a central decision-making tool should be in demand. The need for flexibility in study designs and new drug supply requirements could influence decision making, and more outsourcing work may come to smaller vendors and CROs that have better overall predictive performance analytics.<sup>171</sup>

### Outsourcing for manufacturing capacity

In 2019, as cell therapy manufacturing volumes rise, demand for cell therapy manufacturing and related services is expected to grow.<sup>172</sup> Contract manufacturing organizations (CMOs), and contract development and manufacturing organizations (CDMOs) will continue to be to be a strategic and integral part of the global supply process. The shift to biologics, personalized medicine, and specialized, often low-volume, small molecules is creating a shortage in manufacturing capacity.<sup>173</sup> Only one-third of manufacturing—whether in the development stages or after commercial launch—is estimated to be conducted in-house.<sup>174</sup>

In 2019, pharmaceutical companies should focus on building more strategic, long-term partnerships with CMOs and CDMOs to streamline the supply chain—better managing capacity, improving efficiencies, and minimizing time-to-market.<sup>175</sup> CDMOs are expanding to become full-service providers and "true partners" that can offer a wider variety of capabilities.<sup>176</sup> Sponsors should evaluate a partner, not just on technical capability and capacity, but experience, quality, and reputation.<sup>177</sup>

### The new vendor relationship

The relationship between sponsor and vendor is now much more collaborative, and the most effective relationships are built on shared understanding.<sup>178</sup> Pharmaceutical companies should have an outsourcing game plan and predetermined objectives for how vendors can meet requirements. A broad array of members from cross-functional teams should be a part of vendor selection, including project management, R&D, and quality control.<sup>179</sup>

Building a close relationship with regular facility visits should be key to maintaining

compliant operations as pharmaceutical companies carry the overall responsibility of oversight. Communication should be paramount, and technology can inform better decision making, especially in real time.<sup>180</sup> Advanced technologies, such as AI, machine learning, and the IoT, appear to be taking knowledge management in the pharmaceutical segment to the next level. Novel visualization tools enable data to be interpreted more easily in multiple dimensions.<sup>181</sup>

## Collaborating with new partners for transformation

### Patients as partners

The digitization and consumerization of health care is changing the way patients, providers, and life sciences innovators interact. Today, patients are becoming partners in the design of their health care experience, and companies should explore a greater focus on customer experience.<sup>182</sup> The future of customer experience could become more personalized and patient-centric using interoperable data and AI.<sup>183</sup>

In the future, our groceries would be ordered automatically based on our personal preferences, health status, or nutritional needs. While sleeping, our device or digital assistant might determine that the pollen count is too high for a morning workout. The workout and our schedule would be rearranged with other digital assistants finding a time when air quality is predicted to be better. A refill for our allergy medication would be placed and delivered by a drone before we even leave the house in our self-driving car.<sup>184</sup>



Patient-centricity means moving beyond engagement and developing a true partnership with patients—leveraging patient data and understanding the burden of disease, the caregiver’s role, access decisions, and the health care systems involved. In addition, a patient-centric approach can help life sciences improve R&D productivity and may decrease the number of patients who drop out of studies.<sup>185</sup>

**Elevate the patient experience, from patient engagement to patient-centricity**

- 1. Digitize the core**  
Reimagine the core patient support and engagement systems and processes to build the foundational capability for higher-order initiatives. Digitize and automate core manual workflows with new digital front-ends.
- 2. Focus on patient experience**  
Enable individualized patient journeys and align services, workflows, and interactions to those journeys. Refocus the digitized processes and systems to collect and analyze interaction data that enhances the understanding of patients’ experience on behavioral, clinical, and socioeconomic dimensions.
- 3. Make the engagement precise**  
Leverage the data from patient interactions for insights and evidence that inform targeted and proactive interventions and encourage adherence and behaviors that result in the desired health outcomes.

Source: *Elevate the patient experience*, Deloitte Patient Connect, 2018

**Patient advocacy groups**

As patients’ expectations and demands increase, patient advocacy groups in many disease areas are becoming organized, funding research, and having an effect on the regulatory environment.<sup>186</sup> Life sciences companies are encouraged to take the first step in forming a symbiotic partnership with patient groups. They could start by inviting patients into their research labs and facilities and giving them an opportunity to meet with scientific teams. These groups could also provide regulatory insights due to their relationships with the FDA and other regulatory bodies.

**Public-private partnerships: The changing nature of giving**

Patient advocacy groups, along with national disease organizations and venture philanthropy, fund biomedical research. Many of these nonprofits are cash-strapped. Funding sources appear to be shifting and corporate giving is undergoing a transition, threatening the future of biomedical research. Life science companies should pay close attention to these trends. The more philanthropic capital that is put toward discovering the mechanisms of diseases, the more opportunity there will likely be to develop new therapies.<sup>187</sup>

**Regulators as partners**

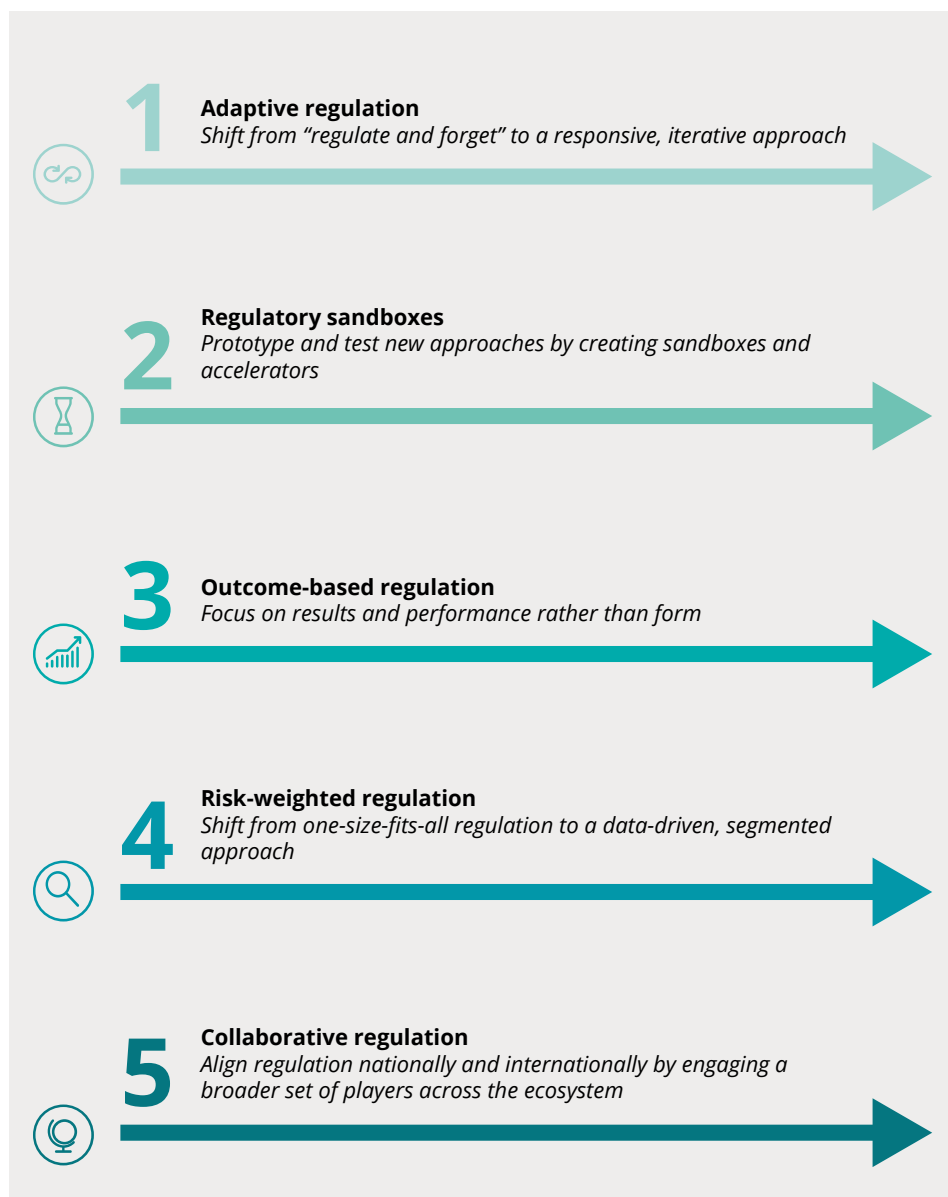
Regulators around the world appear to be benefiting from more collaborative approaches, such as coregulation, self-regulation, and international coordination. This approach protects consumers, while simultaneously encouraging innovation. In today’s new regulatory environment, regulatory relationships are seen as increasingly based on a “win-win” data-driven approach. The life sciences sector appears to now view regulatory functions as a strategic asset and are developing the skills to effectively collaborate with regulators.<sup>189</sup>

**Venture philanthropy: Dementia Discovery Fund (DDF)**

The Dementia Discovery Fund (DDF) is a public-private fund created in 2015, in collaboration with the UK’s Department of Health, the nonprofit Alzheimer’s Research UK (ARUK), and seven Big Pharma companies. Its scientific advisory board is made up of neuroscience and drug discovery experts from several of its partners, as well as independent advisers. By applying the venture capital model, DDF appears to be looking to disrupt dementia research.<sup>188</sup>

The future is expected to be trust partnerships formed between the sector and regulators that optimize the use of new technology and ensure more effective compliance. We expect to see regulators coordinating nationally and internationally to handle products and devices for a broader set of players in the ecosystem—including nontraditional players that have entered the life sciences market.<sup>190</sup>

Figure 8. Future of regulation



Source: *A bold future for life sciences regulation Predictions 2025*, Deloitte Centre for Health Solutions, 2018

