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2023 Global Life Sciences Outlook

Innovating and collaborating for tomorrow

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Overview & Outlook

The underlying growth of the life sciences sector—pharmaceutical, biotech, and medtech—is strong at a combined US\$2.83T.^{1,2,3} While growth has recently remained strong through increased demand and throughout the pandemic response (particularly with COVID-19 vaccines), we are seeing life sciences companies shifting their portfolio strategies with the hope of continuing this growth trajectory by any combination of acquisitions, divestitures of assets deemed not core to growth; investments in R&D and an accelerated embracing of digital; and data technologies which are finally beginning to scale in their adoption. Significant challenges remain though, such as the increasingly competitive market, the changing and evolving regulatory landscape, increasing pricing and reimbursement pressures, and growing demands from patients and health care providers for more effective medications and experiences as they manage health and well-being. All of this also while in the face of broader geopolitical and economic uncertainty.

To maintain their historical and expected growth, life sciences companies are focusing on innovation and collaboration for value creation. They are investing in bringing and expanding platforms like gene and cell therapies, new platforms like mRNA, expanding indications of existing and known biologics platforms, developing novel medicines like antibody drug conjugates (ADCs), and developing novel approaches to make existing medicines even more effective (whether through better diagnostics or exploring different routes of administration). And they increasingly realize they can't do it alone—they are more willing to collaborate with other stakeholders in the health care ecosystem to share knowledge, expertise, and resources.

We anticipate that digital technologies such as artificial intelligence (AI), automation, and blockchain are scaling and creating efficiencies that will lower development and manufacturing costs and accelerate drug research and development efforts.

At the same time, national and local governments around the world are tightening regulations and seeking greater transparency for drug reviews, approvals, pricing, and reimbursement. This pressure is not only on pharmaceutical and biotech manufacturers but also is growing on other stakeholders such as pharmacy benefit managers (PBMs) in the US. Life sciences organizations are seeking to comply with these regulations while still meeting patient needs and generating shareholder returns. This requires a deep understanding of the regulatory environment and a commitment to transparency and ethical behavior.

Amid the volatility of the pandemic and geopolitical conflicts affecting shipping and logistics, biotechnology, pharmaceutical and medical device companies see the need to increase flexibility, streamline manufacturing processes, and enhance real-time tracking. As a result, they are shifting away from planning for inflexible accuracy to designing agile supply chains that can flex and adapt quickly to changing conditions—and multiple scenarios. Here we anticipate greater adoption and scaling of digital technologies to enable more flexibility in the supply chain of medicines will be seen in the sector.

Meanwhile, patients and health care providers are demanding more innovative and effective treatments. Patients increasingly want more personalized care that meets their individualized needs allowing them to access information and care at times and locations that fit their schedule. Meeting these demands requires more than just new technologies and processes. It also requires a stronger focus on patient-centricity and an advancement of value-based care.

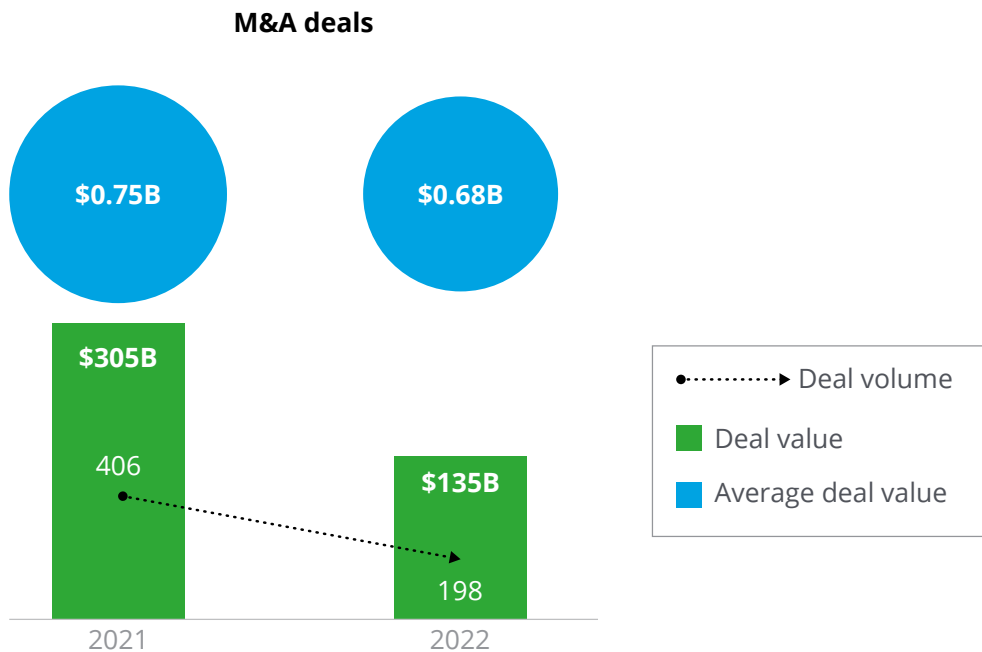
In this year's outlook, we explore more deeply the seven critical areas we see the life sciences sector investing for change: evolving portfolios and value creation; research and development; supply chain; pricing and reimbursement; patient centricity; digital transformation; and health equity. In some of these areas, we see and anticipate real advancement such as greater and more-scaled adoption of digital technologies in core operations and operational activities across the value chain, or the greater advancement and integration of diagnostics into care delivery. At the same time, in other areas, we acknowledge and anticipate change may grind against the gears of our "new normal"—one where we continue to live and manage COVID-19.

2023 Global Life Sciences Sector Outlook



Much of this activity slowed in 2022, during the third year of the COVID-19 pandemic, as life sciences transactions surpassing US\$1 billion fell by 60% compared to 2021 (Figure 1). In total numbers, there were 406 deals totaling US\$306 billion in revenue in 2021, while that number declined to 198 deals totaling US\$135 billion in revenue in 2022.⁴

Figure 1. M&A and venture activity in life sciences (2021 and 2022)



Source: M&A Trends in Life Sciences: Deal-making in 2022, Deloitte, 2022

Notwithstanding, pharma companies with substantial cash balances have increasingly appeared ready to unleash pent-up demand. In June 2022, Bristol Myers Squibb acquired Turning Point Therapeutics in an all-cash deal focused on the experimental lung cancer candidate Repotrectinib.⁵ In October of that year, Pfizer acquired Biohaven Pharmaceuticals, bringing two new migraine treatments into its portfolio in a transaction valued at around US\$11.6 billion.⁶ The following month, Johnson & Johnson (J&J) acquired heart pump maker Abiomed in a US\$16.6 billion cash transaction. A month later, Amgen picked up rare disease specialist Horizon Therapeutics in a US\$27.8 billion acquisition.⁷

One area of potential interest for acquirers comprises multi-indication pharma products with potential applications across therapy areas. These drugs have the ability to treat several diseases, such as disorders that span immunology, oncology, and metabolic illnesses, but are linked to similar underlying causes—demonstrating how one therapy developed for a particular disease can ultimately alleviate another.⁸ A 2022 study of pricing and value of multi-indication drugs in the United States, Germany, France, England, Canada, Australia, and Scotland, highlights how the drugs have become particularly effective for cancer treatments over the past two decades, with 75% of oncology drugs having been approved for multiple indications by 2018. The drugs can offer efficiency gains through a single cycle of as research and testing.⁹ What’s more, investors value the multi-indication treatments because of the potential to provide higher returns compared to single-indication drugs.¹⁰

Prospective acquirers pay a premium for that medicinal versatility, however. A study of 311 acquisitions involving US and EU biopharma companies developing prescription drugs from 2005 to 2020 shows that acquirers paid 37% more for companies with biologics and gene therapeutics, than small-molecule drugs, and paid 12% premium for multi-indication products.¹¹

Researching the path to new revenue

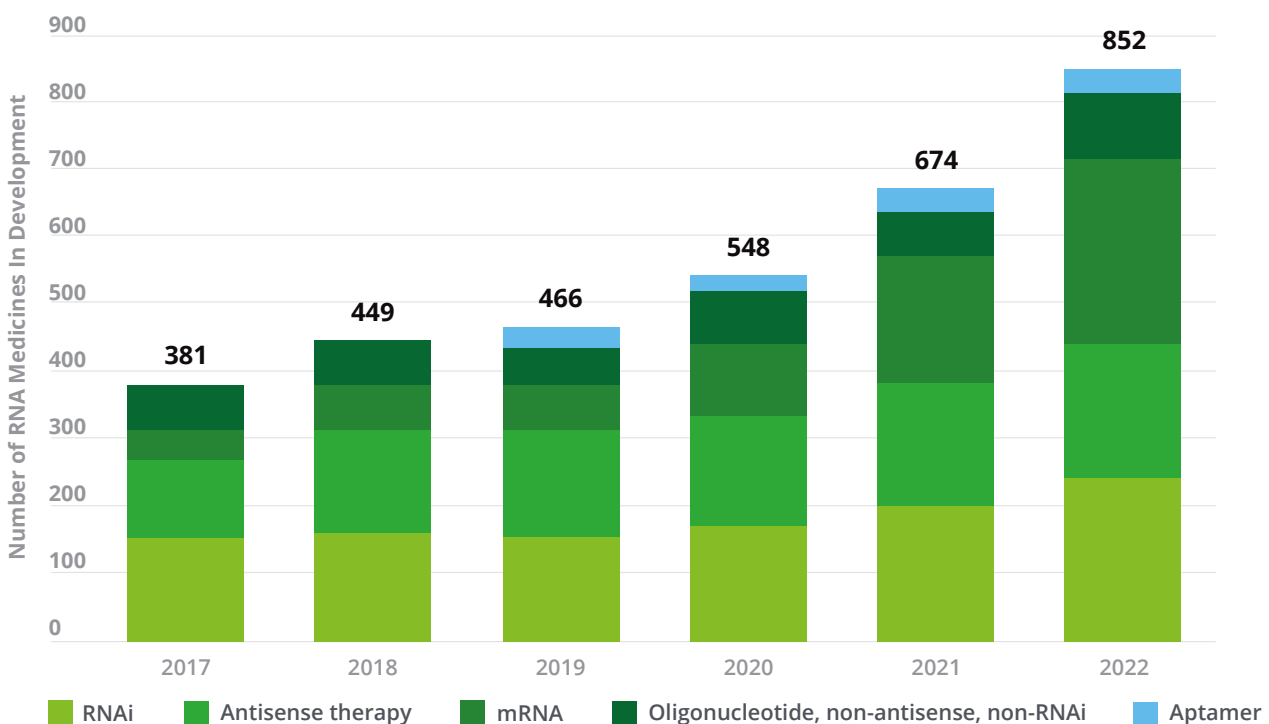
Life sciences executives surveyed by Deloitte appear to be actively preparing for a promising, if turbulent, year ahead in regard to portfolio growth. In a Deloitte US Center for Health Solutions survey of 60 C-suite executives from life sciences companies, 95% of respondents say they intend to focus on the development of innovative products; 91% say they plan to invest in R&D innovation; and 87% say they plan to invest in digital innovation, underscoring the push to adapt portfolios and operations in response to external disruption.¹²

One set of developments that have invigorated pharmaceutical portfolios involve the emergence of mRNA technology. Unlike traditional vaccines, which use weakened or inactivated viruses to elicit an immune response, mRNA vaccines use genetically engineered molecules that teach cells to make a harmless protein, which then triggers the production of antibodies to attack and destroy the protein. What’s more, mRNA technology can be quickly designed and scaled as needed.

Many scientists view mRNA technology as the future of medicine. In the United States, the Vaccines National Strategic Plan 2021-2025 lists its primary goal as fostering innovation in vaccine development and related technologies. In 2022, the US pharma and biotechnology company Pfizer announced the first volunteer recipients of its mRNA flu shot in a study involving more than 25,000 US adults. Meanwhile, Moderna announced a late-stage trial of an mRNA-based influenza vaccine. Both trials will seek FDA approval if successful.¹⁴

There were 49 deals signed involving mRNA companies or assets in 2021, with a combined potential value of US\$5.37 billion (Figure 2). One such deal is Sanofi’s commitment to investing €400 million (US\$476 million) a year to develop mRNA vaccines against a wide range of infectious diseases. The company’s mRNA Center of Excellence will include 400 employees in Cambridge, Massachusetts, and Lyon, France. The teams comprise professionals in R&D, digital, chemistry, manufacturing, and controls, with a goal of having at least six vaccine candidates in the clinic by 2025.¹⁵

Figure 2. Growth in RNA pipeline has doubled since 2017



Notes: Chart includes candidates in development from preclinical through pre-registration. Annual snapshots taken in May.

Source: Pharma Intelligence UK

Pfizer, which used mRNA in its COVID-19 vaccine, has agreed to pay as much as US\$1.3 billion to gene-editing company Beam for the advancement of novel in vivo base editing programs for a range of rare diseases. The programs will use mRNA and LNPs to deliver base editors to target organs. The four-year research alliance will focus on rare genetic diseases of the liver, muscle, and central nervous system.¹⁶

The outlook for mRNA vaccines includes research to develop vaccines against HIV, Zika, and rabies that are currently in the human trial phase.¹⁷ Many of these developments and treatments have largely gone to developed countries, highlighting longstanding inequities in public health. To help combat these disparities in the global south, a South African-based vaccine technology transfer hub comprising universities and pharmaceutical companies is collaborating to make an effective mRNA vaccine against COVID-19, with plans to expand into other diseases such as the measles.¹⁸

Exploring innovations in therapeutics

Research into next-generation therapies, including gene editing, is another area of portfolio expansion for life sciences companies as they look to augment their traditional drug portfolios. As of 2021, there were more than 6,500 active cell and nucleic-acid therapeutic R&D programs, a year-over-year increase of 20%.¹⁹ Trailblazing discoveries such as the Phase 3 trials of the world's first topical gene therapy used to heal decades-old open wounds.²⁰

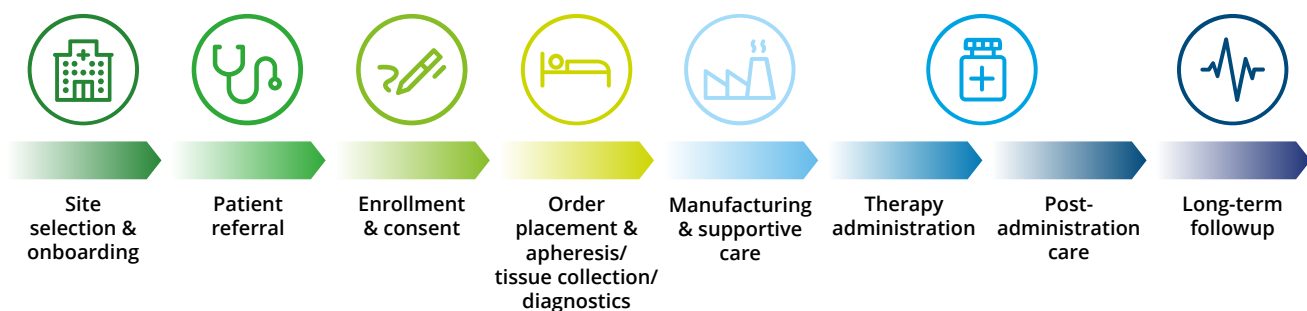
These scientific advancements have taken a significant leap forward since the discovery of CRISPR/Cas9, which could make the elimination of inherited diseases a reality. In 2020, Regeneron and Intellia Regeneron and Intellia expanded their collaboration to develop CRISPR/CAS9-based treatments. By 2025, the regenerative medicine market is predicted to be worth US\$22 billion, growing twofold over the course of a decade.²¹

A number of recent key drug approval are showing promise for new diagnostic and therapeutic technologies. In the United States, the FDA approved Bristol-Myers Squibb's (BMS) BCMA CAR-T cell therapy Abecma in 2021, the first cell therapy approved for multiple myeloma.²²

Figure 3. A typical CGT value chain

Shifting the model from supply chain to a value chain for CGT

Supply chain refers to the integration of all activities involved in the process of sourcing, procurement, conversion, and logistics. On the other hand, value chain is the series of business operations in which utility is added to the goods and services offered by the firm to enhance customer value. Our definition of customers includes treatment sites, patients, and other relevant stakeholders. Figure 3 depicts the typical, made-to-order cell and gene therapies (CGT) value chain.



Source: Cell and gene therapies: Delivering scientific innovation requires operating model innovation," Deloitte Insights, April 17, 2020

However, major challenges persist, notably the exorbitant upfront cost to develop cell and gene therapies, which require bespoke manufacturing processes—to say nothing of the staggering price tags that can make payors hesitant to adopt the experimental therapies. As gene therapies move from ultra-rare applications to other more prevalent disease areas, manufacturing processes also need to scale. This has proven to be a challenge as a lack of manufacturing space and bottlenecks arising from the lack of equipment such as incubators has led to capacity constraints (Figure 3). In addition, CGT companies are still facing shortages of raw materials as a lingering effect of the pandemic.²³ As a result, we have seen pharma companies and contract development and manufacturing organizations (CDMOs) invest heavily to meet demand needs, such as the French contract development and manufacturing organization Yposkesi, which announced plans to build a US\$71 million CGT plant to boost production of the viral vectors used in gene therapy biomanufacturing.²⁴

Life sciences organizations may need to consider alternate funding and payment models to accelerate widespread adoption of their CGTs. For example, Novartis's gene therapy Zolgensma, a one-time treatment for pediatric patients with spinal muscular atrophy, costs more than US\$2 million. To help accelerate adoption and lower the barrier to entry, Novartis is working with payors to develop outcomes-based pacts and pay-over-time options.

Shedding noncore assets

In the current environment, companies are rationalizing their base—carving out assets that don't fit within their overall portfolios or restructuring and rebalancing their portfolios. For instance, in a deal finalized in 2021, Merck created a new drug company, Organon, after spinning off a US\$6.5 billion business to include women's health products and biosimilars. The carve out allowed Merck to not only cut costs by removing manufacturing and sales responsibilities but also focusing on growth areas such as cancer drugs and vaccines.²⁵ In 2022, Novartis announced it was spinning off Sandoz, the company's generics and biosimilars division, into a publicly traded standalone company.

