



2022 Global Life Sciences Outlook

Digitalization at scale: Delivering on the promise of science

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Introduction

While valuations for the life sciences sector in this past year have been mixed, the underlying performance and outlook for the sector is healthy. We saw many companies' growth buoyed by COVID-19 therapeutics, and the majority of others remaining fairly immune to some of the pandemic impacts initially feared (e.g., slowdown in patient recruitment and trial execution). We anticipate further growth in the industry as life sciences companies continue to transform.

Some companies, especially those with limited legacy ways of working, are coming out of the pandemic adopting a digital-first model and challenging norms across their enterprise. Those that made significant digital investments prior to the pandemic are benefitting from their bold vision as digital transformation accelerates every part of the life sciences value chain. In 2022, visionary leaders will continue to drive investments focused on long-term, strategic digital objectives—using automation, smart factories, and artificial intelligence to transform manufacturing and using new technologies to build supply chain resilience.

Uncertain times will require a greater commitment to enterprise agility. The new world of virtual and hybrid work demands flexibility, and most life sciences companies will still be adjusting to new norms and a highly competitive talent landscape in the near future. Reimagining work with a focus on corporate and working culture is a CEO strategic priority and meeting the needs of humans—and human-centered experience in the workplace—has never been more important.

The last two years of the pandemic saw unprecedented collaboration across life sciences and with stakeholders. Everyone was mobilized in the interest of patients, including regulatory agencies around the world digitally sharing research.¹ Over the next year, more patient-centric, co-created experiences will evolve to make patients more equal partners in decision-making throughout their journeys and help life sciences deliver better, more personalized outcomes. We anticipate more diversity in clinical trials driven by patients and a greater focus on health equity, enabled by decentralized trials among other strategies.

In 2022, data-driven scientists, armed with new sources of insights and real-world evidence, will be solving problems for diseases that were once thought intractable.² Scientific breakthroughs, like the mRNA technologies behind the COVID-19 vaccines and cell and gene therapies, have many potential use-cases for the future. The new processes adopted to expedite COVID-19 vaccines and therapeutic products are now also being applied to speed up the development of other drugs and treatments—and companies cannot revert back to old ways.

ESG is expected to remain front and center in 2022, as companies face enhanced disclosures and new global standards. Watchdogs, investors, and customers will be scrutinizing life sciences' progress.³ In the year ahead, life sciences leaders will be expected to focus on material ESG factors for the sector such as access to medicines, drug pricing, environmental sustainability, health and race equity, and diversity in leadership.

Change will persist through 2022 and beyond. Many life sciences companies have experienced growth and are emboldened with stronger balance sheets from which to invest. We anticipate investments in their portfolios, including next generation therapies and investments, to capitalize on their digital progress. With access to a myriad of tools to gather and analyze data, it's time for life sciences companies to employ digitalization at scale. A new bar has been set, and agile companies, willing to move beyond convention to solve the toughest challenges, stand to reap the biggest benefits. The greatest challenge for leaders in 2022 will be how to ensure they accelerate the progress made—and not revert to pre-pandemic norms. Bold leaders with a clear, cohesive vision will continue to take advantage of the many opportunities the pandemic has surfaced and accelerated.



Accelerating R&D productivity and industry collaboration

Driving productivity, a need for speed

Currently, many life sciences companies are showing a 'need for speed' as their focus is on driving research and development (R&D) productivity. New processes adopted to expedite vaccines and therapeutic products to tackle COVID-19 are now being applied to other drugs. In 2022, pressures are expected to be on optimizing processes to fundamentally change the drug development paradigm.¹

“

Collaboration and digitalization have played fundamental roles in bringing COVID vaccines and therapies to market at an unprecedented rate, saving an estimated 750,000 lives in the United States and Europe alone. As an industry, we must bring the same speed and sense of urgency to all our efforts.

”

*Paul Hudson, CEO, Sanofi*²

Impact on timelines

While some worried that life sciences companies would see a negative impact on timelines during the pandemic, others were more bullish about the degree of change life sciences companies were going to embrace and mobilize to accelerate timelines. At large, timelines didn't change.

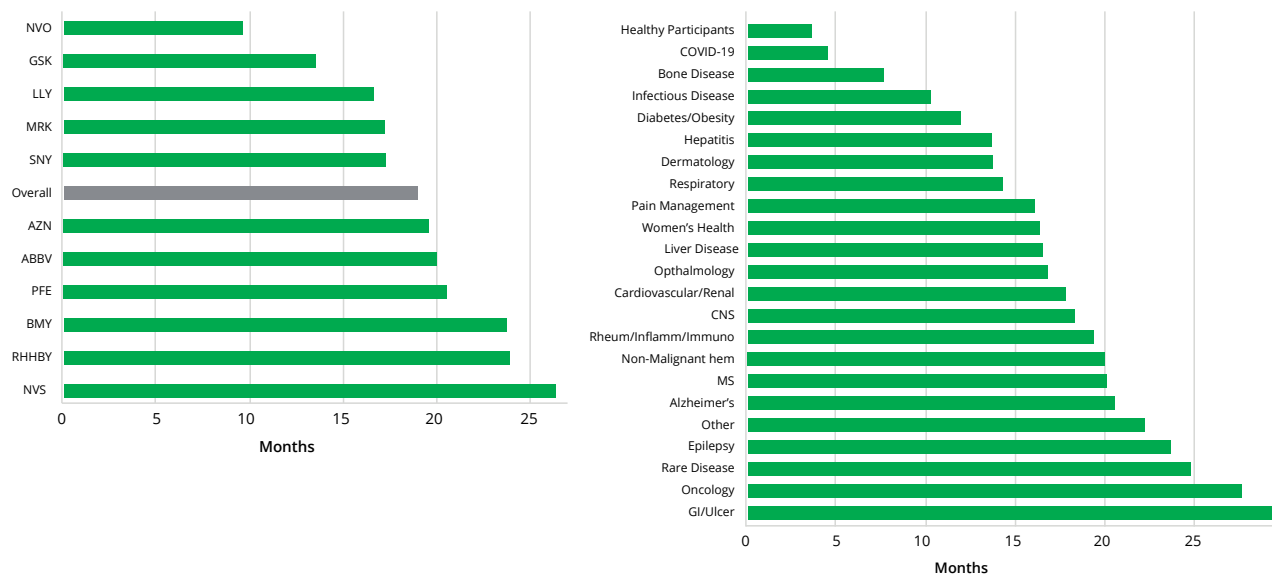
What are typical timelines? Research conducted by Cowen analyzed the performance of 11 leading pharmaceutical companies over more than 15,000 clinical trials across five categories. The time period analyzed was 2012-2021, unless otherwise noted.³

- Pipeline pace: Average time to reach approval, almost 5 years
- Recruiting speed: Average time to enroll patients in trials, almost 19 months
- R&D efficiency (2016-2021): Average R&D spend per active trial, US\$35 million, US\$66 million per active Phase III trial (may reflect a proclivity to in-license late stage assets)
- Trial push-outs: Average percentage of trials not delayed, 52%
- Delay duration: Average change in primary completion rate, 57-day delay⁴

If we look at the results for recruiting speed, (see figure 1)⁵ for example, the data show how timelines for recruiting vary by company and therapeutic area. While it may take only about 4 months to enroll healthy participants, it may take almost 30 months to enroll participants for studies concerning ulcers and the gastrointestinal tract.⁶

Figure 1: Trial recruiting speed by company and therapeutic area, 2012-2021

Weighted average enrollment time in months by company (left) and by therapeutic area (right)



Source: "R&D Pentathlon: Which Pharma's R&D is faster, higher, stronger —ahead of the curve," Cowen, 26 July 2021.

Overall, the leading companies averaged about 19 months to enroll patients, and the best recruiting speed—significantly leading the rest—was Novo Nordisk, with a phase-weighted average of 9.6 months. However, the company’s absence in oncology trials was a tailwind. The average oncology trial took 27.6 months to enroll, compared to non-oncology trials at 14.9 months. Second-place GlaxoSmithKline (GSK) and third-place Eli Lilly also had limited exposure to oncology.⁷

Pharma R&D recruiting timelines were not slowed down by the pandemic. However, clinical trial starts actually increased and are back on track.⁸ Where we did see shortened timelines, companies are keen to replicate, if possible.

Deloitte’s analysis of R&D cycle times for 15 leading pharmaceutical companies shows that, prepandemic, average cycle time was 6.64 years in 2019, followed by an increase to 7.14 years in 2020, a 7-year high. A slight improvement came in 2021—6.9 years—a decrease driven by the expedited completion of studies for COVID-19 therapies and vaccines.⁹

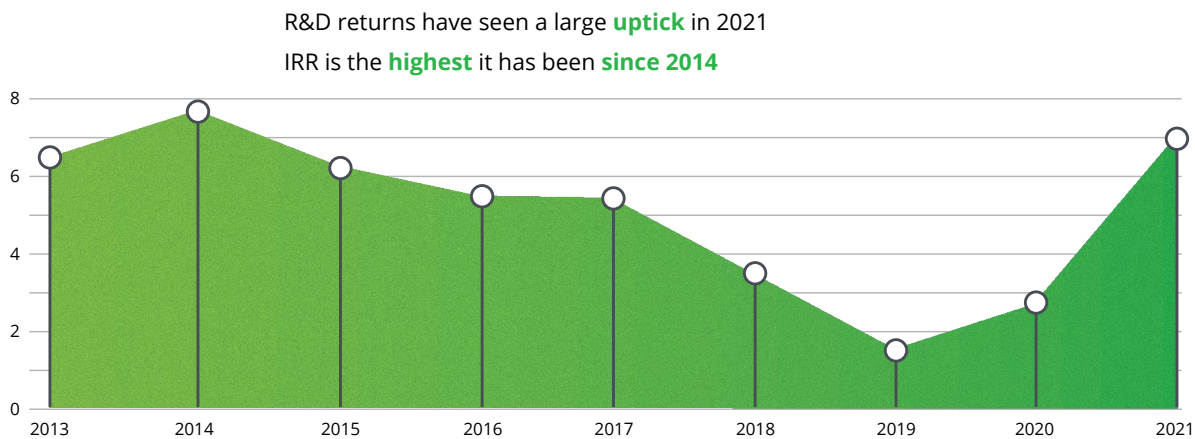
Some accelerated paths for improving productivity include focusing on continued digital transformation, quality and safety, and working in tandem and across geographies with regulators for earlier approvals.¹⁰

Return on pharmaceutical innovation

Deloitte has been tracking return on pharmaceutical innovation since 2010. Up until 2020, companies we tracked experienced a decade-long decline in R&D productivity. But in 2021, Deloitte’s analysis of 15 large pharmaceutical companies shows a significant uptick for the cohort’s internal rate of return (IRR)—7%, up from 2.7% in 2020. COVID-19 related assets buoyed by emergency approvals played a significant role. Excluding those assets, the projected IRR is still higher, at 3.2% (see figure 2).¹¹

Figure 2: Uptick in R&D returns for biopharma cohort for 2021

15 biopharma companies were analyzed by Deloitte



Source: Nurturing growth, Measuring the return from pharmaceutical innovation 2021, Deloitte Centre for Health Solutions UK, January 2022.

Pharmaceutical companies expect to advance scientific breakthroughs and manufacture innovative products in an effort to fulfill unmet needs and stay ahead of the competition. In 2021, the average cost to develop an asset for this group, including the cost of failure, decreased US\$70 million from 2020, to approximately US\$2 billion. This decrease is mainly due to the increase in the number of assets in the late-stage pipeline for the companies analyzed. In 2021, the group had a total number of 242 late-stage assets, an increase from 210 in 2020.¹²

“ We can't revert to our old ways. ”

*Paul Hudson, CEO, Sanofi*¹³

Tracking R&D spend

Drug Discovery & Development analyzed the R&D spend for leading pharmaceutical companies' annual reports. Spending for the top 15 companies ranged from almost US\$4 billion to more than US\$13.5 billion for the year (see figure 3).¹⁴ For R&D spend as a percentage of revenue, Incyte led the industry with an R&D spend of US\$2.2 billion that constituted a whopping 83.10% of its revenue. Regeneron Pharmaceuticals spent almost US\$2.4 billion on R&D, or 32.19% of revenue, to claim the number two spot.¹⁵

When allocating R&D spend for an asset, a pharmaceutical company is often influenced by:

- Anticipated lifetime global revenues from the new drug
- Expected costs to develop the drug
- Policies and programs influencing supply of and demand for prescription drugs¹⁶
- Pressure to innovate¹⁷

Pharmaceutical companies face greater pressure to innovate because of the time-limited patent protection of their name-brand drugs. When a patent expires, companies expect to take a big hit to sales from generics and biosimilars and plan accordingly.¹⁸

Figure 3: Pharma companies' total R&D spend in 2020

	Company	USD for 2020
1	Merck	\$13,558,000,000
2	Roche Pharmaceuticals (division of Roche Group)	\$12,164,234,743
3	Bristol Myers Squibb	\$11,143,000,000
4	Janssen (Johnson & Johnson's pharmaceutical segment)	\$9,563,000,000
5	Pfizer	\$9,405,000,000
6	Novartis	\$8,980,000,000
7	AbbVie	\$6,557,000,000
8	GlaxoSmithKline	\$6,509,126,400
9	Sanofi	\$6,303,060,000
10	Eli Lilly	\$6,086,000,000
11	AstraZeneca	\$5,991,000,000
12	Gilead Sciences	\$5,039,000,000
13	Takeda Pharmaceutical	\$4,611,350,440
14	Amgen	\$4,207,000,000
15	Biogen	\$3,990,900,000

Source: Drug & Discovery 2021

Establishing new norms

Revamping the clinical trial model

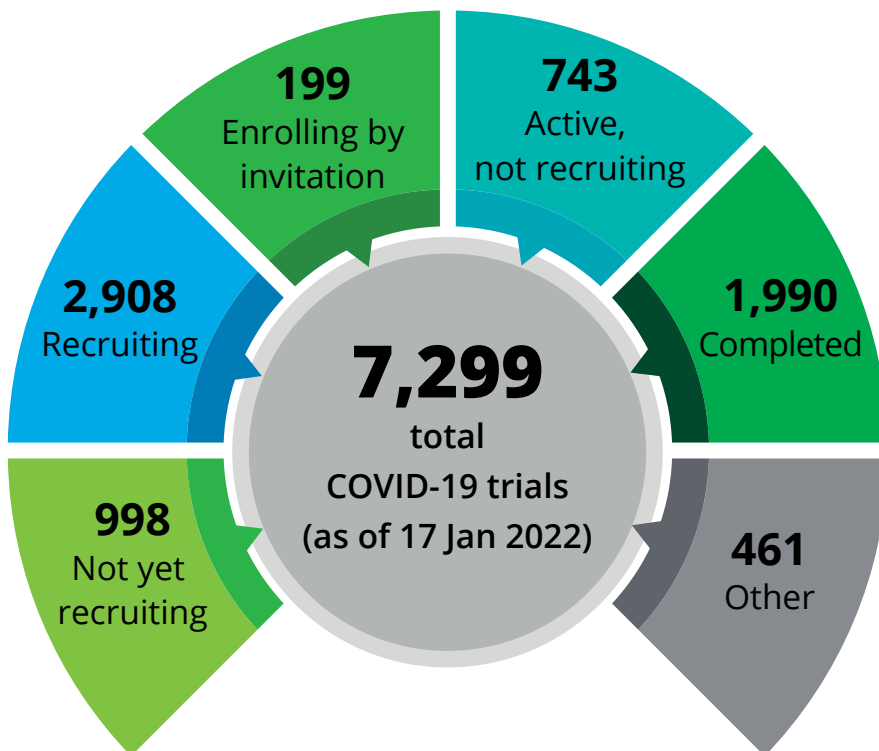
Changes brought about as a result of the COVID-19 pandemic are shaping a new era in clinical trials. Restrictive norms and outdated processes are falling away. With digital and virtual tools, constraints such as geography and set 'business hours' are no longer barriers to participation. Researchers are finding new ways to bring more people into trials through new models that are adaptive, decentralized, and hybrid. Participants expect more personalized care and real-time access, no matter where they are.²⁰

Remote monitoring and remote visits were top strategies for keeping clinical trials open during the pandemic.²¹ Research shows that there were more study starts across the board by the end of 2021 than ever before, with an increase of almost 18% from 2020 to 2021, including more non-COVID trials. Oncology saw the biggest increase at almost 1,300 trial initiations in 2021, a 23% increase.²² Two years after the pandemic started, more than 7,000 clinical trials had been initiated related to COVID-19 in the NIH Clinical Trials database (see figure 4).²³

Investing in the research lab of the future

Accelerated advancements in drug discovery and delivery are expected to fuel industry growth and demand for lab space in the near term.¹⁹ In the R&D lab of the future, an interconnected ecosystem of data, platforms, instruments, and advanced analytical tools supports scientists across teams and geographies to rapidly discover breakthrough therapies. In 2021, Deloitte surveyed 150 leaders across the value chain from large biopharma companies (revenue of US\$1 billion and above) across the United States, Europe, and Asia. Survey respondents say that their organizations are currently prioritizing investments in AI (81%) and cloud (71%). A much smaller percentage believes that over the next five years their organizations are likely to invest in AR/VR (19%) and IoT (24%), both of which are essential for the lab of the future.

Figure 4. Total number of clinical trials related to COVID-19 vaccines and treatments as of January 17, 2022



Source: NIH Clinical Trials

Many hospitals and research institutions shifted from in-person clinical trials to home-based reporting and the clinical trial process was rapidly digitalized with tools such as telemedicine, sensor-based technologies, and wearable medical devices. Many trial participants were able to receive direct-to-patient shipment of investigational products and trial supplies, and remote consent was enabled via mobile—further modernizing the clinical trial process.²⁴

Adapting trials to patient response

Adaptive clinical trials are using the potential of AI to discover the best possible treatments. An adaptive trial can be modified according to a patient's response. For example, if a drug is not working, it might be pulled, and another treatment readily started in its place.²⁵ Researchers used adaptive trials to discover and compare potential COVID-19 treatments during the pandemic. The World Health Organization and groups like the Bill & Melinda Gates Foundation are showing increasing support for adaptive trial designs, particularly as a way to evaluate therapies during epidemics.²⁶

“ The pace of change in trial design and execution will continue to accelerate through adaptive trial design, which allows monitoring of incoming data and modifying the trial protocol based on interim review. Amgen has implemented these tools in clinical programs in inflammation, cardiovascular disease, and others disease areas. ”

Elliott M. Levy, MD, Senior Vice President, R&D Strategy and Operations, Amgen ²⁷

Reducing patient burden through decentralized trials

New types of trials are already proving to be more productive. In particular, research shows that decentralized trials (DCTs) that rely on remote strategies are showing return on investment and are here to stay.²⁸ Digitization is reducing patient burden and reporting subjectivity, while increasing outcome accuracy.²⁹ In developing MyPath for Clinical, Deloitte found that an end-to-end digital platform for decentralized trials was a more streamlined way to address many patient challenges—such as traveling to sites, confusion about treatment protocols, and access to medical teams in real time.³⁰

In a fully decentralized clinical trial, patient recruitment, delivery of trial medication and supplies, and acquisition of trial outcomes data is enabled through virtual and real-time tools—essentially eliminating the need for in-person contact between the study team and the trial participant.³¹



Tufts' study finds 5x to 14x financial return on decentralized trials investment

A recent study from the **Tufts Center for the Study of Drug Development** compared published benchmarks on trial cycle times and costs with data from more than 150 decentralized trials conducted by software firm **Medable**. The study reports that, on average, decentralized clinical trials (DCTs) are associated with reduced clinical trial timelines, recruitment, and higher retention rates. For example, decentralized phase 2 studies were completed 1 to 3 months faster than traditional trials, a net benefit up to five times greater than the upfront investment required; phase 3 was 14 times greater.³²

Improving access to trials and technology through hybrid trials

Decentralized trials and remote monitoring may address convenience and diverse populations in distant locations, but underserved and minority populations are still likely to experience disparities. For example, access to broadband, caregivers, and home health care, may present a challenge.³³

Not all trials can be fully decentralized. Hybrid trials, that also reach patients through the community where they live, are another growing solution.³⁴ Researchers should be aware of the logistical difficulties that some necessary in-person provider interactions and laboratory tests may pose for some participants. For example, some may face travel constraints (e.g., access and cost), nonacceptance of job absences for study activities, and mobility challenges due to medical comorbidities.³⁵

CVS Health expands access to clinical trials through retail locations

CVS Health Clinical Trial Services was initially launched in response to the pandemic with the goal of providing greater access to clinical trials across the communities it serves. Collaborating with the pharmaceutical industry, CVS Health helped facilitate clinical trials for investigational COVID-19 vaccines and treatments. Using a specially designed digital model and screening protocols, the company engaged more than 300,000 volunteers for COVID-19 vaccine trial consideration, connecting them to studies close to where they live.³⁶

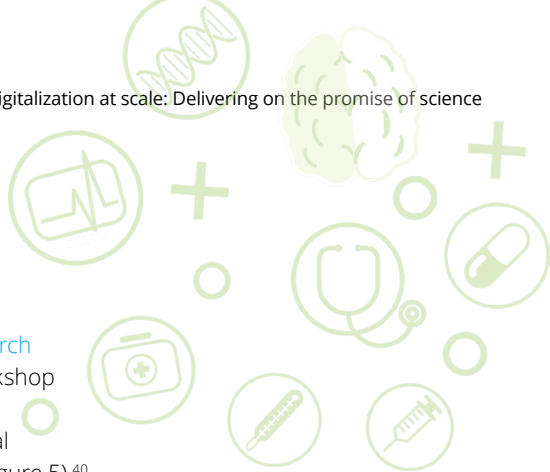
By creating a more efficient, convenient experience to improve participant retention and research effectiveness, CVS Health believes its new clinical trial experience benefits participants, health care providers, clinical research organizations, and study sponsors. The business is initially focused on scaling three core capabilities: precision patient recruitment, clinical trial delivery, and real-world evidence generation and studies.³⁷

Localizing in-person visits and providing digital tools to make it easier for patients to participate in their own communities may be all that is needed.