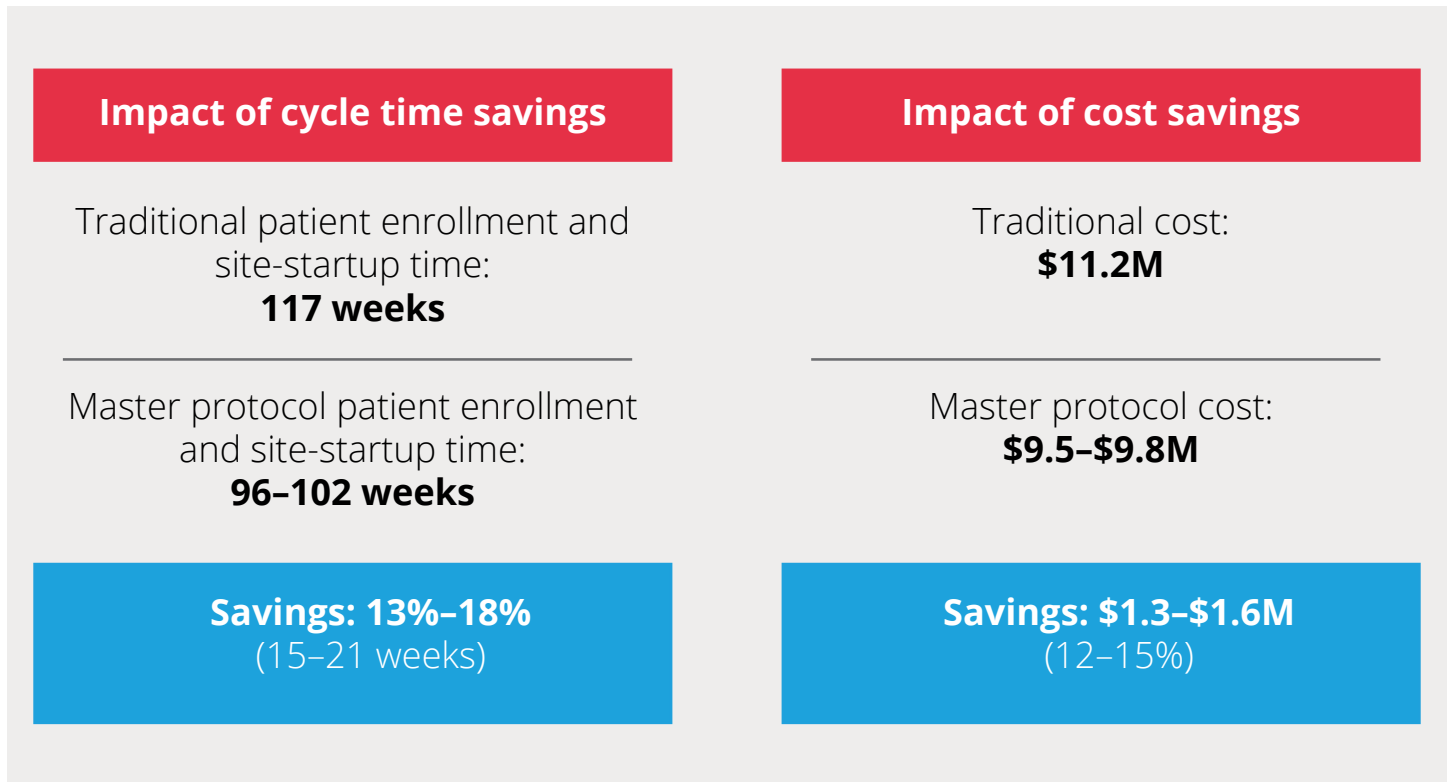
## A collaborative approach to drug development

### Master protocols

Master protocols are a collaborative approach to drug development that can be instrumental in helping biopharma companies de-risk research programs, improve the quality of evidence, and enhance R&D productivity. They are adaptive and collaborative clinical studies that allow for the simultaneous evaluation of multiple treatments for individuals with specific diseases or subtypes within the same trial structure. Typically suited to complex and rare diseases, master protocols could provide access to the latest and best thinking.<sup>191</sup>

Through master protocols, biopharma companies have the flexibility to plug into existing well-established infrastructure and patient cohorts. Combinations or competing drugs can be tested, and investigators can test hypotheses quickly and fail fast. The different stakeholders involved in collaborative trials share the costs related to these trials.<sup>192</sup>

Figure 9. Possible cost and cycle time savings from participating in a phase 2 oncology master protocol



Source: Master protocols – Shifting the drug development paradigm, Deloitte Center for Health Solutions, 2018

Many biopharma companies are just beginning to explore these models. Some are hesitant about working in a new, collaborative environment with a nontraditional regulatory pathway. However, regulatory agencies appear to be supporting master protocols. Companies considering master protocols in 2019 should consider early dialogue with regulatory agencies to discuss how best to support study objectives. Collaborating could not only result in cost savings, but advance promising personalized therapies to market.<sup>193</sup>

**Medical Affairs collaborating with R&D**

Medical Affairs generally does not have a seat at the table for decisions made by R&D teams when it comes to design of clinical trials. This could be a missed opportunity to bring market insights and to appropriately address the concerns of patients. Medical Affairs should be in constant collaboration with R&D, commercial, and other external units that might benefit from their insight into patients, health care providers, and clinical practice.<sup>194</sup>

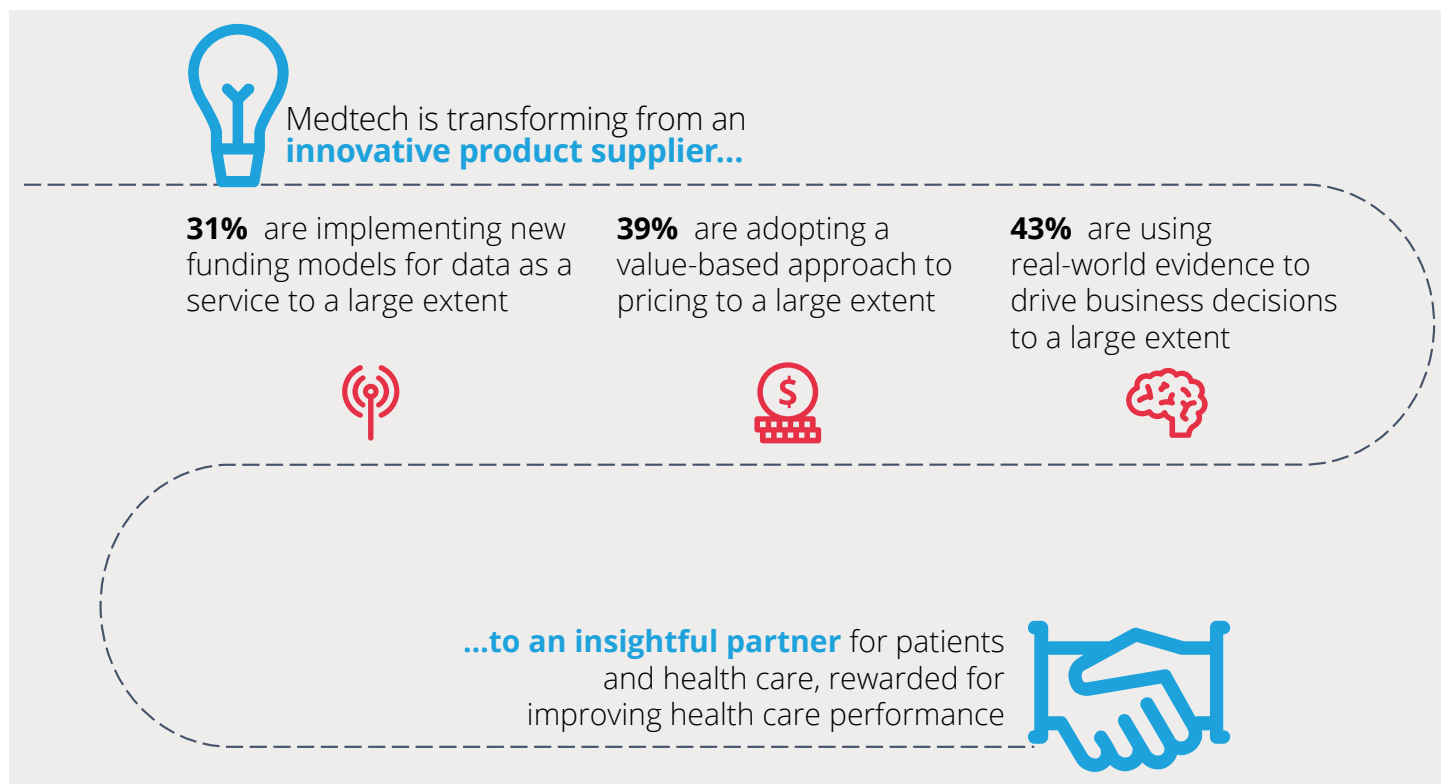
The new Clinical Trial Portal and Database, which will be enforced by the upcoming mandated EU Clinical Trial Regulation, will require industry to no longer operate in a siloed manner across divisions and affiliates,

if they are to respond to the further restricted timelines. Failure to be prepared for this regulation may otherwise result in applications for studies being withdrawn and a costly resubmission required.<sup>195</sup>

**Medtech partnerships in the IoMT**

Integrating connected medical devices into existing care pathways likely requires significant collaboration across the IoMT ecosystem. Partnerships and joint ventures could facilitate the effective transmission, aggregation, analysis, and management of data. Collaborations could allow all stakeholders to elevate their understanding of patient needs and deliver proactive, more cost-effective care.<sup>196</sup>

**Figure 10. Connected medical devices helping medtech companies move from innovative product suppliers to insightful partners in health care**



Source: *Medtech and the Internet of Medical Things*, Deloitte Centre for Health Solutions, 2018

### Medical device cybersecurity

Collaboration between providers, manufacturers, and suppliers is seen as key to bridging gaps in medical device cybersecurity. The risk of cyberattacks on devices, such as wireless implantable devices, is likely to increase alongside device complexity and prevalence.<sup>197</sup> Connected device cybersecurity starts in the early stages of new device development and should extend throughout the product's entire life cycle.<sup>198</sup>

Larger companies report they are better prepared to deal with the challenges of maintaining device cybersecurity than smaller companies. However, in the IoMT, large and small companies will need to work together to minimize risks in the ecosystem.<sup>199</sup> In 2019, leading organizations should be taking a more forensic approach to discerning the timeline and size of cyber incidents so that the impact to intellectual property, client data, and other areas can be addressed more quickly.<sup>200</sup>

# Transform

## Transformative technologies in life sciences

Leading technologies advancing digital transformation in life sciences include: AI, robotic automation, the IoMT, SaMD, blockchain, DIY diagnostics, virtual care, mobility in drug delivery and clinical trials, genomics, next-generation therapies, cloud computing, Real-World Evidence (RWE), and data-driven precision medicine. Some are discussed below, and others are featured throughout the outlook.