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In a news release, the company's chair Joerg Reinhardt said in part that, "A spin-off would allow our shareholders to benefit from the potential future successes of a more focused Novartis and a standalone Sandoz, and would offer differentiated and clear investment theses for the individual businesses."²⁶

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Similarly, in 2022, the Austrian biotechnology company APEIRON Biologics announced it would demerge its pre-clinical and clinical development activities to form a new fully separate holding company, invIOs Holding AG (invIOs). The new company would continue to focus on developing novel immuno-oncology treatments for difficult-to-treat cancers, enabling the company to access funding from investors to build its immuno-oncology pipeline.²⁷

Also in 2022, Danaher Corporation, the global science and technology company, spun off its Environmental & Applied Solutions (EAS) segment to create an independent, publicly traded company. This follows significant growth in the company's diagnostics and life sciences area, thanks to tailwinds from the pandemic, whereas the EAS had been the company's weakest.²⁸

Economic conditions make many of the deals more attractive. Though debt is more expensive because of rising interest rates, valuations slipped during the first three quarters of 2022. In addition, 11 mega-blockbuster medicines with sales exceeding US\$5 billion per year are set to lose global patent protection over the coming decade, setting up fierce competition through the manufacturing of generic products.²⁹

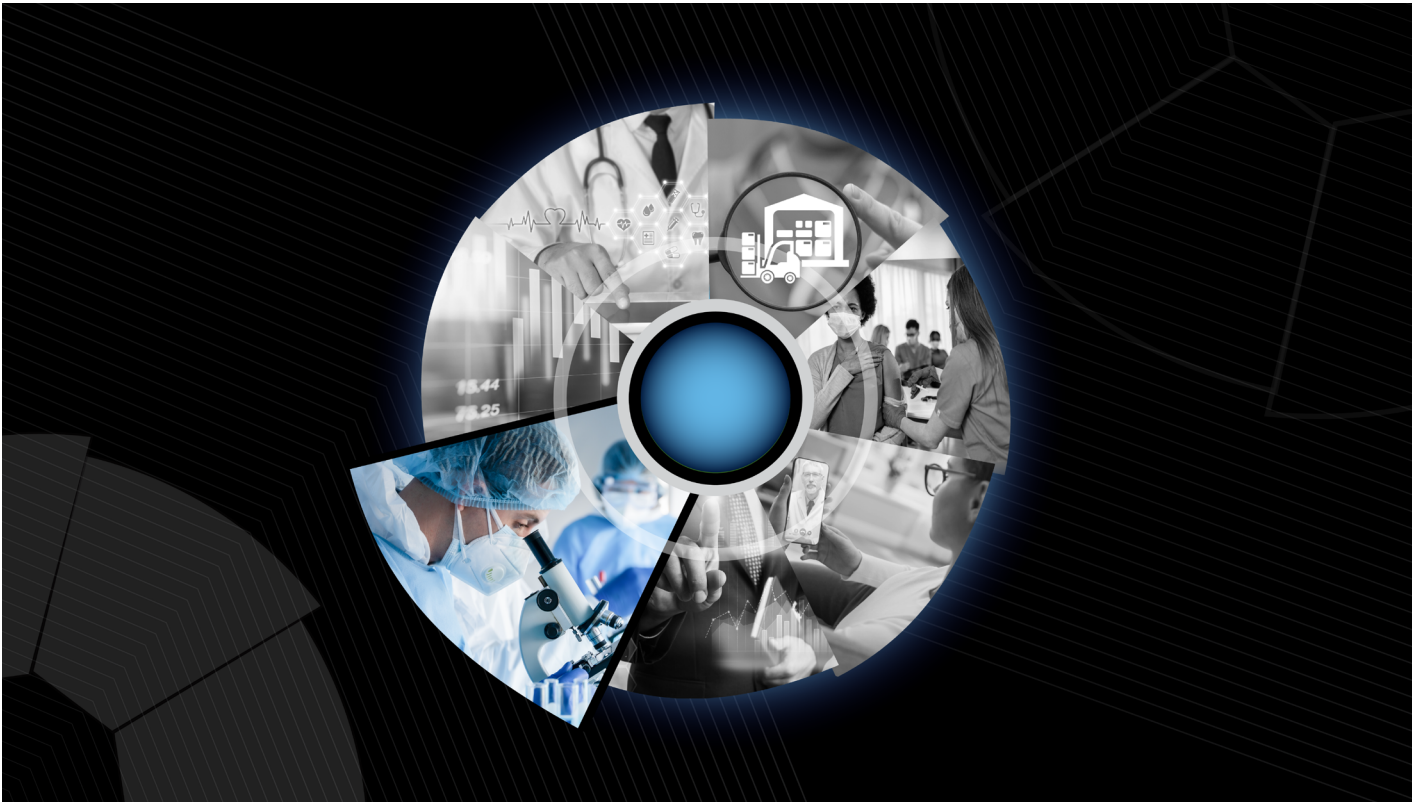
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"When it doesn't make sense in the portfolio, you move it out," says Keith Boettiger, President, Abbott Heart Failure. "You look at the landscape, how it fits into your long-term strategy, and ultimately you make hard decisions."

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Value creation considerations for life sciences organizations

- How are you filling your growth gaps?
- Where can you seek adjacencies to bolt on technologies you don't currently possess?
- How are you balancing diversity in development of a portfolio with focus in a given platform or therapeutic area and how can you avoid becoming too fragmented or too focused?
- How can multi-indication products enhance your portfolio?
- How do next-generation therapeutics fit into your portfolio?



R&D

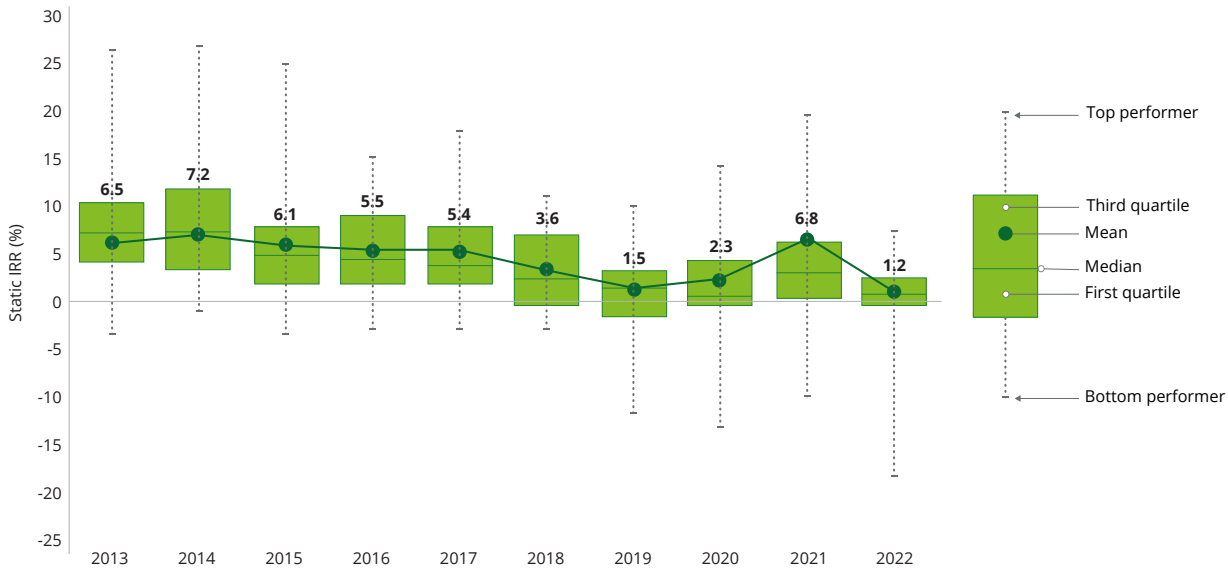
Innovation is fundamental to the global life sciences sector, even as pricing pressures, growing market share for generic drugs, and looming patent expirations remain significant challenges. In the coming year, life sciences companies will continue to build on advances such as translational medicine, big data analytics, and digital innovations in research and development. In addition, other advanced technologies will emerge to improve research and development (R&D) efficiencies, boost long-term returns, and enhance the patient outcomes and experiences.

R&D innovation is one of the top actions that 91% of life sciences organizations plan to invest in more heavily during 2023, according to a Deloitte survey of 60 senior life sciences executives from biopharmaceutical and medical device manufacturers with revenue of more than US\$500 million.¹

Almost half (48%) of the executives in the same survey said they are cautiously optimistic about the sector's outlook in the coming year. R&D investments in composition, drug pipelines, clinical trials, and processes for regulatory approval of new assets will play a critical role in the industry's success, but the financial challenges on achieving a return are significant. Deloitte's analysis of the top 20 pharma companies found that:

- Internal rates of return (IRR) for late-stage assets fell to 1.2% from 6.8% a year earlier. Indeed, IRRs have resumed a downward trend that began in 2014, slipping below the 1.5 rate achieved in 2019. (Figure 1)
- R&D spending among the 20 biggest companies fell to US\$139 billion in 2022 from US\$141 billion in 2021 (though it remains higher than it was in 2020).
- Average asset development costs increased in 2022 by US\$298 million, to US\$2.28 billion, compared with a year earlier. This increase was largely because of increased clinical cycle times, which were compressed during the pandemic.
- The average forecast peak sales per pipeline asset fell to US\$389 million from US\$500 million in 2021 because of the successful commercialization of high-value assets.²

Figure 1. Return on late-stage pipeline, 2013-22



Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 1 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.

Life sciences R&D organizations are under increasing pressure to generate sustainable returns on investment given shifts in the market, regulation, and reimbursement practices. While the industry has recently produced groundbreaking innovation such as mRNA vaccines and platform technology, which have the potential to truly transform global health, scaling the impact will require reinventing and realigning traditional R&D models.

Real-world evidence (RWE), new approaches to clinical trials and partnerships, and artificial intelligence (AI) have the potential to transform R&D—from drug discovery and development to regulatory approval.

The growing benefits of RWE

RWE refers to clinical findings about the use and potential benefits or risks of medical products based on analysis of data such as patients' health status or the delivery of care. RWE helps life sciences organizations better understand disease progression, monitor patient safety, and assess clinical and cost effectiveness. RWE also can help organizations adjust instructions for how medications may be used, administered, or labeled.³

During the COVID-19 pandemic, RWE enabled the sector to innovate faster by understanding the incidence and severity of the virus and its variants for vaccine and drug development. RWE helped vaccine developers predict global hotspots, collect better data from diverse racial and ethnic groups, and understand vaccine effectiveness across age, gender, race, and ethnicity to determine the need for boosters.

Increasingly, RWE is playing an expanded role in R&D in helping life sciences organizations design clinical trials, understand the heterogeneity of treatment effects, and inform price and forecasting assumptions.

Though life sciences organizations lagged other sectors in adopting RWE, it now is a growing part of the decision-making process. Companies are getting faster at collecting and analyzing RWE. Ninety percent of the biopharma executives surveyed by the Deloitte US Center for Health Solutions said their organizations are using RWE to speed product life cycles and design synthetic control arms and adaptive trials. These processes are expected to increase in the next two to three years.⁴

Regulatory agencies are accepting the use of RWE in submissions. Over the past two years, the US Food & Drug Administration (FDA) has released guidelines on its use for claims, electronic health records, and registry data in submissions.⁵ As part of its RWE strategy, the FDA is working on projects exploring the role RWE could play in regulatory decision-making.⁶

For example, Eli Lilly collaborated with Flatiron Health to fill evidence gaps in its FDA submission for a new dosing regimen of cetuximab, which treats metastatic colorectal cancer (CRC). Analysis of real-world data from Flatiron Health’s database found no significant differences in the survival of CRC patients receiving weekly or biweekly doses of cetuximab. The findings were critical to the FDA’s approval of biweekly doses of cetuximab, and infusions can now be scheduled alongside other biweekly treatments, reducing patient visits to infusion centers.⁷

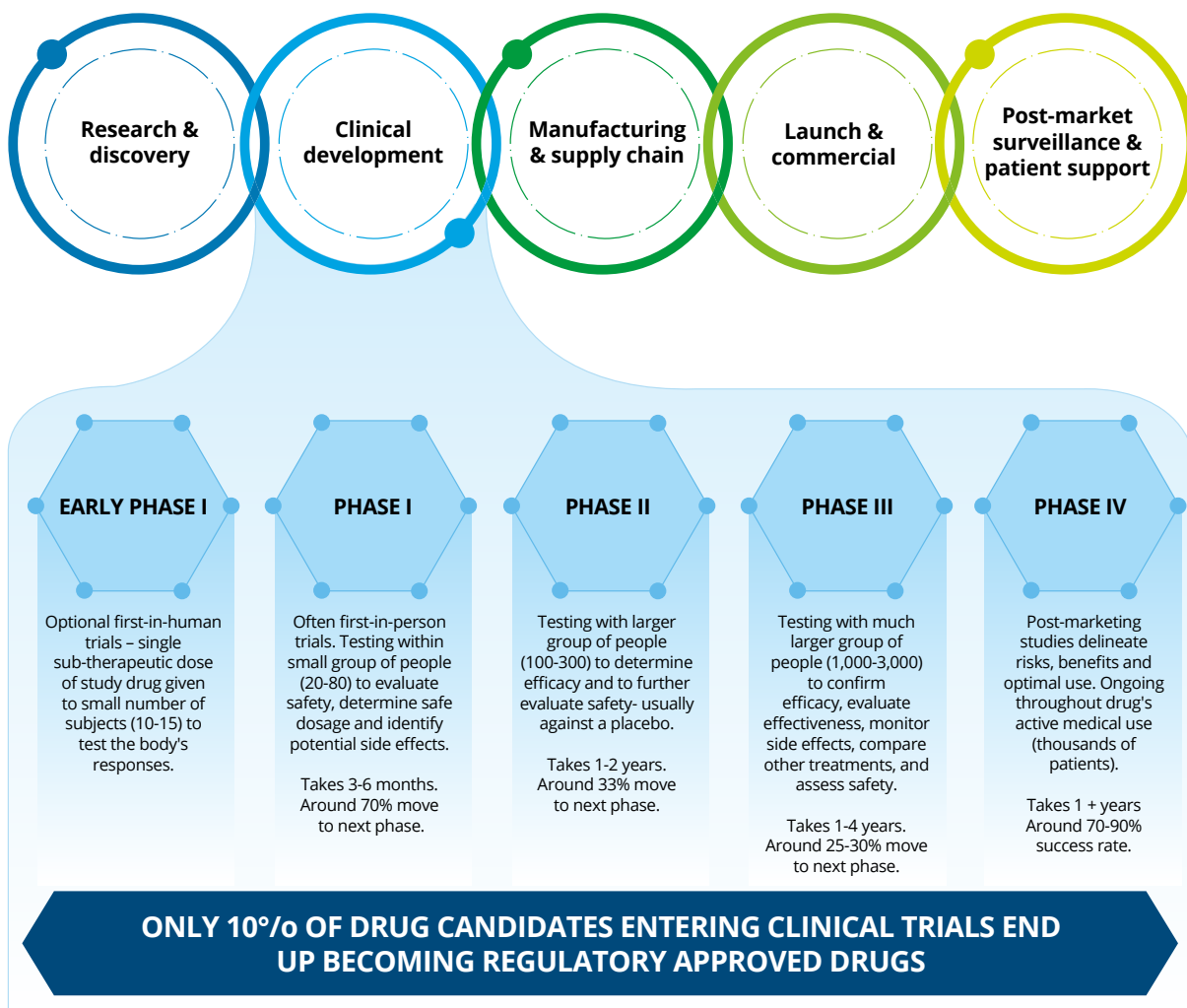
The European Medicines Agency (EMA) and the National Medical Products Association in China also are attempting to expand RWE use to expedite patient access to innovative therapies.⁸

With new regulatory pathways for real-world data, advanced information management and analytics, technologies can enable R&D organizations to access, analyze, and meaningfully act on RWE to advance drug discovery.

Reshaping clinical trials

Clinical trials remain vital to life sciences’ R&D, but the lengthy process of discrete and fixed phases in randomized controlled trials (RCTs) has changed little in recent decades and was designed principally for testing mass-market drugs (Figure 2).

Figure 2. The traditional approach to clinical development is a lengthy process with only 10% success rate



Source: Deloitte analysis.

As of September 2022, more than 16,000 clinical trial studies were underway, and non-COVID study starts through August were on pace to top 5,500, a 17% increase from the 4,700 starts in 2021.⁹

The need for large numbers of studies, however, are hampered by difficulty finding subjects to enroll, and the time it takes to complete them: The average trial time for Phase 3 trials in 2022 was 3.5 years, up slightly from 3.4 years in 2021.¹⁰

The pandemic taught the sector that technology can be used to collect and monitor patient data more quickly. Dublin-based ICON ran a COVID trial in Argentina with 5,000 subjects. Monitoring the data onsite would have been too time-consuming, so the company monitored the data from Japan to ensure it was being collected properly. "That is the sort of technology [that] can now become part of trials in the future," CEO Steve Cutler said.¹¹

It's also important to note that despite slow changes in the trial process, the pandemic accelerated the use of virtual trials, wearables and RWE, and we expect this trend to continue, leading to more widespread adoption.

Digital trials

Trials are being conducted at sites that are more convenient for patients, rather than at centralized testing facilities. Data is gathered remotely through wearables, mobile engagement apps, and medication management. For example, Curebase, a US clinical research firm, conducts decentralized clinical trials without a traditional testing site. Data is collected through wearables, home visits, telemedicine, and reminders sent by apps.¹²

Meanwhile, companies such as Novotech and Obviohealth are working to develop decentralized clinical trials in the Asia-Pacific region, which accounts for more than 60% of the global population and represents the fastest-growing market for pharmaceutical sales.¹³

These remote testing capabilities not only increase the amount of data collected, but they also can give manufacturers greater insight into patient safety by identifying risks. While standards are needed for data collection, analysis, and collaboration, the data gathered could provide better understanding of disease and a broader view of the patient experience before, during, and after dosing.¹⁴

Trial simulation

Digital technology can conduct trials via computer simulations and use analytics to verify trial feasibility. These digital studies can simulate organ response to drugs, employ AI to optimize dosing, and predict disease progression.