By making the clinical trial process more convenient for enrollment and participation, industry leaders stand to gain better research results, fewer failed trials, and more trust from physicians and patients. More accessible trials for diverse populations may provide deeper insights, enabling more tailored drug therapies to be developed and more productive R&D.³⁸

Defining goals for clinical trial diversity

The Pharmaceutical Research and Manufacturers of America (PhRMA) is an industry organization committed to enhancing diversity in clinical trial participation. In last year's Life Sciences Outlook, we introduced PhRMA's industry-wide "[Principles on conduct of clinical trials and communication of clinical trial results](#)".³⁹

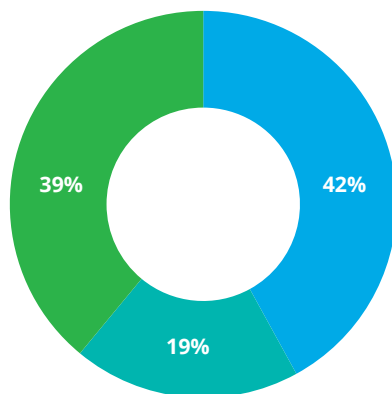


In 2021, PhRMA and the Deloitte US Center for Health Solutions conducted [extensive research on clinical trial diversity](#), including a survey with 31 PhRMA's member companies and a workshop with more than 500 stakeholders from more than 150 organizations. The survey of PhRMA members showed 61% of respondents have defined goals and objectives to enhance clinical trial diversity, and all respondents have or are planning to address trial access issues (see figure 5).⁴⁰

Figure 5: PhRMA member companies survey on clinical trial diversity

Percentage of respondents with defined goals and objectives for increasing clinical trial diversity

- We have defined goals and objectives, identified best practices, and begun to incorporate these across some of our trials
- We have defined goals and objectives and working to identify best practices
- We are working on defining our goals and objectives



Note: N=31 PhRMA member companies

All respondents have or are planning to address trial access issues and are considering the needs of diverse populations in clinical trial design

We are taking specific measures to address trial access issues (e.g., transportation costs, event scheduling, remote/decentralized data collection, patient apps and data access, etc.)



We are considering the needs of diverse populations in clinical trial design (e.g., taking a patient-centric approach to protocol design and incorporating patient input)



We are identifying sites where diverse patients may be located, identifying health care providers that treat underserved or underrepresented populations, and collaborating with investigators to address the goals of enrolling a diverse population



We are enhancing education on the role of clinical trials throughout the medical community



We are increasing clinical trial awareness and diversity by improving individual health literacy and community outreach



We are enhancing information about diversity and inclusion in clinical trial participation (e.g., developing and maintaining policies and procedures, making these publicly available)



We are using real-world data to enhance information on diverse populations beyond product approval



We are enhancing diversity among clinical investigators



We are broadening eligibility criteria to increase diversity in enrollment when scientifically and clinically appropriate



Note: N=31 PhRMA member companies ■ Yes ■ No

Source: "Enhancing clinical trial diversity," Deloitte Center for Health Solutions, 2021.

Most surveyed PhRMA member companies identified areas to address internally to enhance clinical trial diversity—such as legacy processes and systems, data on demographics of disease by race/ethnicity, and protocol design flexibility. Five key strategies were identified for enhancing clinical trial diversity and are discussed in the **ESG section** of this report.

Evolution of real-world evidence

Amount and types of data rapidly accelerating

Life sciences companies strive for consistent, regulatory-quality clinical trial data to prove the effectiveness of treatments, and researchers are expected to gather, analyze, and curate many streams of structured and unstructured data. The amount of data being collected by digital health technologies—telemedicine, mobile devices, wearables, and other sensor-based technologies—is rapidly accelerating due to decentralized trials and remote monitoring.⁴¹

In addition to clinical data, genomic information and improvements in technology—like AI and quantum computing—are evolving the way life science organizations approach drug discovery and development. Real-world data (RWD) and real-world evidence (RWE) collected today have the potential to better inform clinical trial design/execution and deliver insights never before thought possible. In Deloitte's annual survey of C-suite biopharma leaders, 100% identified RWE as strategically important.⁴²

At the end of 2021, the US Food and Drug Administration (US FDA) issued draft guidance for using digital health technologies to acquire data remotely from participants in clinical trials. In addition to sponsors and investigators, developers and manufacturers have the opportunity to benefit by reviewing this guidance.⁴⁴

Selecting digital tools for better clinical trials

When selecting digital and virtual tools for clinical investigations, sponsors should ensure they are “fit-for-purpose” or sufficient to support their use and interpretability in the study. Data transmission with manufacturers and end-user licensing agreements should be designed to secure data collected and transmitted.⁴⁵

Getting better data from devices in clinical trials:

- When validating instruments for trials, collect sufficient data to understand how each tool really works. Some tools may not transfer to a virtual platform.⁴⁶
- Ensure that digital tools have user-friendly interfaces for supervisors and patients.⁴⁷
- Wearables help take subjectiveness out of the data, but wearables are not always accurate. Always question data, and how you are interpreting the data.⁴⁸
- Check that tools are measuring what you need them to measure. Is the data being collected clinically relevant and relevant to the patient?⁴⁹

Teams designing trials should have a clinical expert involved, not just statisticians. These experts have the ability to bring clinical analysis a priori and to look at outliers for clinical relevance. Value is expected to come from human-enabled AI—expert clinical knowledge coupled with AI and machine learning (ML) analysis.⁵⁰

Verana Health: Building a vast database of RWE for clinical R&D

Verana Health is building an extensive database of real-world clinical evidence curated from organizations like the American Academy of Ophthalmology, the American Academy of Neurology, and the American Urological Association. Life sciences companies and health care providers can mine the platform for insights from the electronic health record (EHR) systems of more than 20,000 health care providers. Their population health analytics tool, VeraQ, uses AI to automatically sift through those data, helping drug and device developers with their research and speeding up clinical trial recruitment. The startup has recently garnered support and funding from Johnson & Johnson, Novo Nordisk, and Merck.⁴³

Through AI & ML, life sciences companies have also been able to select investigators and countries for their clinical trials as well as predict their performance.⁵¹

Lessons from the COVID-19 experience

In 2022, biopharma companies are looking to apply some of the more successful COVID-19 development measures to plan, design, and execute studies more efficiently by:

- Enabling at-risk development for high-priority programs, allowing them to bypass certain stage-gates
- Expanding collaborative dialogue with regulators, using data-sharing infrastructure and harmonizing across geographies
- Limiting the number of relevant endpoints, to streamline trial protocol design
- Enabling the rapid assessment and development of therapies with master protocols and adaptive trial design
- Accelerating the use of digital technologies, for conducting decentralized and hybrid studies, optimizing site selection, recruiting diverse study populations, and remotely collecting data and monitoring patients⁵²

During the pandemic, it became both difficult and potentially dangerous for some clinical trial patients to go to the hospital. According to Badhri Srinivasan, head of global development operations for Novartis, his teams worked to set up solutions such as in-home nursing programs or direct to patient shipments of their study medication. “These are options that patients may prefer, regardless of restrictions, and many trial sites have now expanded their capabilities to accommodate these services. Therefore, we need to prioritize building assessment of decentralized clinical trial elements, such as home nursing,” he says.⁵³

New therapeutic modalities are the future of R&D productivity

Highly anticipated biopharma research

The science of therapeutics is maturing with new and compelling modalities. Scientists are now focusing on diseases that were once thought intractable.⁵⁴ Technology and science are converging, and the modality landscape is evolving—from sporadic disease, small molecules, biologics, and protein targets to genetic disorders, Antisense Oligonucleotides, siRNA, gene therapy, and nucleic acid targets, according to Anabella Villalobos, PhD, senior vice-president at Biogen.⁵⁵

Villalobos says that protein degraders are an emerging therapeutic modality showing encouraging results.⁵⁶ Targeted protein degradation (TPD) tackles disease-causing proteins that have historically been highly challenging to target with conventional small molecules. In the future, this modality is expected to expand the use of ubiquitin ligases to enable precision medicine and move beyond oncology.⁵⁷

Dr. Jay Bradner oversees 5600 scientists and 325 discovery programs over 8 disease areas as president of Novartis Institutes for Biomedical Research (NIBR).⁵⁸ He says that it is ironic that returns are diminishing when our understanding of disease has never been better and more granular. He believes R&D productivity can grow thanks to new modalities.

“
My least favorite term in our field is ‘undruggable target.’
”

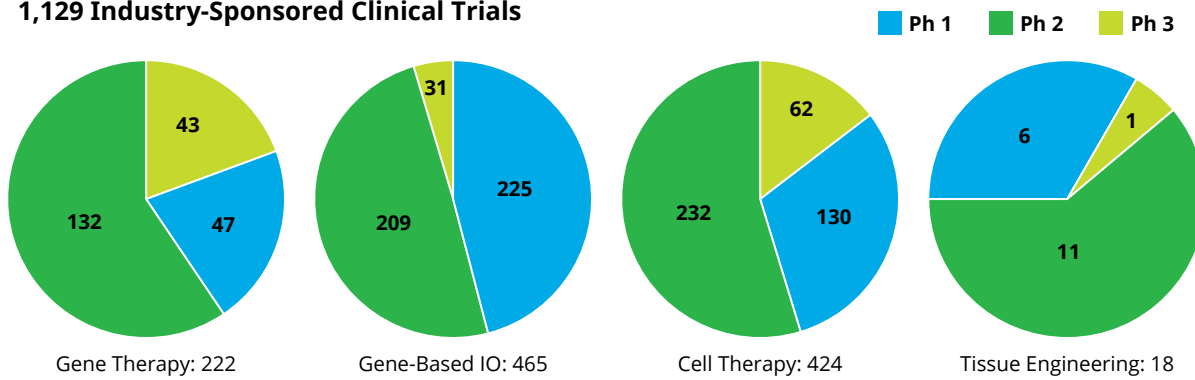
Dr. Jay Bradner, President, Novartis Institutes for BioMedical Research, Novartis

What's next for cell & gene therapies?

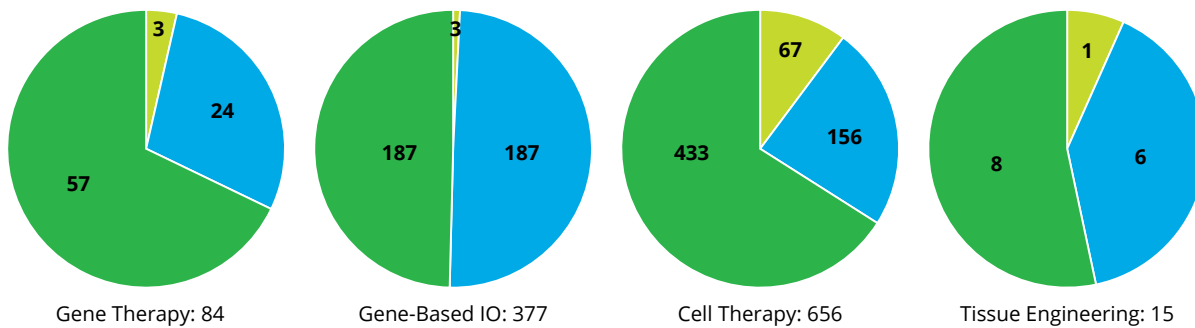
Globally, cell and gene therapies (CGTs) are transforming how humans treat genetic and intractable diseases as well as altering the entire pharmaceutical ecosystem.⁵⁹ As of Q1 2021, there were 2,261 ongoing global cell, gene, and tissue clinical trials—1,129 were industry-sponsored and 1,132 were academic/government-sponsored trials (see figure 6). In 2022, there will be more opportunities to expand cell and gene therapies, especially in rare disease, and more interest in allogeneic therapies.⁶⁰

Figure 6: Cell and Gene clinical trials in development, March 2021

1,129 Industry-Sponsored Clinical Trials



1,132 Academic & Government Sponsored Trials



Data as of March 2021 by Global Data

Source: ARM, 10 January, 2022

“ We need to listen because ideas come from anywhere in the organization. We just need to evaluate and see what we can fund. Whether we do that internally or externally is another question. But we need to make sure that we listen to the project teams who are driving the science. ”

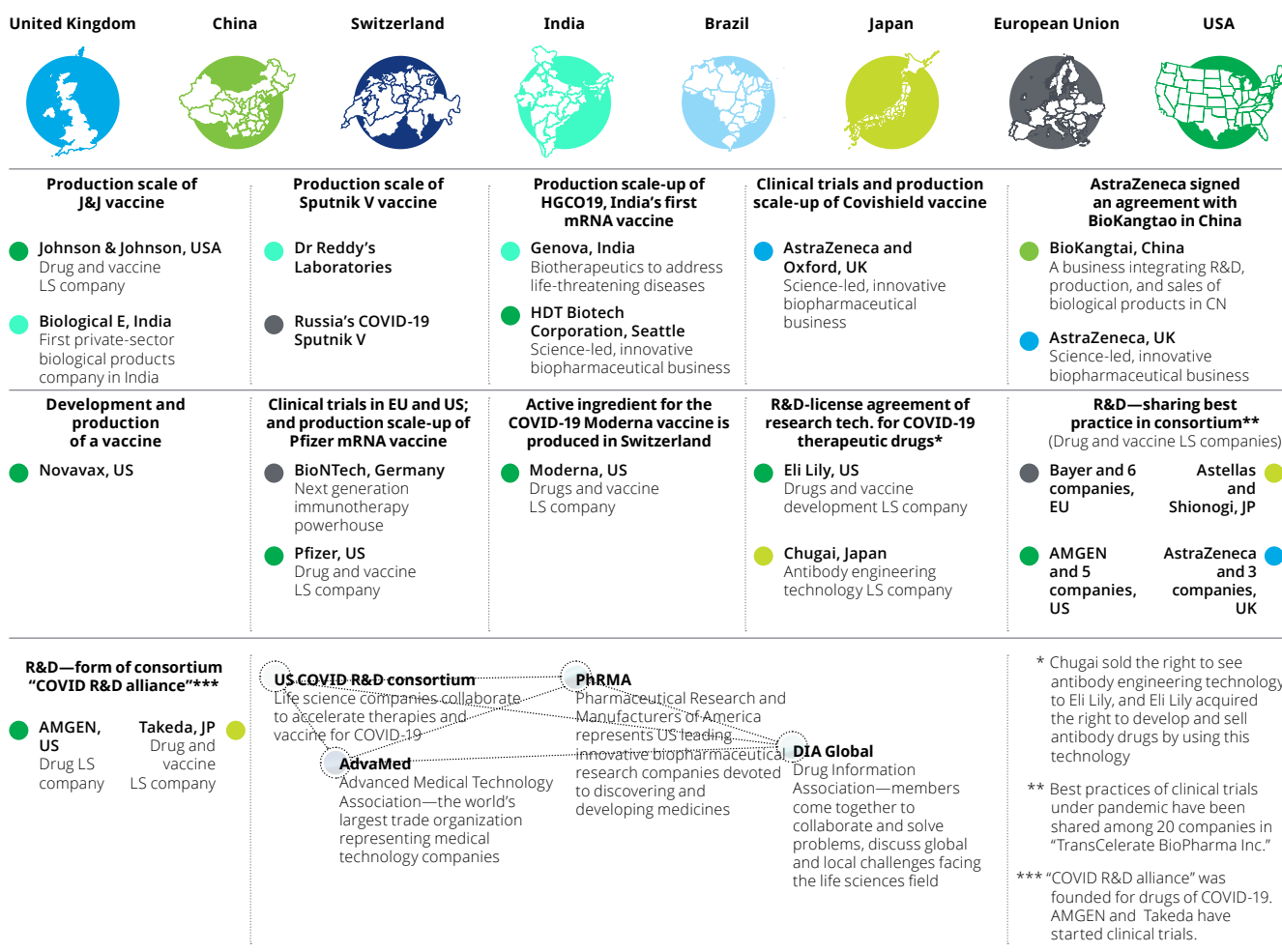
Anabella Villalobos, PhD, Senior Vice-President, Biotherapeutics and Medicinal Sciences, Biogen

Unprecedented collaboration

Growing global ecosystem

During the pandemic, many life sciences companies that had been competitors came together to solve scientific problems to address the urgent need for treatments, vaccines, diagnostics, and medical devices (see figure 7).⁶¹ Companies, including those in other other industries, also joined the effort to help fill raw materials shortages, digitalize more of the drug development process, and enhance manufacturing at high capacities at different locations worldwide.⁶²

Figure 7: Life sciences' global collaborations



Source: "Never the same again, How COVID-19 created seismic change in life sciences regulations," Deloitte, 2021.

Currently, life sciences companies are partnering to develop digital medicine products, playing to their strengths in regulatory science and market access, while leveraging partner expertise in software development.⁶³ Digital product development is an iterative process, and pharmaceutical companies are expected to demonstrate a willingness to be adaptive and nimble.⁶⁴ Most technology companies are interested in a meaningful commercial relationship and not just running pilots.⁶⁵

New partnerships filling the demand for digital therapeutics

Last year, we saw pharma companies forming partnerships with digital therapeutics startups.

- Boehringer Ingelheim partnered with Click Therapeutics to develop a digital therapeutic for patients with schizophrenia
- Sanofi partnered with Happify Health to build a digital therapeutic to help multiple sclerosis patients manage their mental health⁶⁶

In 2022, as the demand for digital therapeutics grows across the ecosystem, new business models will likely emerge beyond the traditional commercialization approaches. We expect to see a shift in favor of insourcing some of this technology as life sciences companies gain more experience in the field.⁶⁷

Mergers & Acquisitions (M&A) for R&D pipelines

COVID-19 negatively impacted the degree of M&A in 2020, with a slight rebound in 2021—but overall activity remained subdued. There were fewer, smaller deals, and we saw companies shifting their portfolio toward rare diseases through their smaller-scale M&A activity.⁶⁸

Pfizer was particularly active in 2021. Flush with cash from its hugely successful COVID-19 vaccine with BioNTech, Pfizer invested in other pipeline-boosting deals, including a US\$2.4 billion licensing deal for an Arvinas cancer drug. The success of COVID-19 vaccines from Pfizer/BioNTech and Moderna put mRNA platforms into the spotlight. Sanofi paid US\$3.2 billion for Translate Bio and its mRNA platform for expressing proteins.⁶⁹

In our outlook, we expect continued focus on bolt-on acquisitions aimed at bulking up R&D pipelines.⁷⁰ With smaller firms, talent, tools, and intellectual property may be ported to the parent, adding value in many ways.⁷¹ When smaller bolt-on acquisitions dominate, the number of deals may be high,⁷² and deal-making activity is expected to pick up this year.

As smaller biotechnology firms and larger pharmaceutical companies position themselves for opportunities to acquire assets, we expect to see many more types of collaborative relationships maximizing new technologies. Pfizer kicked off 2022 with a US\$300 million multi-target research collaboration with gene-editing firm Beam Therapeutics. The deal makes Beam eligible to receive future milestone payments of up to US\$1.05 billion—a potential total consideration of up to US\$1.35 billion. Pfizer looks to leverage Beam's proprietary in vivo delivery technologies, which use mRNA and lipid nanoparticles (LNP) to deliver base editors to target organs.⁷³

More investments in cell & gene therapies

Mergers and acquisitions dominated the funding for cell and gene therapies in 2021, and it appears the trend will continue. CGT represents roughly a third of all private investment in life sciences.⁷⁴ Total funding from all sources for cell and gene companies in 2021 exceeded US\$70.8 billion last year, including:

- IPO and FPO Deals
- SPAC Deals
- Venture Capital and Private Funding
- Strategic Investments
- Mergers & Acquisitions (M&A)
- Technology and Research Collaborations
- Licensing Deals
- Manufacturing and Supply Chain Deals
- Public Outreach, Consumer Education, & Philanthropy
- Distribution & Co-marketing Deals
- Restructurings, Joint Ventures, Terminations and Spinoffs
- Other Types of Deals Impacting Cell and Gene Therapy⁷⁵

More than 50 partnership deals were executed between pharma and promising CGT companies before the first therapy was even approved in 2017.⁷⁶ Tools such as CRISPR and next-generation sequencing have lowered the barriers to entry,⁷⁷ and early approvals are paving the way for new entrants in this nascent market, where CGT represents only 7% of the approved 340 biologics.⁷⁸ A record number of regulatory decisions are upcoming in 2022-2023 (see figure 8).⁷⁹

Figure 8: Upcoming cell & gene therapy regulatory decisions, 2022-2023

United States	Gamida Cell Blood Cancer + HSCT	Atara Bio EBV + PTLD	CRISPR/Vertex Sickle Cell & Beta Thal
	Iovance Melanoma	Krystal Bio Epidermolysis Bullosa	CARsgen Multiple Myeloma
	BioMarin Hemophilia A	uniQure/CSL Hemophilia B	Orchard MLD
	PTC Therapeutics AADC Deficiency	Bluebird bio Beta thalassemia	Adaptimmune Synovial Sarcoma
	Janssen/Legend Multiple Myeloma	Bluebird bio Cerebral ALD	Bluebird bio Sickle Cell Disease
2022		2023	
Europe	Janssen/Legend Multiple Myeloma	BioMarin Hemophilia A	Orchard Wiskott-Aldrich
	PTC Therapeutics AADC Deficiency	Atara Bio EBV + PTLD	
	GenSight Bio LHON	uniQure/CSL Hemophilia B	

BLA/MAA submitted
 BLA/MAA planned

Source: ARM, 10 January, 2022

A significant amount of future success hinges on whether approved treatments are allogeneic or autologous. Since autologous treatments are based on a patient's own cells and made to order, they represent more complexity and cost in treatment planning, manufacturing, and supply chain. Allogeneic treatments are based on cells from a donor, fitting more into the traditional model of distribution.⁸⁰

Currently, as the number of therapies is small and the volume of patients is large, payers have been open to innovative approaches to reimbursements, including annuity and installment-based payments and outcomes-based reimbursement. Experts say it is unclear how these approaches might scale as the numbers rise.⁸¹

However, the future promise of cell and gene therapies is making companies with strong cell or gene therapy pipelines and the most promising technologies, researchers, and intellectual property attractive targets.⁸²



Transforming the patient experience

Patients at the center, taking charge of their health

The pandemic put patients at the center of every conversation, and innovation was catalyzed. Over the last two years, collaboration across life sciences and with stakeholders was unprecedented—all mobilizing in the interest of patients.

Communication between patients, sites, sponsors, and supply partners increased.¹ As of 14 December 2021, sponsors are enrolling or have enrolled more than 90 million people in 775 COVID vaccine-related clinical trials, including 50 million estimated for a post-marketing safety study for the Moderna mRNA-1273 vaccine.²

The pandemic helped to create more patient-centric channels. Digital technologies, in particular, were globally adopted, and telemedicine became broadly available. Digital is allowing companies to collaborate with patients to develop therapies with endpoints that the patients care about—including quality of life measures.³ Collaborating with health systems is enabling insights from data, and patients are now taking charge of more of their health.⁴

Patient engagement has been an essential part of biopharma research and development and disease management.⁵ However, as one patient advocate told a pharma executive—“We’ve been engaged for a long time, it’s time to get married.”⁶

How will life sciences take advantage of this momentum and become truly patient-centric in 2022?

Becoming a more patient-centric organization

Patient-centricity is more than providing good quality care. It means making patients equal partners who are at the center of health care decisions.⁷

Co-creating with patients, the heart of patient centricity

The concept of patient-centricity is decades old—but remains a challenge to master.⁸ Patient input to life sciences companies' designs is increasingly more sophisticated and widespread. But some patient advocates believe that patients should be equal partners in the process with the patient at the center of decision-making.⁹

According to Dana Lewis, patient advocate and founder of OpenAPS, the health care system doesn't have the patient as an equal partner all along. She says that there is a huge gap, and we really need to think about redesigning the system, not just having patients as an add-on to the system.¹⁰

From concept to launch, patient "co-creation" would change many of the micro and macro decisions life sciences companies make along that journey, including—what to research, how to develop, how to package and distribute, how to get into patients' hands, and ultimately, how to measure patient outcomes (see figure1).