## AI at the intersection of the physical, digital, and biological worlds

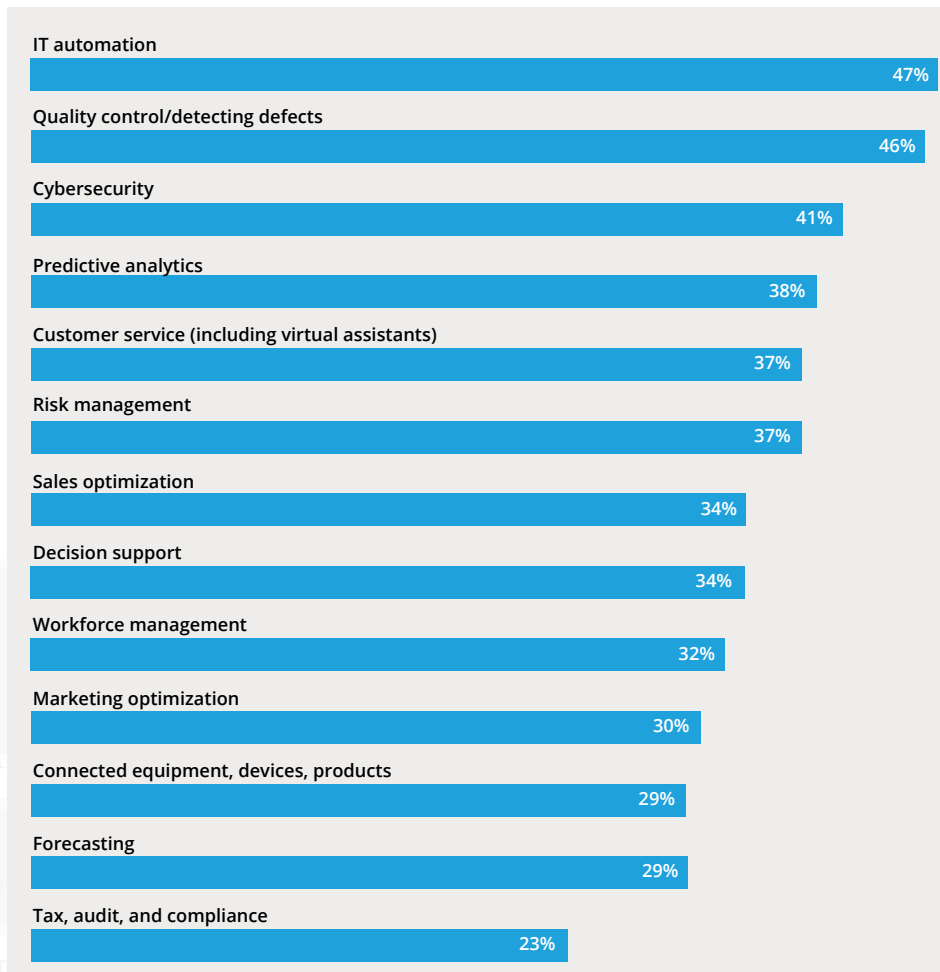
The physical, digital, and biological worlds converge in Industry 4.0. Forward-thinking organizations are starting to select the business-use cases that could deliver measurable value through AI-powered capabilities. However, the excitement of AI's potential must be balanced with the ability to execute. "Out of the box" solutions with the ability to access immense data sets could be used by employees with

no specialized knowledge. In a survey by Deloitte, more respondents said that they gained cognitive capabilities through enterprise software, such as CRM or ERP systems. For transformative efforts that will leverage the best of artificial and human intelligence, the focus will likely go beyond automation and cost-cutting.<sup>201</sup>

AI has the potential to revolutionize diagnoses, treatment planning, patient monitoring, and drug discovery. In life sciences, AI is just beginning to be applied to structured and unstructured data, so that it can be collected and used intelligently. Public data sets, such as PubMed, Clinicaltrials.gov, and US patent office filing data, are being mined and curated by many AI companies.<sup>202</sup>

One area of AI, building unified machine learning (ML) models, could predict the future behavior of compounds and their performance in randomized clinical trials.<sup>203</sup> The validation of predictions using AI will likely require shorter, less-expensive trials as the number of patients required for a trial may be significantly reduced.<sup>204</sup> Another area—deep learning—is predicted to grow at a CAGR of 42 percent from 2017 to 2024.<sup>205</sup> Using deep learning, scientists could make new discoveries and turn them into personalized medicine technologies.<sup>206</sup> However, there is currently a shortage of deep learning experts, especially those with expert knowledge in biomedical sciences.<sup>207</sup>

Figure 11. AI's Top 3 use cases in the enterprise



Source: Deloitte State of AI in the Enterprise, 2nd Edition, 2018



## Israel's AI ecosystem: CytoReason, MeMed

Israel's AI ecosystem is undergoing explosive growth with a cluster of almost 1,000 startups utilizing and developing AI technologies. Rich in AI talent, the country has approximately 4,000 developers, engineers, and data scientists working on AI research, development, and integration.<sup>208</sup>

**Leveraging public gene expression data with ML.** Israeli startup CytoReason uses its machine-learning model of the immune system to discover complex patterns in biological data. Much of disease research is rooted in mouse models, and a new drug typically needs to demonstrate some level of safety and efficacy on mice. But cross-species differences can be a major stumbling block to translating lab-based research into something meaningful for patients and clinicians. CytoReason developed a Found in Translation (FIT) machine-learning model for mouse-to-human inference that leverages public gene expression data.<sup>209</sup>

By applying FIT to data from mouse models of 28 different human diseases, CytoReason was able to identify experimental conditions where FIT predictions outperformed direct cross-species extrapolation from mouse results. The result increased the overlap of differentially expressed genes by 20–50 percent. FIT could help researchers predict novel disease-associated genes and identify signals that otherwise might be missed, reducing false leads in the shift from preclinical to clinical stages.<sup>210</sup>

**Facilitating diagnoses of disease with ML.** Another Israeli startup, MeMed BV, uses ML to differentiate bacterial infections from viral ones.<sup>211</sup> A diagnostic tool that can distinguish between the two would help physicians make better-informed antibiotic treatment decisions at the point of care. The company's assay was recently validated by a double-blind study of 361 patients in a pediatric emergency department and was able to distinguish between bacterial and viral patients with 93.8 percent sensitivity (95 percent confidence interval: 87.8–99.8 percent) and 89.8 percent specificity (85.6–94.0 percent), significantly more accurate than C-reactive protein (CRP).<sup>212</sup> MeMed Key measures a variety of proteins and signatures in a matter of minutes to help diagnose different diseases. A second-generation device is in development, so it can be used in clinics or by general practitioners without requiring access to a lab.<sup>213</sup>

### Internet of Medical Things (IoMT)

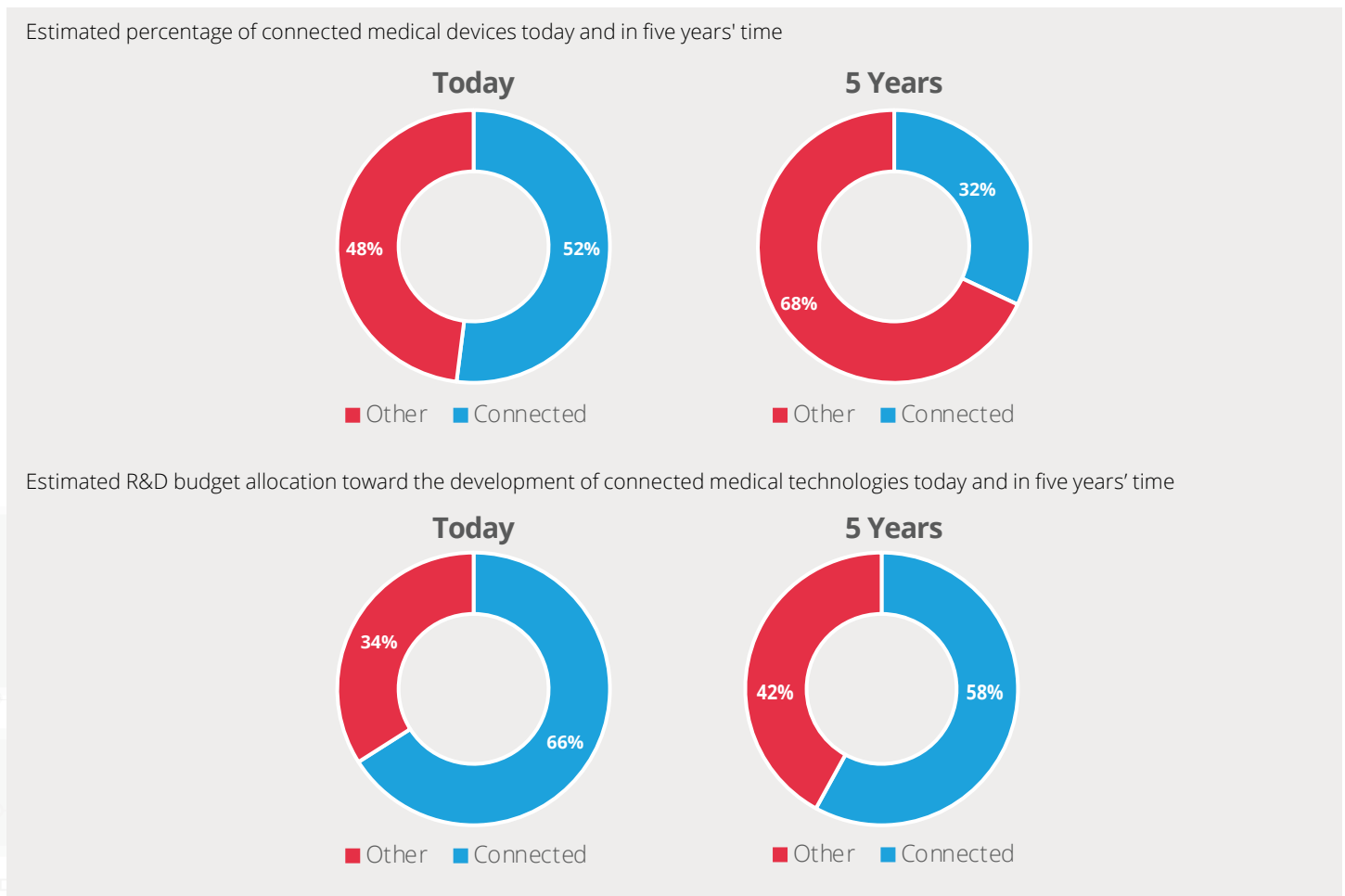
The rising number of connected medical devices together with advances in the systems and software that support medical grade data and connectivity have created the IoMT. Valued at US\$41.2 billion in 2017, the IoMT market is expected to rise to US\$158.1 billion in 2022. The connected medical devices segment (helping to diagnose, monitor, and treat patients) of the IoMT is expected to rise from \$14.9 billion in 2017 to US\$52.2 billion by 2022.<sup>214</sup>

Advanced sensor technology is making the creation of data much easier. Wearable and connected implantable medical devices and remote health monitoring devices allow vital data to be transmitted from a patient's home directly to hospitals and clinicians. In the future, orthopedics could be disrupted by smart joint replacements and spine devices embedded with sensors measuring, for example, temperature, motion, and bacteria levels. Utilizing these types of devices could detect and proactively

treat problems, with the potential for considerable cost savings and operational efficiencies.<sup>215</sup>

The IoMT could allow new business models to emerge and enhance customer experiences.<sup>216</sup> In research by Deloitte, 51 percent of medtech companies report they are implementing new business models in the development of connected devices.<sup>217</sup>

**Figure 12. Connected medical devices manufacturers anticipate increase in percentage of devices produced and increase in R&D budgets**



Source: Medtech and the Internet of Medical Things, Deloitte Centre for Health Solutions, July 2018

Software is changing how clinicians practice medicine, how consumers manage their own health, and how patients and providers interact.