Paris-based Ariana Pharma, for example, designs and executes precision medicine clinical trials using AI. The company integrates pre-clinical, clinical, and RWE data, then uses that information to select patients for trials, determine best dosages and even suggest alternative clinical indications.¹⁵

Trial simulation can help identify clinical outcomes in the discovery or development phase, long before any human trials. Life sciences organizations are adopting modeling and simulation to understand the complexity of human physiology and predict human response to therapies. One key area for growth is addressing relapses from drug resistance in diseases such as cancer, tuberculosis, and other bacterial infections.¹⁶

As a result, the biosimulation market, which was US\$3.17 billion in 2021, is expected to grow at an annual rate of 15%, reaching US\$6.13 billion by 2026.¹⁷

Retail clinics

Some 80% of clinical trials are delayed because of recruitment issues, and about one-third of patients who sign up drop out before a trial is completed. Most clinical trials are conducted in academic medical centers, which may require a patient to travel as much as two hours each way. One solution: bring the trials closer to the patients, most of whom live within 10 or 15 minutes

of a pharmacy or grocery store with clinics that often are open at nights or on weekends. Retail outlets are not suitable for all types of clinical trials, but they are well-suited for drugs to treat skin cancer, diabetes, asthma, or hypertension. The use of retail locations – such as pharmacies, grocery stores or urgent care facilities — could expand the number of trial sites and improve patient access. Using retail locations may also address health equity issues by attracting more racially, ethnically, and economically diverse participants.¹⁸

For example, the health division of the US grocery store chain Kroger established a clinical trial site in partnership with pharmaceutical companies, research organizations and health systems. The first trial began at a Kroger pharmacy in Toledo, Ohio, in early 2023 and enrolled an initial cohort of 55 people in a study to identify microbiome-based biomarkers indicative of colorectal cancer.¹⁹

Intelligent trials

Using real-world data, predictive AI algorithms can accelerate the understanding of diseases, identify suitable patients, assist in site selection, and support novel study designs. The algorithms also collect and analyze clinical data more quickly and from more inputs while also reducing the potential for human error. AI can also improve patient monitoring, medication adherence and retention.

AI-powered simulations and computer modeling with advance the development and regulatory evaluation of new drugs, while reducing the time and costs of clinical trial cycles and improving patient safety.²⁰

AI's growing role in drug development

AI has the potential to transform drug discovery by extracting concepts and relationships from data. It also can cross-reference published scientific literature with alternative information sources, such as clinical trials information, conference abstracts, public data, and unpublished datasets. By mining such information, AI applications in drug discovery have already delivered new candidate medicines, in some cases in months rather than years.²¹

Whiz.AI, a US startup, uses AI to provide data insights gleaned from patient history, remote patient monitoring, and results of previous trials. Life sciences organizations can use the information to expedite R&D and time to market, while also more accurately forecasting development costs.²²

AI's ability to crunch large amounts of data allows it to rapidly identify drug targets, such as molecules and proteins associated with specific diseases, that can be made into medicine. Biotech companies such as Exscientia, Evotec, and Insilico Medicine have announced clinical trials for drugs developed with AI, and Verge Genomics, a US biotech, recently started clinical trials of novel therapy for ALS that it developed using AI to analyze brain tissue databases.²³

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*Data science has now closed the gap with chemistry, biology and physics and really driving innovation in the pharmaceutical industry,” said Frank Nestle, global head of research and chief scientific officer for Paris-based Sanofi. “The predictive models, what we call AI, will give us novel hypotheses, and those novel hypothesis will speed up drug discovery, make it more affordable, and cheaper and also get us better quality medicines.”*²⁴

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As the number of compounds identified using AI increases, drugs capable of treating specific pathologies will become available. By 2030, more drug discovery will be done using AI-controlled simulations in collaboration with academia. The time from screening to preclinical testing will be reduced to a few months and new potential drug candidates identified at increasingly lower costs.²⁵

Collaboration and shared services

Prior to the pandemic, developing, testing, and releasing a new vaccine, therapy, or medical device in less than 10 years was almost unheard of. Today, companies, shareholders, and consumers all want faster cycles, but they can't do it alone. Long drug and device development times can add significant human, health, and economic costs to R&D efforts. By working to reduce those times through international interagency collaboration, regulators could help mitigate those costs.

During the past two years, regulators globally have been working more closely together than ever. While many regulatory bodies were involved in working groups prior to COVID-19, the pandemic accelerated those relationships, which are likely to continue in the years to come.

Regulators also stepped up information sharing with private companies. These collaborations focus on creating clusters of technical experts, sharing research results, leveraging inspection reports, and disseminating information. Regulators also showed they were willing to relax certain requirements, lower barriers to entry, and accelerate approval processes for new products to facilitate faster and more comprehensive responses from both the public and private sectors.²⁶

This newfound sense of collaboration is particularly important in Europe, where biopharma products must receive regulatory approval from the EMA, and the UK's Medicines and Healthcare products Regulatory Agency (MHRA). The EU recently changed regulations for clinical trials and medical devices, for example, and cross-border collaborations remain challenging.²⁷

Collaboration also has increased within the industry. Biopharma companies and medtech manufacturers are sharing information in ways they never have. In March 2020, after COVID-19 was declared a pandemic, companies such as Eli Lilly, Novartis, Gilead, and AstraZeneca formed a research group that shared knowledge and resources to accelerate development of vaccines and treatments.²⁸

And life sciences organizations are turning to external providers for services such as robotic cloud labs, or lab-as-a-service (LaaS). In these labs, companies provide proprietary hardware, single-platform software, and services that allow automated research to be done remotely. Researchers log in to a dashboard, specify the experiments they want to run, and configure the equipment remotely. The labs can run experiments around the clock, greatly reducing the time it takes to develop new drugs.^{29,30}

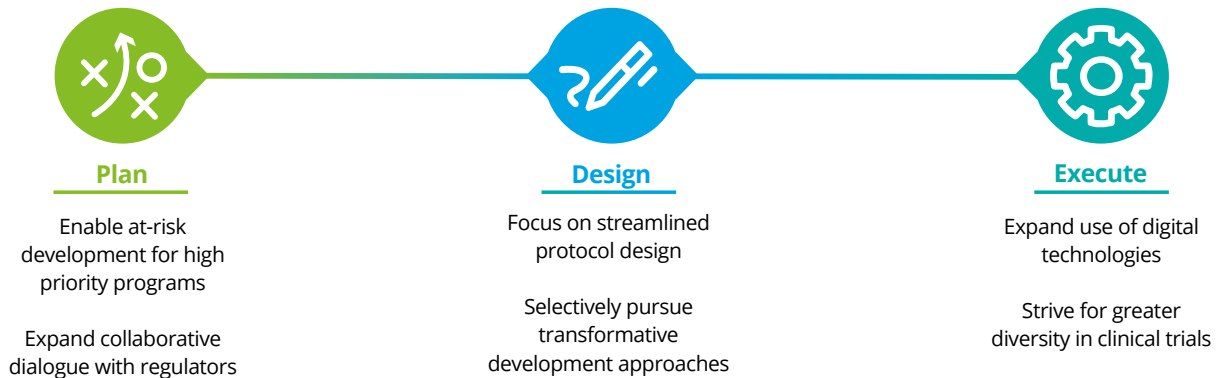
Life sciences organizations are increasingly seeking to augment their drug development pipelines through collaborations and scientific partnerships. A Deloitte survey of 15 life sciences companies found that they relied on external sources for innovation for more than 50% of late-stage revenue.³¹

Ipsen CEO David Loew said French biopharma company has almost stopped doing internal research. "We have only very little internal research left, and we partner now on the three years before entry into human space ... with biotechs or with universities," he said.³²

The post-COVID outlook

The response to the COVID-19 pandemic has created new opportunities for innovation in the life sciences sector (Figure 3). In the coming years, it should continue to explore and embrace these new approaches, such as identifying programs with a high probability of success and ensuring they progress seamlessly from one phase of development to the next.

Figure 3. Incorporate the lessons from the R&D approaches adopted for COVID-19 into routine clinical development



Source: Deloitte analysis.

Other benefits from the pandemic response include expanding dialogue with regulators to accelerate development of urgently needed therapies, streamline trial protocols to avoid deviations, speed development time and strive for greater diversity in clinical trials to ensure subjects match the prevalence of diseases across racial and ethnic groups.³³

COVID-19 has highlighted the vulnerability of R&D to the traditional, site-based clinical trial system. Deloitte surveyed R&D and commercial leaders at both large and small biopharma companies, most of whom said they expect the shift to decentralized, patient-centric trials to continue for the long term. They also anticipate more reliance on innovation and both real-time and remote monitoring tools and diagnostics. Organizations also may develop extensive data and intelligent workflow to support improved decision-making.³⁴

Organizations that can continue to capitalize on the momentum gained by accelerating digital transformation programs, strategic shifts, and commercial reorganization before or during the pandemic, will be well-positioned to benefit from the more agile post-COVID market in 2023.

R&D considerations for life sciences organizations

To drive a more productive future for R&D, with more equitable and quicker access to new therapies, life sciences leaders should ask themselves these key questions:

- Is our R&D capital allocation sufficiently balanced to foster sustainable pipeline flow?
- Are we investing enough in the new capabilities and way of working that will transform our ability to execute the pipeline?
- Are we making the most informed project-level investment decisions given the shifting scientific, commercial, and reimbursement landscape?
- Can we unlock the power of data sharing? How can we build on emerging knowledge, reduce duplication of research efforts, and curate data in the cloud that be accessed by our organizations and our partners?
- Can we create a digital talent pool with the skills to expand the use of data-driven approaches? How do we rethink our talent strategies to leverage alliances for accessing talent? How do we best invest in retraining the talent pool we already have? Can we incorporate patient centricity to improve health equity and develop more comprehensive clinical trials that better assess the impact of our products for all races and ethnicities?
- How can we meet society's expectations about equity of access to experimental and approved therapies?



Supply chain again a CEO agenda

Global life sciences companies are trying new approaches to respond to hidden risks within supply chains.

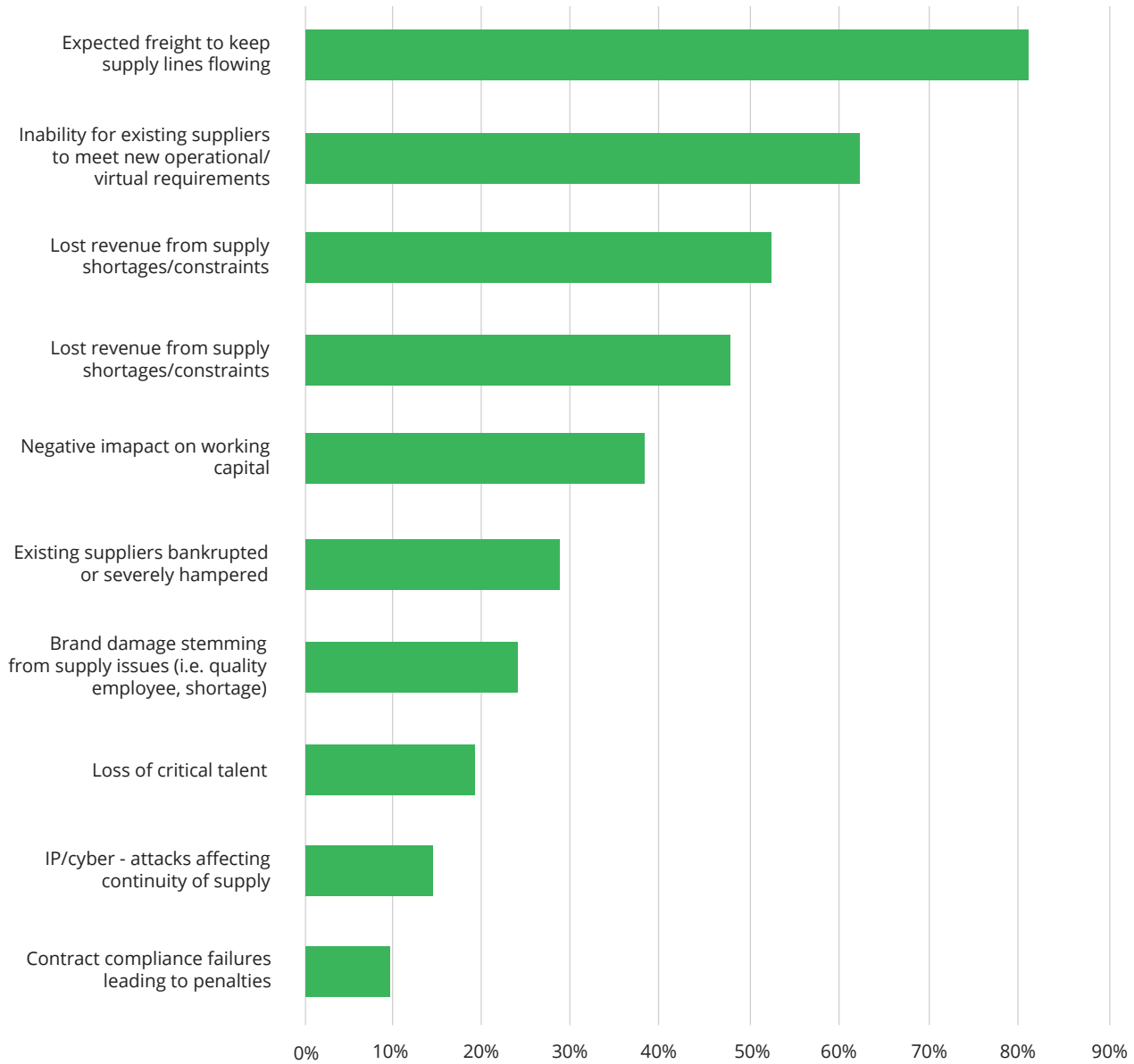
Supply chain management has long relied on static assumptions. In this deterministic view, organizations create forecasts using historical data to design specific scenarios likely to result from familiar circumstances. For enterprises using an array of suppliers for a particular product, the deterministic view dictates that the business can absorb a shock if one of its suppliers abruptly halts production – with the understanding that another provider can take up the slack. When unanticipated emergencies arise, such as a massive breakdown of supply and distribution channels, having a range of suppliers might not be enough to overcome the disruption.

Amid the volatility of the pandemic, geopolitical unrest affecting shipping and logistics, and inflation at a four-decade high, an alternate view on supply chains is emerging in the global life sciences industry. This model, known as the probabilistic approach, aims to increase flexibility, streamline manufacturing processes, and enhance real-time tracking. Within this framework, biotechnology and pharmaceutical companies are shifting away from planning for inflexible accuracy to designing agile supply chains that can bend and adapt quickly to changing conditions – and multiple scenarios.

This complex picture includes a rapidly diversifying portfolio of next-generation treatments such as personalized cell and gene therapies that require specialized manufacturing facilities, ultra-low temperature requirements, and last-mile delivery to treatment centers and patients. To keep pace with such changes, leaders at life sciences companies are prioritizing advanced digital processes such as artificial intelligence within production systems.

Accordingly, supply chain concerns have moved to the top of the CEO agenda: A Fortune/Deloitte survey reveals that the majority of life science and healthcare chief executives say supply chain disruptions have raised the cost of doing business and cut into margins. A total of 88% of respondents cited production or logistics issues, and reduced logistics capacity, as key challenges. What's more, the CEOs predicted continuing challenges will disrupt business strategy during the next 12 months (Figure 1).¹

Figure 1. Have you experienced any of the following disruptions to your overall supply chain in the last 12 months?



Source: "The Semiconductor Chip Shortage Hits MedTech: Strategies to built resilient Supply Chains," Advamed Deloitte, 2021

To better understand vulnerabilities in their supply chains, life sciences companies are exploring an array of practices to enable proactive scenario planning and risk mitigation. Among the emerging and transformative trends include the acceleration of digital investments, the deployment of human-centered and AI-enabled digital automation, trust-based supply chain systems that are responsive and agile to changing stimuli in the business environment, the embedding of sustainability into supply chains, and the expansion of connected networks to reinforce system-wide supply chain cohesiveness.

Enabling end-to-end visibility

Enhanced visibility into suppliers and investments in digital sensing capabilities helps life sciences companies avoid costly missteps.

Today's supply chain professionals potentially have access to thousands of suppliers—each with their own supply chains, corresponding digital platforms, and risk management approach within this second tier of suppliers. For life sciences companies, one barrier to adoption of a high connected, agile supply network is a lack of visibility into participants beyond the first tier.

Some of this may occur by design, as suppliers withhold information about their own vendors because of contractual restrictions.² Life sciences companies also risk becoming beholden to a single provider. For example, one major global biotechnology company has pinpointed the risks of having a sole provider for products used in conducting clinical trials. If this supplier suffered a shutdown, it would jeopardize the biopharma company's innovation activities.

Prioritizing digital governance is one way life sciences companies are attempting to avoid such delays. For example, smart sensors can provide timely feedback on operations and help companies react to supply chain bottlenecks and disruptions. The devices include onboard technologies such as microprocessors, diagnostics, and connectivity tools.³ The sensors, which can be leased to companies through a software-as-a-service (SaaS) model, allow global medical technology companies for example, to rapidly flag a downtime event that threatens timely manufacturing and distribution. Thanks to the alert from the sensing technology, companies can initiate advance purchases of supplies, and benefit in savings off typical rates by getting ahead of the production delay.