Pharma companies are starting to adjust their enterprise decisions by reflecting the patient needs in more decisions, and health tech and other ecosystem companies are gaining traction filling this need.

Integrating engagement, fully partnering with patients

According to Dr. Freda C. Lewis-Hall, former chief patient officer for Pfizer,¹³ life sciences organizations need to stop trying to solve problems themselves, and instead, they should fully partner with patients. "Get insights into what patients' preferences and needs are, what their current skills are, and how they can help us shape ourselves as companies and industries. Let them know that their input is important for what we are ultimately going to offer to them. When we bring the solution, they'll know that we've worked on it together to provide it," she says.¹⁴

Figure 1: The patient and life sciences co-creation process



Source: "Patient co-creation is a tall, but worthwhile, order for health innovators," MobiHealthNews, 27 November 2019.

Voice tech captures the true voices of patients providing trial sponsors with deeper insights

TrialPulse is a patient insights platform helping hundreds of pharmaceutical companies better listen to the true voices of patients. Using voice technology, patients provide insights on various parts of the R&D process, including patient experience, disease burden, unmet needs, trial design, recruitment, and retention optimization.¹¹ Language analysts and advanced natural language processing (NLP) tools are used to process, evaluate, and analyze multiple aspects of each patient's response, including emotion which may provide deeper insights for the sponsor.¹²

For accurate patient insights, it is important that life sciences companies are proactive, involving patients early, and not waiting until there is a final product such as an app or website for patients to review.¹⁵ Begin with the initial brainstorming through to the launch of the product (see figure 1),¹⁶ Be flexible—see the process of co-creation as an open dialogue and change direction based on the feedback you receive.¹⁷

In addition, life sciences companies need to plan for the investment required to really involve patients, including patient compensation. When patients aren't compensated for their time, sponsors risk bias by design and lack of diversity, because only patients who are able to—can afford to and have the time to—be involved, will.¹⁸

Just ask patients: Savvy Cooperative digital health startup

Companies and innovators are likely to waste time and money creating products and services that don't meaningfully impact patients' lives. Often, this is because developers never bothered to ask patients. They create products for patients and not with patients. **Savvy Cooperative** is an online marketplace for patient insights. The platform allows innovators to connect directly to patients and caregivers that match their objectives. Companies post a "Savvy Gig", and patients choose gigs that they want to participate in or that are relevant for a particular disease. Patients have the opportunity to earn rewards. The goal is to co-create a product or service that offers a better patient experience and brings real value to patients.

“ In life sciences, we have brilliant people. We have technology and deep science. But what we often don't have, is deep patient insight. We really have an opportunity now to build that in by creating an end-to-end partnership with patients. ”

*Freda C. Lewis-Hall, M.D., DFAPA, MFPM, former Chief Patient Officer, Pfizer, Inc.*¹⁹

Enhancing engagement, creating value

Digital and data solutions can help embed patient centricity across the value chain.²⁰ Digital health, medicine, or therapeutic technologies offer many ways to provide value:

- Empowering patients to monitor and self-manage their health
- Increasing access to therapies which are clinically effective and safe, with side effects that are typically less severe than in traditional pharmacological interventions
- Improving medication management and patient adherence
- Helping alleviate the limited access to therapy
- Providing updates on outcomes through regular monitoring
- Reducing medication dosages for patients who adopt healthier lifestyle habits as a consequence of tracking their symptoms and health status
- Reducing the number of face-to-face interventions, e.g., through digital cognitive behavioral therapies
- Enhancing patient experience by receiving care in a more convenient setting, e.g., in the comfort and privacy of patients' homes or wherever a patient may be
- Increasing access to interventions for underserved populations
- Enabling more predictive, preventative, personalized, and participatory care²¹

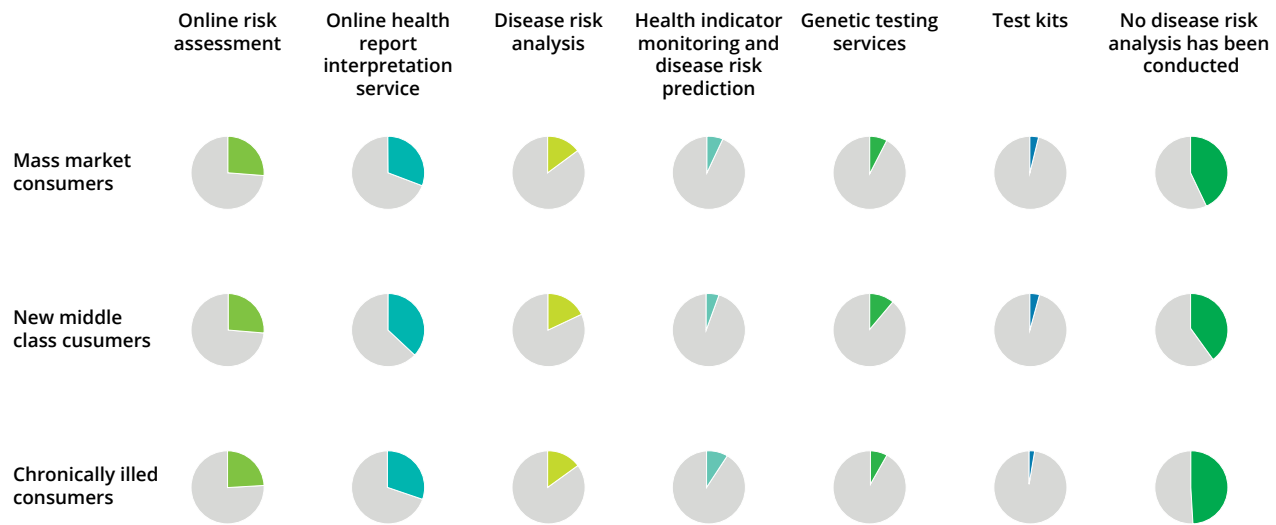
Creating an end-to-end screening, scheduling, and results delivery platform

In the early days of the pandemic, both public and private organizations were forced to develop fast, piecemeal solutions to tackle the challenges of outbreaks. But **Quebec's Ministry of Health and Social Services (MSSS)** had a vision to proactively combat these outbreaks by optimizing the testing and screening processes for its citizens. The goal was to reduce complexity, improve connectivity, automate manual tasks, and create a more efficient patient experience. Deloitte worked with the Canadian Ministry to create a centralized platform that gives citizens their appointments and results faster and provides ministry workers the tools they need for getting ahead of the virus in their community.²²

Monitoring value and use of products and services

Tracking consumer interest and actual use of technologies enables life sciences companies to be more patient-centric. For example, consumer use of risk assessment and early intervention products and services is increasing. These products and services provide early warnings regarding infectious diseases, genetic diseases, and cancer, among others. According to a survey of Chinese consumers' preferences by Deloitte, higher utilization of these products was among those with chronic disease (see figure 2).²³

Figure 2: Consumer preferences for products or services for disease risk analysis and early intervention in China



Source: Integrating digital health care solutions to better serve and protect consumers, Deloitte China, 2021.





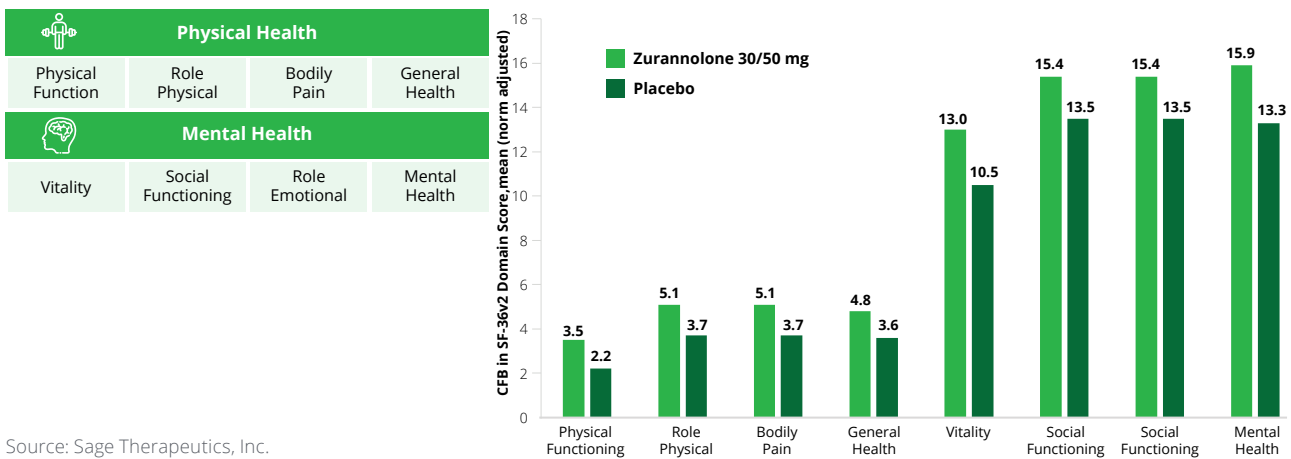
Shaping clinical trial design with patient insights

Patient-focused drug development

Patient-focused drug development incorporates patient experiences, needs, and outcomes to further drug development and evaluation—with greater emphasis being put on quality of life measurements.²⁴ The SF-36v2 (36-Item Short Form Health Survey, version 2) is a widely used and validated instrument for patient-reported outcome (PRO) measures.²⁵ Patients answer questions regarding their quality of life and overall physical and mental health (see figure 3).²⁶

Sage Therapeutics, Inc. and Biogen Inc. were able to receive patient feedback on a clinical trial for zuranolone for major depressive disorder (MDD) with the SF-36v2. The assessment reported rapid improvement in quality of life and overall health for patients across all domains at Day 42 of the trial²⁷ (see figure 3).²⁸

Figure 3: SF-36v2 Day 42 clinical trial PRO with Zuranolone treatment for MDD



Source: Sage Therapeutics, Inc.

Co-creating patient-friendly outcome measures

Pharmaceutical companies should consider more patient-friendly outcome measures and functional outcomes, as opposed to just regulatory or clinical outcomes, according to Gautam Gupta, senior vice president and head of strategy for Pfizer. He says that when selecting metrics for clinical trials, you should involve the patient, and consider:

- What metrics does the patient care about?
- What outcomes does the patient want to see?
- Is the medicine making the patient’s daily functioning easier?
- Is it increasing mobility, if relevant to the disease?

Adding the endpoints patients care about should become part of the clinical trial.

Predictive engagement, using data for personalized experiences

Anticipating needs and meeting expectations

Transforming clinical trials and patient services often requires catching up to other consumer experiences. Patients have a mental picture of expectations, that they may not even be aware of, shaped from other experiences.²⁹ For example, when someone has a great customer service experience in retail or online, or a seamless experience with a tech giant's app, they expect no less from their health care app, website, or consultation.³⁰

A leading customer service experience is provided by the Ritz-Carlton, whose goal is to 'delight' customers by anticipating the unexpressed wishes of their guests. Customer data is used to shape a personalized experience, and an innovation database stores ideas to share across properties.³¹ In health care, we can anticipate adverse health events by using data and digital tools to predict and prevent, according to Gilles Marrache, senior vice president in Europe for Amgen.³² For example, building algorithms from Electronic Medical Records (EMRs) may predict who is likely to have a second heart attack, and we can work with that patient to prevent it.³³

“
Everyone aspires to be healthy and happy.
”
*Christophe Jauquet, author of Healthusiasm.*³⁴

Sparing patients an unpleasant experience with synthetic control arms

Sparing patients an unpleasant experience is also valuable. According to Alicia Staley, vice president of patient engagement for Medidata, synthetic control arms essentially enable running a clinical trial with data. “With the evolution of what can be done with data, and particularly with AI, you are perhaps sparing the patient the actual experience of taking the medicine and living through side effects. You can figure out what a potential response would be,” she says. Staley suggests companies continuously look at data sources and act upon the signals they provide.³⁵

“
Life sciences and medtech companies need to build a company culture around the patient experience and the data they're learning about the patient. Data without analysis is just ones and zeros. If you're not looking at the data and acting on that data, it's useless and has no value.
”
*Alicia Staley, Vice President, Patient Engagement, Medidata.*³⁶

This shift to predictive health and using data also requires trust. Trust by the patient that their data is being used responsibly and for their benefit. It requires pharma and device companies to invest in building that trust, to communicate openly and to be transparent.³⁷

Enhancing engagement with leading-edge technology

Life sciences companies can drive purposeful digital innovation by creating precision experiences with leading-edge technology (see figure 4).³⁸ AI-driven engagement, connected patient, and health care provider (HCP) platforms may provide patients and partners timely access to content and treatments that are relevant and personalized.³⁹

Figure 4: Sample digital innovations powering precision experiences

Digital innovations	Description
360-degree view of patients and partners (cloud/data lakes)	<ul style="list-style-type: none"> By combining behavioral and socioeconomic patient data (e.g., buying propensities, workout tendencies) with marketing data (interactions with online ads, impressions, conversions) in data lakes or the cloud, companies create 360-degree view of patient behavior across digital and physical footprints. Similarly, data on how physicians interact with the company ad affiliate web ads, email, and social media content is aggregated to provide a view of their engagement across channels and platforms and can be cross-referenced to specific patients.
AI-based engagement recommendations (AI)	<ul style="list-style-type: none"> AI marketing solutions analyze patient datasets to recommend how, when, and with what customized content to engage patients and partners (such as personalized ads, tailored medication regimens, and adherence programs) across channels and the patient journey.
Next gen HCP portals (chatbots, NLP)	<ul style="list-style-type: none"> Next generation HCP portals with NLP and AI chatbots enable on-demand access to information and seeking peer opinion to improve care delivery, while broadening access opportunities for companies.
Connected patient platforms (cloud/wearables)	<ul style="list-style-type: none"> Cloud-based connected patient platforms aggregate data from patient wearables and medical devices, track and analyze patient outcomes, and link patients to physicians and support groups to create longitudinal engagement.
Proactive market intelligence (AI/cloud)	<ul style="list-style-type: none"> AI enables curation and analysis of unique information sources to sense changes in the marketplace (such as likely changes to reimbursement practices, regulations, competitor tactics) that could affect launch strategies and competitive dynamics.

Source: Biopharma digital transformation: Gain an edge with leapfrog digital innovation. Deloitte, 2021.

Investing in more patient-centric digital capabilities

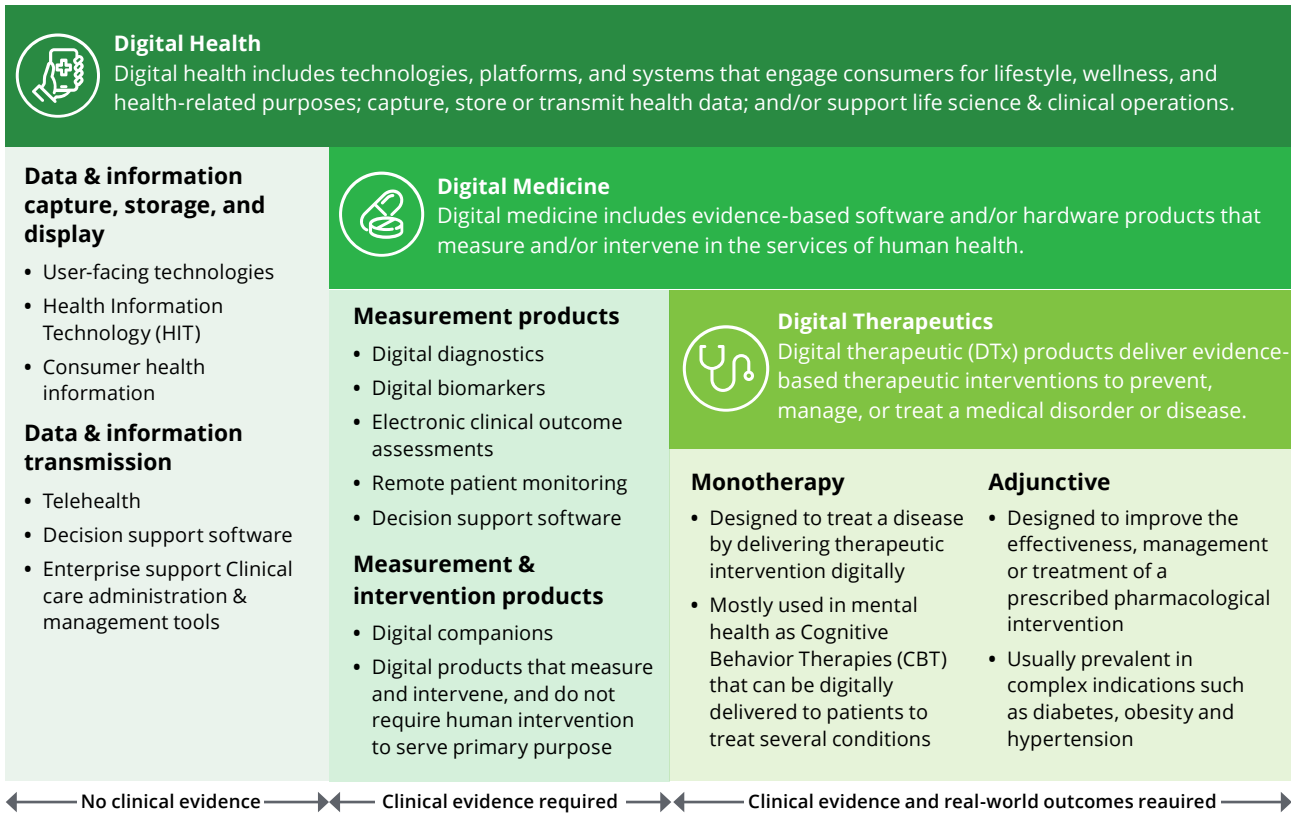
Digital becoming a strategic priority

Digital health, digital medicine, and digital therapeutics offer life sciences and stakeholders an opportunity to create more personalized experiences and new ways to become patient-centric. In the coming year, life science and medtech companies plan to grow investments in digital capabilities for more personalized therapies and patient support (see figure 5).⁴⁰

According to a recent study by Deloitte, executives from life sciences, technology, payer, and provider organizations expect digital medicine products to become a strategic priority. Digital therapeutics, in particular, are starting to impact patient outcomes and show clinical validation.⁴¹

The need for education around these solutions is intensifying. If physicians are not educated on what digital therapeutics are and how they may help patients, they are unlikely to prescribe them. Staying up to date on regulations, the types of solutions available, clinical applications, digital biomarkers, etc. will remain an on-going need as technology evolves exponentially.⁴²

Figure 5: Differences between digital health, digital medicine, and digital therapeutics



Source: Digital therapeutics, Deloitte, 2021.

Digital health venture funding boom

In 2021, US-digital health startups aimed at R&D in biopharma and medtech received funding totaling US\$5.8 billion. Investor interest was fueled by the COVID-accelerated adoption of real-world evidence and decentralized trials. Overall, 2021 was a blockbuster year for US-based digital health startups, raising US\$29.1 billion across 729 deals—nearly double the US\$14.9 billion raised in 2020, a previous record. There were nearly 23 exits via merger or acquisition monthly, almost double 2020's monthly average of 12.⁴³

2021 was also a big year for digital health in Europe. Europe had 34 digital health company exits in 2021 alone—half of the 68 exits in Europe over the past decade. Babylon became the first European digital health company to list on public markets in a SPAC (Special Purpose Acquisition Company) in deal worth US\$4.2 billion.⁴⁴



Merging different data silos from digital health partnerships or acquisitions remains a challenge for many health care and life sciences companies. There should also be a better flow of data across payers, providers, and even manufacturers. Regulators are requiring data to become more transparent and user-friendly for patients.⁴⁵ Enabling patients to provide feedback and concerns, allows patients to have more of a voice regarding how data is being captured and actioned upon.

Building holistic patient services experiences

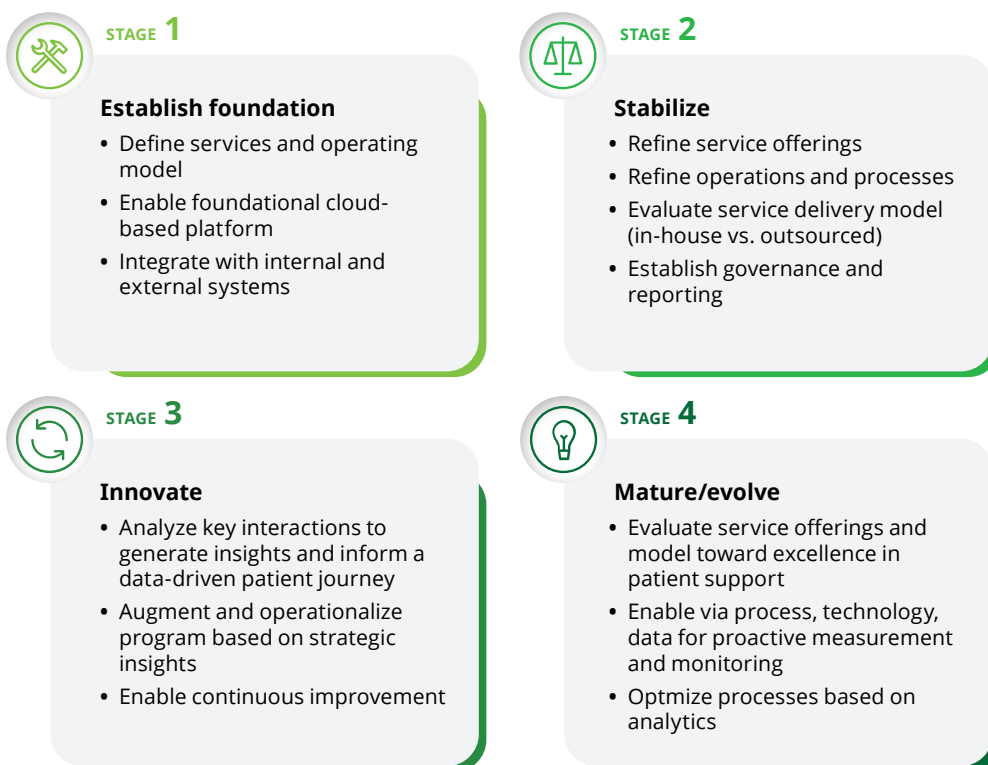
Developing patient services in-house

Life sciences companies typically manage patient services programs by therapy or therapeutic area. As patient engagement becomes more comprehensive—potentially with more value to the patient over a lifetime—an increasing number of life sciences companies are moving patient services in-house. An important first step to proving value for an in-house platform is starting small—with one or a limited number of therapies. A comprehensive program typically includes five areas:

- Financial
- Clinical
- Engagement
- Education
- Access to therapy⁴⁶

Operationalizing a patient services program and moving it in-house requires integrating with internal and external systems and refining operations and processes. Service offerings should be modelled toward excellence in patient support. Innovating means analyzing key interactions to generate strategic insights that will inform the patient journey (see figure 6).⁴⁷

Figure 6: Four stages to operationalizing a patient services program



Source: Building patient services programs to deliver better patient experiences, therapy adherence, and improved health outcomes, Deloitte Digital, 2020.