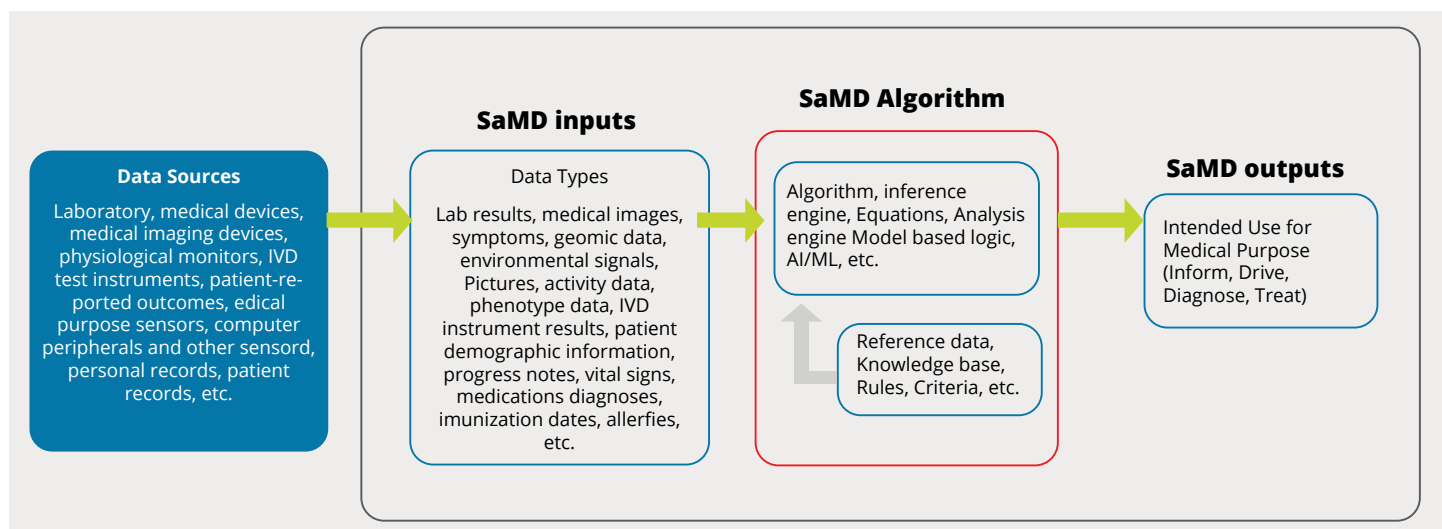
**Software-as-a-Medical-Device (SaMD)**

Software is transforming virtually every industry, including life sciences and health care. SaMD also allows patients to play a more active role in their own health care. While the software may be embedded in a piece of hardware (as is often the case), it is the software that performs one or more medical functions.<sup>218</sup> When powered by AI-enabled algorithms, SaMD has, at times, outperformed the accuracy of diagnoses by trained clinicians. Google's DeepMind

algorithm that can analyze 3-D retinal scans may soon be able to detect early signs of eye disease six months ahead of clinicians.<sup>219</sup>

As SaMD technology becomes cheaper, more accessible, and more sophisticated, it can play a transformative role in health care delivery, personalized medicine, and medical research. To realize its full potential and keep pace with technology's rapid evolution, regulation of these products is expected to need to become more agile.<sup>220</sup>

**Figure 13. FDA's description of SaMD components including data sources**



Source: US Food and Drug Administration, "Developing a Software Pre-Certification Program: A Working Model"

**Blockchain**

Blockchain is a potential solution to more easily aggregate health data in a secure, trusted, automated, and error-free way. Smart-contracts between patient and health care stakeholders can be an important enabler for clinical research. Patients may be able to more easily share their data with physicians and researchers of their choosing. With blockchain, the patient may gain greater control of their health and well-

being, while companies could benefit with better privacy controls and data security.<sup>221</sup>

In 2019, companies should collaborate with different stakeholders on blockchain pilots and look to standardize technology, talent, and platforms. Collaboration allows organizations to share the costs of experimentation and model the multi-party commitments that a later, full-scale blockchain implementation will involve.<sup>222</sup>

## Blockchain: Pfizer, IBM's Crypto-anchors

**Bringing companies, regulators, and patients together for blockchain innovation.** More than 50 individuals across 20 companies, regulators, and patients took part in a blockchain workshop at Pfizer's Research Center in Cambridge to understand issues inherent to patient data donation and to ideate blockchain applications. They found that giving patients a place to store and share information through the trusted blockchain network could empower patients to seek out clinical research opportunities or even develop their own networks of support groups to help one another with similar diseases.

**Ensuring a product's authenticity with blockchain.** In some countries, almost 70 percent of some life-saving pharmaceuticals are counterfeit. Fraudsters may falsify labels and expiration dates on diagnostic tests for diseases like HIV, malaria, dengue fever, or Ebola. Crypto-anchors is a new security technology in development that could be attached to medical devices, tests, and pills and scanned via a smartphone. A security code is used to conduct a biochemical test using microfluidics and authenticate a device using blockchain technology. In the next five years, cryptographic anchors may provide faster diagnoses in the field for clinicians, less expensively.<sup>223</sup>

### DIY diagnostics and virtual care

Consumers are increasingly open to new channels of care—particularly at-home diagnostic testing, according to a Deloitte survey of health care consumers.<sup>224</sup>

Increasingly sophisticated tools may have the potential to improve health outcomes through faster diagnoses, 24/7 access to health coaching, and recognizing mood and lifestyle changes that could affect adherence to a treatment plan. Moreover, DIY diagnostics could help low-income or rural consumers determine if a condition warrants a visit to a doctor or hospital.<sup>225</sup>

### Future of mobility in drug delivery and clinical trials

The emergence of connected, electric, and autonomous vehicles are shifting attitudes toward mobility and changing the way

people and goods move, affecting many industries including life sciences and health care. As cheaper, faster, and more flexible distribution channels increase, health care systems could deliver clinical supplies more efficiently and at lower costs.<sup>226</sup> The future of mobility may soon affect last-mile deliveries for pharmacy products. Robot delivery services or drones are poised to provide same-day delivery to consumers.<sup>227</sup>

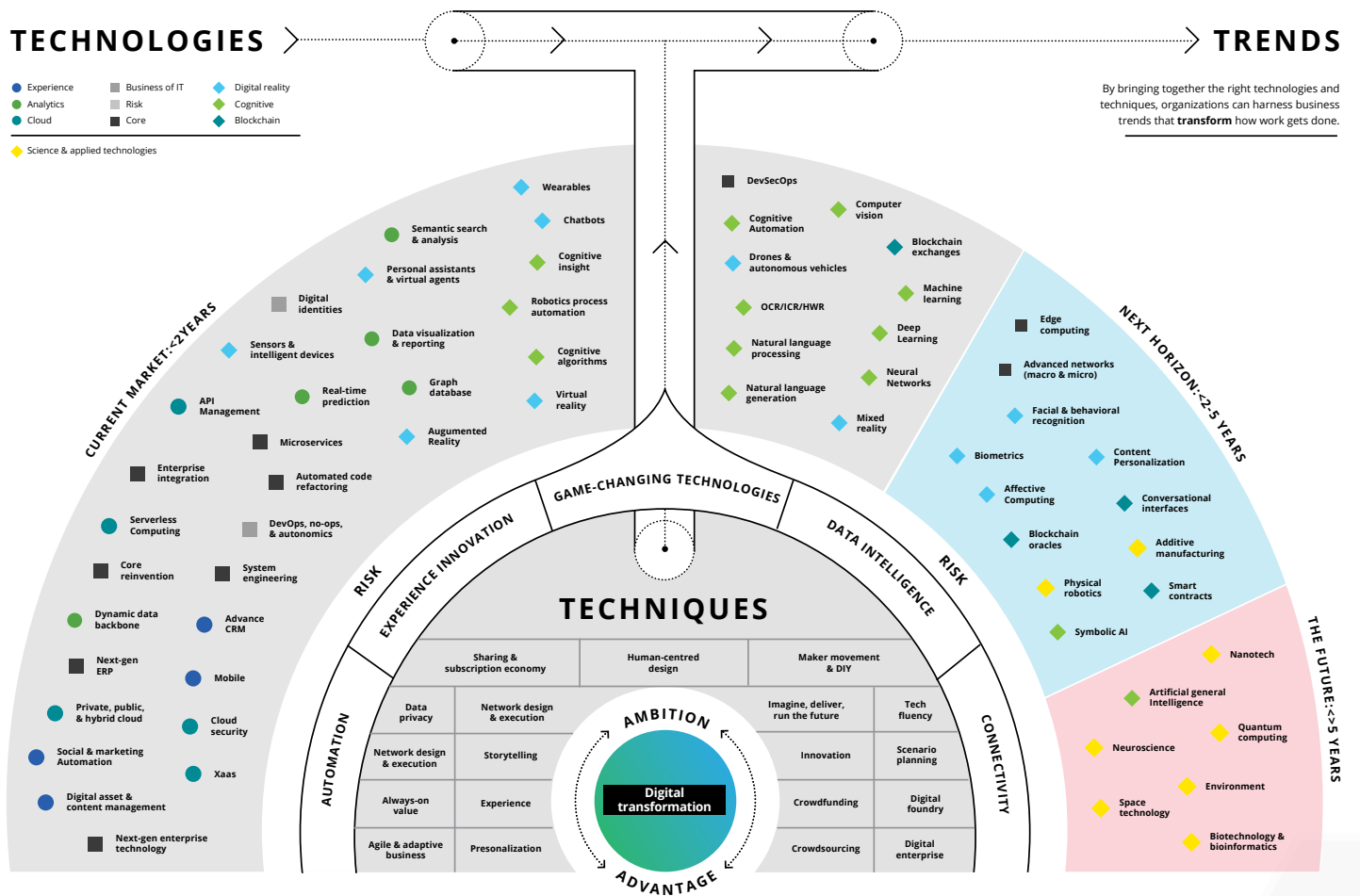
Expanded patient mobility could improve access to care. With ridesharing and carsharing becoming more prevalent, vulnerable populations, such as the elderly, disabled, or those without cars, could experience greater access to health care.<sup>228</sup> Clinical trial locations could become agnostic. Many patients quit trials or never sign up at all because of the associated travel and time commitments. "Site-less"

or cyber trials could make it much easier for patients to participate with remote monitoring technologies, such as heart rate sensors, blood pressure devices, and electronic diaries.<sup>229</sup>

### Convergence of technologies, trends, and techniques in the digital transformation

Exploring individual technologies is no longer enough. Life sciences organizations should look at how disruptive technologies could work together symbiotically to drive meaningful transformation.