Sanofi, a French pharmaceutical and health care company, has launched an initiative to digitize its supply chain and related processes. Its Digital Accelerator effort develops products using digital, data, and AI—further proof that life sciences companies are accelerating data management strategies to integrate, unify, and standardize data from different sources.⁴

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“You generate so much data, but you have to bring the capability to transform that data into something that’s useful,” says Roberto Silveira, Senior Vice President, Global Technology and Engineering at Pfizer. “The path forward is not even predictive, it’s adaptive. It’s transforming data and using AI and machine learning to make data control your process. That’s the ultimate vision.”⁵

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Converting data intelligence into actionable insights is how Amgen, another biopharmaceutical company, is using technology to enhance collaboration among suppliers. The organization is sharing demand signals, adding visibility and production status to function as an in-house aggregator of supply chain information, improving the understanding of risks across its value chain. Specifically, the company has implemented high-grade product barcoding and tracking devices for greater monitoring throughout the cold chain journey, allowing for the shipping of biosimilars, which are copies of patent-expired biologic drugs.⁶

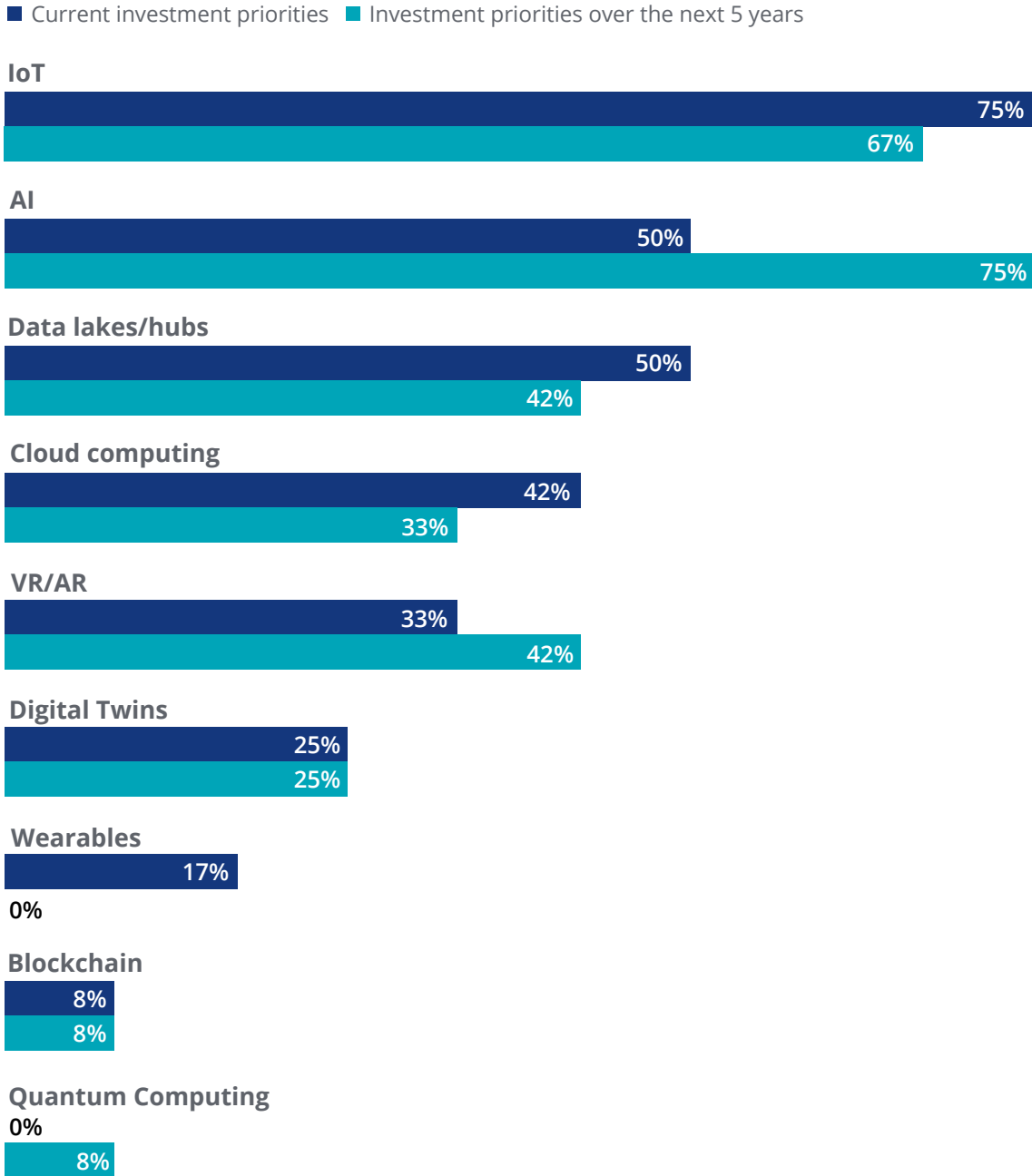
Additional supply chain challenges such as increasing cost pressures, evolving requirements for advanced therapies, and the increasing reliance on external partners in the clinical development process, offer areas of innovation that life sciences companies can address with the application of digital twins.⁷ A digital twin is a virtual model of a physical process, allowing companies to simulate conditions, contemplate what-if scenarios, and create instructions to manipulate the physical world.⁸

A potential use of digital twins among biopharma companies is the simulation of clinical trials to include budgets, patient selection, and probability of success.⁹ Digital twins can form part of a strong digital core housing relevant data allows life sciences companies to create a supply chain that can efficiently assess the current state—and make informed decisions during clinical trial execution.¹⁰

Still, the technology still ranks relatively low among planned investments for life sciences companies, a signal that many are still in the pilot phase when it comes to connectivity within the manufacturing ecosystem (Figure 2).¹¹

Figure 2. Manufacturing: Current and planned investments in digital technologies

Respondents were asked to rank the most innovative technologies in which their function is currently investing and plans to invest in the next five years.



Note: Percentages indicate options ranked among the top 3 by survey respondents.
Source: Deloitte's Biopharma Digital Innovation Survey 2021.

Human-centered design: Boosting success on the production floor

Life sciences companies that focus on high-value, relationship-driven investments in their people create more resilient supply chains.

Even with accelerating investments in digital capabilities, managing a supply chain is a human-driven endeavor. When Deloitte interviewed more than 50 supply chain leaders including life sciences companies, academic institutions, and technology companies, interviewees overwhelmingly cited people accepting and adopting the new ways of working — more than digital investments — as a key factor to boost supply chain resilience.¹²

One of the key threats to resilience is difficulty of talent retention, an issue that predates the pandemic: In a 2018 [survey by global shipping company DHL](#)¹³ on the supply chain profession, 70% of respondents said that the profession lacked status and opportunities for career growth. Research in 2022 by the recruitment firm Hays shows that 59% of UK professionals working in supply chain and logistics said they planned to switch jobs within a year, while 77% of US respondents said they planned to quit.¹⁴

These headwinds make it more critical for life sciences companies to enhance the value proposition for current workers and potential ones. As a complement to digital investments, some life sciences companies are making their operations more people-centric, empowering real-time decision making, and enhancing value chain efficiency. To meet these goals, biopharmaceutical and biotechnology companies are emphasizing human-centered design.

As a matter of quality control, life sciences organizations have had continuous improvement programs in place for some time to increase efficiency. But newer dimensions of human-centered design help companies rethink how the work gets done – from deciding how to digitize one step in a process or unit operation to pinpointing the precision output or outcome of a step in the supply chain.

Overcoming unplanned deviations can achieve these goals - while increasing trust in the supply chain. Companies that adopt this approach are attempting to flag common human errors – or identify when a similar error occurs in isolation across multiple sites. A review of deviations from standard production procedures aims to spot a deviation, determine how it happened, and develop action to prevent it from occurring again at any location.

Likewise, life sciences companies are taking smaller successes to scale. One leading biopharma manufacturer conducted digital immersion sessions, assessed its existing capabilities, and quantified the benefits of expanding two pilot sites into a company-wide smart factory approach. The company projected approximately US\$50 million in year-over-year operational expense reductions on a US\$700 million baseline.



The US pharmaceutical company Eli Lilly and Company has five manufacturing plants under construction endowed with highly automated systems that learn and self-tune throughout the production processes, offering automatic notifications to technical support, says John Neal, associate vice president, manufacturing strategy. The company hired 1,800 people for its manufacturing operations in 2022 with a digital-first focus governing the recruitment process.

Neal says the smart factories approach demonstrates how life sciences companies are taking an end-to-end approach to embed next-generation technology in different parts of their supply chains.

“Utilizing the latest manufacturing technology throughout the supply chain enables Lilly to impact more patients at speed,” Neal says. “We use that sentiment as our north star for recruiting, hiring and educating our workforce to ensure we’re meeting the needs of patients who rely on our medicines.”¹⁵



Sustainability: The long-term view

Circularity is becoming a prerequisite for supply chain design among life sciences companies.

The global supply chain network of life sciences companies includes the R&D facilities, manufacturing plants, and transportation channels that eventually help products reach patients and consumers. To put this massive network into perspective, consider that the estimated market for pharmaceutical drug delivery is expected to grow from US\$1.17 trillion in 2022 to US\$1.45 trillion by 2028, representing a compound annual growth rate of 3.6% during the forecast period.¹⁶

Leaders at life sciences companies are actively discussing how to move growing quantities of goods while maintaining supply-chain sustainability over the long-term. There is broad industry consciousness on the issue as seen through the Science Based Targets initiative (SBTi), which seeks to limit global warming through corporate commitments. As of February 2023, 88 pharmaceutical, biotechnology, and life sciences companies had submitted targets.¹⁷

To fulfill such commitments, life sciences companies are embedding sustainability as a supply chain advantage. They're starting by focusing on Scope 3 emissions – those that result from activities or assets not owned or controlled by the organization, such as waste, end-of-life treatment of sold products, or business travel.¹⁸ Transportation and distribution, which also fall under Scope 3, are driving some life sciences companies to consider shifting from air freight to ocean travel. An MIT study found that based on emissions generated by moving one ton of goods per mile, long-haul air freight generates 47 times as many emissions per ton-mile as ocean freight.¹⁹ What's more, Life Sciences companies are building in sustainable supply chain material, network and manufacturing choices earlier in the development process so that the impact is measurable by the time pipeline reaches commercial manufacturing and distribution.

Merck, the global pharmaceutical company, is attempting to move 90% of health care shipments from air transport into ocean freight to reduce carbon emissions. Between 2019 and 2020, switching from air to sea freight helped the company to reduce CO₂ emissions by 5,000 metric tons.²⁰

AstraZeneca also incorporates sustainability as a key component of their supply chain. The company is reducing its water footprint and total waste by leveraging a circular economy approach and implementing lean manufacturing techniques, such as limiting freshwater use for drug development to sources within site boundaries whenever possible.²¹ As part of the company's Sustainability Partner Guide and Framework, it assigns sustainability assessment scores to suppliers that meet certain thresholds such as the use of renewable energies such as biomass, solar, or wind across global operations.²²



"We're taking bold action on climate because there's a strong connection between a healthy planet and healthy people", says Arun Krishnan, Global Supply Chain Planning, AstraZeneca.²³



Industry-wide efforts are also underway to improve supply-chain transparency. The Pharmaceutical Supply Chain Initiative (PSCI) is a global coalition of more than 45 pharmaceutical and health care companies focused on safety, environmental, and social outcomes across supply chains. Meanwhile, the Energize collaboration of global pharmaceutical companies seeks to boost renewable energy access for hundreds of pharmaceutical suppliers – equipping the companies with expertise and resources to vie for electricity purchase power agreements.²⁴

The push for sustainability is also driving life sciences organizations to avoid inventory imbalances when available supply doesn't match demand. Some inventory management applications rely on "base stock" policies in which inventory of a certain product triggers an order – potentially creating excess inventory if demand drops after an order is processed.²⁵

When demand is uncertain, companies can consider a replenishment model in which products are made to stock and manufacturers check inventory levels of finished goods on a continuous basis, schedule production to prevent shortages, and keep raw materials on hand as needed.²⁶ This type of strategic inventory process allows life sciences organizations to ensure the supply of their critical medicines while also avoiding excess inventory.²⁷

Geopolitical security

Geopolitical conflicts are necessitating vast new security capabilities among global life sciences companies.

Achieving supply chain resilience in the face of complex global disruptions is a far greater challenge than solving for economics or logistics. The existence of geopolitical threats such as trade wars, cyber risk, and inflation have made supply chains more interdependent and critical to national security.²⁸

In response, some life sciences companies are using blockchain – a digitally distributed, decentralized, public ledger system – for anti-counterfeiting, genomic, and clinical data sharing, revenue management, and materials transfer. For instance, Novartis and Merck are exploring blockchain to improve supply chain security and improve communication by ensuring that patients receive more accurate, up-to-date information by supplanting the paper inserts with digital ledgers.²⁹

Promoting supply chain visibility, industry partnerships, and distribution agility across national and regional markets is another key goal of life sciences companies. Consider that approvals of one medicine in a particular market may encounter regulatory challenges in another. Multiple countries are expected to phase in requirements for pharmaceutical barcoding, serialization, and reporting through 2025.³⁰ By inserting these new requirements into the supply chain in the present, life sciences companies can increase compliance and efficiency over the long term.

Supply chain considerations for life sciences organizations

- How are you capturing changes in demand, delivery, and consumption across your supply chain?
- What upgrades can you make in the short term to realize immediate value?
- How have you incorporated principle of trust in supply chain systems?
- How are you balancing human and machine inputs in your digital supply chain systems?
- What are the biggest training gaps that are holding back your team?
- How can you institute more circular practices within the supply chain starting from product development stages?
- Are you deploying effective strategies in order to integrate, unify, and standardize data from different sources?
- Is your talent strategy flexible enough to keep up with rapidly changing needs?
- Where can you easily scale supply chain innovation for system-wide impact?
- How would you grade your supply chain governance strategy?



Pricing and reimbursement

Historic global shifts in drug pricing and pharmaceutical reimbursement policies are colliding with intensifying competition to boost market access in the race to produce innovative therapies. Life sciences companies are responding to these commercial pressures through dynamic pricing techniques in which prices fluctuate based on real-time data such as customer demand; robust data analysis of market data to identify trends related to reimbursement and coverage decisions; and portfolio management approaches that account for a growing number of specialized treatments for a range of ailments.¹

In the US, life sciences leaders are developing new commercial strategies to address the pricing impact from the 2022 Inflation Reduction Act (IRA), which includes provisions aimed at lowering out-of-pocket costs for patients. These maneuvers are arising as pharmacy benefits managers anticipate a surge of biosimilar drugs that are expected to hit the market, offering an opportunity to lower drug prices through 2024 and beyond.²

At the same time, pharmaceutical companies worldwide are reconfiguring their commercial teams to better understand niche diseases such as genetic disorders through hyper-targeting of patient populations. These developments are reshaping tactics in the life science sector as companies reposition pricing in an increasingly competitive landscape.

Across non-US markets there's also a recognition of the increasing pressure on pricing and equitable access to treatments. The Access to Medicines Foundation, a non-profit that monitors the pharma sector's progress in addressing access to health care in more than 100 low- and middle-income countries, is tracking increased global awareness and demand for addressing inequities in health care, such as a need for greater regulatory harmonization in Sub-Saharan Africa.

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“There's definitely more awareness among different stakeholders on the issues of global inequity,” Jayasree K. Iyer, CEO of the Access to Medicines Foundation. “Products are available, but they're not available for people who really need them in resource-limited settings. So, awareness has definitely crept into the industry, investors, and governments to better demand leadership from companies.”³

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Confronting pricing uncertainties

One of the most significant pricing changes came under the IRA in the United States, which for the first time empowers Medicare, the US national health insurance program, to negotiate drug prices and compels drug makers to pay inflationary rebates. The number of drugs it can negotiate is limited, but the impact could be outsized as the IRA allows Medicare to negotiate prices of some of the most expensive drugs. The IRA will also cap Medicare patients' out-of-pocket expenses to about US\$2,000 a year. It's the most consequential legislation addressing drug costs since the passage of the Medicare Modernization Act in 2003, which established the original drug benefit.⁵

The IRA, as written, will cap Medicare Part D out-of-pocket drug costs for beneficiaries at US\$2,000 by 2025. Life sciences companies can negotiate drug prices through the end of the decade, but the law will have specific implications for high-cost medications. Drug makers will need to assess the financial impact, conduct negotiations with the US Centers for Medicare and Medicaid Services (CMS), and adjust agreements with customers. According to the current changes, the law empowers Medicare to negotiate prices for 10 drugs in 2026, which may increase to 60 by 2029.

We anticipate the sector will consider arguing that the government acted beyond its statutory authority. Another: Claiming that the IRA runs afoul of the US Constitution's Eighth Amendment, which protects against excessive fines. One provision in the IRA allows the government to levy an excise tax of up to 95% on drug companies that don't comply with price negotiations.⁶

For now, the sector is confronting lower prescription costs for Medicare patients as drug pricing provisions take effect in 2023.⁷ Among the drugs that could be affected are the anticoagulant Eliquis, manufactured by Bristol-Myers Squibb and Pfizer; Eli Lilly's diabetes medicines Trulicity and Jardiance; and the cancer medicine Imbruvica from AbbVie and Johnson & Johnson.⁸ In 2020, Medicare spending on these four medicines totaled US\$18.6 billion across more than 3.7 million beneficiaries.⁹

Drugs without a single source and competing products that are approved and marketed will not be eligible for negotiation. Small-molecule and biologic drugs derived from living sources are exempt from negotiation until they have been on the market for nine years and 13 years, respectively, which could limit the law's incremental impact on drug sales.¹⁰ These drugs will be excluded from negotiation until generics and biosimilars are available.

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Richard Saynor, CEO of Sandoz, the Swiss pharmaceutical company said, "True innovation is about giving people access to high quality generics and biosimilar-originated products in a fair and transparent way."