Takeda’s OnePath is an example of a comprehensive in-house services program. OnePath is a dedicated ‘patient support manager’ that provides one-on-one service to make sure patients have access to their prescribed therapy and a personalized product support plan. Services include navigating insurance, managing costs, getting prescriptions filled, and arranging training from a nurse. There is a dedicated website for the OnePath journey that also includes a library of resources for the patient.⁴⁸

There are specialized solutions along the patient journey, with which companies will want to partner (vs. seek to build themselves). Services to facilitate scheduling, pharmacy e-commerce, drone distribution of medical supplies, best in class Natural Language Understanding, and the plethora of digital applications enhancing a specific touchpoint are all capabilities life sciences companies can harness and integrate to their in-house services programs.

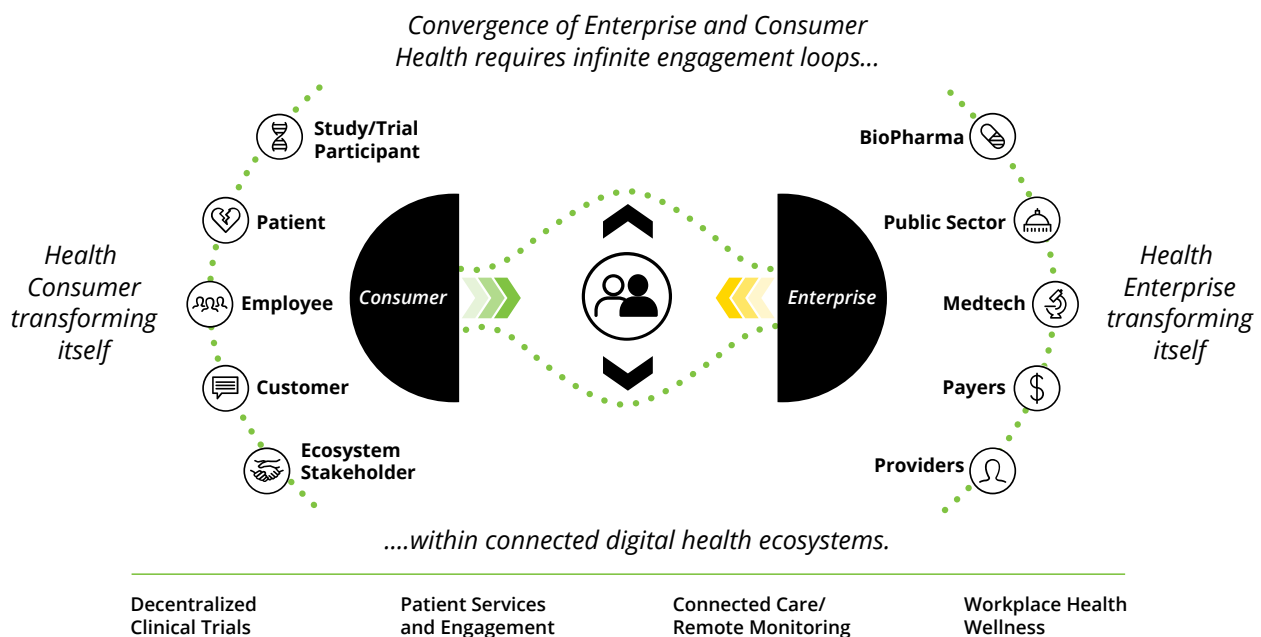
Working with partners in the ecosystem

Partnerships across the ecosystem are also key. According to Betül Susamis Unaran, chief strategy and digital officer for Zur Rose, Europe’s largest e-commerce pharmacy. When different companies deliver different parts of the journey, everyone needs to come together to create ‘one experience’ for the patient.⁴⁹

Enabling many companies to come together to create a unified experience for the patient, Deloitte’s ConvergeHEALTH Connect platform prioritizes supporting patient journeys within connected ecosystems (see figure 7). Whether for observational studies, clinical trials, or therapy support, the patient service workflows extend beyond a single life sciences or health care enterprise. ConvergeHEALTH Connect drives standardization of workflows, like enrollment, benefits checks, and authorizations through a set of interfaces and APIs. Wherever opportunity exists, it eliminates manual workflows through automation.⁵⁰

In addition, the platform provides personalization and enables the “whenever, wherever” paradigm of patient access by providing seamless integration of communication channels like phone calls, secure messaging, and video chats. In each scenario —standard workflows, communication channels, or automation—the ConvergeHEALTH product team builds partnerships with best-in-class vendors for joint innovation.

Figure 7: Delivering effective patient/health consumer experiences in connected systems



Source: Deloitte analysis.

Ping An Good Doctor and Chugai Pharma China strategic partnership for osteoporosis

Ping An Good Doctor (Ping An Healthcare and Technology Company Limited) and **Chugai Pharma China** (Chugai Pharma China Co., Ltd.) are establishing a whole course management system for osteoporosis patients, including an osteoporosis clinic. Approximately 20% of the population over 50 years of age suffer from osteoporosis in China, but only 7% are aware of the disease. The treatment is complex—involving multiple medical departments including orthopedics, endocrinology, rheumatology, and immunology, etc.—but lacks a professional full-cycle care management platform.⁵¹

Ping An Good Doctor is a health care platform working with pharmaceutical company, Chugai Pharma China, to enhance drug accessibility, medication guidance management, and sharing of pioneering academic findings to benefit more patients. The clinic is integrating services for osteoporosis patients, including health education, disease prevention, consultation, drug purchasing, and rehabilitation etc.—optimizing the online and offline closed-loop management system. Ping An Good Doctor is offering personalized solutions for patients and adjusting treatment strategies by tracking health data.⁵²

There are more than 400 million users on Ping An Good Doctor's health care platform, and China's health care sector is projected to grow by more than 10% annually. Ping An Good Doctor is forging many alliances, including offline-to-online co-operation deals with 189,000 pharmacies, over 4,000 hospitals, around 1,700 checkup centers and more than 1,800 medical institutions, a network that keeps growing every month.⁵³

In 2022, it's time to fully partner with patients as longitudinal partners to better understand their disease and improve care outcomes.⁵⁴ Successful life sciences companies and stakeholders will be involving patients in co-creation, making investments in patient-centric digital capabilities, and working to create holistic experiences whether in-house or with partners in the ecosystem. Organizations that reimagine their business models, and put the consumer-patient at the center, are likely to succeed in transforming the patient's journey of care and deliver better outcomes.⁵⁵



Transforming the talent experience

The COVID-19 pandemic permanently altered society's view of work. The biggest transformational shift came from, not "where" work was done, but "how"—a wholly digital way of working.¹ Life sciences companies are still optimizing virtual ways of working, and other issues of concern for life science leaders in 2022 include:

- What is our talent acquisition strategy? How do we secure in-demand skills and capabilities in a competitive market?
- What are the "Great Resignation" effects on our company? How can we create a more meaningful talent experience?
- How can we become a more agile and adaptable organization?

Life sciences companies that want to succeed in the future of work will need to be flexible in how work is done and how talent is sourced, trained, and managed.² Human resources is also undergoing a massive transformation. Instead of trying to predict the future, leaders might consider how they can develop an open culture of experimentation, learning, and iteration.³

Developing new talent strategies will be a challenge for Human Resources (HR) in 2022. Leaders will need to find competitive advantages to address skills and talent shortages (e.g., digital and data analytics skills).⁴ Competition for workers will grow as the effects of the "Great Resignation" are now being felt at every level. Many older workers chose early retirement, and more than 40% of the global workforce is looking for new jobs, including 54% of Gen Z.⁵ Even high-level executives, including the C-suite, are quitting their jobs to spend time with their families.⁶

Aggressive hiring practices are poaching talent at all levels—potentially inflating titles and compensation. Rising inflation poses more challenges. Recent Deloitte research looks at a variety of potential inflation scenarios and key decisions executives will need to consider going forward. In the worst case scenario, inflation rises to 8-9% and becomes embedded in worker expectations and a “wage-price spiral” takes off. Companies may need to seriously consider cost-saving labor models—offshore, automation, and labor-as-a-service.⁷

Throughout the next year, many life sciences companies will continue to grapple with how to solve these issues, and each will land in a different place on the spectrum. The “Great Resignation” is calling for a “Great Re-imagining”, and a winning strategy includes creating value for workers as whole human beings and key stakeholders—including internal and external workers.⁸

In a technological world, meeting the needs of humans has never been more important.⁹ By harmonizing technology and worker preferences, life sciences companies can deliver more flexible and meaningful talent experiences and become more adaptable organizations.¹⁰

“ In a business-as-usual environment, HR is a trusted partner to the business but, in a pandemic, we are leading the fight. The future of work remains undefined, I believe it will be marked by continuous organizational change with HR orchestrating transformation from within. ”

Agnieszka Romanczuk, Director, Human Resources, Japan and Asia-Pacific, AbbVie¹¹

Massive shifts in talent models

Successful companies are no longer concentrating on just hiring the smartest people, but rather on having access to the smartest people.¹² New workforce ecosystems include in-house employees combined with a diverse mix of external contributors—e.g., contractors, app developers, other gig workers, external partners and suppliers, and even software bots.¹³ According to recent research from MIT Sloan Management Review and Deloitte, only 28% of global managers feel they are sufficiently preparing to manage a workforce that will rely more on external participants.¹⁴

One agile strategy is to shift from a hierarchical structure to a more team- and networked-based approach that may combine internal and external workers into specialized or cross-functional teams. To support cross-functional engagement, organizations might consider sharing owned facilities with suppliers and partners.¹⁵

An agile work environment allows for choice and flexibility. Teams are formed to address specific problems, such as launching a new product, optimizing a process, analyzing market trends, understanding customers and their needs, and so on.¹⁶ In 2022, effective leaders in team environments will be mentors—more than managers—and digital enablers, embracing role mobility and job agility.¹⁷

Helping people thrive in a large organization, ditching hierarchy for teams

Roche Pharmaceuticals, based in Basel Switzerland, is moving away from traditional hierarchy to autonomous, self-organizing teams—putting people and patients first. According to Roche’s pharma CEO, William (Bill) Anderson, with a team approach, workers are much more accountable to their teams. Anderson says that Roche is allowing teams to request the funds necessary to fulfill an objective or to solve a problem. “We only ask that they: 1) drive medical advances, 2) thrill customers and patients, and 3) make best use of company resources. We talk about how they did later,” says Anderson. The team approach is proving to be much more efficient. “Spending actually went down,” he says. There is more team pressure to deliver on an objective and use company resources wisely.¹⁹

“ I strongly believe when you invite folks to co-create a transformational process from the beginning, they’re more likely to contribute to the longer-term effort required to make it a reality. ”

Eva McLellan, Head of Business Strategy, Transformation, and Innovation, Roche Pharmaceuticals²⁰

The workplace is now a virtual place

As organizations are reimagining work, physical space and the need for facilities, and who needs to be in the office,²¹ they might start thinking about the workplace as a virtual place—a digital office for working. A virtual office is where team members gather digitally and use collaborative tools to solve problems in the pursuit of organizational goals—no matter where anyone is physically located (see figure 1).²²

Figure 1: Concepts for thinking differently about the workplace

Term	Definition
The digital workplace	The digital overlay that enables the physical work experience (typically in an office), including smart building technology, digital user interfaces (apps, portals), data collection, predictive technology.
Working digitally	Work that is agnostic of physical space or place, as it is done digitally (rather than physically) and so adheres to different rules and norms.
The virtual office	A “digital” place to work: the technologies (tools and media) that allow people to work individually and as a team anywhere, anytime, anyhow.

Source: Reconstructing the workplace: The digital-ready organization, Deloitte, 2021.²³

Digital offers a way to unbundle the workplace and create new solutions. For example, the pandemic caused some employees to feel isolated with remote work, in addition to experiencing loneliness in everyday life.²⁴ Workers may also want to set boundaries between work and homelife for virtual work. A return to the office may not be the only option for someone unhappy working from home. Organizations might provide a co-working space close to home for the desired work environment, along with the benefit of a shorter commute.²⁵ Empowering workers to work from a location that suits them promotes a better work/life balance.²⁶

Supporting flexible, hybrid work

Offering workers a choice

Every life sciences organization must determine the work environment best-suited to its various operations and teams. Processes that require labs, such as clinical research or toxicology, are not viable for remote work, but many other pharmaceutical processes can be executed remotely.²⁷

Deloitte research finds employee engagement—which is directly correlated with productivity—is at its highest among employees who spend **60-80%** of their time working remotely.²⁸

Almost half of employees²⁹ and a majority of millennials report they would give up some work benefits for a more flexible working space.³⁰ As the workforce shrinks, attracting and retaining young talent by offering a choice of work style may be a competitive advantage.³¹

Before the pandemic, it was rare to ask: “What would be your preference, if your role allowed for greater flexibility?”³² However, the success of a hybrid model depends on researching preferences. In Japan, despite being offered a choice of work style, many still carry the belief that an office presence is required. These workers may need to be encouraged to take a remote or hybrid option by companies asserting that the choice is acceptable, and maybe even preferred.³³

In Germany, ‘modern rules for mobile working in Germany’ are in development, creating a legal right to work from home. With this change, all employees would be allowed to work from home, so long as their presence isn’t necessarily required at the office; employers would only be allowed to refuse for compelling reasons.³⁴

“ We believe that the key to an energized work environment is recognizing individual needs and supporting a healthy work-life balance. That’s why we offer flexible workspaces and benefits, with some of our sites organizing volunteer activities, while others offering a range of initiatives that include gyms and sports events. ”

*AztraZeneca in China*³⁵

Culture, collaboration, and co-location

Can life sciences’ company culture evolve and thrive?

New ways of working are testing whether life sciences company culture can evolve and thrive. Work may never revert to pre-pandemic culture, and preserving collaboration is central to life sciences companies. Challenges of hybrid and virtual work may become a source of tension between an organization and its workforce as they try to figure out how to build community, culture, and engagement—critical for retaining talent.

Geographical differences also complicate global strategies for remote work and employment models. For example, Swiss global life sciences companies must consider tax compliance risks. Switzerland has separate tax agreements with different countries regarding frontier workers—workers who typically return to their foreign place of residence every day. The pandemic’s working-from-home arrangements prompted new cross-border agreements, but in 2022, Switzerland is expected to clarify post-pandemic terms for frontier workers.³⁶



Reevaluating the need to keep workers in “expensive” locations

While considering administrative and operational implications and tax compliance risks, life sciences organizations are also reevaluating their location strategies for various teams and individuals and the need to keep people in “expensive” geographies. Some office-centric, knowledge-based work does not need to be in legacy locations.

Global life sciences enterprises should consider:

- What are the reasons to maintain or retain talent in those areas?
- How can we be more targeted in getting the best talent where it’s needed most?
- How can some tactical, less-knowledge centric work be moved to a better location or to remote work to suit talent preferences and growth needs?

The culture for the type of work also matters, and organizations should facilitate different types of collaboration tailored to the specific work to be done. Certain specialized team members, like data scientists, may benefit from co-located teams and face-to-face collaboration. Organizations should create a space for a data-driven and connected community.

Fierce competition for digital and data science talent

Data is changing life sciences. New products with greater digitization—such as next-gen therapies and software-powered medical devices—require an understanding of customer needs and feedback through data. Life sciences companies need digital talent, software engineers, and data scientists who understand how to design a digital product and solution that meets patient needs.

Hiring data science talent is completely different from how the sector has hired in the past. Organizations will need to differentiate hiring practices because these specialists are difficult to source. There are also so few people that are true data scientists. Organizations should consider retraining existing employees who already have the necessary scientific background.³⁸

“

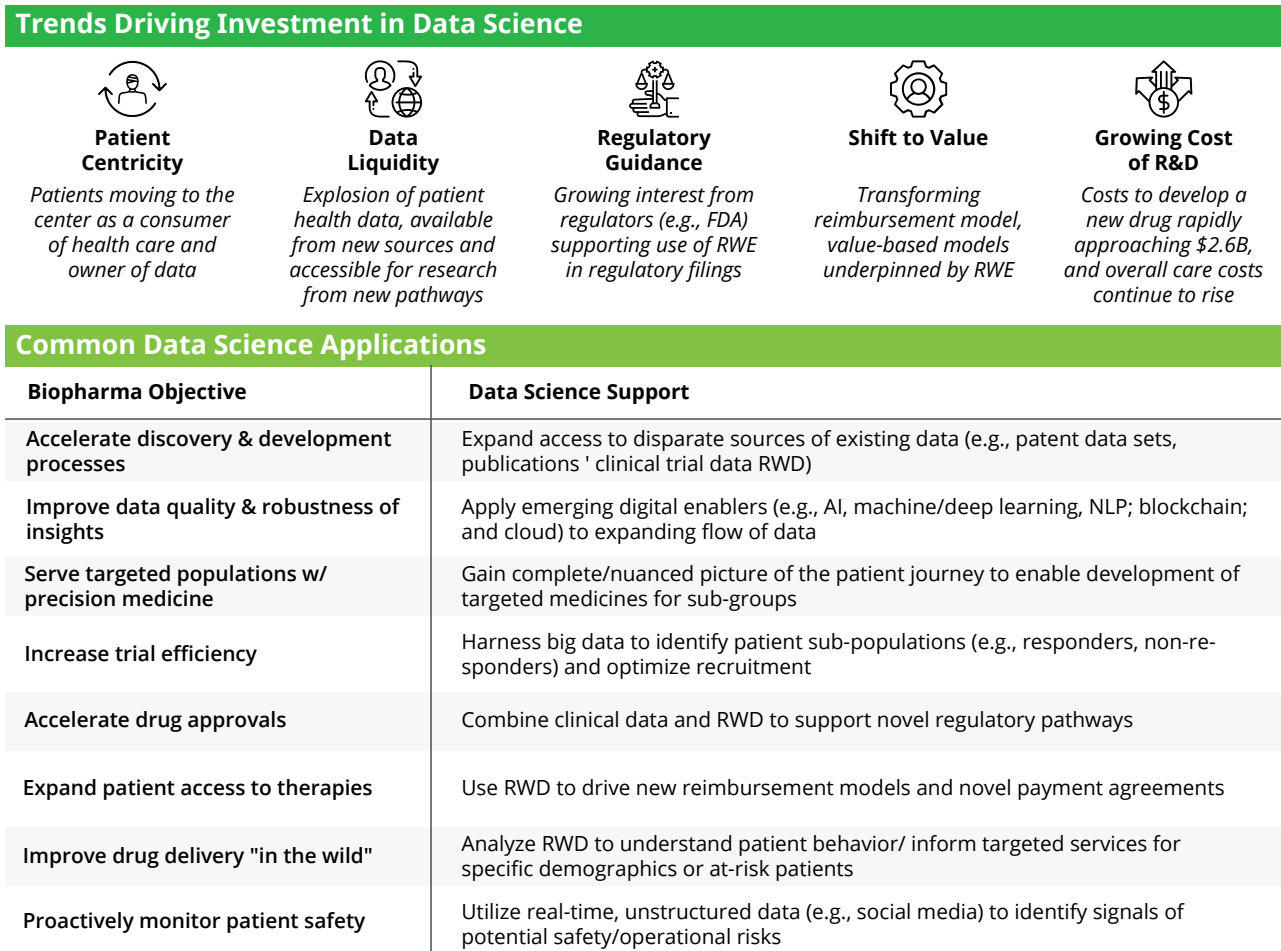
Incorporating data science into everything we do is transforming the way that our organization answers the question of ‘what is possible,’ including the way we conceive of, develop, and provide treatment options to our patients.

”

*Mathai Mammen, Global Head of R&D, Janssen Pharmaceutical Companies of Johnson & Johnson*³⁷

In addition, data scientists in enterprise offices differ from data scientists in the Research & Development (R&D) lab. R&D relies more heavily on data to drive towards specific outcomes—requiring intricate and deep skill sets (see figure 2).

Figure 2: Data science in biopharma



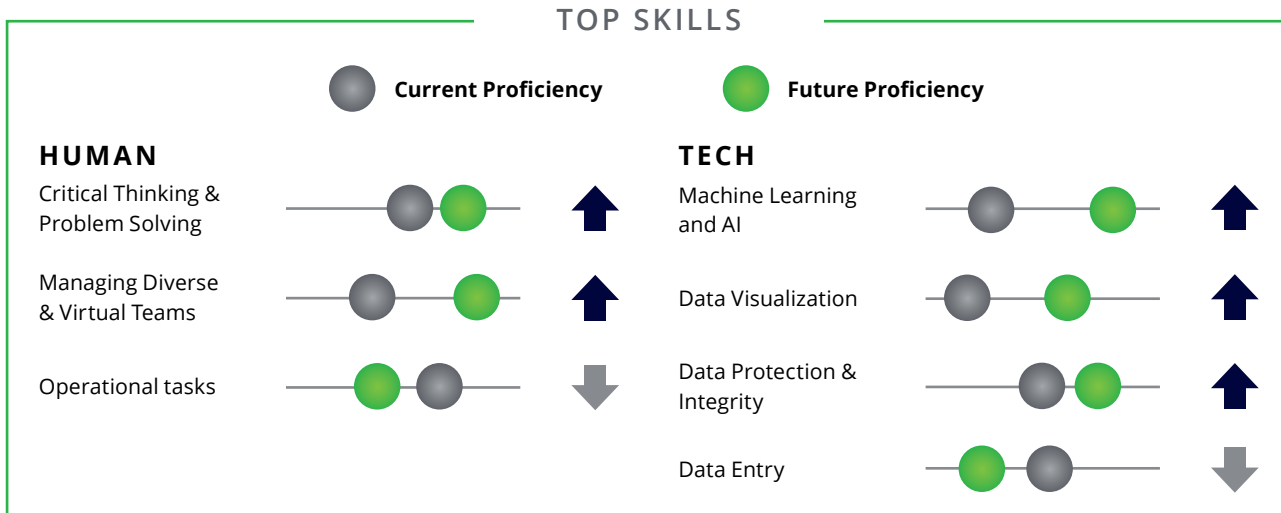
Source: Deloitte analysis

Future-proofing data science roles in life sciences

The skills in demand in biopharma companies are rapidly changing, and the types of new skills needed are growing. R&D organizations are posting 7 times more data science positions than they did 5 years ago. In addition to overall data science, the skills growing in most demand are python and machine learning.