Figure 14. Digital transformation network for tech trends 2019



Source: Tech Trends 2019 – Beyond the Digital Frontier, Dbriefs webinar, 2018



### Mobilizing data, the currency of life sciences innovation

Effectively using data intelligence can help organizations uncover breakthrough business insights and develop products, services, and experiences tailored to customer needs.<sup>230</sup>

#### Using new data sources for value-based care

Digital could help life sciences deliver impactful experiences to customers, the workforce, and ecosystem partners. In biopharma, emerging data sources could come from many external stakeholders including hospitals, physicians, health plans, and patients.<sup>231</sup> In clinical development, valuable insights from multiple sources of data could radically improve the patient experience. Big data analytics could enhance clinical trial productivity and increase the amount and quality of data collected in trials.<sup>232</sup>

In 2019, innovative life sciences leaders who adopt big data analytics and digital platforms should be better able to measure value and outcomes, while also moving forward in their digital transformation.<sup>233</sup>

#### Transforming clinical development with digital R&D

Digital technologies can support many of the goals of patient-centricity by making trial participation less burdensome and more engaging by redefining how patient care is delivered during clinical trials. By treating trial participants as collaborators instead of subjects in the research process, companies can gain better insights, in addition to achieving greater efficiencies and lowering costs.<sup>237</sup>

### Data platforms: Doc.ai, Science 37

**Using new data sources.** Doc.ai is an AI platform that leverages blockchain to develop insights based on personal data that users are willing to share. Doc.ai can use AI to get inferences from many data sources, including health records, wearable device data, and/or social media accounts, and could also be used for patient-reported outcome data.<sup>234</sup>

**Digital technology expediting recruitment and diversifying participants.** Using the technology platform NORA (Networked Oriented Research Assistant),<sup>235</sup> clinical research company Science 37 recruited patients for a rare-disease, phase-3 trial at its meta-site approximately 20–30 times faster than is possible through traditional recruitment methods. Using NORA's built-in e-consent module, the Science 37 team gathered medical records and screened patients from seven states in the United States and covered a more diverse study population—30–40 percent were from minority groups, compared with the typical 2–10 percent.<sup>236</sup>

Figure 15. Application of digital in clinical trial design

			Low activity	Medium activity	High activity
	1. Trial design	2. Trial startup	3. Trial conduct	4. Study closeout	
Data analytics	Assess feasibility of protocol design for patient recruitment using EHRs and claims data  Synthetic trial arms: Compare data from completed studies with data from ongoing trials		Real-time monitoring to assess site performance (enrollments, dropouts)		
Mobile applications, wearables, biosensors, connected devices		E-Consent: Simplify and speed up the informed consent process  Cloud-based applications to expedite recruitment and create a diversified study population	Collect digital endpoints on disease progression, mobility, and quality of life indicators  Smartphone alerts and text reminders to enhance adherence		
Cognitive technologies	Artificial intelligence (semantic technologies) to analyze and interpret unstructured data from previous studies and scientific literature	MINE EHRs, patient records, registries, lab data to match patients with trials	Artificial intelligence to visually confirm medicine ingestion, identify missed clinic visits, and trigger nonadherence alerts	Natural language processing to write portions of clinical study reports, for example, populating standard information in tables	
Automation		Workflow automation to draft site and investigator contracts and confidentiality agreements	Esource (electronic recording and integration of all findings, observations, or other trial activities)	Simple rule-based automation for data cleaning and validation  Machine learning for data cleaning	
Other technologies	Crowdsource investigator and patient inputs on study eligibility, dosing, and endpoints		Electronic tracking of medication kits and smart blister pills packs to track medication ingestion		

Source: Digital R&D – Transforming the future of clinical development, Deloitte Center for Health Solutions, 2018

### Novel clinical trial designs: Virtual trials

Virtual trials enable patients to participate in studies from the comfort of their homes, reducing or even eliminating the need to travel to sites. Conducting trials virtually expands the geographic reach of participants outside traditional academic medical centers and democratizes trials for patients and physicians who currently are not part of the process. According to Deloitte research, as many as half of all trials may be done virtually in the not-so-distant future, netting significant cost savings.<sup>238</sup>

In 2019, biopharma companies that are early adopters of digital technologies and platforms could benefit from:

- Better access to, and engagement with, patients,
- Deeper insights from clinical trials, and
- Faster cycle times for products in development.

However, they will likely need an integrated approach and comprehensive digital R&D strategy, requiring new capabilities, skill sets, and partnerships. Partnerships are expected to be central to the success of their digital programs.<sup>239</sup>

### Machine learning in clinical trials: Antidote

#### Machine learning helps patients find the right trial.

Antidote, through its platform, Antidote Match, extracts data from ClinicalTrials.gov. Using machine learning, along with minor human intervention, it creates structured eligibility criteria for single or multiple studies. The platform automatically generates a pre-feasibility questionnaire to translate complicated medical terms for patients. By filling in the questionnaire, patients can easily sift through hundreds of studies and determine eligibility. As of September 2017, Antidote had made it easier for patients in the United States to search close to 14,000 trials and plans to extend coverage to all US trials in 2019.<sup>240</sup>

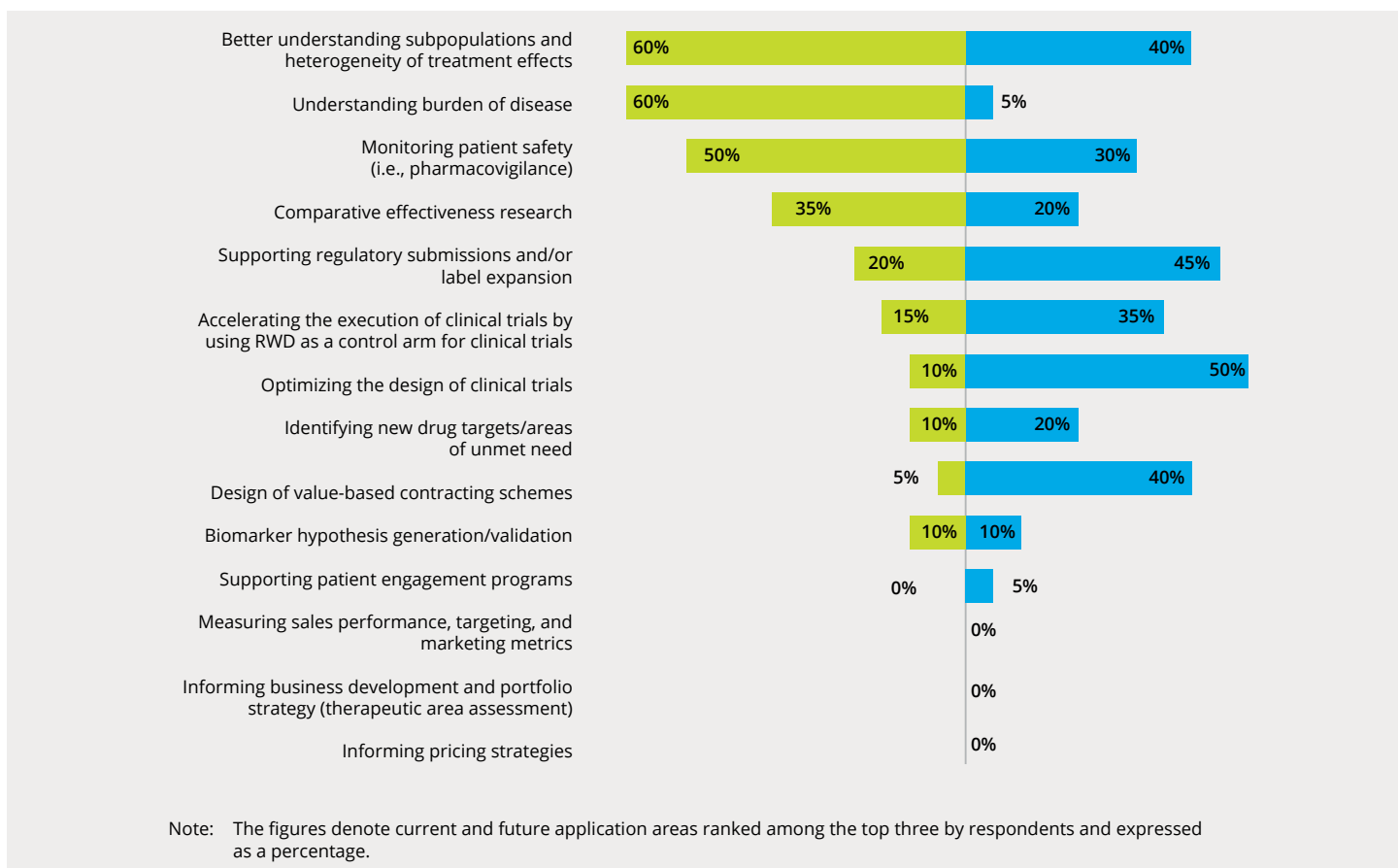
### Expansion cohorts modernizing oncology and adaptive clinical trials

In late 2018, the US FDA released draft guidance—Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics.<sup>241</sup> The guidance is meant to expedite adaptive clinical trials and allow researchers to evaluate multiple aspects of a drug in development in a single trial.

Adaptive clinical trials enable investigators to identify subgroups of patients who are responding well to a treatment and correct mid-course during the trial where needed.<sup>242</sup> The agency also released updated guidance in 2018 for Adaptive Designs for Clinical Trials of Drugs and Biologics Guidance for Industry.<sup>243</sup> The FDA also plans to waive consent for some clinical trials involving no more than minimal risk to human subjects.<sup>244</sup>



**Figure 16. Ranking the three most impactful areas of current and future RWE application**



Source: 2018 RWE Benchmarking Survey, Deloitte Center for Health Solutions, 2018

**ROI of real-world evidence (RWE)**

The data landscape is evolving rapidly. A Deloitte life sciences study finds executives are placing greater emphasis on RWE and focusing on end-to-end, AI-driven, internally developed solutions.<sup>245</sup> The future data landscape is likely to be shaped by an increase in strategic data partnerships and new ways of procuring data. AI and machine-

learning methodologies will likely be able to derive meaningful insights from real-world data (RWD).<sup>246</sup>

In 2019, biopharma companies likely need to identify potential external sources of data to fill evidence gaps. Strategic partnerships with Integrated Delivery Networks (IDNs), technology companies, or industry consortia will likely be required for access to more

comprehensive data sets and to understand the complete patient journey. Companies may benefit from establishing end-to-end evidence-management strategies supported by the right talent, platforms, partnerships, and operating model.<sup>247</sup>

## Creating value with new business and operating models

### Learning how to scale enterprise-wide solutions, creating value in novel ways

Digital transformation helps companies gain business advantages by applying innovation, design, process, and digital technology to new and existing business models. According to a study by Deloitte, digitally maturing biopharma companies are exploring new ways of doing business and applying an enterprise-wide approach to digital transformation.<sup>248</sup>

### Adopting a consumer-driven model

#### B2C thinking transforming the patient experience

Organizations that understand customer expectations and execute based on how customers like to use any product or service—for example, digital health apps, telemedicine, wearable monitoring devices, etc.—should be well positioned to formulate engagement strategies. It is also important to discover the reasons behind any resistance to engagement. Understanding how health consumers' behavior and expectations are transforming—and acting on that—will likely win the hearts and minds of consumers.<sup>249</sup>

#### Digital tools for engaging patients

Patients who are informed about their condition and involved in their treatment decisions tend to have better health outcomes and typically incur lower costs. A Deloitte consumer health survey found that a third of respondents are interested in using apps for engagement.<sup>252</sup>