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Promoting flexible pricing approaches

As a result of the IRA drug pricing provisions, Medicare may broaden its acceptance of value-based pricing, which some health providers already offer. For instance, Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other providers that deliver coordinated high-quality care to Medicare patients. These organizations treat almost 20% of Medicare Advantage and about one-third of traditional Medicare patients.¹²

Adopting similar pricing for prescription drugs, however, would require an independent assessment of clinical value that would determine payment, rather than current models that define payment by the manufacturer's list price.^{13,14}

Many companies have called the IRA reforms an attack on innovation. AstraZeneca CEO Pascal Soriot warned that the negotiation requirements could inhibit patent protections under which pharmaceutical companies can recoup drug development investments over a decade. Soriot has also called the law an "imposition of price" rather than a negotiation.¹⁵ Eli Lilly attributed its decision to stop development of a US\$40 million cancer drug to the IRA.¹⁶

Despite these concerns, companies such as the Swiss pharmaceutical firm Novartis have said they will continue to invest in the US, the world's biggest pharmaceutical market.¹⁷

Tailoring pricing and reimbursement to regional markets

Creating policies on drug pricing and reimbursement depends on factors such as health records, competition, and profit margins.^{18,19} For instance, a study of almost 60 Dutch health care decision makers found they were less likely to reimburse products with higher margins, with 61% of respondents saying profit margins should play a role in reimbursement decision making.²⁰

To more accurately assess health care costs and benefits, markets such as the European Union (EU), the UK, and Australia use health technology assessment (HTAs). The tools provide recommendations on medicines and other health technologies that can be financed or reimbursed by members. HTAs consider a drug’s initial price, target population, and clinical effectiveness in determining its value.²¹

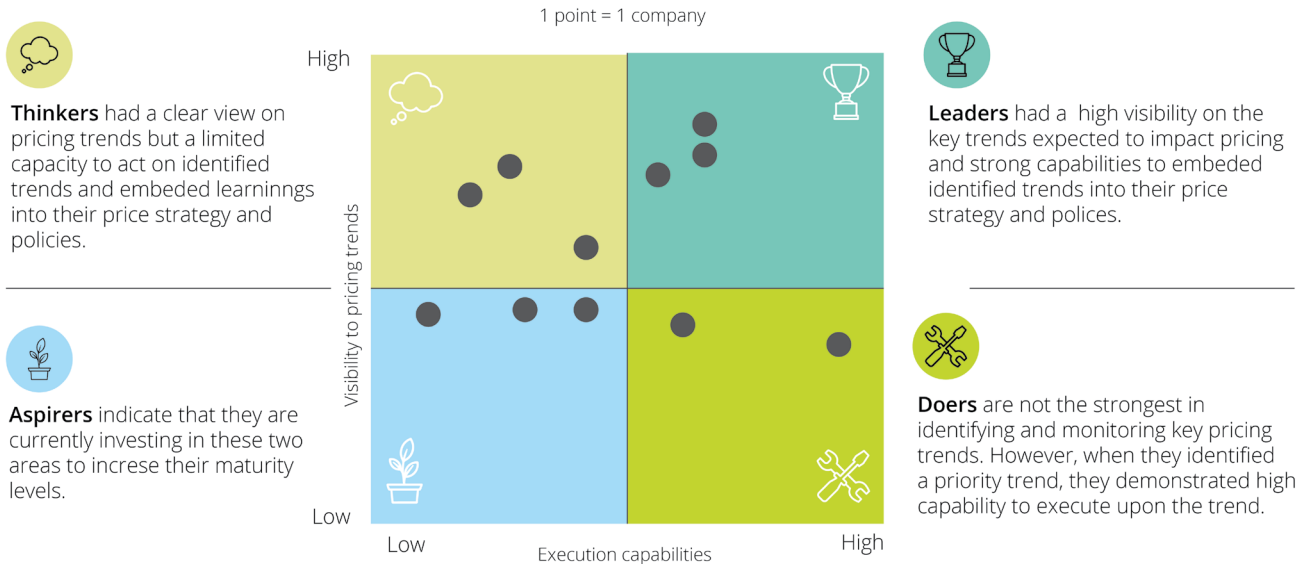
Beginning in 2025, the EU will require that pharmaceutical manufacturers align their clinical development programs with HTA requirements to improve clinical value, pricing, and reimbursement.²²

In the nearer term, the European Commission is actively discussing plans to bring medicines to patients underserved parts of the EU by trimming two years from exclusivity agreements. The EU legislation would allow pharma companies to earn back one or both years of the protection if they agree to launch the medicine in all areas of the political bloc – with significant implications for price negotiations for companies that wish to delay the entry of generic competitors to the market.²³

To prepare for these new pricing rules, life sciences companies are incorporating pricing and market access decisions more consistently and earlier in the product development process (Figure 1). The US Food and Drug Administration (FDA) offers guidance to manufacturers for communicating economic information before receiving marketing approval.²⁴ The process creates more comprehensive planning and budgeting for new therapies.

Figure 1. Pharma perspectives study on visibility into pricing trends and execution capabilities.

Four archetypes emerged from the study:



Source: Deloitte analysis

One measure for addressing shifts in drug pricing involves balancing a country's ability to pay with the individual needs of patients. Some pharmaceutical companies are using data analytics to predict local market responses to specific products. For instance, the biopharmaceutical company Amgen, working with local health systems, is using digital capabilities and advanced customer data and analytics to predict customer responses. This approach has also allowed the company to establish access closer to regulatory approval.²⁵

AstraZeneca relies on tailored payment models, such as Tiered Pricing, which is based on Gross National Income. The company has also prioritized value-based agreements to align cost with economic prosperity, clinical benefits, and other predetermined conditions. AstraZeneca also considers factors including national budgets, health economics data, and gross domestic product (GDP) when considering a government's ability to pay.²⁶

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“These agreements allow us to make sure that you know the right medicine is being given to the right patient at the right time in the right setting,” according to Ana Plata, Global Pricing Head, BioPharmaceuticals, AstraZeneca. “It’s becoming much more common to discuss the impact our medicines are having on health care systems and make sure that patients indeed have timely access to those medicines we’re providing.”²⁷

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In China, health care reforms are improving access to quality drugs, and life sciences companies are aligning their reimbursement strategies to gain access to the National Reimbursement Drug List (NRDL). The NRDL, which went into effect in January 2022, includes more than 2,800 drugs - more than 1,400 of which are Western-made and the rest from Chinese patents. The average negotiated price decrease across all drugs is 61.7%.²⁸

China prioritizes domestically produced drugs for the NRDL, but it's more likely to add foreign manufacturers of rare disease treatments to the list because of a lack of homegrown alternatives.²⁹ Multinational companies such as Pfizer, AstraZeneca, and Biogen recently reduced drug prices by more than 50% to secure a place on the NRDL. Despite the reduced prices, companies can take advantage of a large population to offset the lower margins. Through this strategy, AstraZeneca expects that new treatments will contribute to about 60% of its China revenue by 2024.³⁰

Marketing specialized, next generation therapies

The comparatively high cost for treating diseases that affect a small population, is one of the key pricing challenges for this group of medicines. Consider that the average annual cost of orphan treatments, designated in the US as a drug to treat, prevent, or diagnose a disease affecting fewer than 200,000 people.³¹ That figure was US\$32,000 per patient, with 39% costing more than US\$100,000 annually, according to a 2022 literature review and interviews with health plans and pharmaceutical manufacturers.³² As a result, the growth in specialized, next generation therapies requires its own type of commercialization strategy for pricing and reimbursement.

For instance, commercial teams must be conversant in niche disease areas to engage the right stakeholders. Some are bringing in health economics and outcomes research (HEOR) professionals to support commercial teams by combining commercial and pricing strategies with clinical knowledge.³³ Novartis and Takeda, the Japanese pharmaceutical company, are hiring third-party HEOR professionals, while other companies are upskilling their existing sales teams or tapping external HEOR consultants.³⁴

In 2021, the European Commission launched an open public consultation to consider revising legislation on pediatric medicines as well as treatments for rare diseases. The move came after a prior evaluation showed that while regulations had spurred research and development, there continued to be shortcomings in areas of unmet need, as well as a lack of accessibility to treatments for all EU patients.³⁵

Pursuing specialty and curative therapies often requires companies to spend a disproportionate amount time on a comparatively smaller patient population. Yet payment models often depend on delivering that outcome over 10 to 15 years. Therefore, some companies either accept payment later or give rebates if the patient enters remission or dies. This makes it difficult for companies to know how much they may have earned at any given time.

For example, if a company spends US\$500,000 a year for 50 years on hemophilia factor therapy, compared with a US\$3 million gene therapy that cures once, the two approaches require vastly different business models for investing in curative treatments with upfront payments, as opposed to long-term chronic treatments.

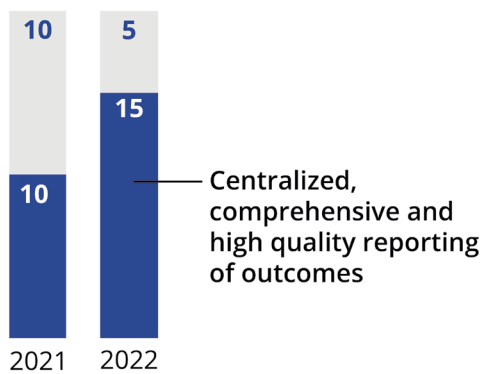
The rise in transformative therapies not only changes the modality from treatment to cure but also fundamentally changes the dynamics around pricing, requiring creative commercialization strategies as new treatments take center stage.

Managing implications of pricing trends and transparency

To increase drug access, life sciences companies' have potential legal hurdles and reputational risks. In the decade since Vermont became the first US state to pass a drug price transparency law, more than 20 other states have put price taken similar action, adopting provisions for price increase notification, price reporting, or budget controls. Pharmaceutical companies must keep up with a patchwork of rules or risk substantial fines: Nevada issued more than US\$17 million in penalties against non-compliant companies in 2019, while California fined companies more than US\$28 million for reporting violations the same year.³⁶

In its annual review of equitable access and pricing transparency, The Access to Medicines Foundation asserts that in a future pandemic, the governments should work with companies to create procurement agreements that are transparent with equitable pricing and global access. The foundation's Access to Medicine Index also stresses the importance of sharing knowledge to reduce disparities in access to medicine (Figure 2).³⁷

Figure 2. More companies are increasing transparency about their access-to-medicine activities



Source: 2022 Access to Medicine Index.



“We see a lot of debate in the global context around R&D, cost, and transparency, and we're really only at the foothills when I think of value-based pricing,” says Richard Torbett, chief executive of the Association of the British Pharmaceutical Industry. “We're only now starting to see the technology starting to come through in terms of data capture and access in health care systems to fuel genuinely value-based approaches. There's an exciting future there.”³⁸



Pricing and reimbursement considerations for life sciences organizations

- How are we integrating pricing and access trends into our early clinical development decisions and data strategies?
- How can we communicate pricing updates while highlighting real-world evidence?
- How can we assure rapid access to market data to quickly identify trends related to coverage decisions?
- How can we ensure pricing transparency and more effectively manage our reputational risks in regard to pricing?



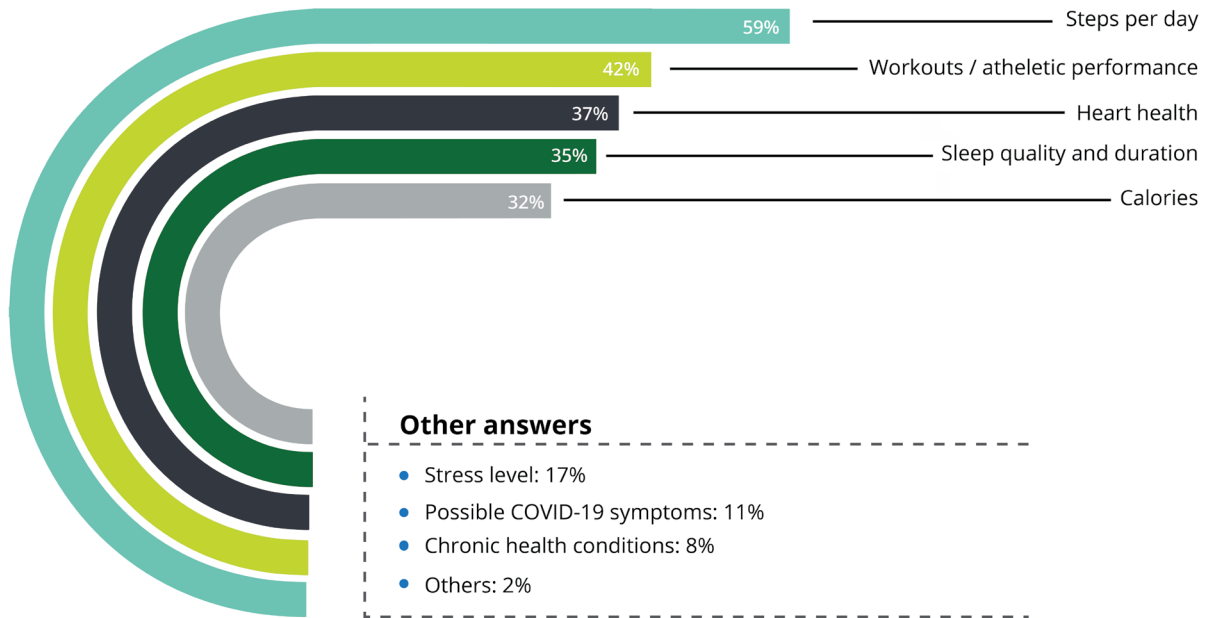
Patient centricity

Habits, capabilities, and data have all changed significantly in the last year. Three-fourths of people around the world now have experience with at-home tests for a global virus, and companies are increasingly able to access, interpret, and act on the billions of patient data points. And patient expectations and their ability to voice them have risen. The conditions for true(r) patient centricity are here.

On a given day, people actively participate in their own medical plans, treatment, and disease research across millions of touchpoints in the patient journey. There are more than 435,000 active clinical trials underway across the globe, and more than two million different types of devices spanning more than 7,000 groups of instruments, machines, and software used for medical purposes.^{1,2} To help capture the increasing amount of data from these inputs, devices such as fitness trackers provide around-the-clock monitoring (Figure 1). Together, these insights are propelling life sciences enterprises toward the next frontier of patient-centricity: the deployment of decentralized diagnostics and direct-to-consumer channels and solutions, the gathering of real-world information from wearables and sensors, and the creation of new digital alliances to achieve optimal patient outcomes.

Figure 1. Using health and fitness trackers to count steps, calories and more

Which of the following do you use your smartwatch/health and fitness tracker to measure?
 Respondents selected all that applied.

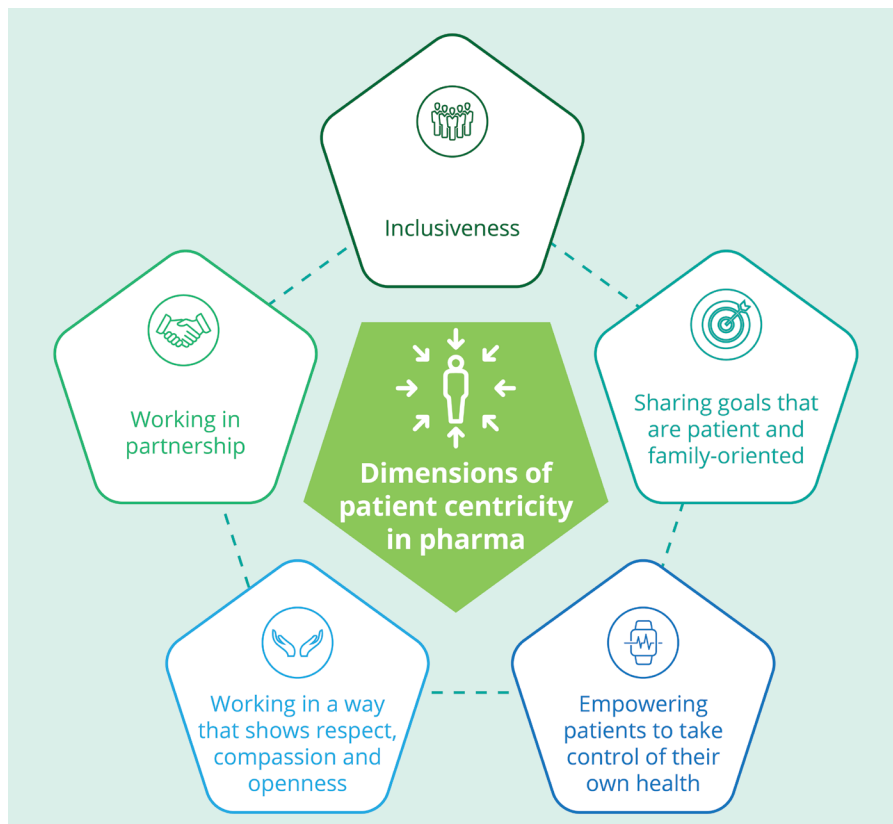


Source: Deloitte’s Biopharma Digital Innovation Survey 2021

With the connected health care ecosystem, life sciences companies can expand their patient-centric ambitions beyond drug and medical device manufacturing. Increasingly, pharmaceutical companies and medical technology developers are collaborating with third parties to create more digitally interoperable systems and thus getting closer to 360° of patient understanding and experience. This focus on improving the patient experience also can help identify patient populations that might be undiagnosed or misdiagnosed, empowering people to have better conversations with doctors about treatments.

In building a strategy to enhance their understanding of patients, companies are making targeted investments in technology that can tailor product offerings and navigate complex rules as they learn what patients are experiencing – and what they’ll need in the future (Figure 2).

Figure 2: Pharma companies are now facing up to the need to frame their patient-centric strategies for operating in a new customer-centered, digital ecosystem.



Source: Deloitte analysis

Decentralized diagnostics

Thanks to virtual checkups and smartphone-enabled diagnostic tools — and with COVID pandemic habits now increasingly entrenched — fewer patients are visiting centralized care sites. Instead, life sciences companies can collect data through personal devices from the comfort of a patient's home. In China, where 95% of the population is covered by social health insurance, the private supplementary insurance that was introduced in 2015 is emerging and helping reduce the financial burden of severe diseases such as cancer.³ By 2019, nearly all 31 provinces and municipalities in mainland China had established regional telemedicine centers, as the country aims to resolve the unequal allocation of health care resources.⁴

As “hospitals without walls” become more prevalent in health care, life sciences companies can use the innovations to collect real-time diagnostic information. The US-based medical equipment company ResMed has an outcome-based reimbursement strategy for its digitally connected sleep apnea machine. The strategy aims to increase adherence and improve patient outcomes; patients who are both remotely and self-monitored using cloud-connected devices are 87% compliant, compared with 50% to 60% on non-connected devices.⁵

As life sciences companies advance patient-centricity, many are exploring “real” direct-to-consumer (DTC) channels. DTC enables direct patient engagement when and where they seek it. The US-based medical technology company Becton, Dickinson and Company, also known as BD, acquired privately held Scanwell Health Inc., which makes smartphone-enabled at-home medical tests, and wants to expand the availability of diagnostic tests for an array of infectious diseases.

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“The COVID-19 pandemic has accelerated the shift to new care settings, and BD is ready to deliver a smart, connected at-home diagnostic ecosystem to support traditional and telehealth providers and consumers,” Dave Hickey, president of Life Sciences for BD, said when the transaction was announced.⁶

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Drug discovery and development

Wearable devices comprise another realm of active exploration and investment for life sciences companies as they seek to broaden access to clinical trials and gain more real-time data in a more patient friendly way. Companies can collect data by using biosensors and wearables to generate and track digital biomarkers.