Roles are also evolving, and anticipating change is critical to future-proofing an organization. For example, the worker profile for a Statistical Programmer or Biostatistician may evolve into a Data Strategy Manager role. To prepare, life sciences organizations can start by developing future proficiencies now (see figure 3).

Figure 3: Biostatistician to Data Strategy Manager, current skills and future proficiencies



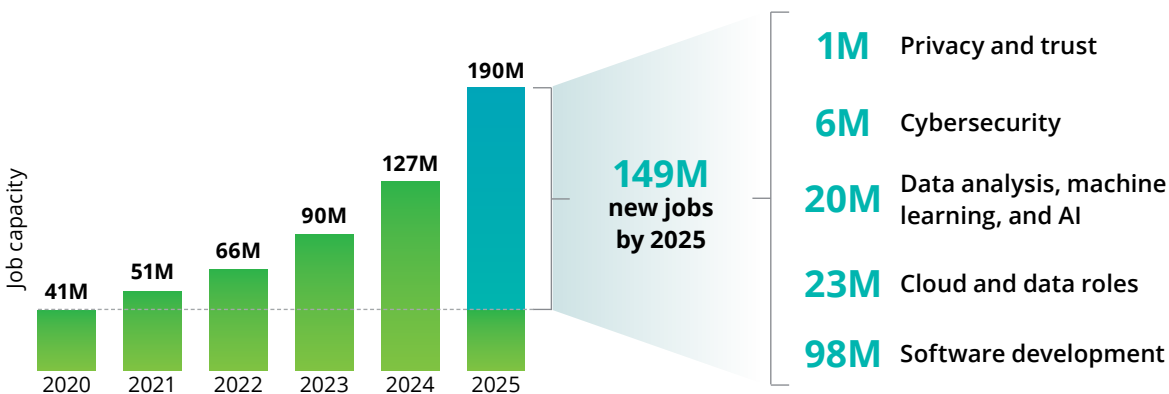
Source: Deloitte analysis

Reimagining work is a CEO strategic priority

According to a recent Fortune/Deloitte CEO Survey, attracting and retaining talent in a tight labor market has ascended to the top of CEOs’ list of strategic priorities. Companies should reimagine work as a landscape of tasks and skills that dynamically evolves with business priorities.³⁹

By 2025, an estimated 40% of core skills will change for workers.⁴⁰ Life Sciences will be competing from within and outside the industry for the same digital and data talent (see figure 4).⁴¹ The dearth of talent to support digital transformation initiatives is one of the biggest barriers to overcome, and expanding and upskilling talent should be a top investment priority.⁴²

Figure 4: Digital Job growth acceleration, 2020 to 2025



Source: Microsoft

Virtual work, recruiting from wider geographies, and acquiring talent outside of the industry (e.g., consumer-tech companies with different perspectives and skill sets) are strategies for expanding the digital talent pool.⁴³ Life sciences companies should also clearly define career pathing options and tasks, provide opportunities for all colleagues to improve their digital and data literacy, and implement scalable technology. A new distributed work model coupled with efficient, secure network communication tools will be essential to an organization’s success.⁴⁴



Regulatory: Mastering external forces

Seismic changes in the life sciences regulatory landscape

Responses to the pandemic varied by country but still drove significant, broad-reaching change in the regulatory landscape. Public- and private-sector actors engaged in wide-scale collaboration, cooperation, and information sharing. Research and regulatory processes were digitalized and accelerated and may never be the same again.¹

Reducing timelines from 10 years to 10 months

The speed at which vaccines were able to be developed and approved through expedited regulatory processes was unprecedented, and the focus remained on safety and efficacy despite the speed. The 10 months it took for the Pfizer-BioNTech COVID-19 vaccine to be developed, and to gain Emergency Use Authorization, is in direct contrast to the 10 plus years it takes for a typical cancer drug. As a result, the pandemic created a paradigm shift in expectations, and regulatory processes will likely become more streamlined going forward.

Getting medicines to patients quicker while maintaining safety is a priority for regulatory agencies as well as stakeholders. Tools such as Accelerated Approval, Priority Review, Breakthrough Therapy, Fast Track, and Rolling Submissions (see figure 1)² expedited approval of COVID-related vaccines and treatments.³

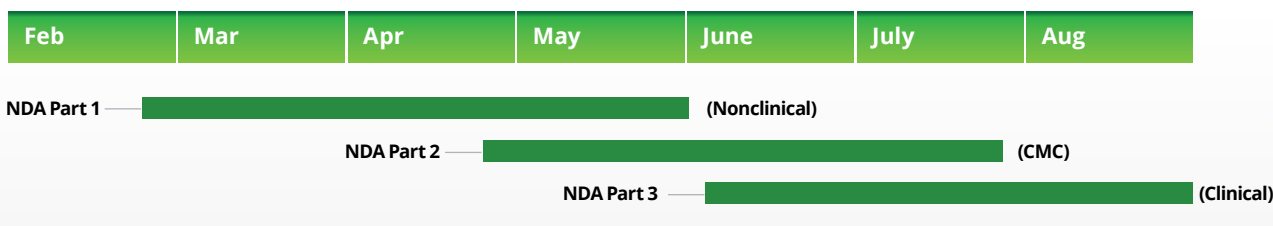
Growing trend in rolling submissions fueled by Real World Data

In the coming year, more companies are likely to accelerate regulatory approvals through rolling submissions and clinical, production, and distribution activities done in parallel as these practices became more widely accepted.⁴ For example, Canada never used the rolling submission or rolling review process before the pandemic.⁵ The option is now available under Canada’s Federal Drug Regulations.⁶

What is a rolling submission or rolling review?

A regulator receives key portions of a drug application as it becomes available, instead of waiting for the full data package. Regulators can request additional information and get clarification quicker. Being able to review data in waves expedites timelines.⁷

Figure 1: Example of rolling submission timeline



Source: Certara

Rolling submissions illuminate the power of real-time, real world evidence as a critical tool for regulators. More innovation is expected in 2022 as companies adopt data management tools that automate and speed up the work of ingesting, aggregating and cleaning data so that it’s easier to analyze, report on, and share with regulators.⁸

In the United States, the FDA is committed to understanding the full potential of RWD and RWE in regulatory decision-making. The agency is engaging with sponsors on the topic and creating mobile and web applications that can collect RWD.⁹

While emergencies demand speedy responses, regulatory agencies cannot operate on a permanent emergency footing. Many life sciences and medtech companies will be working with regulators to see how some of the processes utilized during the pandemic may be maintained for non-COVID submissions as well.

In 2022, automating manual processes, finding new ways to process information, and simplifying data management systems will be part of improving patient safety and maintaining compliance. Modernizing pharmacovigilance data management to streamline safety operations and allowing safety departments to focus on the opportunity of managing their end-to-end pharmacovigilance processes more holistically and compliantly is expected to have a significant impact on speed throughout the regulatory process.¹⁰

'Lightspeed' paradigm: Raising the end-to-end clinical success rate

The cost of failure is a significant challenge for the biopharma industry, making success rate a crucial driver of R&D productivity.¹¹ For example, developing new cancer drugs is considerably difficult and expensive. Between 2000 and 2020, 1,481 cancer drugs were selected for clinical trials, and only 115 were approved—at an average cost of US\$650 million per drug.¹² Vaccines have higher chances of being approved than other categories, but the failure rate is still high.¹³

A decade ago, **Pfizer** began its journey to improve its R&D productivity—which was lagging industry benchmarks—without compromising scientific innovation.¹⁴ Improving its asset success rate is a Key Performance Indicator (KPI) for Pfizer and a 'bold move' initiative to deliver first-in-class science.¹⁵ The company was able to raise its end-to-end clinical success rate (First-in-Human to regulatory approval) from 2% in 2010 to 21% in 2020—when the peer average was 11%. Pfizer credits its lightspeed paradigm as the driver behind the success of the Pfizer-BioNTech COVID-19 vaccine.¹⁶

In December 2021, Pfizer published its paradigm for [achieving end-to-end success in the clinic](#) to share information with other biopharmaceutical R&D organizations. Deloitte spoke with Gautam Gupta, Pfizer's senior vice president and head of strategy, for insights on the lightspeed paradigm and its role in regulatory approvals.

What can you tell us about Pfizer's lightspeed process for maximizing R&D productivity?

Gupta: Lightspeed is more than a mindset, it's also an investment approach. It's how you make decisions around the progression of assets and **which activities you do at risk before you have the data versus when you have data** and certainty. It's **doing certain activities in parallel versus sequentially** (e.g. starting commercial manufacturing while late phase trials are still ongoing) and **having a very different governance process** for how decisions are made.

All of these things contribute to the speed at which we were able to move for the vaccine and our COVID antiviral pill, Paxlovid®. We plan to bring this approach to other key assets in our pipeline—oncology, rare diseases, and even follow-on mRNA programs in the vaccine space. We designate an asset for lightspeed, **if there is a significant medical need to move quickly**, and often, there is competitive pressure as well.

How do you not revert?

Gupta: It's always tricky to be honest. But there are three imperatives. In large companies, you do need **top-down push and sponsorship**. Our CEO, Albert Bourla, or one of his direct reports, has to almost personally be championing a program or the default mechanism is to go back to traditional ways of working. Senior leadership is meeting regularly, asking for updates. They're not accepting anything less than lightspeed in terms of timelines and project plans, etc. That's one way.

Another is **making sure funding follows that intent to move quickly** and to do things differently with these programs. You need to prioritize how you're going to deploy your capital and your R&D budget, making sure these programs are absolutely getting the right amount of resourcing. Then, everything else gets funded and resourced.

Third, is a very **proactive dialogue with regulators**, making sure external stakeholders are coming along for that speedy journey where possible. Regulators need to move equally quickly—whether it's approving R&D plans, reviewing data, rolling submissions, etc. We make sure to invest the time with them and bring them along the journey.

What is a key learning from lightspeed in the vaccine process?

Gupta: Real world data, real-time analytics, real world evidence were critical, especially in the early days of the pandemic. Determining where outbreaks were going to happen, how the virus was mutating, and how it is affecting certain populations and comorbidities. Also, using the predictive power of AI to try and predict where we should be opening clinical sites or recruiting globally.

“ We had an interesting experiment collaborating with Israel to exclusively use the Pfizer-BioNTech vaccine across the entire country. It was almost a controlled clinical trial, but for the whole country. We received unmatched real world data about efficacy and safety that is still yielding essential insights on the fast changing virus—what's needed, what's effective and what's not—for boosters, children, and variants. ”

Gautam Gupta
Senior Vice President and Head of Strategy, Pfizer

What is it like to drive strategy through uncertainty?

Gupta: The pure strategist part of me is very excited because you get to do strategy work that you wouldn't necessarily need to do if the world was very, very certain. The other part that's exciting—and maybe this is a bit more about being at Pfizer and the success we've had—is that it's encouraging us to be bigger and bolder in our thinking, in terms of our future ambitions and our goals.

Comments edited for brevity.

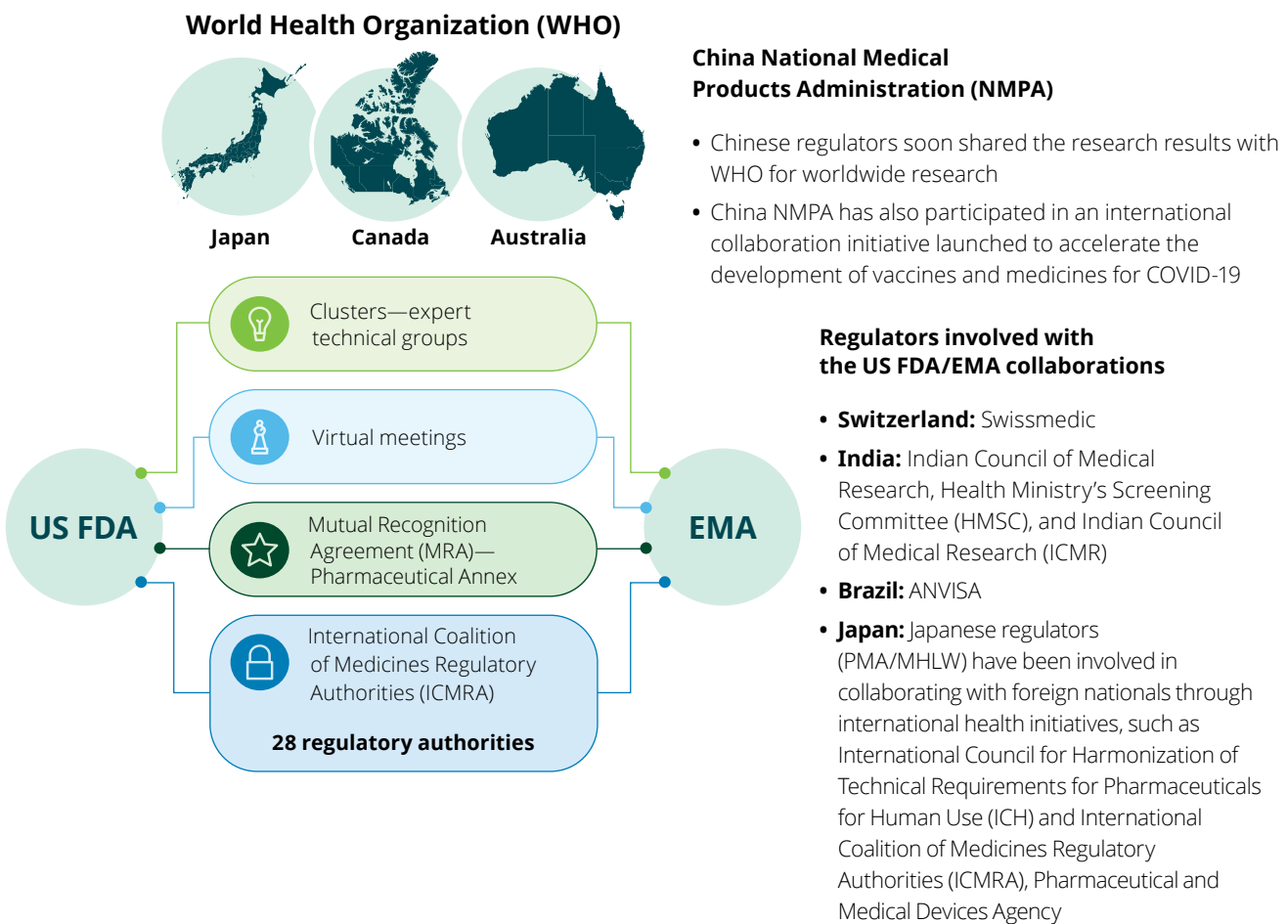


New levels of international collaboration

Weekly virtual meetings for international regulators

International and regional collaboration—among national and international regulators, stakeholders, and industry—has never been as important to medicines lifecycle development as it proved to be over the last 18 months.¹⁷ International collaborations among regulators focused mainly on expanding pre-existing collaborative working groups, creating clusters of technical experts, sharing research results, leveraging inspection reports, and disseminating information on how to help health care workers treat patients and stay safe (see figure 2).¹⁸

Figure 02: Examples of regulators' global collaborations



Source: Never the same again: How COVID-19 created seismic change in global life sciences regulations, Deloitte, 2021

In 2022, as technology accelerates and more digital processes and real-time sources of data are adopted by regulators, this international collaboration is expected to grow with ripple effects throughout the life sciences sector. The willingness to provide support and cooperation among regulators globally enhances the ability of work done by one authority to extend its reach—ultimately, harmonizing and speeding up the work of other regulators and approvals, getting patients access to medicines quicker, and driving even more innovation in R&D.¹⁹

Modifying regulatory processes across the globe

Regulatory agencies across the globe came up with accelerated approval pathways for COVID-19 vaccines. Some changes affected long-term policy or opened the door to new processes.²⁰ However, regulators missed developing an accelerated pathway for post-approval changes which is now a necessity.²¹ The following examples showcase modifications by country or territory.

United States: Operation Warp Speed (OWS) provided strong government financial and logistical support to accelerate vaccine development, distribution, and countermeasures such as the Coronavirus Treatment Acceleration Program (CTAP).²² Regulators relaxed some requirements. For example, requirements for good manufacturing practices (GMP) for non-life sciences companies were relaxed, especially for ventilators and Personal Protective Equipment (PPE). Also, regulators allowed parallel processing of activities that are usually done sequentially to fund production before clinical trials were approved. This process also allowed phases of clinical trials to proceed before prior steps were approved.²³

Other regulatory modifications included issuing guidance to industry, closer interactions between regulators and life sciences companies to deliver real time scientific advice, waivers of certain application periods, improving engagement and communications pathways, and postponing and changing inspection processes.²⁴ Inspections also moved virtually and/or international inspections relied on other regulatory bodies inspection results.

China: Regulators accelerated the process for vaccines and drugs by offering priority conditional approval and priority review and approval, with the medical affairs department quickly generating clinical evidence after launch. The government also established the National Bureau of Disease Control and Prevention elevating the status of public health and the importance of disease prevention, a major shift in policy.²⁵

European Union: The European Medicines Agency established a pandemic Task Force (COVID- ETF) that provided, for example, rapid scientific advice, rolling reviews, expedited marketing authorizations and extensions, and compassionate use.²⁶

India: A rapid regulatory framework was created to fast-track regulatory approvals for vaccines, diagnostics, prophylactics, and therapeutics designed to prevent or treat COVID-19. India relaxed import requirements and amended clinical trial requirements, steps that helped India to obtain remdesivir.²⁷

Australia: The Therapeutic Goods Administration (TGA) does not have an 'Emergency Use Authorization' pathway for COVID-19 vaccines but does accept rolling data.²⁸ Through the International Coalition of Medicines Regulatory Authorities (ICMRA), the TGA meets regularly with 30 international medicines regulators to address potential COVID-19 vaccines.²⁹

In 2022, regulators and life sciences companies might consider:

- Where did relaxing requirements present no, or extremely limited, new risks?
- Where might it make sense to permanently modify requirements?
- How can we develop a framework to be more flexible in the future?

Over the next year, finding ways to make drug development, manufacturing, distribution, and approval process timelines faster across the board while ensuring safety of users is likely to save money, time, and resources—and most importantly, benefit patients.

Impacts on 'business as usual'

The pandemic did not have the huge impact on non-COVID regulatory approvals many feared, and concerns are likely to dissipate further in 2022³⁰ (see figure 3). 'Normal business' became a lower priority and experienced some setbacks. There was minimal disruption in clinical trials for non-COVID-19 products and a reduction in regulatory inspections and oversight.

Figure 3: Impacts on 'business as usual' in the United States, China, EU, Japan, and India

	US	China	EU	Japan	India
Approvals for non-COVID-related products: 2019	91 Drugs: 45 MDs: 46	1,779 Drugs: 53 MDs: 1,726	Drugs: 66 MDs: N/A	167 (all product approvals)	336
Approvals for non-COVID-related products: 2020	112 Drugs: 53 MDs: 59	1,620 Drugs: 48 MDs: 1,572	Drugs: 97 MDs: N/A	153 (all product approvals)	61 (through Q1)
Regulatory inspections of LS companies by country regulators: 2019	4,770	No public data	643	155	453
Regulatory inspections of LS companies by country regulators: 2020	2,788	19,900	185 (Q1 & Q2)	Unknown	113 (through Q1)

Source: Never the same again: How COVID-19 created seismic change in global life sciences regulations, Deloitte, 2021

What's next? Continued digitalization and collaboration

Embracing new ways of working: digital, virtual, and remote

Regulators adopted digital and virtual ways of working and collaborating as did the rest of the world during the pandemic. In the coming year, regulators are looking to improve data integrity of real-world evidence and are expected to continue embracing digital technologies and sharing worldwide research.³¹

Remote approaches were adapted to conduct GCP (Good Clinical Practice) and GMP (Good Manufacturing Practice) regulatory oversight. Remote oversight is utilized to:

- Share documents
- Access relevant electronic systems and review data
- Interview subject matter experts
- Conduct facility tours and inspections³²

Regulators found video conferencing to be a valuable tool to develop an experience as close as possible to an on-site

inspection, including building rapport with inspectees. The way regulatory inspections may be conducted evolved into several models, and models are determined case by case (see figure 4). Direct access to documentation—electronic or otherwise—is expected, whether the inspection is on-site or remote.³³

In 2022, some on-site manufacturing inspections are, once again, being paused—now as a result of the Omicron variant. In the United States, the US FDA accrued a backlog of manufacturing inspections over the past two years. Prior to Omicron, the agency had been on track to complete its backlog of domestic drug plant inspections in 2022.³⁴

Figure 4: New models for regulatory inspections

Term	Definition
On-site inspection	An inspection conducted physically on-site.
Remote inspection/distant assessment/evaluation	The process of conducting inspections, evaluations or assessments at a distance/virtually, supported by technology for communicating, sharing, reviewing, accessing systems, without the inspectors being physically present at the sites where they activities subject to an inspection have taken place/where the inspection would routinely be hosted.
Hybrid Inspection/assessment	An inspection/assessment performed using a combination of on-site and remote means.
Collaborative inspections	Inspections involving two or more regulatory authorities.