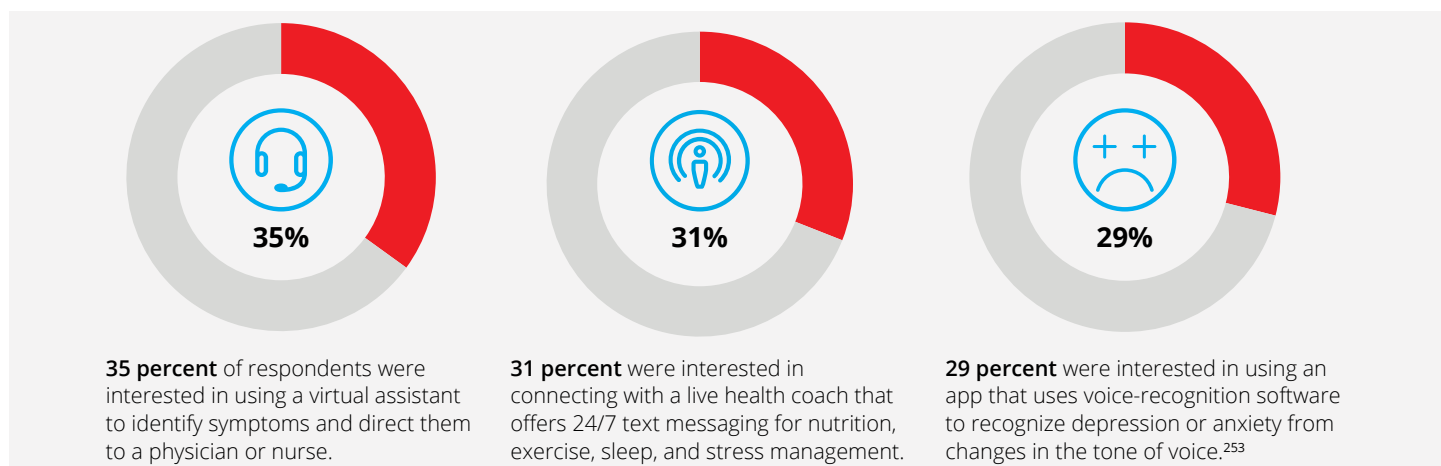
## Consumer-driven model: CareMore

**A new model of health care consumerism.** CareMore, a US\$1.4B Medicare and Medicaid delivery system, has three principles that drive its view of the consumer in health care:

- Health care should anticipate and deliver on consumers' needs proactively.
- Sick people should not have to shop for the care they need.
- Consumers should not pay out of pocket for the things that they need.<sup>250</sup>

According to CareMore, many in the health care industry assume that patients have data literacy and prioritize services, like access to online medical records or transparency of lab data. CareMore believes these services, though worthwhile, do not fundamentally change health care for the 80 percent of high-cost, high-need consumers with chronic health conditions.

The average CareMore patient is 74 years of age, and many have yet to hear about progressive modes of transportation, such as Uber or Lyft. These patients may live in total denial of their chronic condition and engaging them requires acknowledging this denial. They may want to be empowered to make choices, but most just want to know that the people caring for them have their best interest at heart.<sup>251</sup>

**Figure 17. Consumer health survey, respondents' interest in using health apps**

Source: Deloitte 2018 Health Care Consumer Survey

## App adoption: Medtronic MyCareLink Smart mobile app

Age is not a clinically significant factor in activating or adhering to app-based remote cardiac monitoring, and there is high use among older patients, according to a Medtronic study. The study evaluated 15,595 patients with Medtronic pacemakers who were assigned a MyCareLink Smart app-based remote monitor. At 12 months, 89.4 percent of patients aged 71 and older were still actively using the app to transmit data, compared to 86.7 percent of patients 18–50 and 91 percent for those 51–70. “There is often a misperception that older patients aren’t adapting to newer technologies, but this study shows that is not the case,” Khaldoun Tarakji, MD, MPH, electrophysiologist and director of clinical electrophysiology research at the Cleveland Clinic, who led the study.<sup>254</sup>

### Finding new revenue models

#### Transforming from a product sector to services sector

In today’s health care landscape, the life sciences sector will likely need to harness the shift from product to service. Companies should have a vision for their role in the patient journey and the value they provide to both the patient experience and health system. Patients appear to be demanding care and solutions that are simplified, coordinated, customized, and accessible.

New entrants are demonstrating that health consumers are willing to pay for convenience.

#### Focus on prevention and digital therapeutics

Digital therapeutics can be a new source of revenue for life sciences, potentially providing reimbursement through insurance plans in the same way as drugs or medical technologies.<sup>255</sup> Aimed at prevention of disease, digital therapeutics combine technology with behavior modification for

clinical benefits that can be as good as some medications.<sup>256</sup> Providing a measurable outcome that has an economic impact on the payer differentiates digital therapeutics from digital health tools focused solely on wellness.<sup>257</sup> Digital therapeutics may not only help improve health outcomes but can also improve quality of life.<sup>258</sup> The global digital therapeutics market is expected to grow at a CAGR of 20.8 percent from 2018 to 2025, reaching US\$8,941.1 million by 2025.<sup>259</sup>



**Data as a revenue generator in medtech**

Consumers with a chronic condition are more willing to share tracked data, with half willing to share data for emergency situations. Forty percent are willing to share their data for health care research or to improve a device. Fewer are willing to share this information with medical device manufacturers (35 percent). Medical device companies could play an important role in the future of care and should explore new revenue opportunities through data. One way could be to let consumers own their own data and develop tools for sharing and monetizing that data. As the consumer takes more control of their health and data in 2019, establishing trust should be critical.<sup>260</sup>

The Deloitte Center for Health Solutions and AdvaMed surveyed 22 medtech companies and found that new payment models are changing the innovation focus for 68 percent of companies. They are developing products, services, and software that can help providers improve outcomes, reduce cost, decrease post-treatment complications, and increase procedural efficiency.<sup>262</sup>

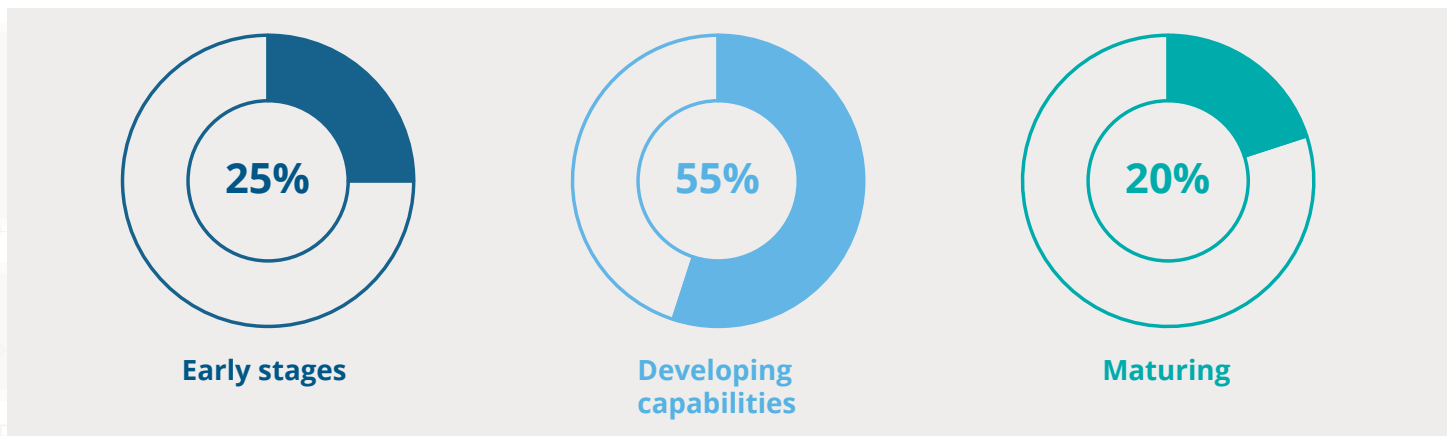
**Patient access to data: Ciitizen**  
**Giving cancer patients access to their own records.**  
 Ciitizen is a startup developing technology to make it easy for patients to access electronic versions of their labs, genetic test results, and images, which they can share with doctors, researchers, and their broader care team. Having access to their health records in one place helps cancer patients connect to relevant clinical trials and potential lifesaving therapies.<sup>261</sup>

**Advancing digital transformation in life sciences**

The majority of biopharma companies (55 percent), surveyed by Deloitte and MIT Sloan Management Review, report they are developing capabilities for digital transformation. Only 20 percent say they are digitally maturing. More than three-quarters of respondents agree that their organizations need new leaders to succeed in the digital age, and more than half say adequate funding is a challenge

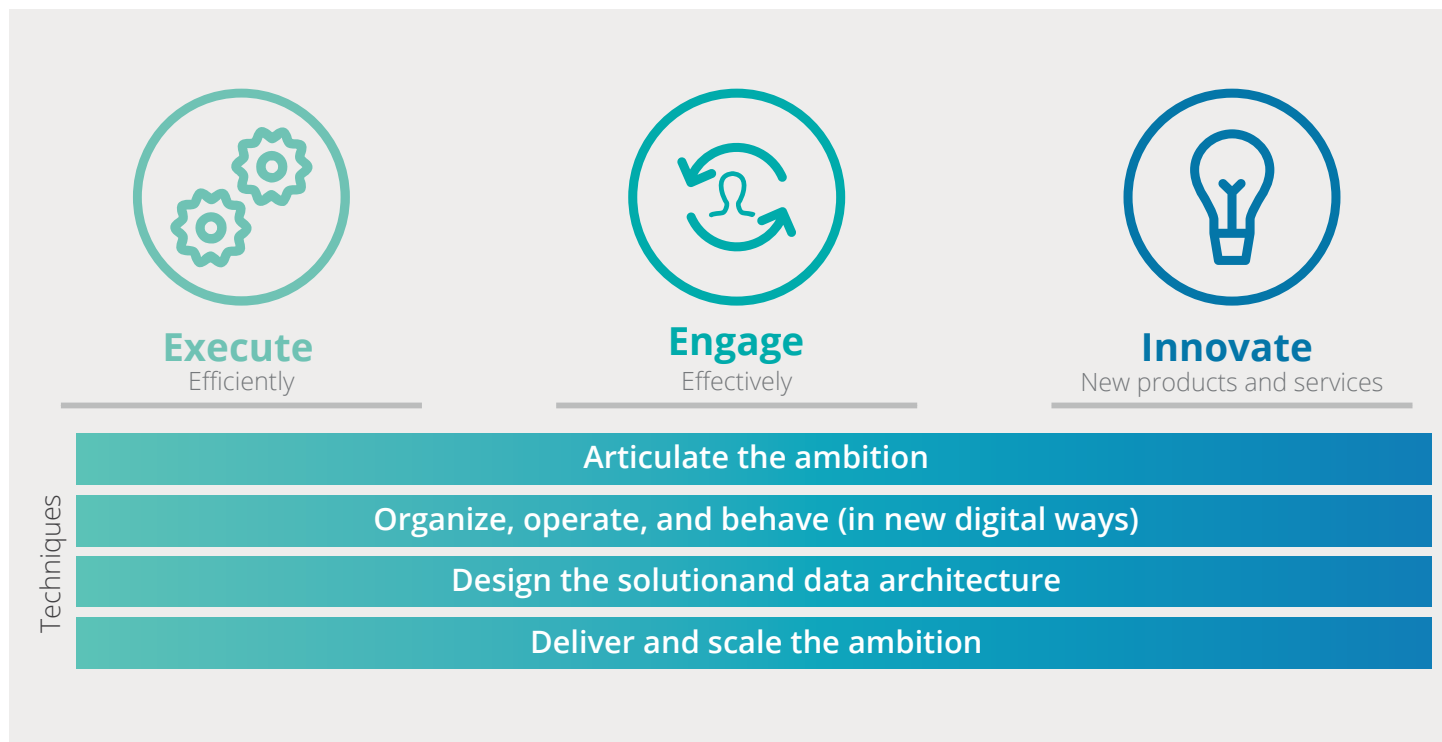
impacting digital initiatives.<sup>263</sup> To advance digital transformation in 2019, life sciences companies should start with determining and articulating their ambition. This means prioritizing initiatives, anchoring decisions, and focusing on the future. Leaders can then be poised for adapting new operating models and culture, implementing technology, and scaling solutions. Investment in digital technologies and the organizational transformation is critical not only for success but for survival.<sup>264</sup>