“The digitization and visualization of individual lifestyle data will dramatically accelerate patient-centered drug research and development,” Ceri Davies, Head of Neuroscience Drug Discovery Unit at Takeda, said in a statement about the expected outcomes of the research. “Combined with this, we hope to develop new methods of utilizing big data, which will not only lead to the creation of high-precision pharmaceuticals, but also contribute to medical care tailored to the characteristics of patients.”



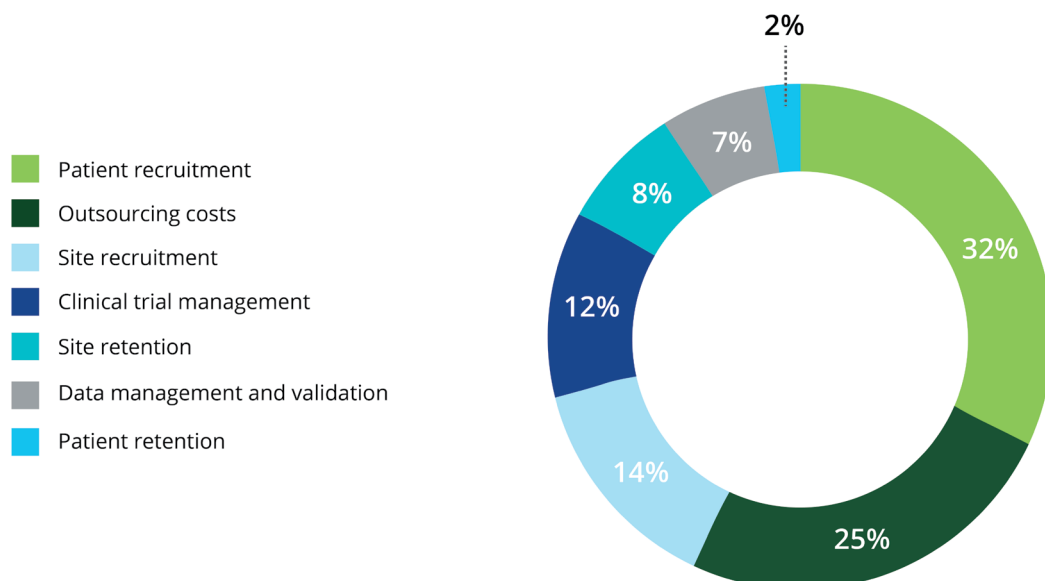
In a multi-year arrangement, Johnson & Johnson’s Janssen pharmaceuticals division is licensing physIQ’s accelerateIQ™ platform to collect data across clinical studies using wearable biosensors. The collaboration allows the companies to perform continuous biosensor data collection, processing, and analysis while across discrete sensors, data types, and algorithms – enhancing the opportunity to create real-world insights for patients.⁸

At Tohoku University’s Tohoku Medical Megabank Organization in Japan, the pharmaceutical firms Daiichi Sankyo and Takeda, and the medical IT company MICIN, are using a wearable device to track long-term lifestyle habits of 2,000 subjects through 2025, to create new drugs. The device captures sleep status, heart rate, and other activity levels that can be tough to pinpoint through self-reporting.⁹

In 2022, AstraZeneca tracked fluid volume in clinical trials for patients with chronic kidney disease using the medical software from Impedimed’s SOZO system. The platform is designed around patient-centricity, measuring fluid status in less than 30 seconds. The platform helps provide early detection of secondary lymphedema, indicates fluid status for patients living with heart failure, and processes results immediately for online access and sharing across the entire health care system.¹⁰

The number of clinical trials has grown by more than 400% since 2010.¹¹ Recruitment, however, remains a challenge for discovery research (Figure 3). A study on the benefits of virtual randomized clinical trials shows that more than 80% of in-person studies are delayed because of insufficient patient recruitment, while 80% of research sites fail to meet enrollment goals. The study found that accessibility is a key barrier to participation, as 70% of the patients live more than two hours from a research institution, and 30% of participants drop out before the conclusion of clinical trials.¹²

Figure 3. Cost drivers in clinical trials



Source: Deloitte Analysis

The emergence of remote and virtual-participation trials is one method pharmaceutical companies are using to be more cost-efficient and to address patient barriers to traditional trial designs.

In 2021, the Swiss multinational health care company Roche developed the first virtual rare-disease clinical trial. The company wanted to test a new molecule for cancers with a specific genomic alteration in a range of tumor types, but only found in about 0.2% of all cancers. Capturing a statistically significant sample would mean screening 25,000 patients to enroll 50 patients for an in-person trial over a decade. Instead, the company used a virtual approach to remove geographical barriers – relying on virtual collaboration between the lead researcher and local medical teams and monitored through home visits.¹³

In an attempt to ease some of these barriers, this year the French multinational pharmaceutical and health care company Sanofi announced a partnership with the US consulting and technology provider THREAD, which will serve as the sole provider of unified decentralized clinical trials. The objective is improving access to customized clinical trials by providing a uniform experience for patients, investigators and sites where trials occur.¹⁴

In countries or regions where privacy laws and social norms render some of these approaches unfeasible, life sciences companies may need to adjust their approach. For instance, in 2021, a new EU regulation expanding the definition of “medical device” took effect, with a requirement that the product or service be certified by the appropriate regulatory authority. A subsequent EU regulation in 2022 introduced stricter controls before devices could be taken to market, highlighting the steps life sciences companies should consider when designing patient-centric products and services.¹⁵ Also in 2022, the US Food and Drug Administration issued new guidance on medical device data systems, signaling intensifying scrutiny of software, security, and device effectiveness.¹⁶

Patient-centric partnerships for better diagnostics, experiences, and outcomes

The diagnostic data collected by life sciences companies emanates from across a spectrum of locations, and many medical device companies need functional expertise or even third-party expertise to help organize the findings and share them with clinical professionals. Digital partnerships comprise another approach that life sciences companies are embracing to enhance their patient-centric offerings.

For instance, a major collaboration among the pharmaceutical companies AbbVie, Janssen, Novartis, Pfizer, and UCB is providing a “digital” endpoint for atopic dermatitis, which causes nighttime scratching and can affect sleep quality. The collaboration is developing an alternative for capturing patient-reported outcomes, which currently are gathered through passive, unsupervised monitoring. By developing a “digital” endpoint, the team hopes to gain a more precise understanding of the condition and reduce the time and cost to commercialize new therapies.¹⁷

In another collaboration, Biogen Inc., and MedRhythms are developing and commercializing an investigational, prescription digital therapeutic aimed at improving gait deficits in patients with multiple sclerosis (MS).¹⁸ A significant share of MS patients have a walking impairment. The MedRhythms technology includes sensors on shoes to detect walking gait, relaying the information to a smartphone app that can adapt the music to match rhythm in real-time.¹⁹

Other companies want to improve patient health by predicting the likelihood of future health implications. The US-based data platform DNAnexus, a cloud-based genomic and biomedical data access and analysis software, allows scientists to analyze large data sets. Another US-based health intelligence company, Human Longevity, has used the DNAnexus platform to collect and analyze data from whole-genome sequencing, imaging, and different biomarkers to create data-driven personalized health platforms.²⁰

Meanwhile, MolecularYou, a Canadian biotechnology research company, has created a health assessment blood test kit and associated app that can produce a unique health report with more than 200 biomarkers, offering insight into current and future health risks. Molecular You can identify early biomarkers outside of normal ranges and provide interventions to help normalize them before chronic symptoms and disease occur.²¹ The technology uses nutrition and exercise modification research to develop action plans to normalize biomarkers detected outside of normal ranges – information that provides users more comprehensive analyses of their health before as they age.²²

Prescription-based digital therapeutics are also contributing to patient-centricity by improving safety signaling and medication adherence – all through connected devices. Akili, the US-based prescription digital medicine company, has developed an

ADHD treatment for children ages 8 to 12. The treatment uses video games on mobile devices, targeting areas of the brain that help regulate attention function. As an FDA-authorized medical device, the EndeavorRx digital therapeutic has helped 68% of patients improve in ADHD-related impairments after two months of treatment. Meanwhile, 73% of children using the tool reported improvements in their attention.²³

The technologies are also being used to help patients quit smoking. Click Therapeutics' Clickotine is a digital therapeutic that uses a mobile app integrated with nicotine replacement therapy. Thirty percent of study participants achieved 30-day sustained abstinence from smoking.²⁴

An analysis of the only FDA-authorized prescription digital therapeutics for chronic insomnia, showed both real-world health care resource use reductions as well as cost savings compared with sleep medicines alone. Patients using the therapeutic could save more than US\$8,200 over 24 months, compared with insomnia medications alone.²⁵

This type of real-world data curation enables life sciences companies to more precisely target patient cohorts that would benefit from their therapeutics. Optum, the US pharmacy benefit manager, offers access to real-world data for use by various life sciences teams, including epidemiology and commercial, health economics, and outcomes research. The company's electronic health record data comprises more information from more than 100 million unique lives, allowing researchers to examine treatment patterns and outcomes for specific populations.²⁶

By focusing on technologies that enhance the interoperability among distinct entities, life sciences companies can create a digitally interoperable ecosystem, improving patient care. To be clear, patients themselves who play an outsized role in their care – interacting with health care providers on a limited basis while they manage medications and cope with the stress of an illness – giving life sciences companies additional incentive to understand the drivers of patient behavior.²⁷

What's more, full digitization may only be worthwhile if patients are receptive to sharing sensitive personal information. A Deloitte survey in Switzerland revealed a trust crisis among health entities, with 62% of respondents saying they didn't want their health data shared with private companies under any circumstances.²⁸

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“When we think about all these things in med tech whether they're wearables, whether they're devices, whatever they are, they seamlessly need to fit into a patient's life, and then they seamlessly need to fit into the clinicians or the hospitals,” says Keith Boettiger, President, Abbott Heart Failure. “A lot of what you see in med tech today is somebody using engineering to solve the problem. But it's not ideal for the patients, not ideal for the physicians or ideal for the hospital. We need to develop devices and workflows that make the data easy to see and put it in the hands of patients so they can take action and manage their own care.”

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Patient-centric considerations for life sciences organizations

1. Where are the opportunities to broaden existing alliances to help patients navigate the health care ecosystem more easily?
2. How can we deliver more personalized content?
3. How can we identify at-risk reaching patients and ensure they get access to our services and products?
4. How can we adopt a direct-to-consumer approach?



Digital transformation

COVID-19 has had a profound impact on the life sciences sector, including the digital transformation that it ushered into the sector at scale and in some cases overnight. Before the pandemic, life sciences organizations, which include biopharma and medtech companies, lagged other industries in digital innovation. However, as COVID-19 spread, they quickly embraced a variety of technologies that allowed them to run their businesses remotely or virtually.¹ Innovation projects that had been on the books for years received funding and advanced rapidly. Now three years later, we can see the impact of this digital transformation: what works, what is still in progress, and what remains elusive.

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“Digital innovation has been accelerated by 10 years by what has happened over the course of the last 18 months,” said Manoj Raghunandan, President, Global Self-care and Consumer Experience, Johnson & Johnson.²

Alex Gorsky, the company’s former CEO and Chairman, goes further: “I can’t think of a more exciting time. I’ve never seen the kind of opportunities now where we’re seeing science, technology and innovation accelerating at such a rapid rate.”³

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During the pandemic, cloud technologies and platforms gave organizations the scale and flexibility to enable employees to work remotely and collaborate, which includes storing and sharing data across third-party networks and enabled by artificial intelligence (AI) and machine learning (ML) algorithms. Cloud technology also helped reduce costs, improve time-to-discovery and insight, and collect data to improve manufacturing and supply chain operations. At the same time, pressure to develop vaccines and therapies required competitors to become collaborators and share digital information.

Technology that was still in the planning stages in 2020 is now an integral part of many life sciences companies heading into 2023.

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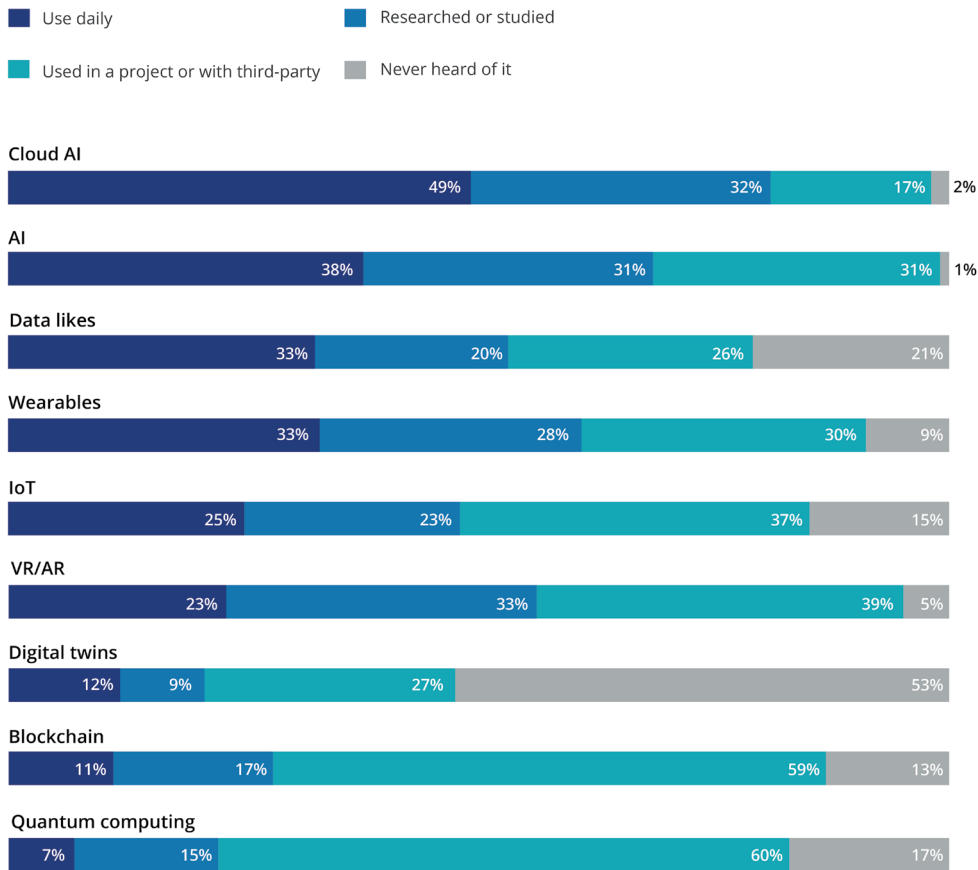
“A few years ago, we were all talking about Data and Digital as a concept. Today, we’re talking about how it drives value in the operations and innovation engines of our company,” says Gregory Hersch, senior vice president for enterprise strategy and venture for Merck. “And now, we need to start scaling these innovations across products, countries, and operations.”⁴

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However, not all technology has been adopted equally. Biopharma companies have embraced cloud platforms, AI, and wearables more than the Internet of Things (IoT) or blockchain (Figure 1). Nevertheless, the pandemic has fundamentally changed how these companies view digital solutions, and those companies that continue to embrace innovation will gain a competitive advantage in the years ahead over the competitors who do not.

Figure 1. Biopharma’s experience with digital technologies is highest in cloud, AI, and wearables

Which of the following best describes your experience with each digital innovation technology within your organization?



Source: Deloitte’s Biopharma Digital Innovation Survey 2021

Among leading biopharma and medical technology companies, digital solutions that were once seen as long-term projects for CIOs, are becoming vital to business operations. Life sciences organizations are now focused not on the technology itself, but how it’s integrated into the business.

“*Innovation tightly integrated into operations has worked that best,” Hersch says. “The things that we’re still waiting to see really gain traction are the ones that are farther away from operations.*”⁵

For example, biopharma companies are using data to improve site selection for clinical trials and the oversight of supply chains, both of which have been effective. Technology further removed from operations, such as applications for patient safety, have been slower to advance.

The pandemic accelerated the application of digital solutions to optimize how work is done across the pharmaceutical and medical technology value chain. Initially, limitations on physical interactions drove demand, but patients preferred many of the digital solutions, and as payers reimbursed for them, it expanded capacity and reduced no-show rates. Technology in this environment has less to do with transformation than with making processes faster and less expensive. Below is a sample of how new and emerging technologies are helping industry players optimize:

Software-as-a-Service (SaaS): In clinical development, companies are using SaaS platforms to simplify operations such as revenue and vendor management and to track data on clinical trial participants. The industry is adopting an analytics-driven approach to support price management and tender processes, which helps in improve decision-making and optimize resource allocation.⁶ Software is generating value in areas such as drug discovery as biopharma organizations look to cut research costs, shorten timelines, and improve transparency. The market for life sciences software is expected to reach US\$18 billion by 2025 from US\$11 billion in 2020.⁷

Artificial intelligence (AI): Biopharma companies are adopting AI for clinical and patient data analysis, supply chain and logistics management, physician understanding and predictive behavior analysis. In addition, they are using it internally to analyze and predict employee behavior, especially for ethics and compliance. AI can enhance drug design, improve quality checks, and provide predictive maintenance for manufacturing operations. It can also identify appropriate subjects for clinical trials by analyzing claims data. Even though the tech industry is currently experiencing disruption, we expect we will see more life sciences organizations collaborating with tech companies as they have in the past such as Google Health, Enlitic, and Owkin to use AI to improve clinical trial design and automate manufacturing processes.⁸ AI can also be used to predict failure rates in medical devices.

We also are seeing broader adoption of AI in parts of clinical practice and workflow. As this accelerates, it will have additional implications for how life sciences manufacturers work with care providers. For example, if AI solutions become a broadly accepted tool in a clinician's approach to screening, it will have implications on study design, endpoints, and data strategy.