Source: Reflections on the regulatory experience of remote approaches to GCP and GMP regulatory oversight during the COVID-19 Pandemic, ICMRA, December 2021

Expanding Software as a Medical Device (SaMD) with AI

Technology giants continue to disrupt Life sciences and MedTech, including how work is done with regulators. Starting in 2017, Apple³⁵ and Google's Verily participated in the development of the US FDA's Software Precertification (Pre-Cert) Pilot Program, an initiative to iteratively build and test a reimagined framework to regulate software-based products. The proposed approach aims to look first at the software developer or digital health technology developer, rather than primarily at the product, which is what US FDA currently does for traditional medical devices.³⁶

In 2022, SaMD is expected to evolve with a boom in AI/ML-based medical devices, and new policies are emerging:

United States: In 2021, the US FDA recently issued new guidance, the AI/ML-based SaMD Action Plan, to address the development, safety and effectiveness, and post-market monitoring of AI/ML tools. The agency is encouraging public input.³⁷

United Kingdom: The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is working on making software and AI devices more accessible, while protecting consumers from harm. A bold change is expected this year for a regulatory framework that will ensure that the United Kingdom is the home of responsible innovation for medical device software.³⁸

European Union: The Medical Device Coordination Group (MDCG) is defining regulatory standards for all EU member states through the development of a first-ever legal framework dedicated to ensuring trustworthy AI, including products qualified as medical device software (MDSW) with AI-driven functionalities.³⁹

Japan: The number of AI-based medical devices approved in Japan is still relatively low. Japan's Ministry of Health, Labour and Welfare is implementing a five-year program for industry, academia, and government to work together on policy for AI-based medical devices, including the predictability of models and quality of data.⁴⁰



Over the next year, as agencies review and authorize a growing number of AI- and ML-based medical devices, regulators and manufacturers will likely gain new and important insights.⁴¹ These devices will also help move the burden of many practical tasks from skilled physicians to clinical engineers, nurses, and other staff. Providers, as well as regulators, are likely to need additional skills and training.⁴²

AI algorithms are different than conventional software. In order for regulators and providers around the world to trust the decisions and answers that AI-powered tools provide and allow their use for patients, manufacturers and developers will need to provide transparency and protect against errors and bias. Bias in training data may present not only ethical concerns, but the safety and performance of a medical device.⁴³

Changing policies for digital therapeutics

Regulators are enabling changes that will contribute to speeding up the adoption of digital therapeutics (DTx), with the United States, Germany, and Belgium leading the way. DTx are software-based products that provide clinical, real-world and, often, real-time evidence. They are most frequently SaMD, but not all DTx products qualify as SaMD.⁴⁴

United States: The Pre-Cert Pilot Program will help inform the development of a future regulatory model/process that will provide a more streamlined and efficient regulatory oversight of software-based medical devices. As the US FDA continues to identify, evaluate, and improve on Pre-Cert Pilot Program approaches to assure safety and effectiveness of products that require marketing authorization, the US FDA's marketing authorizations for these products will continue under the US FDA's existing regulatory pathways.⁴⁵

Germany: The Digital Healthcare Act 2019 (Digitale-Versorgung-Gesetz, DVG) paved the way for reimbursement for digital therapeutics (Digitale Gesundheitsanwendungen, or DiGA). Through DVG's 'Fast-Track Process', digital therapeutics undergo a streamlined review in order to be included in a central registry of apps that can be prescribed by health care practitioners (HCPs) and psychotherapists and reimbursed by Germany's statutory health insurance providers.⁴⁶

Belgium: The National Institute for Health and Disability Insurance is approving digital therapeutics for reimbursement, provided the criteria for the top level of Belgium's mobile health (mHealth) validation pyramid is met. This includes: CE marking as a medical device and meeting GDPR requirements, interoperability and connectivity tests, and demonstration of clinical and socio-economic added value.⁴⁷

Meeting the moment for consumers

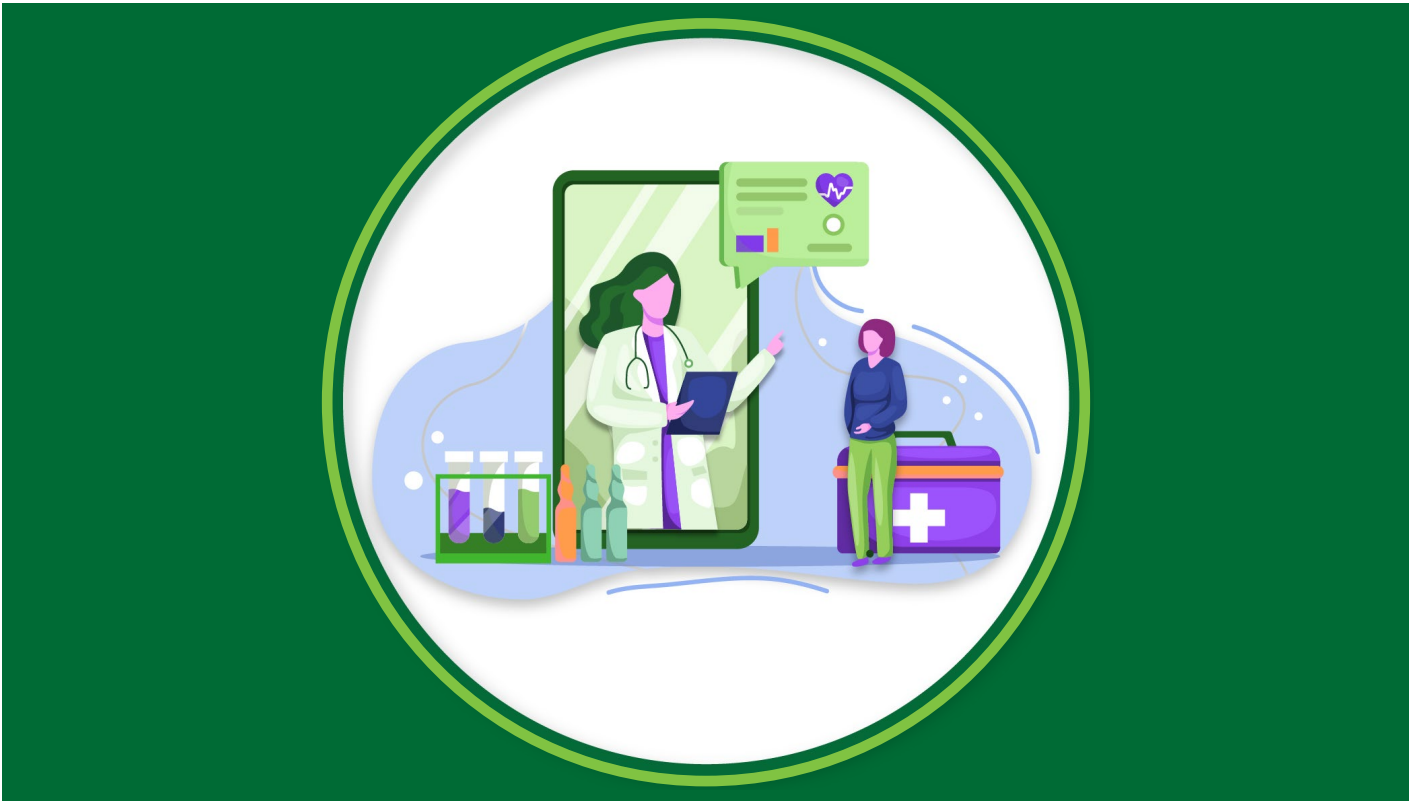
Consumerism is driving the rapid growth of digital health technologies. Regulators, along with life sciences and medtech organizations, are starting to meet the moment. Actions taken by governments, regulators, and organizations during the pandemic accelerated innovation in products and supply chains and increased the adoption of new technologies and processes.

New entrants were also welcomed into the life sciences market to meet consumer needs. In 2022, tech giants, as well as startups, are expected to continue to threaten the status quo. The sector must continue to collaborate with regulators and other stakeholders to make sure that the positive changes driven by digital technology innovation during the pandemic are preserved and improved upon for the future (see figure 5).

Figure 5: Digital technology adoption at full tilt (US, China, EU, Japan, India)

<p>United States</p>	<p>The FDA used digital platforms for reviews and approvals of products and clinical trials and for remote inspections. The Center for Medicare and Medicaid Services (CMS) issued temporary measures for people enrolled in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP) to receive telehealth services during the public health emergency. Changes allowed providers to conduct telehealth visits in patients’ homes, practice remote care across state lines, and bill for telehealth services as if provided in person. Many individual states also relaxed telemedicine restrictions and allowed out-of-state professionals to provide telehealth services.</p> <p>Accelerated use of technologies:</p> <ul style="list-style-type: none"> • Wearables for real-time vital signs monitoring • Electronic diaries for real-time data capture • Image harvesting through smartphone cameras • Telemedicine technology and advanced analytics • Electronic signatures for patient consent forms • Use of electronic health records as a source of truth for remote monitoring
<p>China</p>	<p>The National Healthcare Security Administration (NHSA) and National Health Commission (NHC) issued guidance on “Internet +” medical insurance services during the pandemic. This guidance enables medical institutions to provide online follow-up for diseases and obtain insurance reimbursements.</p> <p>The government also proposed relaxing the scope of internet diagnosis and treatment, including qualified services in the scope of medical insurance reimbursement, and unifying internet medical examination and approval standards.</p>
<p>European Union</p>	<p>The EMA expanded the types of trials that may use remote source data verification (rSDV) in addition to onsite, centralized, and offsite trial monitoring.</p> <p>As needed, remote site inspections of facilities were to be carried out, with onsite inspection to follow when circumstances permit. EU governments approved remote working for life sciences companies where possible.</p> <p>To enable business continuity, in April 2020, the EMA issued guidance on regulatory expectations related to processes such as remote batch certification, remote audits, and remote inspections.</p>
<p>Japan</p>	<p>Regulators conducted remote GCP inspections. In April 2020, MHLW deregulated the ban on use of telemedicine for first-time visits to hospitals and permitted prescriptions using fax.</p> <p>Although that is temporary, MHLW promised to enact telemedicine as a new form of health care based on expert opinion. MHLW will also likely consider promoting a system to complete interactions online, including medical examinations, electronic prescriptions, online medication guidance, and drug delivery.</p>
<p>India</p>	<p>Clinical trial sponsors and contract research organizations (CROs) employed a number of initiatives to minimize disruptions to clinical trials. Key among these is use of telemedicine and virtual media by doctors to track the well-being of clinical trial patients and remote monitoring of data by the trial sponsors and CROs to ensure data quality.</p> <p>Bangalore-based Cardiac Design Labs developed its Telemetric Patient Monitoring System, which is a vital signs monitoring system, to monitor multiple patients remotely and simultaneously from a central location. The system, which uses wearable devices, can monitor a patient’s ECG, respiration, blood oxygen level, body temperature, and blood pressure.</p>

Source: Never the same again: How COVID-19 created seismic change in global life sciences regulations, Deloitte, 2021



The digital enterprise at scale: A CEO imperative for 2022

Digital becomes our reality

Continued accelerated growth and record investment

A recent Deloitte and Fortune report shows that 77% of CEOs across 15 industries say the COVID-19 crisis accelerated digital transformation, and CEO optimism about the year ahead remains strong.¹ The digital transformation trend is expected to accelerate in 2022 with a renewed drive towards more long-term strategic digital objectives.²

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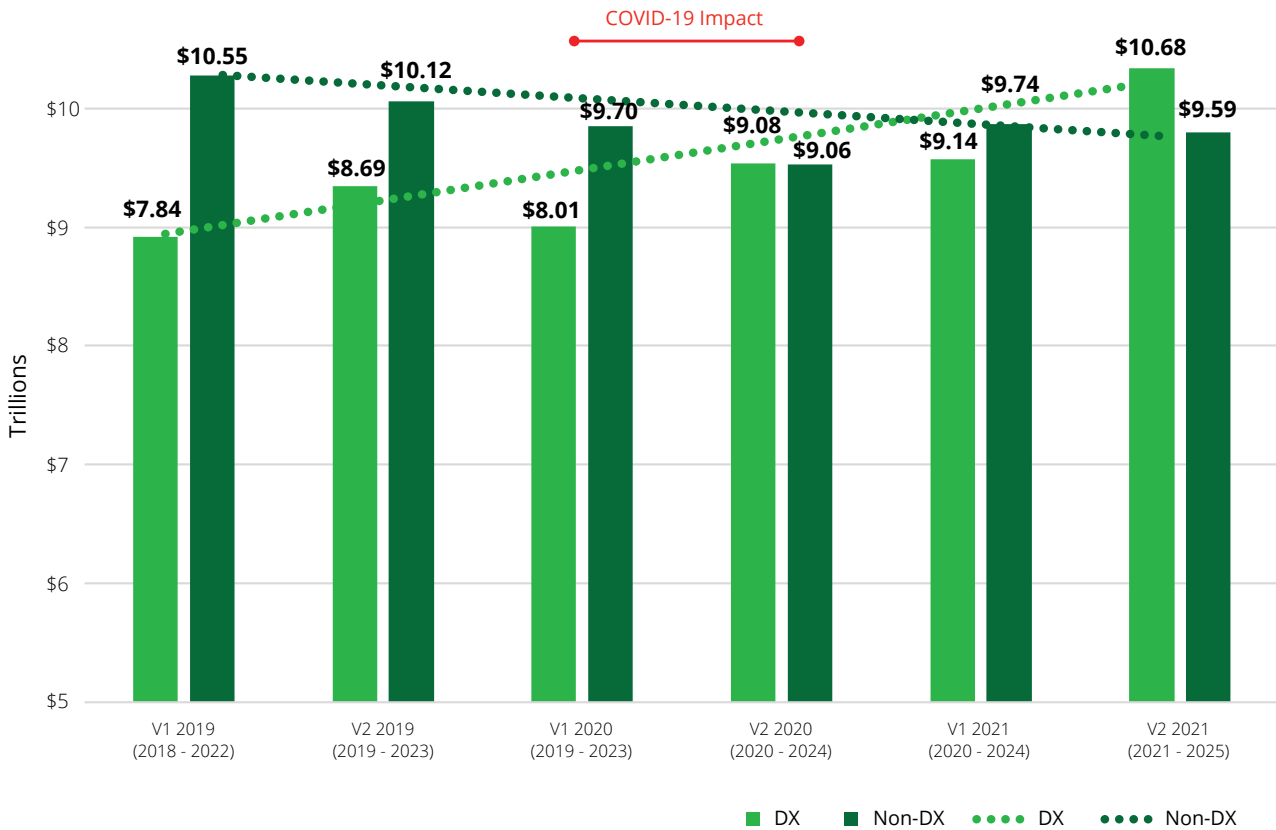
Digital innovation has been accelerated 10 years by what has happened over the course of the last 18 months.

”

Manoj Raghunandan, President, Global self-care and consumer experience for Johnson & Johnson.³

Deloitte also surveyed biopharma executives, and 82% believe that this trend will continue post-pandemic. Almost half believe they will need a better digital innovation strategy.⁴ For the first time, digital transformation spending is forecast to exceed US\$10 trillion worldwide over the next five years, according to IDC (see figure 1).⁵

Figure 1: Global digital transformation spending forecast, 2019-2025



Note: DX represents digital transformation

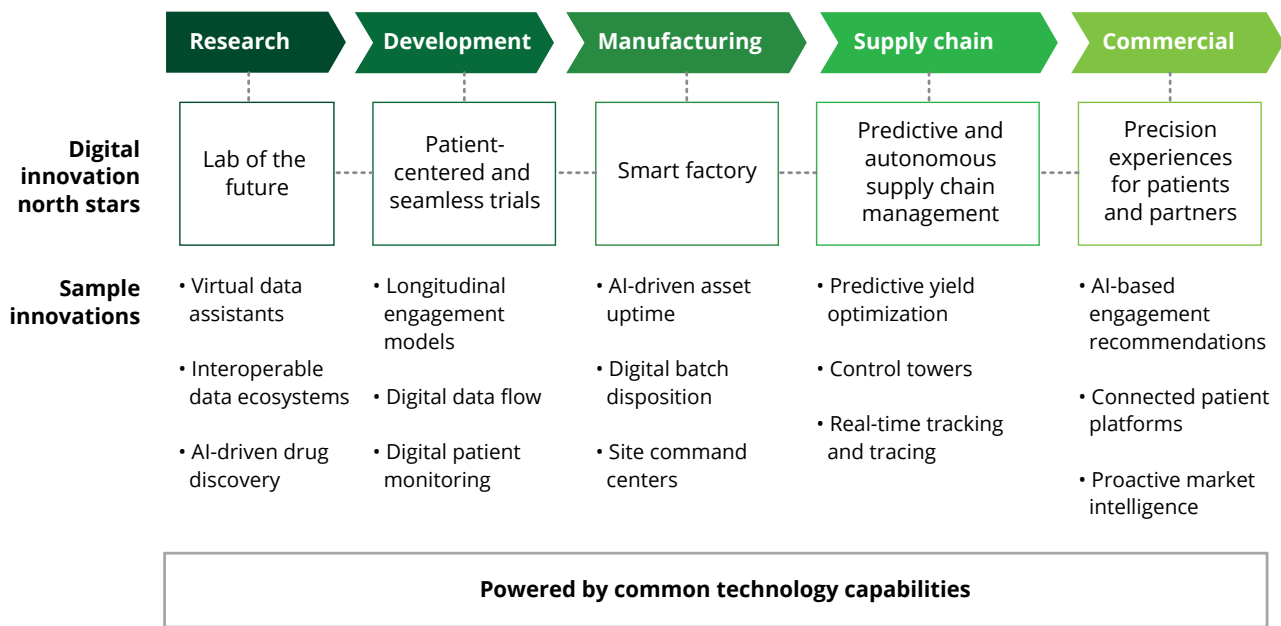
Source: "IDC Spending Guide shows continued growth for digital transformation," IDC, 9 November 2021.

Scaling digital for end-to-end transformation

More holistic and enterprise digital transformation in the life sciences sector is no longer a question of if or when, but how (see figure 2).⁶ As companies push digital at scale across the value chain, we are seeing digital transformation being tackled head-on by executive leadership—not just by the Chief Information Officers (CIO) or Chief Digital Officers (CDO), but by management teams at large.⁷ The digital imperative is being embedded in every business function—R&D, manufacturing, supply chain, and commercial—as well as core functions such as HR.⁸

Scaling digitalization and utilizing AI are likely to produce novel insights across the organization. According to Raghunandan, Johnson & Johnson’s focus is on connecting the organization end-to-end to create an improved and more transparent experience for consumers, customers, and suppliers. “This requires connecting all the data from the very beginning of research & development, through the supply chain, to our retail customers, and through to the consumer,” he says.⁹

Figure 2: From ‘molecule to market’, digitalization across the value chain

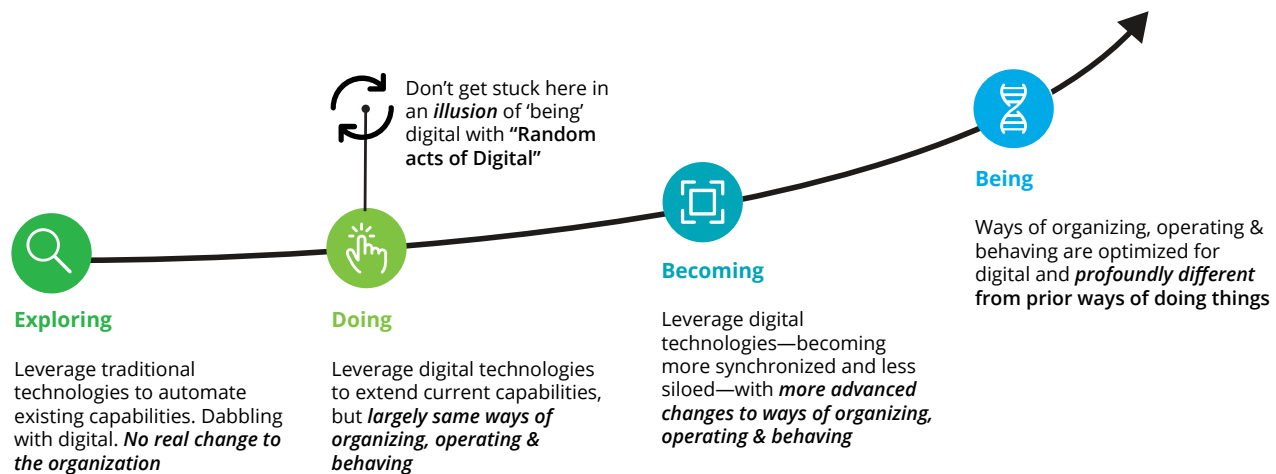


Source: “Biopharma digital transformation: Gain an edge with leapfrog digital innovation”, Deloitte Insights, 8 December 2021.

Shifting from ‘doing digital’ to ‘being digital’

A scattershot approach to digital will no longer work for those who want to succeed in driving business value and delivering customer- and patient-centric experiences. Biopharma and medtech companies are expected to evolve from just doing digital—to being digital.¹⁰ Companies that ‘do digital’ still apply digital capabilities in an ad hoc manner without a cohesive vision. “Being digital” means designing and implementing a differentiating digital strategy and incorporating it into the organization’s DNA (see figure 3).¹¹

Figure 3: Progression of ‘doing digital’ to ‘being digital’



Source: MedTech commercial transformation: Moving from “doing digital” to “being digital”, Deloitte, 2020

What does “being digital” at scale really mean?