**Figure 18. Biopharma companies' digital maturity**



Source: Survey finds biopharma companies lag in digital transformation, Deloitte Insights, 2018

Figure 19. Digital transformation approach



Source: Survey finds biopharma companies lag in digital transformation, Deloitte Insights, 2018

### Transforming work

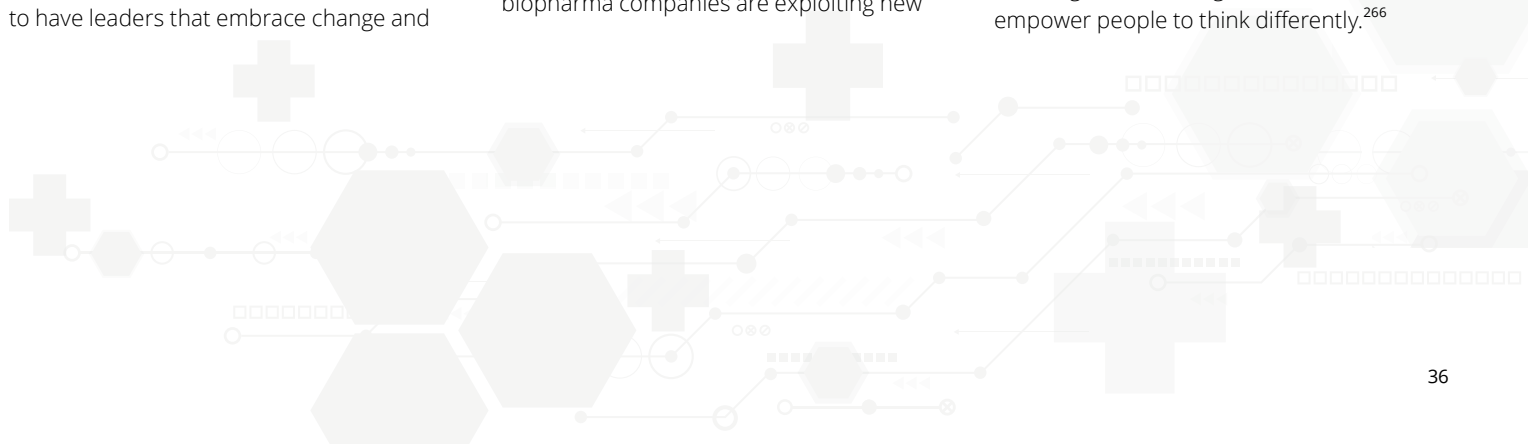
#### Leadership embracing change

The life sciences sector's commitment to digital transformation is increasing, but relatively few organizations appear to be maturing digitally. Organizations positioned for exponential growth appear to have leaders that embrace change and

employees who are willing to get on board with new initiatives. These organizations display higher digital engagement and data analytics skills, according to a new study by Deloitte and MIT Sloan Management Review.<sup>265</sup>

A greater percentage of digitally maturing biopharma companies are exploiting new

ways of doing business as opposed to exploiting organizational competencies. Collaboration is seen as a key differentiator. Leaders should not only encourage collaboration internally, across functions, but also externally. They also need to provide a clear vision and purpose for their organization's digital investments and empower people to think differently.<sup>266</sup>



**Figure 20. Top three traits biopharma employees are looking for from their leaders**



Source: Survey finds biopharma companies lag in digital transformation, Deloitte Insights, 2018

**Digital well-being**

Well-being is emerging as a strategic priority for many major organizations. Well-being benefits are particularly important to millennials, who now make up more than half of the workforce in many countries and spend almost twice as much on “self-care” as baby boomers.<sup>267</sup>

Programs addressing well-being could be both a responsibility of good corporate citizenship and a possible key element of an enterprise talent strategy. These programs now include tools for financial wellness, mental health, healthy diet and exercise, mindfulness, sleep, and stress management, as well as changes to culture and leadership behaviors to support these efforts.<sup>268</sup>

**Figure 21. What role does the C-suite play in promoting well-being? How can individuals adjust?**

<b>CHRO</b>	Well-being is a personal matter, so it needs to evolve as individuals' needs evolve. Invest in ways to take a constant pulse of employees' needs, even looking at ways to leverage predictive analytics to stay ahead of trends in the space.
<b>CIO</b>	The cornerstone of a sustainable well-being strategy is the integration of technology to promote, track, and manage well-being programs. Avoid offering a multitude of disparate apps that may provide bells and whistles, but defeat the purpose of an integrated platform that can increase the value of well-being investments.
<b>CFO</b>	The link between well-being and productivity is clear. Work with others on the executive team to quantify the financial costs and benefits of continued investment in well-being programs that can improve the bottom line.
<b>Chief risk officer</b>	Consider ways to manage the increased focus on personal data and the associated risks. With more technology and applications in use around well-being today, getting involved early can help to put the appropriate controls in place to guide against future adverse impacts.
<b>Chief marketing officer</b>	Position well-being programs as critical components of your employer brand and rewards strategy, and as integral to your organization's performance and productivity strategy.
<b>Individuals</b>	Look for and take advantage of well-being programs available through your employer, and consider these programs when making employment decisions—to join, stay, or leave.

Source: Well-being: A strategy and a responsibility, Deloitte Insights, 2018

### Attracting digital and data-savvy talent

Some Chief Digital Officers (CDOs) are being recruited from the retail and fashion industries to life sciences with the expectation that they could provide fresh perspectives to some conservative and risk-averse companies. Incumbent sector players are competing for the same talent as technology companies.<sup>269</sup> Strategies to attract this expertise could include:

- Looking for digital-first skills, including advanced data analytics and machine learning
- Looking for data science backgrounds, including data mining and data visualization skills
- Looking outside traditional recruiting grounds and collaborating with outside groups (e.g., scanning academic papers and industry conferences in fields such as cognitive science, behavioral economics, and mathematics)
- Creating a digital culture—investing in a digitally savvy presence and office space<sup>270</sup>

Collaborations and partnerships with companies outside of life sciences could offer access to digital and data skill sets likely required for innovation. In medtech, technology companies could provide the technical capabilities required to improve device efficiency, data management, and insight generation.<sup>271</sup>

### Reskilling and putting humans in the loop

To maximize the potential value of advanced and automated technologies today and minimize the potential adverse impacts

on the workforce tomorrow, organizations should put humans in the loop—reconstructing work, retraining people, and rearranging the organization.<sup>272</sup> Open learning platforms for acquiring AI expertise are offered by Alphabet for TensorFlow,<sup>273</sup> and Amazon has its own Machine Learning University open to developers.<sup>274</sup>

While robotic cognitive automation can help execute repetitive tasks more efficiently, humans can focus on high-level tasks. Fifty-five percent of medtech companies surveyed by Deloitte plan to develop automated protocols to accelerate clinical trials in the future.<sup>275</sup> The greatest opportunity is not just to redesign jobs or automate routine work, but to fundamentally rethink “work architecture” to benefit organizations, teams, and individuals.<sup>276</sup>

### Increasing computational space

New lab designs at life sciences research facilities show space utilization is now evenly split between 50 percent computational space and 50 percent lab space. This represents a doubling of computational space over traditional designs in the last few years.<sup>277</sup>

### Incubator labs and innovation clusters

Real estate is becoming a key component for collaborative R&D environments.<sup>278</sup> In order to engage with startups and gain access to new talent, life sciences, biotech, and medtech companies are creating incubator spaces in innovation clusters around the globe.<sup>279</sup> Incubators are specifically designed to support early-stage companies that need

facilities, mentoring, and networking to progress.<sup>280</sup>

Many of the top pharmaceutical companies have established a presence in the top three clusters in the US for life sciences—the Greater Boston/Cambridge area, San Francisco Bay area, and San Diego metro area. According to MassBio, the life sciences sector in Massachusetts has grown to more than 70,000 employees and is expected to add another 12,000 jobs by mid-2023. However, it takes more than two months to fill a job opening.<sup>281</sup> Smaller, second-tier markets may still support life sciences companies and provide access to world-class research facilities, without the hassles of major markets.

Digital health startups enjoyed one of the most lucrative quarters of funding since 2010 in Q3 2018, according to StartUp Health, raising US\$4.5 billion. Total investment through 2018 hit a record \$US14.6 billion.<sup>283</sup> Innovation hubs supporting these startups are burgeoning throughout the world. Beijing was responsible for five of the top 10 international deals worth US\$863 million, and the Chinese cities of Zhenjiang, Shanghai, and Hangzhou also raised over US\$100 million each.<sup>284</sup> Leading international metro hubs through Q3 2018 include: Beijing (16 deals), London (16 deals), Stockholm (15 deals), Bengaluru (13 deals), Toronto (10 deals), and Tel Aviv (9 deals).



# Questions/actions leaders should consider for 2019



## 1. What will sustain you in times of consistent change?

- Unshackle yourself from the old life sciences mentality, business, and technology architectures. Don't hesitate to innovate in all three.
- Continue to invest in talent and recruit from other industries. The combination of new thinking and best practices from outside the traditional life sciences industry coupled with industry expertise can be transformative.
- Don't lose sight of regulatory and quality needs. Regulators are not averse to early engagement and actually welcome it.
- Form deep, concentrated, and true partnerships with your ecosystem stakeholders. Work toward improving the process and reducing cycle times.
- Innovate toward reducing the cost of the end-to-end product supply. Get economies of scale by partnering with other organizations and even other competitors. Form utilities, consolidate volume, and make investments in fledgling technologies.

## 2. What strategy can you commit to, for the long term?

Be committed to the strategy you choose and pursue it passionately. The seeds that you plant and nurture today will create your ecosystem, which should be rich and networked.