Internet of things (IoT): Smart sensors and smart meters will monitor real-time data to improve product efficiency, increase supply chain visibility, and enhance operational effectiveness. These devices and other linked IoT elements can bring greater efficiencies to manufacturing, packaging, warehousing, and other aspects of supply chain management. The prevalence of IoT services offers biopharma and medtech organizations the chance to optimize costs by streamlining supply chains, analyzing operations, and identifying new value-creation opportunities. Greater visibility of supply chains, for example, could help identify how drugs such as opioids fall into the wrong hands or quickly notify patients of a medical device recall.⁹

Automation: Companies such as Zenith Technology and Rockwell Automation are partnering with life sciences organizations to develop robotic process automation and business process modeling that can automate repetitive tasks, such as documentation at clinical sites, safety processing, and clinical research.^{10,11} Automation can reduce costs for energy and raw materials, while improving product quality and consistency, and promoting safer work environments. It also speeds processing and packaging of pharmaceuticals while reducing human error.

Blockchain: Though not yet as widely embraced across the sector, some life sciences organizations are using distributed ledger technology to improve trust, provide greater transparency, and support patient safety and empowerment. Blockchain can help biopharma companies track counterfeit medicine and simplify supply transactions with hospitals, clinics, and other treatment facilities. Greater visibility of supply chains and traceability of pharmaceuticals and devices, for example, could help identify how drugs such as opioids fall into the wrong hands or quickly notify patients of a medical device recall.¹²

Data lakes: Cloud platforms such as ServiceNow are helping life sciences organizations build control towers or data hubs so that organizations can merge production, inventory, and other internal data with that of intermediaries and partners to provide real-time visibility into material and product flow.¹³

Wearables and AR/VR: The pandemic disrupted many clinical trials because participants could not readily access trial sites. Life sciences companies responded by adopting hybrid study approaches that included delivering medications and wearable technology directly to patients and monitoring and assessing them remotely, resulting in reduced trial cycle times and study protocol deviations that would render results inconclusive. Similarly, travel restrictions forced manufacturing sites to operate with skeleton crews, and companies deployed wearable and AR/VR technologies so on-site staff could configure equipment, manage processes, and troubleshoot. Many companies plan to continue to use these technologies post-pandemic because they can increase data collection without imposing an undue burden on patients or study site staff.

Digital Therapeutics: Web-based applications that help patients with certain conditions, such as diabetes, improve their health and wellness or improve outcomes. Some applications are designed to help patients modify behavior, increase engagement with health care providers, or prevent more expensive treatments. For pharmaceutical and medtech companies, digital therapeutics can differentiate products with less capital investment than R&D. Total investment in digital therapeutics has already topped US\$600 million and the market is still in its infancy. The growth potential has attracted technology giants looking to change the health care landscape, payers applying it to reimbursement models and exploring how the patient data collected through such products can be leveraged to inform coverage, and start-ups that are introducing innovative ideas to attract investors.¹⁴

New threats

The advantages that made digital technology so attractive during the pandemic can also leave companies vulnerable. While a digital strategy can help a life sciences company improve, it also can expose companies to new risks as data starts to flow outside proprietary systems and into data lakes that sit on various cloud platforms.

Law enforcement agencies say pharmaceutical companies are increasingly being targeted for cyberattacks. In the past few years, cyberattacks¹⁵ against biopharma and medical technology companies have disrupted supply chains, hobbled manufacturing processes, erased years of research, and resulted in hundreds of millions of dollars in damages. Cybercriminals likely assume that these companies, and other health organizations, are willing to pay ransoms because their services are critical. The attackers may also be drawn to the industry's trade secrets and intellectual property, its vast stores of personal health data, and its financial resources.¹⁶ At the same time, the cyberattacks raise concerns that hackers also could target implantable devices such as pacemakers, defibrillators, and neurostimulators that are monitored or programmed remotely.

Migrating systems to the cloud or adopting virtual clinical trials can expose companies to new types of attacks. These threats should be considered throughout the process—from requirements for architecture and design to development, testing, and deployment. Gaps can occur when cybersecurity is not integrated from the beginning. Such gaps could be exploited, potentially negating any progress or trust that would have been gained through the new approach.

The risks only increase as digital data becomes more consumable and accessible from multiple platforms and mobile devices, much like banking information. The easier data is to access, the more it needs protecting. This isn't always as easy as it sounds. For example, a company might not know exactly what its data contains if any portion of the data is tagged incorrectly. Companies must ensure that only designated users can access designated data through a designated channel. At the same time, the data must be retrievable for audits or other internal reviews. Companies must ensure that only designated users can access designated data through a designated channel. At the same time, the data must be retrievable for audits or other internal reviews.

About half of US consumers do not trust biopharma companies.¹⁷ As life sciences operate more closely with consumers, patients, and customers, garnering end-user trust can become even more important. Allowing end-users to securely access their data when they want to often is the first interaction a consumer has with the company. Finding the perfect balance of accessibility, while protecting critical information, brings cybersecurity and data protection to the forefront of building and growing trust.

In addition, as technology such as AI advances and becomes used more widely, it invites new risks, such as understanding how AI is deriving its answers and where the data it's using is coming from.

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We really need to understand what biases are already there and how embedded they are in something that is going to propagate those biases for as long as that model is used,” Hersch says “Another point is the data sets we’re using. AI requires massive amounts of data. “We’re often relying on patient source data that has come through third parties. Those third parties have assured us that patient’s privacy rights have been respected in the collection of that data. But how do we really know that is true? And to what standard?”¹⁸

”

Transforming the organization

As the world emerges from the pandemic, the life sciences industry is at a crossroads. COVID-19 has shown companies that they need to embrace digital transformation, and most of them are taking more risks and investing in new technology. Those that don't may be left behind or at least find themselves at a competitive disadvantage. Alex Gorsky's perspective is that "there's not a place in health care from development to even patient delivery ... all these areas which we would usually only equate with Silicon Valley. I think they are going to be ubiquitous in health care in a way we haven't seen."¹⁹

A Deloitte survey of 150 biopharma leaders found that almost 80% said their organizations needed to be more aggressive in adopting digital technologies.²⁰ But simply adopting technology to address specific issues isn't enough. Data, for example, should be considered an asset—one that can be used to improve the business, enhance efficiencies, and develop new strategies and competitive advantages.

As life sciences organizations continue their digital transformation in 2023, they need to move from doing digital to being digital by embracing enterprise-wide digital integration.

This broad, holistic embrace of digital technology cuts across value chains, business units, therapeutic areas, and strategic focus. This means moving from transactional engagements to an insight-driven, value-based enterprise. The transformation should connect and elevate all technology as part of a companywide digital strategy.

Achieving digital maturity

As the challenges of the pandemic ease, life sciences organizations are reassessing their digital strategies and determining what to retain and what to advance to make 2023 the year of digital optimization.

There's much work to do. Deloitte's research has found that only about 20% of biopharma companies are digitally maturing (Figure 2).²¹ And while the adoption of digital solutions has accelerated since the pandemic, life sciences still lags other industries such as banking in its embrace of cutting-edge technology.

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*If we go back to 2017, we were all getting used to the idea of a cloud being a secure place to put things,” Merck’s Hersch says. “The one thing that is different now is ... how embedded tech is in all of our basic processes. But frankly, I’d hoped we’d be much further along than we are today.”*²²

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Figure 2. Digitally mature biopharma companies are most likely to explore new ways of doing business (vs. those in the developing or early stages of digital adoption)

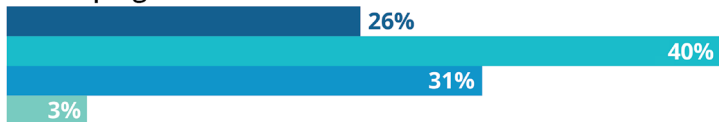
- New business methods
- New business methods and competencies
- Existing competencies
- Don't know

Digital objectives breakdown by maturity

Maturing



Developing



Early



Source: Deloitte Center for Health Solutions analysis of MIT SMR and Deloitte's 2018 Digital Business Global Executive Survey data



Too many companies are still distracted by the “hype cycle” of the latest technology, Hersch says, rather than looking at ways to scale and improve the technology they already have.

The hype cycle drags people down because the stuff that’s tangible, proven, and works doesn’t sound as cool, he says. Focusing on things that are actually delivering value is what needs to happen.²³



As companies rethink their future, they will move from adopting digital technology in pockets and instead initiate broader digital transformations that to position themselves for a more competitive marketplace where patient engagement and traditional selling models are being transformed out of necessity.

Companies that fail to successfully navigate these digital transformations risk becoming minimized or boxed in (or boxed out) by the digital health care ecosystem. Enterprise digital transformations deliver more significant business advantages by applying innovation and digital technology to existing and new business models in strategic, creative, and agile ways for patient, partner, and employee impact, which allows companies to accelerate their core mission to deliver improved health, wellness, and experiences for their patients; drive business impact; and inspire company employees and stakeholders.

Digital transformation and maturity considerations for life sciences organizations

No strategic business transformation is easy. Many companies in many industries talk about it. As life sciences leaders drive digital transformation and maturity in their organizations they will need to address six key questions:²⁴

- 1. What is my holistic digital ambition?** The strategic business question is what digital transformation strategy fits a company's strategic objectives, financial, and competitive needs.
- 2. How do I value and position a broader digital transformation?** Successful companies use a structured digital value model that consists of value, operational performance, and capability measures.
- 3. How do I activate my ecosystem to accelerate digital value and realization?** Life sciences companies should engage their wider ecosystem to leverage non-traditional approaches.
- 4. How do I structure, mobilize, and align my organization for success?** Digital transformations should be structured to drive alignment, reinforce what works, scale quickly and mobilize for success to meet critical strategic objectives.
- 5. How do we future proof our capabilities and become an adaptable organization?** Leaders should view digital transformation as an ongoing process that requires flexibility. It's important to avoid hardwiring processes.
- 6. How do I monetize it to add value to my organization and the existing payer system since it will take large investments to create and maintain?** Digital technology can bring greater efficacy to drug and device development, improving the margins for each and encouraging a broader range of products.



Elevating health equity

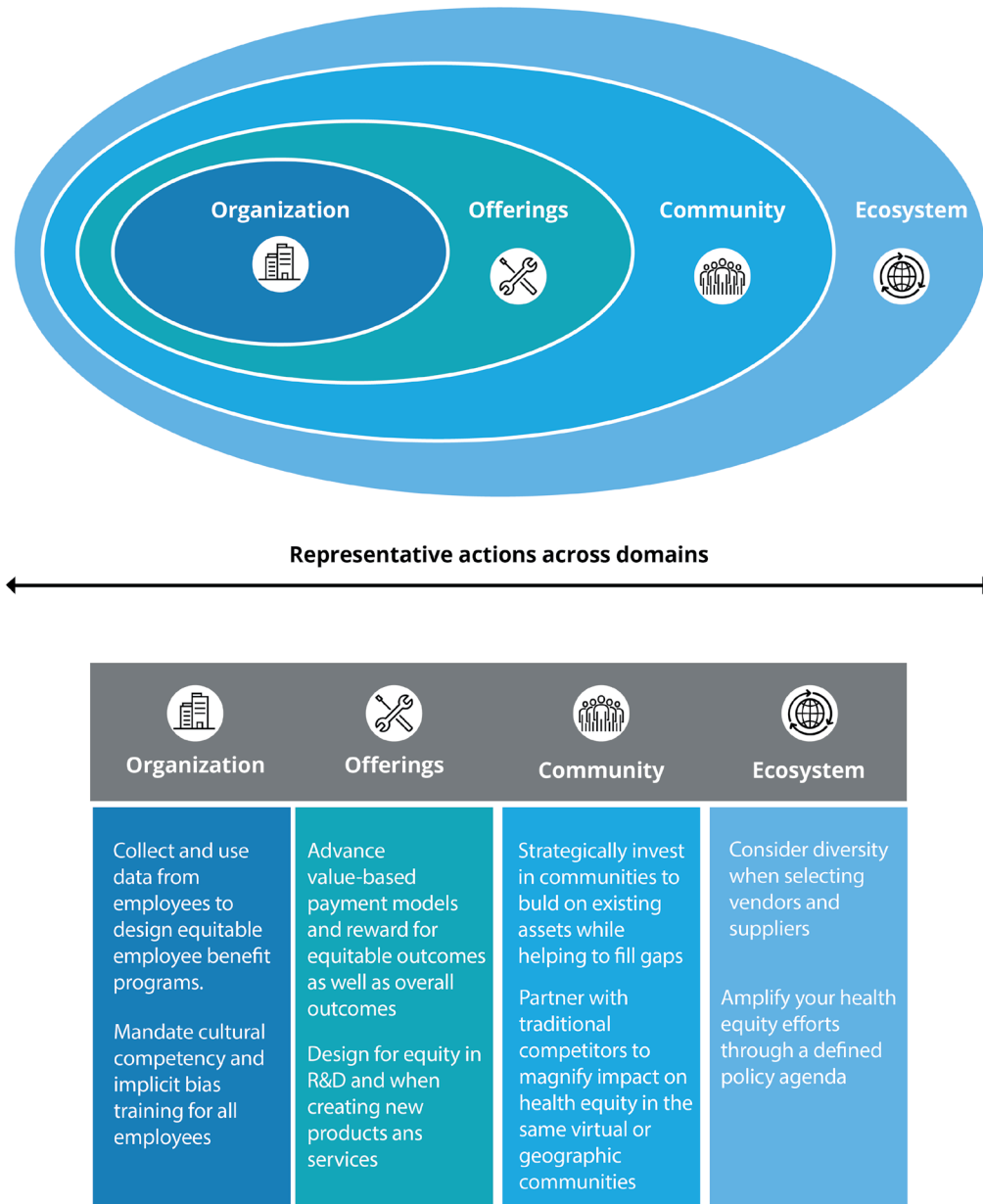
Life sciences organizations develop therapies and devices that can save or change lives, but their products don't always reach the people who need them. Inequities in health systems are both broad—including significant variations in global care delivery resources, investment, and access to care—and more localized—such as unconscious bias, a lack of trust, and language barriers.

These inequities fall disproportionately on underserved populations and result from a complex interplay of social, economic, and political factors that contribute to systemic underinvestment in poorer countries. While this results in inadequate health outcomes for the people who live there, it also affects communities, companies, governments, and other stakeholders. Like environmental, social and governance initiatives, health equity is a growing concern among investors and stakeholders. Health inequities strain workforces and productivity, create supply-chain challenges, and influence consumers' purchasing decisions. They cost life sciences companies trillions of dollars in lost productivity annually.¹ By addressing health inequities, life sciences leaders can boost productivity, increase market opportunities, generate growth, and improve their competitive advantage.

Medical device manufacturers and biopharmaceutical companies can make a significant difference by changing their approaches to developing and distributing their products and more deliberately focusing on underserved and untapped markets. It's a business model choice not a charity model.

Advancing health equity effectively involves a comprehensive set of choices. Life sciences leaders can make decisions that improve the health and well-being of everyone with whom their organizations engage: employees and their families, customers, contractors, suppliers, alliance partners, and communities. This requires developing a strategy that places health equity at the center of the business and extends across four domains: the organization, its offerings, its community, and its ecosystem (Figure 1).

Figure 1. Four domains of action



Source: Deloitte Analysis and National Academy of Medicine

Industry players can take specific actions in all these domains to meaningfully advance health equity:

Organization: Employees increasingly want their organizations to address health equity, from providing health care coverage to offering childcare to addressing mental health concerns in the workplace. Businesses have an incentive to improve workplace wellness. Health disparities result in an estimated US\$42 billion in untapped productivity globally.² Dental and oral health problems cost employers 164 million hours of work each year in the US alone.³ In South Korea, 21.5% of lost productivity is attributed to employees with depression and another 13% is from workers experiencing chronic pain.⁴ Identifying and responding to these health needs, and offering comprehensive benefits to address them can increase productivity, reduce turnover and sick days, lower employer health care costs, and improve the quality of work. Investing in family-friendly policies can boost productivity, reduce workplace accidents, and improve an organization’s ability to attract, motivate, and retain employees. For example, The Bank of Tokyo-Mitsubishi UFJ, Ltd. in Japan increased retention of new mothers by more than 400% and saved US\$45 million in turnover-related costs by providing childcare services and extended maternity leave to its employees.⁵

Offerings: How companies create, price, market, and distribute their products affects health equity and public perception. The participants who are chosen for clinical trials influence the outcomes and ultimately determine who benefits from a drug. Those outcomes, in turn, affect market share.^{6,7} For example, if a clinical trial for an HIV prevention drug only includes cisgender men and transgender women, the drug may have unforeseen implications for individuals assigned female at birth.⁸ Coincidentally, these women are disproportionately impacted by HIV globally.^{9,10} To prevent these outcomes, life sciences organizations should ensure drugs and devices are developed without biases in data and algorithms and recruit trial participants from a broader ethnical and economic backgrounds. Even if a drug is equitably formulated, its cost and a lack of accessibility may prevent it from reaching its target patients. The public increasingly demands a health-first approach, and they are willing to pay for it.¹¹ Eighty percent of consumers are willing to spend more when they know they are buying from a company that is environmentally or socially responsible.¹²

Community: Companies that invest in addressing health inequities by improving health outcomes among employees and their communities create a larger market of healthy and economically empowered consumers. These consumers can spend more and generate incremental revenue growth. Consumers value ethical and socially conscious organizations and are likely to remain loyal to companies that support their communities. By investing in community health, life sciences organizations also can better retain workers and attract more qualified recruits.¹³

Ecosystems: Vendors and suppliers that operate inequitably may expose their clients to legal and financial risk. In 2018, the province of British Columbia, Canada, accused opioid manufacturers, drug distributors, and consultants of deceptive marketing practices that fueled addiction and overdose deaths.¹⁴ The companies settled the lawsuit for CAD US\$150 million. On the other hand, companies that review fair labor practices throughout their supply chain can avoid potential legal action or loss of customers because of the actions of their partners. Poor labor practices can compromise worker health and wellbeing, compounding lost productivity and absenteeism. Companies that evaluate potential vendors and partners for fair practices, transparency, and living wages before entering contracts can help create positive health equity impact across their ecosystems.

At the same time, life sciences companies can partner with other organizations to expand health equity. By sharing insights and forming more public-private partnerships, companies can help address inequities locally. For example, AstraZeneca is working with governments and local health care professionals to close gaps in asthma care in Africa. The initiative, known as PUMUA, has partnered with more than 20 local health systems, reached almost 2,000 physicians, and expanded access to asthma treatments for patients at 700 public hospitals and faith-based facilities.¹⁵

Businesses, of course, can't address health equity alone, but they remain an influential voice. That's why the Deloitte Health Equity Institutes—which are dedicated to advancing health equity through cross-border collaboration, philanthropic investment, and research activity—teamed with the World Economic Forum (WEF) to develop the Global Health Equity Network (GHEN). The network brings together large-scale organizations to support how global leaders think about—and act on—health equity.