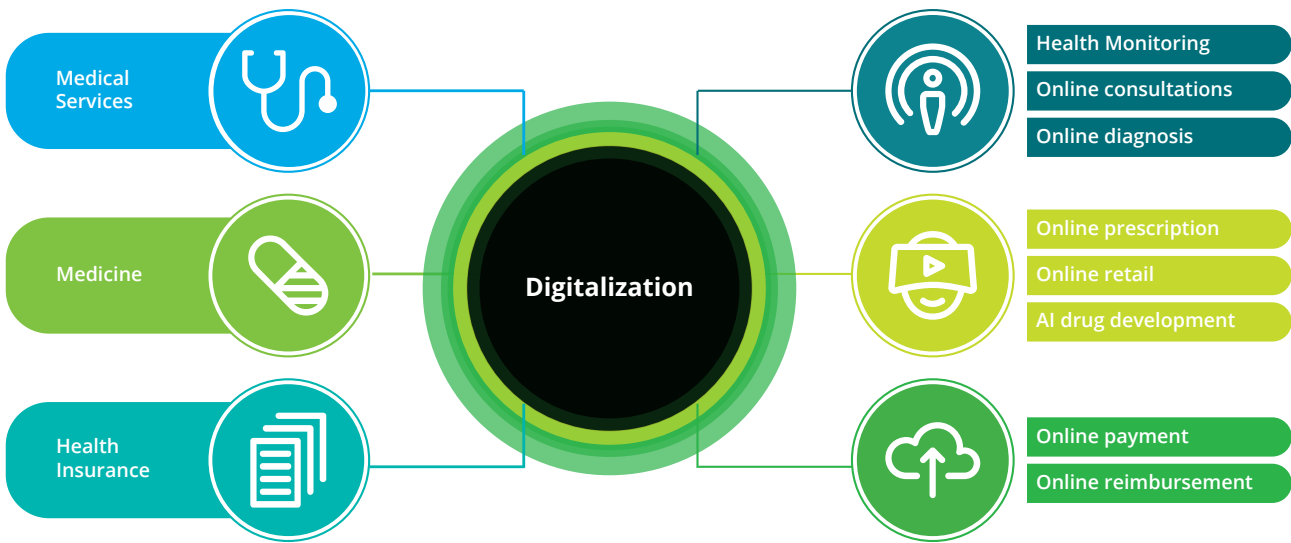
Digital at scale means companies are investing in agility, analytics, and automation—and integrating data. Without a plan for strategic use of data, tools are not likely to deliver the full value of digitalization.¹²

At the core, being digital involves:

- Moving beyond transactions creating a meaningful, differentiated, and personalized experience for customers and patients
- Enabling more evidence-based decision-making for health care and payment
- Modernizing processes/systems across the entire value chain and in core functions
- Leveraging data/analytics to create actionable insights that drive growth and operational efficiency
- Breaking down functional silos to create empowered and accountable multi-disciplinary teams that drive and track investment decisions and performance¹³
- Enhancing business agility to keep pace with the constant sea of changes¹⁴

In the next 12 to 18 months, we will see more companies taking on the challenge of scaling digital and moving out of the trial and error phase. In China, favorable long-term policies, infrastructure upgrades, abundant capital markets, and the pandemic are promoting digitalization across Life Sciences and Health Care (see figure 4).¹⁵

Figure 4: Going digital in life sciences and health care



Source: Deloitte analysis



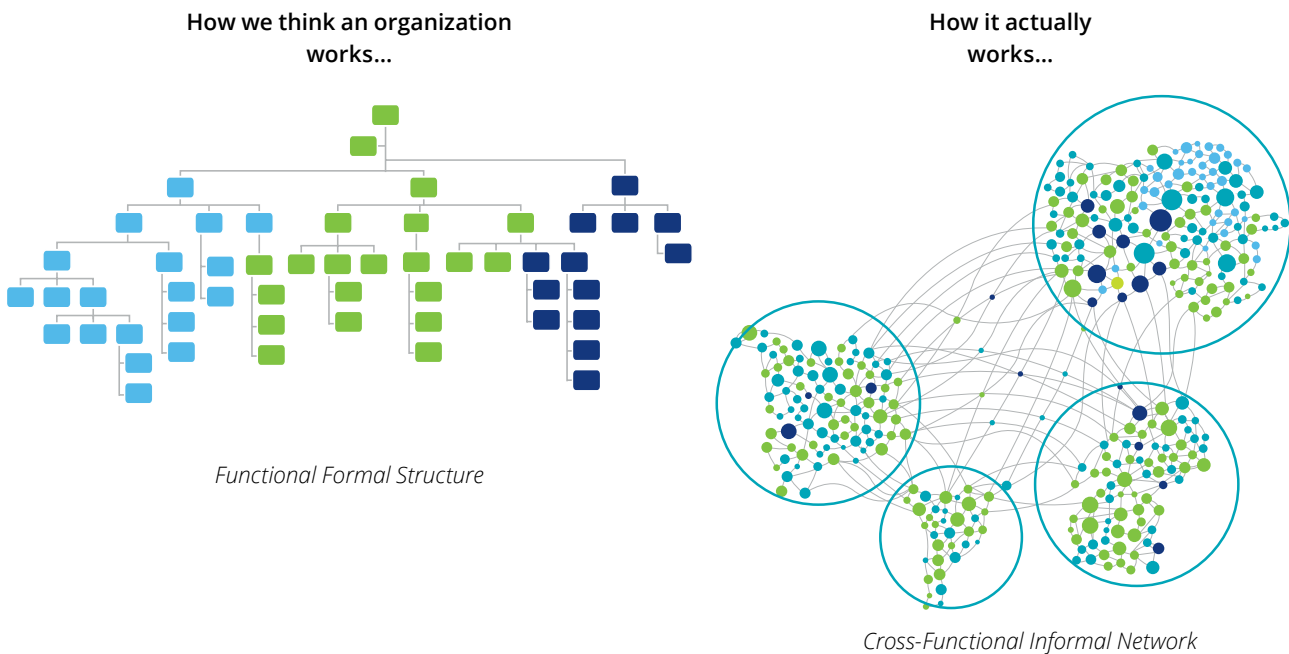
Bringing enterprise agility to scale

Fully transforming and scaling digital requires being agile and adaptable—one of the biggest challenges large, enterprise life sciences and medtech companies are struggling with in 2022. For many, becoming an adaptable organization represents a fundamental shift in operating and management philosophy.¹⁶

Adopting a team-based approach to meet changing needs

Adopting enterprise agility enables large-scale global organizations to operate with a start-up mindset through empowered networks of teams that can pivot to meet changing needs.¹⁷ Team-based design focuses less on who people work for and more on who people work with.¹⁸ Organizing work along informal systems in the way people naturally behave helps maximize opportunities to drive experimentation, innovation, and idea generation—and makes for a happier workplace (see figure 5).¹⁹

Figure 5: Top-down formal structure vs. cross-functional collaboration



Source: “The Adaptable Organization, Harnessing a networked enterprise of human resilience,” Deloitte, 2018.

Leading transformational change with continuous improvement

In life sciences, we are seeing more companies adopting agility-rooted models throughout their organization—requiring leaders to know how to be more agile themselves. Agile leaders know how to lead through a crisis with resilience, and the pandemic tested these capabilities.²⁰

Those proven to be the most resilient were digitally savvy and adaptive—doing things differently.²¹ In a rapidly changing world, these capabilities will continue to be challenged, and winning life sciences enterprises will have the capacity for change and continuous improvement.

“ For Roche, being agile and displaying organizational agility means having a creative mindset and striking the right balance between speed, flexibility, and stability. Our investment in building creative leadership skills and a creative mindset has recently enabled us to overcome tremendous challenges during the pandemic and to find innovative ways to develop and deliver products urgently to patients and health care professionals. ”

Cris Wilbur, Chief People Officer, Roche.

Sustainable, scalable agility requires leaders who embrace an agile way of working—creating an environment for people to be great and a culture that fosters curiosity and learning.²² It requires leaders to think thematically to communicate across functions.²³ Open and honest communication enables leaders to stay responsive to their workforce and the broader, still uncertain, pandemic landscape.²⁴

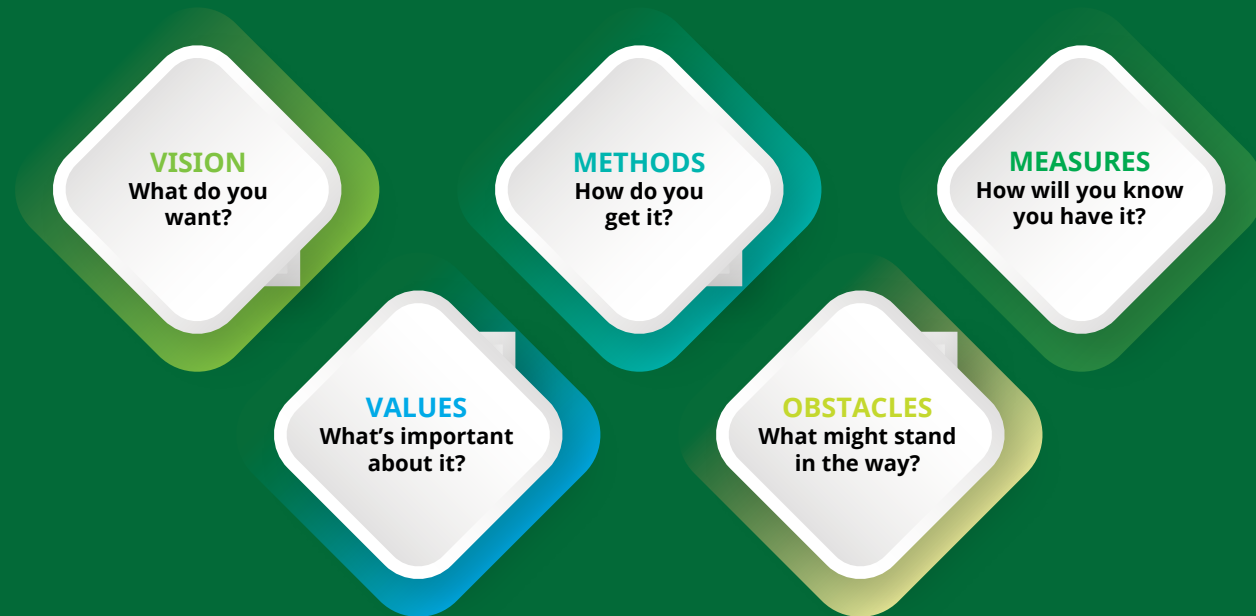


As individuals in the workforce navigate this change, they are also solving for change in their personal lives. Successful leaders ensure that teams are supported with empathy and optimism, and that they provide psychological safety—allowing individuals to also communicate openly and safely.²⁵

How do you want to change the world?

Enterprise agility starts with a clear vision. Leaders need a clear vision to connect with their workforce and to convince others to align with that vision. The V2MOM (Vision, Values, Methods, Obstacles, and Measures) framework can help leaders clarify and communicate their vision and plot a course forward (see figure 6).

Figure 6: V2MOM framework to guide enterprise agility



Source: Deloitte analysis

The VRMOM framework is also a guide to decomposing an organization's vision into actionable methods and measures. Metrics are established before anything else to track levels of customer value (not costs) and to drive decision-making. Four metrics to measure how change is making an impact include:

- **Are we better?** Tracking reduction in production incidents and increased resilience
- **Are we delivering sooner?** Tracking flow and increases in delivery times (from idea to delivery)
- **Are we safer?** Tracking compliance issues and incidence rates
- **Are we happier?** Tracking if employees and customers are happier

Large, legacy organizations vs. nimble, digitally-native organizations

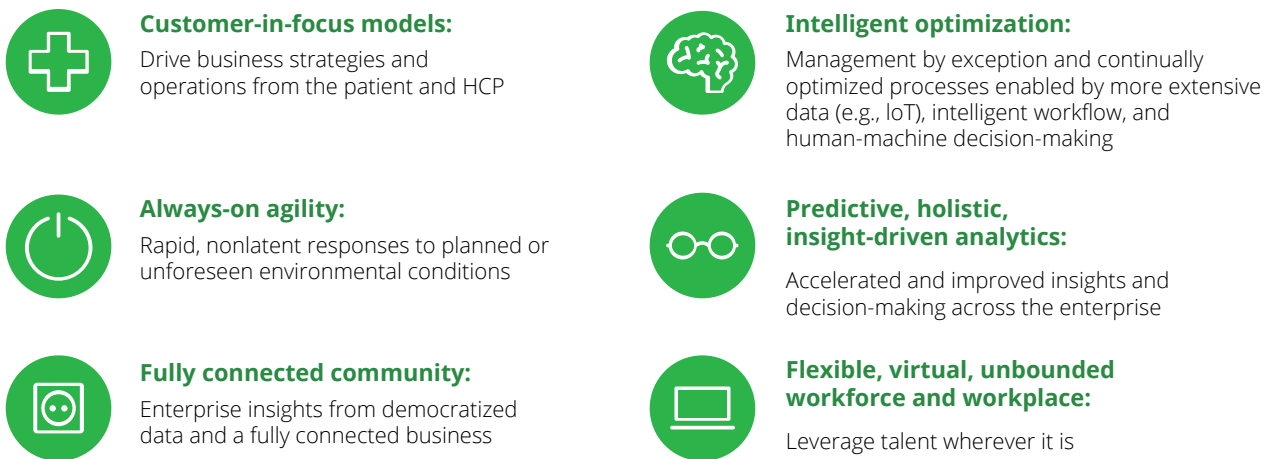
Legacy life sciences organizations are being challenged by nimble startups—digitally-native companies that are already digital across the board. These companies are not tied to legacy systems, are more cloud ready, and have a different mindset.²⁶

Adopting more digitally-strategic objectives

Unlike traditional pharma companies, startups are likely to challenge the way things have historically been done. New players may question “why” problems are approached a certain way, jump right in to solve them, and then, get other players such as regulators on board—establishing new frontiers. Legacy organizations tend to focus on all the barriers to solving the problem, not the opportunity.²⁷

By leveraging enterprise digital transformation, life sciences companies are starting to connect and elevate existing digital efforts into wider enterprise digital strategies for greater business value.²⁸ Digitally-native companies are strategic in many ways that large enterprises can learn from and adapt, to become more insight- and experience-driven (see figure 7).²⁹

Figure 7: Digital strategic objectives



Source: “Enterprise digital transformation as a competitive necessity,” Deloitte, 2021.

Currently, startups and legacy organizations are swapping executive talent to close their opposing experience gaps. Startups are looking for traditional pharma expertise to navigate an unfamiliar ecosystem, in particular, regulatory. Traditional pharma is looking to tech companies for consumer and digital experience, and agility.

Moderna: A peek into some processes of a digitally native biotech

One of the first digitally native biotech companies, **Moderna**, is unshackled from legacy organizational structures and norms, and building its digital infrastructure from the ground up. Its strategy is the enablement of parallel progress and shared learning. As a result, it is advancing its mRNA medicines at a breadth, speed, and scale uncommon in the life sciences industry. The startup has demonstrated its ability to rapidly and seamlessly move mRNA medicines from concept through research and clinical development to delivering for patients.³⁰

Moderna's digital building blocks include: Cloud enablement, Integration of processes and data, smart interconnected devices, automation, analytics, and AI. Its scientific digital environment prioritizes two goals, the rational design of mRNA medicines and the acceleration of programs through research.

Technical development requires a broad spectrum of digital capabilities including electronic notebooks, structured data capture, integrated equipment, and high throughput testing. Early stage analytical development is performed using off-the-shelf analytical software. When possible, Moderna leverages the same systems between Analytical Development and Quality Control to accelerate the transfer of testing methods to production—including a shared, cloud based HPLC (High-Performance Liquid Chromatography) management system and integrated laboratory execution system.

Clinical trial documentation is digitized using Veeva's eTMF (electronic trial master file) system, and for clinical data collection, Moderna standardized on Medidata's suite of products. Separate apps were designed for IMO (Investigational Medicines Office), Supply, Regulatory, and Toxicology.

In Norwood, MA, Moderna's fully-digital manufacturing site was designed to be integrated and paperless without silos of legacy systems or data. Data is synchronized from dozens of source databases and systems into a single data warehouse using Amazon's Redshift database. Moderna scientists run queries and discover insights from data collated from dozens of ongoing experiments stored in the cloud to refine their mRNA sequence designs. Then, its automated manufacturing facilities convert these sequences into physical mRNA for further experimentation and use in clinical trials.

The company's commercial engine is in its early stages and developing with the view that digitally-savvy patients will be looking for more than medicines, wanting digital solutions to better understand and manage their conditions.

Moderna's core business functions (HR, Finance, Legal, Infrastructure) also take advantage of the cloud and a bevy of SaaS (software-as-a-service) applications. In addition to digital technologies, Moderna's productivity is based on its platform technology and the 'software-like' nature of mRNA when used as a drug.³¹



Establishing new ventures to gain agility

In medtech, the ability to translate customer sentiment and desires into new product development is becoming more critical as startups also challenge incumbents. Software-oriented products and consumer-focused technology companies utilize rapid development and iteration—a direct contrast to the more linear way medtech companies have historically engineered hardware products. Being agile allows startups to continuously create value and perfect what target users want.³²

To gain agility, some large medtech companies are acquiring or forming partnerships with smaller technology companies. However, a startup that comes into a legacy culture may not survive or thrive when absorbed into the larger parent company. The preferred path may be to establish a completely separate venture—underpinned by a growth- and transformation-oriented mindset.³³

A small, nimble new venture might be better equipped to:

- Capitalize on rapid shifts
- Enter new markets
- Monetize growing data assets
- Execute on bold new ideas
- Navigate nontraditional competitors
- Leverage changing customer needs, demographics, and behaviors
- Extend boundaries of the business, while building a legacy of leadership³⁴

Also key for success is selecting the right person to run the new venture. This individual should be both a realist and a visionary, have the trust of the CEO and board, and be confident enough to champion the entity's independence, rather than trying to shoehorn it into an existing business unit.³⁵

Scaling AI across the value chain

Being agile means anticipating and responding to changes in market conditions, and digital technologies such as AI enable leaders to react and respond with more informed and tailored decision-making. AI is now widely recognized as a strategic business issue in Life Sciences and actively discussed at the board and C-suite levels.³⁹ While AI is becoming mainstream, enterprise AI at scale remains a challenge for many organizations.⁴⁰

Integrating AI into the organization, top outcomes and challenges

Companies are prioritizing building AI capabilities for improving innovation across the organization.⁴¹ According to a recent Deloitte survey about the use of AI in life sciences globally, respondents expect top outcomes for AI will include enhancing existing products, creating new products and services, and making processes more efficient.⁴² Top challenges include difficulty in identifying business cases with the highest value, managing data, and integrating AI into the organization.⁴³

In the year ahead, life sciences companies are expected to integrate AI more holistically into all processes—from preliminary research and clinical trials, to manufacturing, supply chain, and commercialization.⁴⁴

Startups leading medtech

Deloitte teamed up with [MedTech Innovator](#) (MTI) to look through the lens of 1,000 medtech innovators participating in MTI's global accelerator program in 2021.³⁶ These startups are developing a new class of digitally-enabled technologies—including Software as a Medical Device (SaMD), bespoke algorithms, wearables, and other connected devices. About 70% of their technologies include a digital-health component, and nearly 30% that identify as digital say they employ artificial intelligence (AI) and machine learning.³⁷

Most of these companies are focused on prevention, wellness, and diagnosis rather than treatment. Over the last three years, the share of point-of-care products has grown significantly—from 62% to 70%—among start-up companies that have diagnostic products. Because site of care is shifting away from traditional inpatient settings, many early-stage innovators are designing products for use in outpatient locations or in the home. These products address diverse populations and accessibility, and 67% say they are designing products with health equity in mind.³⁸

Need for high quality data

For most organizations, the single most important AI building block is data. Getting access to the rich data that AI systems require and managing that data in a coordinated way across the enterprise are critical.⁴⁵ Often, that means overcoming historically separate and siloed organizational structures that impede the accessibility of high quality data.⁴⁶ Data scientists rely on having high quality, standardized, and referenceable data to produce the best insights.⁴⁷

“ All the data needs to be cleaned and curated to make it machine-learnable. This is hard and cumbersome work, but it frees up our data scientists to focus on answering questions with data. Once all the data is curated, the potential to generate new insights is likely to be enormous. ”

Peter Speyer, Head of Products, data42 at Novartis.⁴⁸

Advanced data collection and analysis is essential to:

- Shortening the R&D cycle
- Meeting the needs of patients
- Transforming surgery from an isolated event to a connected, data-driven endeavor⁵¹
- Deepening the understanding of access issues across the globe
- Creating tailored experiences for health care providers
- Anticipating key challenges across the ecosystem, including those of suppliers and manufacturers⁵²

AI has the potential to expedite drug development, provide better decision-making for diagnosis and surgeries, help companies launch and market products more effectively, and make supply chains smarter and more responsive. With robust data, the potential use cases for AI in life sciences are nearly limitless,⁵³ and the breadth of AI applications and rate of innovation are only expected to increase.⁵⁴

Asking the right questions to reimagine medicine for the 21st century

Data42 is Novartis’s research & development platform and one of the pharmaceutical industry’s largest data pools, hosting clinical data from nearly one million patients. The big data system—equipped with AI and “[The Map of Life](#)”—allows Novartis’ more than 20K researchers and developers access to a treasure trove of curated and linked data sets.⁴⁹

Today, if a researcher has a question about cardiovascular disease, they are not limited to only cardiovascular data. They can explore links between all the data in 500 disease indications over decades of research through data that is clean and connected in one environment. The challenge of such a rich data set is that you need to ask the right questions to extract meaningful data. data42 works with their scientists on asking the right questions and finding new and creative uses for the data such as using already approved drugs for new uses.⁵⁰

Gaining an edge requires ongoing transformation

Life Sciences is in a stage of continuous improvement and ongoing transformation. Technology isn't an end in itself but enables the capabilities essential for surviving an uncertain future.⁵⁷

“

Technological innovation is continuous and accelerating, and technology needs to be applied to the very core of how a company operates and competes. The stakes are very high, and there is no finish line. Continuous transformation requires a growth mindset, a different way of leading an organization.

”

Rich Nanda, Principal, Deloitte Consulting, and Author, "The Transformation Myth"⁵⁸

Transforming digital surgery and colonoscopy with artificial intelligence

Data and analytics, machine learning, and artificial intelligence are also advancing a more holistic digital surgery ecosystem. **Johnson & Johnson Medical Device Companies** are looking beyond robotic-assisted surgery systems to reimagine the entire care pathway. Data and analytics are being used to turn learnings from surgeons who have performed countless surgeries into insights and technologies that bring informed decision-making across the continuum of care.⁵⁵

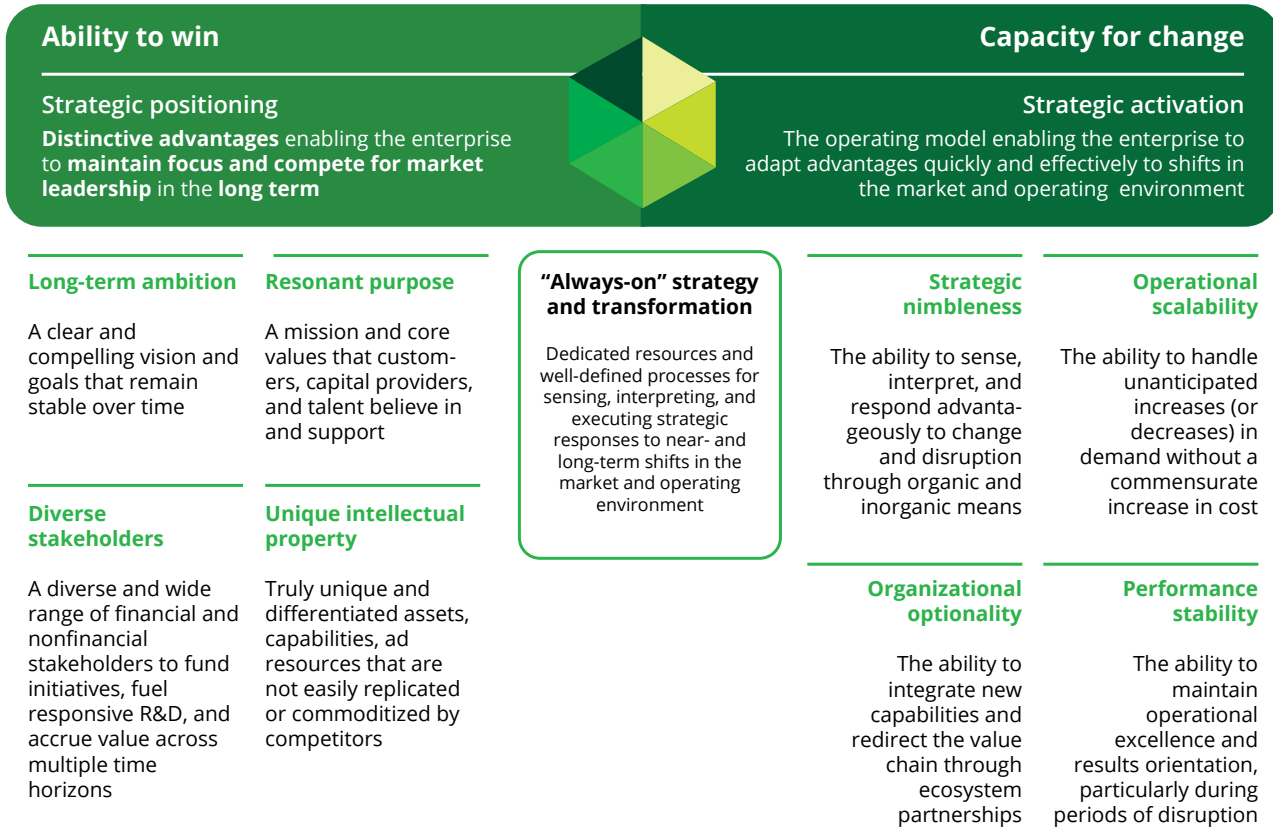
Medtronic was given de novo clearance from the US FDA for its artificial intelligence system for colonoscopy. The company's GI Genius intelligent endoscopy module uses advanced AI as a second observer (compatible with colonoscopy video) to highlight the presence of precancerous lesions with a visual marker in real-time. Algorithms are used to identify and mark abnormalities consistent with cancerous polyps. Compared to colonoscopy alone, the GI Genius module demonstrated a 14% absolute increase in adenoma detection rate (ADR).⁵⁶

Those who made investments prior to the pandemic— ahead of a known clear benefit—benefited from their bold vision and conviction. By doing things differently, they proved to be the most resilient.⁵⁹ Through the pandemic, investments in AI and digitizing trial operations enabled most of the top 20 companies by R&D spend to keep pivotal trials moving without affecting anticipated launch timings.⁶⁰

In 2022, as life sciences executives address the urgency for more investments and take more risks, digital technology and AI are expected to come together to change the status quo and transform functional areas and value streams.⁶¹ It's time to take advantage of this technological momentum and lessons learned from the pandemic—operating by being digital and competing by being agile.