## 3. Based on your strategy, what is available in-house vs. what you need to get externally?

From an innovation, science, and culture standpoint, determine the capabilities, assets, and people you need. Whatever gaps need to be filled organically can be accomplished by ongoing talent development and M&A. If you're looking for a partner to bring in expertise, ongoing commitment, innovation, or culture, chemistry will be extremely important. Make sure you align your mind-set with your goals.

## 4. How will you handle your extended enterprise risk?

To regulators, your company is the sum total of all the individual agents and vendors you use. Don't be afraid to move your innovation forward, even if it has never been done before, but do so in the context of evolving regulatory models. Have an innovation-friendly framework for considering and dealing with the risk and regulatory considerations.

## 5. Are the right governance and partnership models in place to cultivate relationships with nontraditional partners?

Successful collaborations with companies outside of life sciences may require new ways of working. Specifically, you may want to consider centralizing relationships through teams focused on digital innovation. These teams tend to have the resources to invest in long-term strategies and are not constrained by meeting the business units' short-term goals. These teams should also consider intellectual property protection, revenue-sharing models, and management of parallel product development processes. An increasing network of collaborations may require companies to establish new governance models.<sup>285</sup>

## 6. How will you demonstrate value?

Think outside in and design value chains from the patient and provider backwards. Look at creating coherent and meaningful experiences through the entire chain of patient interactions and unmet needs—from R&D to commercialization and product launch phases.

In the coming year, life sciences companies should focus on value-based pricing and reimbursement approaches that incorporate outcomes data and de-risk health care budgets. As the ability to collect and analyze health care data improves, it should become easier to implement solutions.

## 7. What is your new market access and pricing strategy? Is your pricing strategy affecting products coming to the market or existing products?

Start thinking about market access, pricing, and reimbursement strategy in preclinical. For new products, figure out what assets you want to bring to market or buy, and evaluate them on:

- Market access,
- The ability to have market access, and
- Costs associated with access.

Be more methodical in how you deploy rebate dollars, coupon dollars, and field force dollars by patient, Master Service Agreement (MSA), and cluster. Some companies are moving their list price down to a net price to get ahead of the likely loss of rebates.

## 8. What steps can you take to transform customer interactions into an “obsession for customer experience”?

Extraordinary customer service meets or exceeds a customer’s, or patient’s, expressed and unexpressed needs.<sup>286</sup> Excel beyond engagement and create scenarios that anticipate actions that can be taken proactively to promote health and wellness, even before a customer or patient knows what they need. It’s fundamentally about a deep understanding of the customer or patient experience for life sciences or medtech companies.

## 9. What actions can you take that will benefit patients in the IoMT?

- Examine the level of connectivity of devices in your ecosystem and develop a business intelligence strategy, including determining what data to collect
- Pursue data integration and build interoperability into all connected medical products
- Ensure products are built on widely accepted, open standards (e.g., FHIR) and can accept or utilize APIs
- Be generous in sharing data<sup>287</sup>



# Appendix

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

[www.deloitte.com/us/healthsolutions](http://www.deloitte.com/us/healthsolutions)

[www.deloitte.co.uk/centreforhealthsolutions](http://www.deloitte.co.uk/centreforhealthsolutions)

[www.deloitte.com/lifesciences](http://www.deloitte.com/lifesciences)

## 2018 global life sciences outlook

Innovating life sciences in the fourth industrial revolution. The 2018 outlook reviews the current state of the global life sciences economy and explores the trends impacting life sciences companies as they Embrace, Build, and Grow.

## The board's role in shaping digital transformation

From blockchain to artificial intelligence (AI), no organization can afford to fall behind the latest technological innovations that are redefining how organizations connect with their customers, employees, vendors, investors, and other stakeholders.

## Survey finds biopharma companies lag in digital transformation

The life sciences industry's commitment to digital transformation is increasing, but few organizations are digitally maturing. A review of the life sciences respondents of Deloitte and MIT Sloan Management Review's fourth annual study on digital maturity shows that digitally maturing life sciences companies are changing their leadership and culture to adapt to and succeed in a rapidly changing market.

## Return on pharmaceutical innovation 2018

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

## Medtech and the Internet of Medical Things: How connected medical devices are transforming health care

With the Internet of Medical Things (IoMT) market estimated to be worth \$158.1 billion in 2022, medtech companies need to get the IoMT right from a business perspective and deliver more value to health care.

## Reimagining digital health regulation: An agile model for regulating software in health care

Over the last decade, software has begun to permeate and transform virtually every industry—and health care is no exception.

## China's economy cools as US trade tension heats up

There are signs that the Chinese economy may be decelerating. The government reports on a sharp slowdown in retail sales and fixed asset investment, come at a time when credit expansion is also decelerating.

## Software as a medical device: An agile model for Food and Drug Administration (FDA)-regulated software in health care

Over the last decade, software has begun to permeate and transform virtually every industry—and health care is no exception.

## Focusing on the climb ahead: Third-party governance and risk management

Extended enterprise risk management global survey 2018. Survey responses reflect the views of senior leaders from a variety of organizations in 15 countries. A record number of participants (almost 1,000) in 2018 is reflective of the ever-increasing profile and investment third-party risk management is getting within organizations.

## PatientConnect, elevate the patient experience

Life sciences organizations need to create coherent and meaningful experiences

through the entire chain of patient interactions, from R&D to product launch and commercialization phases.

## Traditional outsourcing is dead. Long live disruptive outsourcing

Deloitte Global Outsourcing Survey 2018. Our 2018 survey of more than 500 executives from leading organizations indicates that disruptive outsourcing solutions—led by cloud and automation—are fundamentally transforming traditional outsourcing.

## A bold future for life sciences regulation: Predictions 2025

Life sciences operates in an increasingly complex regulatory landscape. Over the past few years, the industry has seen a proliferation of regulatory changes, with a plethora of new regulations due to come into force over the next few years. Regulators face the challenge of continuing to protect patients, while fostering innovation.

## Master protocols: Shifting the drug development paradigm

Master protocols, a collaborative approach to drug development, could help biopharma companies de-risk research programs, improve the quality of evidence, and enhance R&D productivity by cutting down research cost and time.

## Digital R&D: Transforming the future of clinical development

Biopharma R&D has changed the face of disease management. Yet many in the field admit that clinical development has fallen behind in adopting digital technologies. While digital transformation is a complex, resource-intensive, and lengthy undertaking, the rewards are well worth the effort.

### **Blockchain opportunities for patient data donation & clinical research**

Life sciences and health care have the potential to be a new frontier for blockchain technology as a novel solution for securely storing and sharing medical information. A diverse group of stakeholders—including companies, regulators, and patients—came together in November 2017 to ideate blockchain solutions.

### **Inside the patient journey: Three key touchpoints for consumer engagement strategies**

Deloitte 2018 Health Care Consumer Survey. Improving engagement at three key touchpoints in a consumer's health care journey could help health care stakeholders improve patient outcomes and reduce the cost of care.

### **The future of real-world evidence, biopharma companies focus on end-to-end, AI-driven, internally developed solutions**

Biopharma executives are placing greater emphasis on real-world evidence (RWE), a Deloitte life sciences survey finds. Leaders increasingly must show value for access, understand the patient journey, and provide more data. The survey shows how RWE plays a role.

### **Introduction: The rise of the social enterprise, 2018 Global Human Capital Trends**

Organizations are no longer judged only for their financial performance, or even the quality of their products or services. Rather, they are being evaluated on the basis of their impact on society at

large—transforming them from business enterprises into social enterprises.

### **EU Clinical Trial Regulation: Building a successful program, Deloitte UK, 2018**

The new Clinical Trial Regulation has brought certain key changes to the clinical trial application process in the EU.

### **Tech Trends 2019: Beyond the digital frontier**

Deloitte's 10th annual Tech Trends report identifies trends that are likely to disrupt businesses in the next 18–24 months, including advanced networking, intelligent interfaces, serverless computing, and more.



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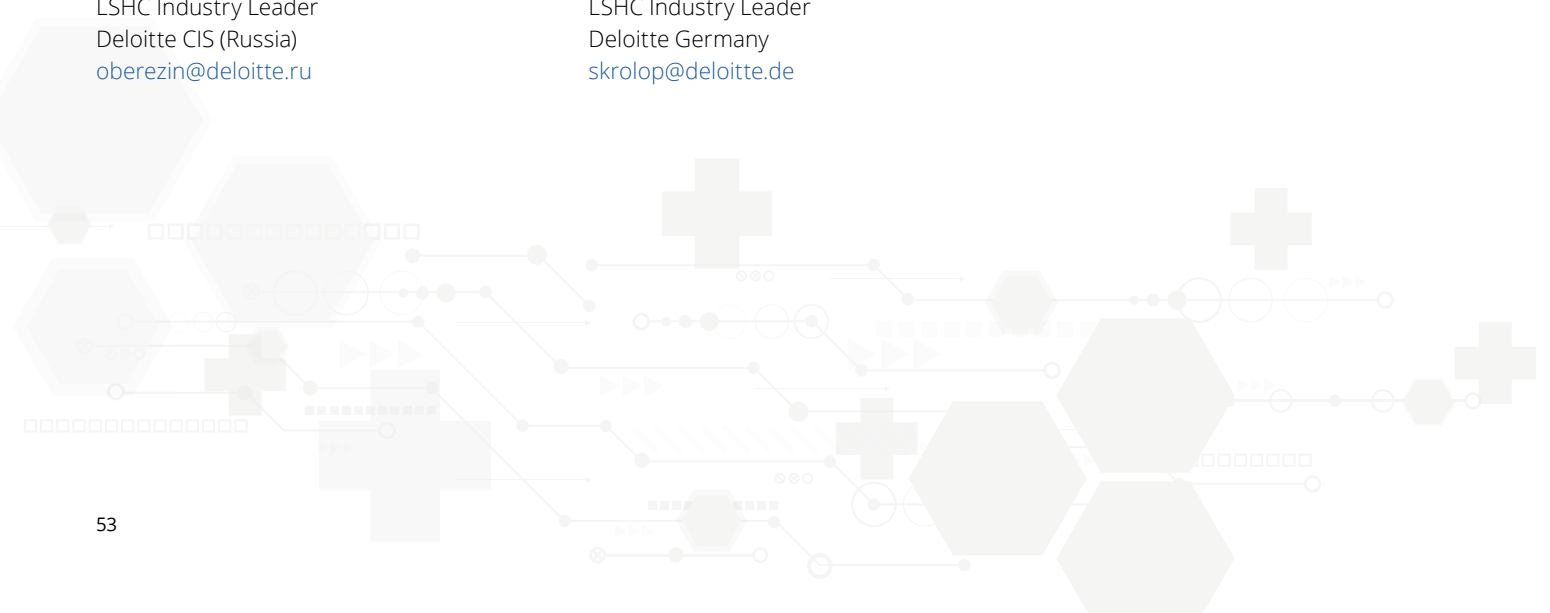
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