As part of that effort, in January 2023, Deloitte and 38 other organizations signed the signed GHEN's Zero Health Gaps Pledge, a commitment to advance health equity globally. The pledge includes 10 key commitments all signatories have made to embed health equity principles throughout their operations, workforce, and guiding philosophies. It recognizes that eliminating health inequities will require a multi-disciplinary approach that includes supporting strong diversity, equity, and inclusion (DEI) programs; providing accessible high-quality health and mental health services; paying employees across the supply chain a living wage; and investing in safe living environments.¹⁶

Participants pledge to:

1. Continually seek to understand how our organization can help address the root causes of health inequities and create a positive health equity impact.
2. Assess our own organization's health equity impact across our workforce (e.g., employee workplace health exposures), offerings and services (e.g., quality and accessibility for underserved populations), communities (e.g., investments in community health) and ecosystems (e.g., health equity promotion through advocacy and public statements).
3. Consistently seek to understand health equity needs across our workforce, consumer base, communities, and ecosystem to make strategic decisions, inclusive of investments, and use insights to inform our organization's choices from strategy to execution.
4. Measure the impact of our health equity efforts, such as health and wellbeing benefits, in ways that identify variations between and across groups, and use insight to inform decisions. Seek to employ ethical use of data and strong privacy controls.

5. Seek to employ ethical use of data and strong privacy controls.
6. Look for opportunities to share progress externally, including potentially as a part of environmental, social, and governance (ESG) and other sustainability reporting.
7. Establish and strengthen accountability systems within our organization by creating an environment where lessons can be shared and scaled, including having health equity as an agenda item at board meetings.
8. Collaborate with communities to identify key health equity needs and identify potential solutions, and to measure impact.
9. Inspire other organizations across sectors to act, to share learnings and collective investment decisions, and to accelerate the work of the GHEN and beyond.
10. Support the creation of a concrete, measurable roadmap with achievable global milestones towards health equity. Seek to employ ethical use of data and strong privacy control.

Life sciences organizations must make addressing health inequities a business imperative and implementing the Zero Health Gaps Pledge can benefit them both financially and reputationally.

“We believe that access to equitable and high-quality health care is a fundamental human right, and we are committed to working with global leaders and organizations to improve the lives of millions of people throughout the world,” said Helen Giza, CEO of Fresenius Medical Care, one of the signatories of the pledge. “We will also look inward and achieve clear, actionable steps to make our processes economically and environmentally sustainable, while increasing access to the care we provide in the global communities we serve.”¹⁷

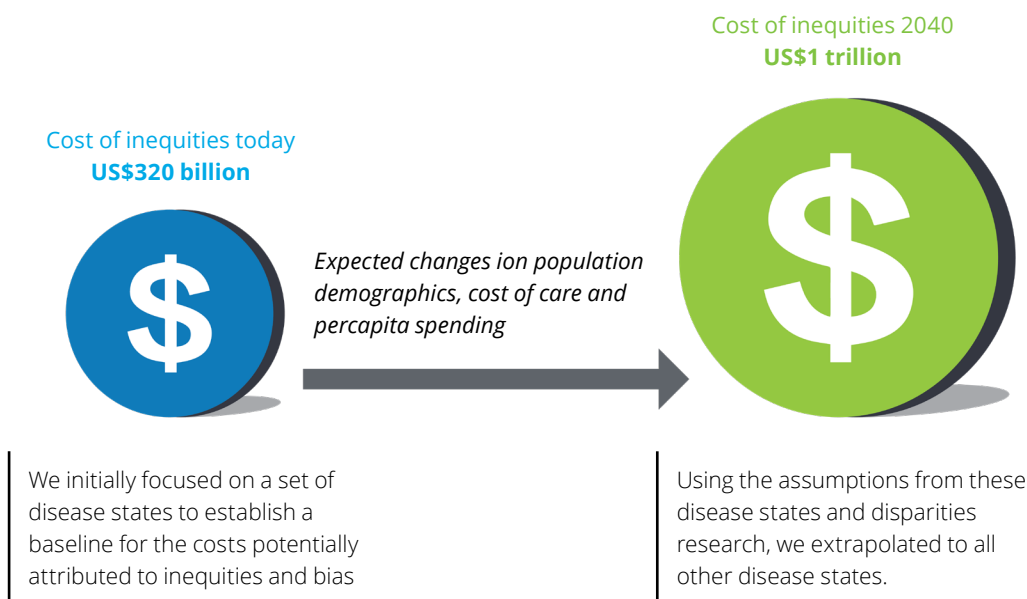
Deloitte estimates that biopharma and medical device companies could generate returns of as much as 10-to-1 on their investment by supporting access to care in underserved markets and by working to ensure that all patients—regardless of race, ethnicity, age, sex, or socioeconomic status—have access to the devices and therapies they need.¹⁸

The cost of health inequities

The cost of inaction is too great to ignore. Across the health ecosystem, inequities can limit people's access to affordable, high-quality care, create avoidable costs and financial waste, and impact every individual's potential to achieve health and well-being.

In the US health system, for example, inequities cost about US\$320 billion and could exceed US\$1 trillion in annual spending by 2040 if left unaddressed (Figure 2). This projected rise in health care spending could cost the average American at least US\$3,000 annually, up from current costs of US\$1,000 per year.¹⁹

Figure 2. Modeling the cost of health inequities in 2040



Note: All values are in US dollars.
Sources: Deloitte analysis

Meanwhile, the European Parliament estimated that health inequities in the European Union cost about 1.4% of GDP each year, almost matching defense spending of 1.6% of GDP.²⁰

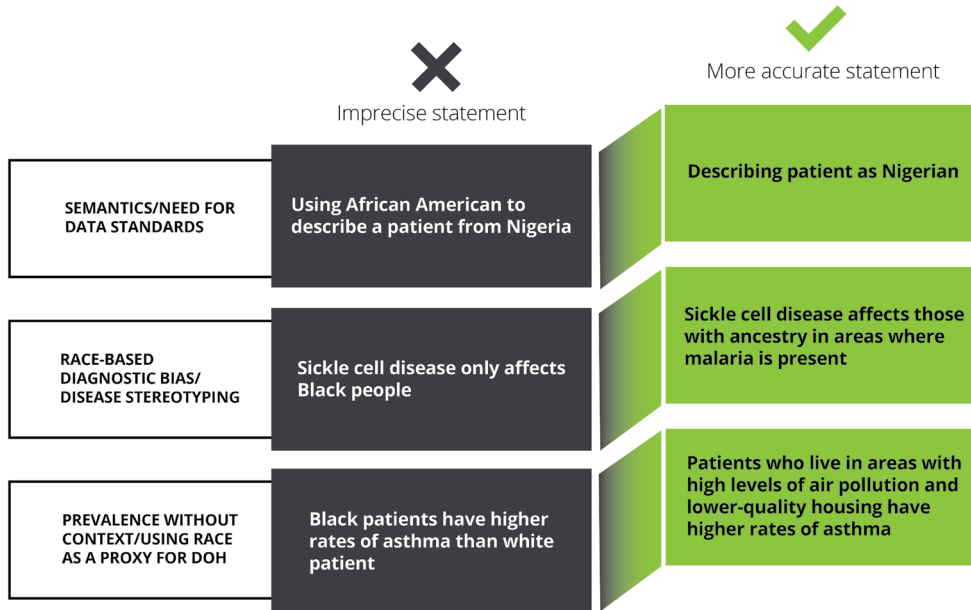
Data inequity

The first step in reducing inequities is identifying them. Unfortunately, a lack of data standards makes addressing systemwide biases much more challenging. In many cases, data on race and ethnicity is not collected or properly recorded, in others, it is misused in determining treatment and diagnosis. Some countries ban the collection of such data all together. Technology can exacerbate these issues. Algorithms may inappropriately account for race factors based on biased data, for example. If these systemic issues aren't sufficiently addressed, inequities will likely continue to widen, possibly at exponential rates.

Collecting data about race, ethnicity, language, disabilities, sexual orientation, and gender identity can be difficult. Patients may skip these questions on forms because they don't understand the importance of providing the information. They may feel uneasy answering them verbally. As a result, administrative or clinical staff may simply guess at the answers, which can lead to data errors, deficiencies, and inconsistencies.

In addition, different providers, insurers, and government organizations may have different definitions or methods of collecting data, such as having one category for Asian and Latinx populations, despite the differences between the two groups. These discrepancies can limit the effectiveness of data. And systemic bias can lead to poor understanding of certain diseases, such as the longstanding believe among US researchers that sickle cell disease only affects Black people, when in fact it is correlated with an evolutionary adaptation to malaria exposure, not skin color (Figure 3).^{21,22}

Figure 3. Examples of misrepresentation of race



Sources: NEJM and Deloitte analysis.

Improving clinical trial diversity

Clinical trials provide essential care for patients by offering therapies that can treat disease often years before drugs are approved. Trial participants also receive additional medical care they might not receive otherwise.

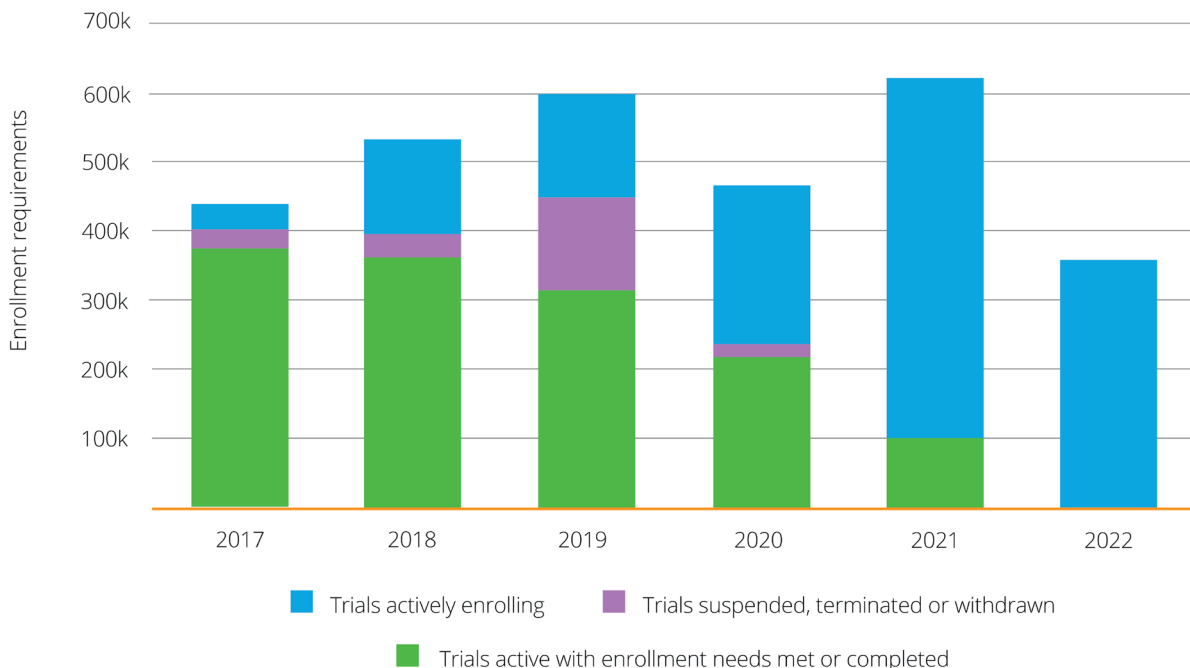
Yet barriers to trial diversity persist in part because life sciences organizations have not done enough to boost awareness that trials are being offered, provide suitable access for all groups, or address issues of mistrust in underrepresented communities. Trust across the system, from individual practitioners to institutions and in data and technology, is crucial. It will be important to rebuild trust with people and communities intentionally by understanding needs, improving experiences, and building a more diverse and inclusive workforce

The lack of diversity in clinical trials is critical because people of different ages, races, and ethnicities may react differently to differing therapies and devices. At the very least, participants in clinical trials should represent the patients who will use therapies and devices, but they often do not. For example, 40% of US citizens are racial or ethnic minorities, but 78% of clinical trial participants are white. While cancer is the leading cause of death for Asian-Americans, they make up only 3% of clinical trial participants for cancer treatments.^{23,24}

In Europe, it's much the same. A study of clinical trials for new cancer treatments between 2009 and 2019 found that patients in Western Europe had access to far more treatments than those in the central or eastern parts of the continent. Belgium, for example, conducted 11.06 trials per 100,000 people, compared with 0.14 in Albania.²⁵

The industry has a business case for addressing the inequity of clinical trials. By late 2022, it was short 1.4 million participants for Phase 3 trials that were seeking enrollment. Only 46% of trials started in the last five years reported meeting enrollment requirements (Figure 4).²⁶

Figure 4. Examples of misrepresentation of race



Sources: Clinicaltrials.gov

To address these shortcomings, the Deloitte US Center for Health Solutions, Pharmaceutical Research and Manufacturers of America (PhRMA), and its member companies published their first industrywide principles on clinical trial diversity in November 2020, reflecting member companies' voluntary commitment to enhancing clinical trial diversity.²⁷

Pharmacy chains Walgreens and CVS recently entered the clinical trials business, hoping to use their thousands of retail outlets to boost both recruitment and diversity of participants.²⁸ By offering more locations, with more flexible hours, more people from different socioeconomic backgrounds can participate more easily in clinical trials.



Bristol-Myers Squibb has launched an initiative to increase trial participation globally among people with disabilities.²⁹ A recent study found that 12.4% of people with intellectual or developmental disabilities, and 1.8% of those with physical disabilities were specially excluded based on trial criteria, even though the disabled are the world's largest underrepresented group.³⁰

“People with disabilities are omitted from conversations about diversity and inclusion, despite being the largest underrepresented group in the world—and the only underrepresented group anyone can join at any given moment”, said Tinamarie Duff, who leads the company's Global People and Business Resource Group.³¹



Meanwhile, Swiss drug maker Novartis recently invested US\$17.7 million in a 10-year plan to address inequities in clinical trials through collaboration with 26 historically Black colleges, universities, and medical schools. Merck and Sanofi have also signed on to the program.³²

Reliable information from trusted messengers in the community—such as historically black institutions—is critical to encouraging participation from underserved communities in clinical trials. Valued partners can help ensure that communications are culturally sensitive and free of unconscious or unintended bias. Many community leaders—faith-based organizations, civic leaders, educators, barbers, and beauty shops—can be trusted messengers, working with life sciences organizations and health providers to communicate important information. For example, nurses can advocate for clinical trials and educate their local communities about them. This is especially important in rural communities, where health workers are often liaisons to underserved populations.³³

Taking action

Achieving health equity requires leaders to design and build systems that advance health equity as an outcome. To do this, they should root out racism both within and outside the life sciences sector to break the vicious cycle of inequity that stands in the way of all individuals reaching their potential for health and well-being. Disparities in outcomes should not, and do not have to, be driven by racism and bias.

For life sciences organizations, addressing racism and other biases to advance health equity can be a point of competitive advantage. Not only can it help them attract the best talent and elevate their brand and reputation, but healthier workers have fewer sick days, are more productive on the job, and have lower medical care costs. And life sciences organizations have even more reason to pursue health equity because it can drive direct improvements to their mission to continually advance innovation through new therapies and devices for improving care.

Every organization should plan to address health inequities by designing and enabling the future of health care around people and equity. Life sciences incumbents, industry disruptors, community organizations, and government agencies each have a role to play in removing the barriers that lead to health inequities and turning unaffordable costs into opportunities.

Health equity considerations for life sciences organizations

To elevate health equity, life sciences companies need to develop specific strategies that prioritize equity and overcome barriers that can limit access to their products. Companies should:

- **Be intentional:** Infusing equity-centered thinking into business choices should be prioritized to build wellness-focused, outcomes-driven prevention and delivery systems that seek to serve everyone, regardless of race, ethnicity, and socio-economic status.
- **Form cross-sector partnerships:** Forge alliances among existing stakeholders, new partners, and the government to create change. Life sciences organizations should collaborate with agencies, organizations, and coalitions that work on initiatives to address the root causes of health inequities.
- **Measure progress:** Accessible, platform-agnostic, and inclusive data and technology infrastructure paired with representative data collection, key performance indicators, and ongoing evaluation likely will be necessary to define and track progress in tackling health equity. But, don't get too wound up around measurement or attracted to overly complex measurement initiatives and schemes. In the end, progress is directly measurable by an increase in outcomes in a given area of focus.
- **Address individual and community-level barriers:** Up to 80% of health outcomes are affected by social, economic, and environmental factors. These drivers of health (DOH)—also known as social determinants of health—include physical environment, food, infrastructure, economy, wealth, employment, education, social connections, and safety.³⁴ These nonmedical factors can have a negative impact on health. Moreover, barriers, such as health and digital literacy and care infrastructure, can hinder access to care. Addressing the DOH, removing barriers to access, and creating healthy environments will likely require investments in data, technology, and public health infrastructure at the federal, state, and local level.
- **Promote awareness:** Educate clinicians about the impact unconscious biases can have when it comes to prescribing medications and suggesting treatments. Peer-to-peer examples of success in reaching underserved populations can be a powerful tool.
- **Build trust:** Form relationships with local community leaders and with trusted organizations that serve those communities.³⁵
- **Tailor products to diverse needs:** Consider cultural nuances in making translations from English. At least 350 different languages are spoken in US homes, according to the US Census Bureau, and more than 65 million people have limited English proficiency. Many medical devices are aimed at English-speaking consumers, and directions for prescription drugs tend to be written only in English.
- **Improve access:** Develop innovative strategies and education that open doors to medications and technologies. This includes reducing financial barriers, especially in the US, where the tiered health insurance system can make it difficult for everyone to have access to the same therapies and medical devices. High deductibles, for example, could put some devices and therapies out of reach for some patients. But putting off needed care could turn a preventable or treatable illness into one that is difficult or expensive to manage.

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