While some life sciences companies may remain ill-equipped to win in an environment teeming with disruptive forces,⁶² others will be positioning themselves to win with a capacity for change (see figure 8).⁶³ The ability to sense, interpret, and execute strategic responses to major swings in the market and operating environment is enabled by bold strategic investments aligned to clear and compelling long-term ambitions.⁶⁴

Figure 8: Triumphant traits: Ability to win and capacity for change





Future-proofing manufacturing and supply chains

Today's headwinds, and the uncertainty that is expected to continue, will require life sciences companies to have agile manufacturing processes and resilient supply chains. This includes retooling technology and transforming environments.¹

Scaling smart factory transformation

In 2022, more life science organizations are scaling smart factory capabilities to boost agility. Biopharma and medtech companies are investing in fully digitizing and integrating information technology (IT) and operational technology (OT) capabilities in manufacturing.² As smart factories scale, manufacturing organizations are looking for ways to:

- Improve performance
- Make data integration sustainable
- Upskill workers' digital and data skills
- Transform infrastructure and culture
- Minimize cyber risk

Deloitte believes there are four drivers of performance for life sciences companies looking to get the most out of smart factory investments:

1. Human performance, reducing error rates on the production floor
2. Process performance, getting that extra yield, extra gram of product from the current processes
3. Asset performance, getting more up time from manufacturing assets
4. Network performance, optimizing the performance that you need across the entire manufacturing network³

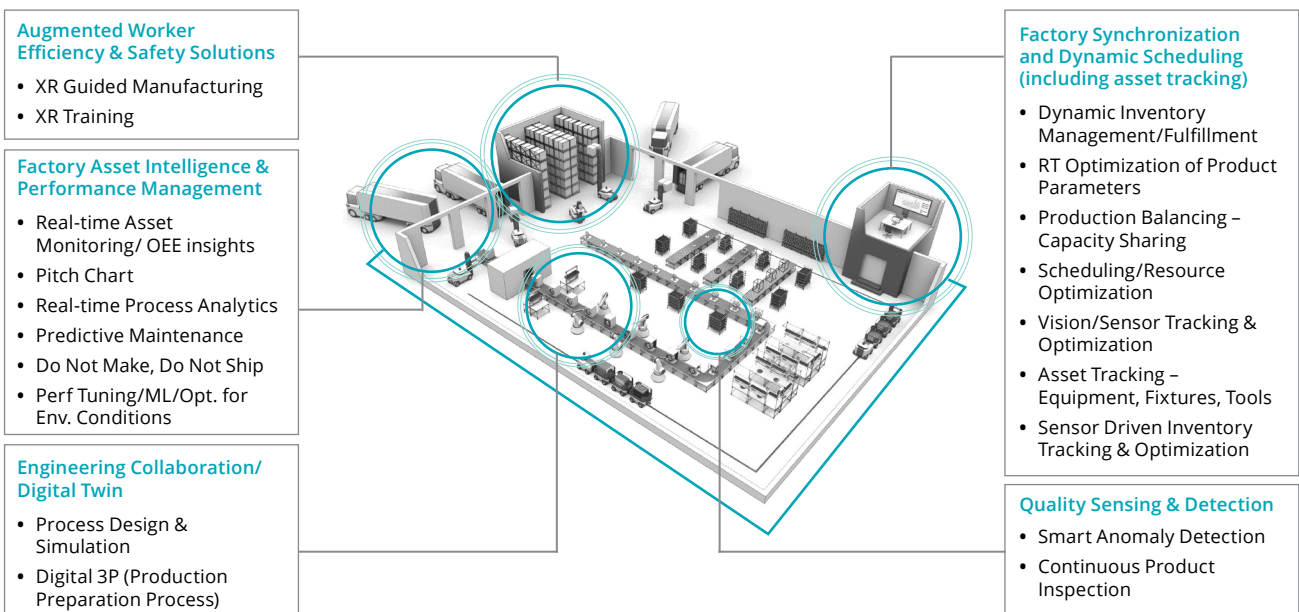
A high-performing smart factory empowers shop floor personnel with predictive analytics to take productivity and quality to the next level. As they analyze reams of data, asset performance issues can be revealed, allowing for more proactive and corrective optimization. The optimized processes, in turn, result in cost-effective production.⁴

Making data integration sustainable

Smart factories employ data-driven technologies—like artificial intelligence (AI), machine learning (ML), and the Internet of Things (IOT). (see figure 1). By seamlessly connecting and integrating disparate manufacturing systems and processes, companies increase visibility and performance capabilities. Figure 1 shows the level of business case-based opportunities for various medtech capabilities.

For example, on a digitized shop floor, machine intelligence is able to monitor processes and provide actionable insights for floor staff to reduce errors, deviations, and production losses.⁷ For biopharma, AI can predict asset maintenance requirements based on operational and maintenance history data stored in the cloud to prevent disruptions and loss of expensive APIs (Active Pharmaceutical Ingredients).⁸

Figure 1: Smart factory digital transformation



Estimating the net value of a smart factory investment

After a rapid assessment and identification of where digital capabilities could be scaled more effectively, a leading biotech/pharmaceutical manufacturer put numbers against a smart factory's expected benefits. The company combined top-down financial analyses with bottom-up evaluations of the impact of the proposed use cases on operational key performance indicators (KPIs) at two pilot sites. The company then scaled the opportunities across the network at full potential to determine which benefits were recurring and which were one-offs. Finally, the company validated the scaling and clustering approach and confirmed business case input parameters such as duration, rate of return, and cost of capital.⁵

The net value of the smart factory platform was projected to be at \$50 million to \$75 million year-over-year in operational expense reduction on a baseline of \$700 million—a direct bottom-line impact. This approach also created additional capacity that effectively negated the need for \$500 million in capital expenditures over a five-year period.⁶

Figure 2: Business case-based opportunities for medtech capabilities

Industry Sector	Augmented Worker Efficiency & Safety Solutions		Factory Asset Intelligence and Performance Management					Engineering Collaboration/Digital Twin		Factory Synchronization & Dynamic Scheduling (Including Asset Tracking)					Quality Sensing & Detection			
	XR Guided Mfg.	XR Training	Real-time Asset Monitoring/OEE Insights	Pitch Chart	Real-time Process Analytics	Predictive Maintenance	Do Not Make, Do Not Ship	Perf Tuning/ML/ Opt. for Env. Conditions	Process Design & Simulation	Digital 3P	Dynamic Inventory Management/ Fulfillment	RF Optimization of Prod. Parameters	Production Balancing - Capacity Sharing	Scheduling/ Resource Optimization	Vision/Sensor Tracking and Optimization	Asset Tracking - Equipment, Fixtures, tools	Sensor Driven Inventory Tracking and Optimization	Smart Anomaly Detection
Overall MedTech Capabilities	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Electromechanical Implantables	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Mechanical Implantables	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
External Electromechanical Devices	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Capital Equipment	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Disposables	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Instruments	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Implant/Implant Support	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Tissue/Biologic	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High

Source: Deloitte analysis

LEGEND: Business Case-based Opportunity
 High Medium Low

“ Legacy biopharmaceutical companies have grown and proliferated sources of data by establishing different systems across their operations. One of the fundamental challenges for a smart factory transformation is integrating those data sets from different sources—and making sense of them—with the least possible effort and investment. ”

Laks Perrenkil, Principal, Life Sciences Operations, Deloitte.⁹

Data integrity, a global issue for regulators

While investments already made represent huge opportunities, too often, they are impeded by manual and disconnected processes and documentation, especially if paper-based. Data integrity issues are a risk for life sciences companies,¹⁰ and a global issue for regulators. Poor documentation is a top data integrity concern covered in the US FDA’s Compliance Program 7356.002M implemented 1 October 2021.¹¹

Regulatory intelligence platform REDICA Systems analyzed US FDA warning letters to manufacturing sites for 23 countries over a five-year period (see figure 3).¹² Their research identified letters that included data integrity issues, and they were surprised to find that Canada led the list by percentage of issues.

Figure 3: Country comparison: Manufacturers with US FDA warning letters (WL) and letters identifying data integrity (DI) issues, 2014-2019.

Country	Number WLs with DI n-grams	Total Number of WLs	Percent with DI Issues
Canada	10	11	97
India	40	51	78
Japan	5	7	71
USA	9	13	69
China	40	62	65
South Korea	7	14	50

n-gram: Natural Language Processing (NLP) identifies a series of n items in text, in this case, data integrity issues.

Source: "What can regulatory data tell us about data integrity trends?" REDICA Systems, 31 August 2021.

Automated processes still require upskilling workers' digital and data skills

Solutions that automate batch records and other documentation processes are designed to prevent incorrect, missing, or out-of-date entries, but automation tools can be deployed with greater speed by less-technical people and that may pose a risk.¹⁴ As companies pursue automation capabilities, they should develop a flexible, mature validation strategy to implement controls that support regulatory compliance and product safety.¹⁵

Insufficient training and awareness is one of the factors that has made data integrity challenging for a while. Staff members are expected to fully understand all the requirements and standards relating to data integrity, and today's environment requires upskilling workers' digital and data capabilities.¹⁶

If work is outsourced, life sciences companies maintain responsibility for the integrity of all data involved.¹⁷ Two clinical research organizations in India were recently told by regulators that studies would need to be redone due to data integrity issues—affecting an untold number of drug makers.¹⁸

Transforming infrastructure and culture

In 2022, as life sciences companies look to change the innovation-averse DNA in some manufacturing organizations, they are also looking at ways to transform their infrastructure and culture. Companies might adopt a think-digital-to-be-digital mindset—considering how digital technologies augment human capabilities and change execution of processes. Shifting away from siloed manufacturing systems and processes requires building connectivity for the flow of information, data, and actionable insights.¹⁹

Minimizing cyber risk

As connectivity expands, cyber risk increases. In 2020, manufacturing moved up the list of most targeted industries from 8th to 2nd—a rise of 300% globally, according to the 2021 Global Threat Intelligence Report.²⁰ Over the year, attacks against manufacturing increased from 7% to 22%; health care increased from 7% to 17%.²¹

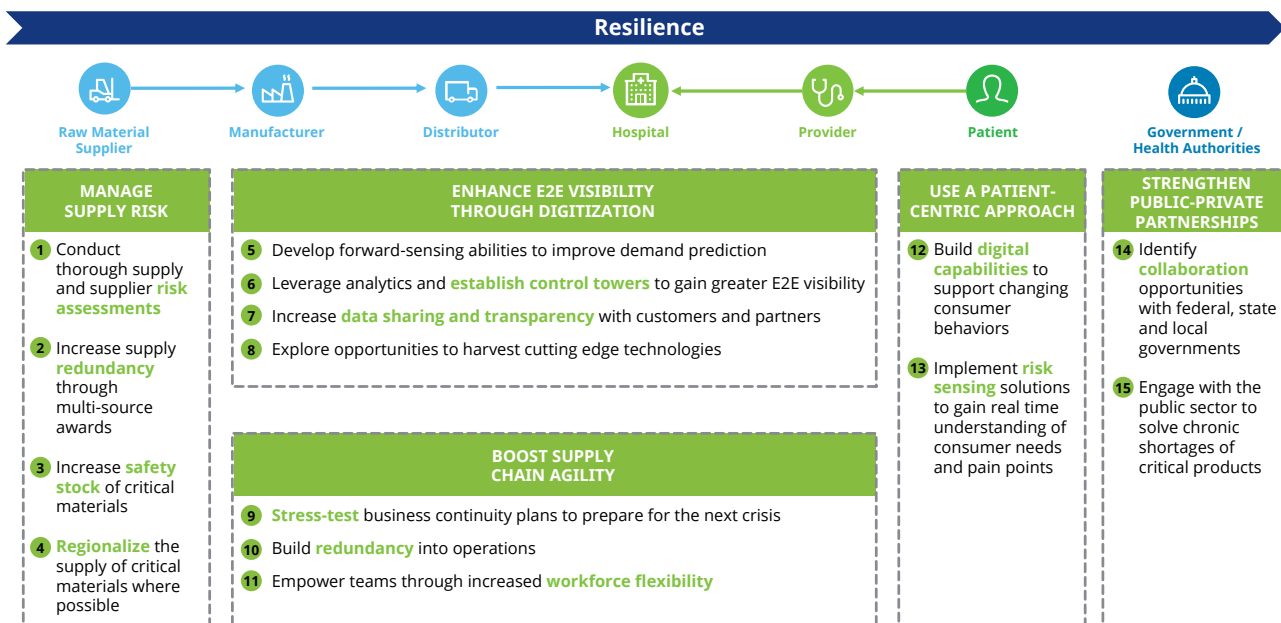
Organizations should have clear agreement on which data is most critical, who has access to that data, and an understanding about the potential impact if it is compromised. While no amount of money can make the risk completely disappear—and the long-term costs associated with data breaches can be difficult to quantify—brand reputation, supply chain, patient safety, and consumer trust may all be affected.²²

Building supply chain resilience

Starting with a global supply chain strategy

As disruptions to logistics and transportation impacted the timely delivery of products during the pandemic, life sciences companies rapidly digitalized their supply-chain operations. IoT solutions tracked and traced product shipments in real time and plugged gaps in supply-chain visibility.²³ The ability to anticipate and react to disruptions and shifts quickly requires a resilient global supply chain strategy (see figure 4).²⁴

Figure 4: Building a resilient global supply chain strategy



Source: "The Semiconductor Chip Shortage Hits MedTech: Strategies to Build Resilient Supply Chains," AdvaMed/Deloitte, 2021.

Regionalizing supply and continuous manufacturing

The pandemic created new urgency to reduce dependence on bulk active ingredients and generic drugs sourced from India and China. Manufacturers in Europe and the United States are building new in-country API development and manufacturing capabilities.²⁵ In addition to reshoring and regionalizing the supply of critical materials, companies are using innovative, continuous manufacturing to mitigate supply chain risks.²⁶

Continuous manufacturing is a way for drug manufacturers to more easily adapt supply to demand

Fully end-to-end systems, like **CONTINUUS'** Integrated Continuous Manufacturing (ICM) platform, seek to encompass both API and final dosage form manufacturing in one integrated system. More cost-effective manufacturing for small molecules can be performed at CONTINUUS sites or even clients' facilities through a Mobile Pharmaceutical (MoP) offering.

GlaxoSmithKline says its agile, continuous flow chemistry manufacturing has smaller operations that are more efficient and environmentally friendly. In Singapore, the company's commercial continuous API manufacturing process requires a facility approximately one-ninth the size (100 m²) of a facility required for a batch process (900 m²).²⁷

Continuity Pharma, a start-up out of Purdue University, is using flow chemistry to develop a system for continuously manufacturing multiple APIs with shorter turnaround times and higher volume. Innovative, streamlined, and automated systems are needed to compete with offshore API manufacturing.²⁸

In 2022, as life sciences companies conduct risk assessments, data analytics tools can be leveraged for deeper insights across the supply chain. These tools are designed to improve demand prediction and support data sharing with customers and partners.²⁹ Other digital innovations, like AI, can predict or forecast supply chain-related events (e.g., logistics challenges, geopolitical issues, and supply disruptions), either executing actions autonomously or recommending actions stakeholders should take—ultimately, helping life sciences companies build resilience and gain competitive advantage (see figure 5).³⁰

Figure 5: Sample innovations driving predictive and autonomous supply chain management

Digital innovations	Description
Control towers (data lakes)	<ul style="list-style-type: none"> By building control towers or data hubs, organizations can merge internal data (such as production and inventory data) with data from intermediaries and partners to provide real-time longitudinal visibility into material and product flow.
Machine-assisted business response (AI)	<ul style="list-style-type: none"> As part of day-to-day operations, self-healing AI solutions analyze supply chain, manufacturing, and market data to highlight potential issues (e.g., stockout of a raw material), analyze their root causes (inability of a vendor to make a delivery due to logistics issues) and suggest next steps to supply chain operators (ordering from an alternative supplier or changing production schedules).
Machine-driven resilience management (AI)	<ul style="list-style-type: none"> AI predicts or forecasts events (such as logistics challenges, geopolitical issues, and supply disruptions) to execute actions either autonomously or recommend actions to stakeholders to respond to long-term risk/disruptions.
Market and product tracking (AI, IoT, blockchain)	<ul style="list-style-type: none"> Companies track and analyze nontraditional data such as consumer sentiment, competitor, product user, and experience data along with traditional data (such as order patterns, demand signals) to optimize supply chain planning. As more next generation therapies enter the market, IoT, and blockchain are increasingly applied to track and trace product movement and temperature and coordinate timely delivery of such therapies to treatment centers.

Addressing external forces disrupting supply chains

Research shows that the life sciences sector expects to experience continued disruption in 2022 to its supply chains from external factors, including inflation and labor shortages.³¹ We see the pandemic, global volatility,³² and the semiconductor shortage (affecting two-thirds of the medtech industry)³³ continuing to be major supply chain issues.³⁴

Pandemic-era inflation linked to supply chain constraints

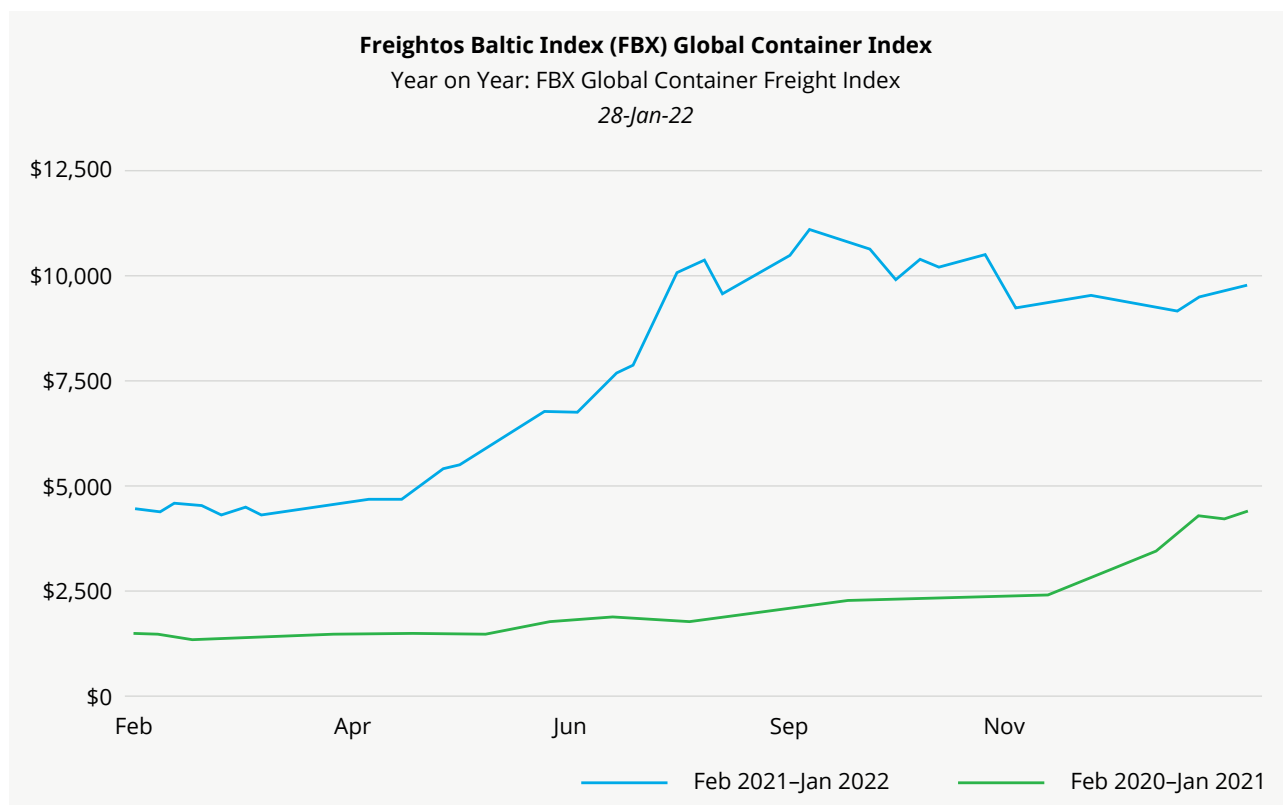
Today's economic climate and inflationary pressures present challenges not seen since 2008.³⁵ But pandemic-era inflation is different³⁶—attributed mostly to constraints connected to transportation and supply chain bottlenecks.³⁷

Access to raw materials is a factor.³⁸ Global ocean freight rates increased substantially in 2021 (see figure 6),³⁹ and trucking spot rates increased by 20%.⁴⁰ Air freight rates in January 2022 were ahead of last year.⁴¹ According to Abbott CFO Bob Funck, inflation and the supply chain are really linked together.⁴²

“ The global supply chain has not been able to keep up with strong demand out there. So, like others, we’re seeing some increased input costs across areas of our business. We’re experiencing some higher shipping costs and, in some cases, higher commodity costs. ”

*Bob Funck, CFO, Abbott.*⁴³

Figure 6: Year-on-year global container freight rates, Feb 2020 – January 2022



Source: [Freightos](#), 28 January 2022.

Today's market headwinds are different; inflation is higher, but also more volatile,⁴⁴ and inflation is not likely to go back to pre-pandemic levels.⁴⁵ While price increases did not significantly impact the financial results of many sector companies in 2021, change could come when Q4 2021 reports are released in early 2022.⁴⁶ Going forward, companies will need to look holistically across a range of levers—analyzing people, financial, and operational data—for effective inflation margin management.⁴⁷

Addressing volatility

Increasing global trade friction, on top of the global pandemic, have, in places, led to disruption in tariffs, regulatory changes, diminished access to suppliers/vendors, limitations on cargo capacity, and shortages of products.⁴⁸

Some life sciences companies are looking to minimize trade uncertainties and reduce customs taxes by rethinking operations and diversifying supply chains. Diversification or business model changes can lead to unintended tax costs or presence. Tax leaders should be engaged early to analyze potential impacts.⁴⁹

Semiconductor chip shortage

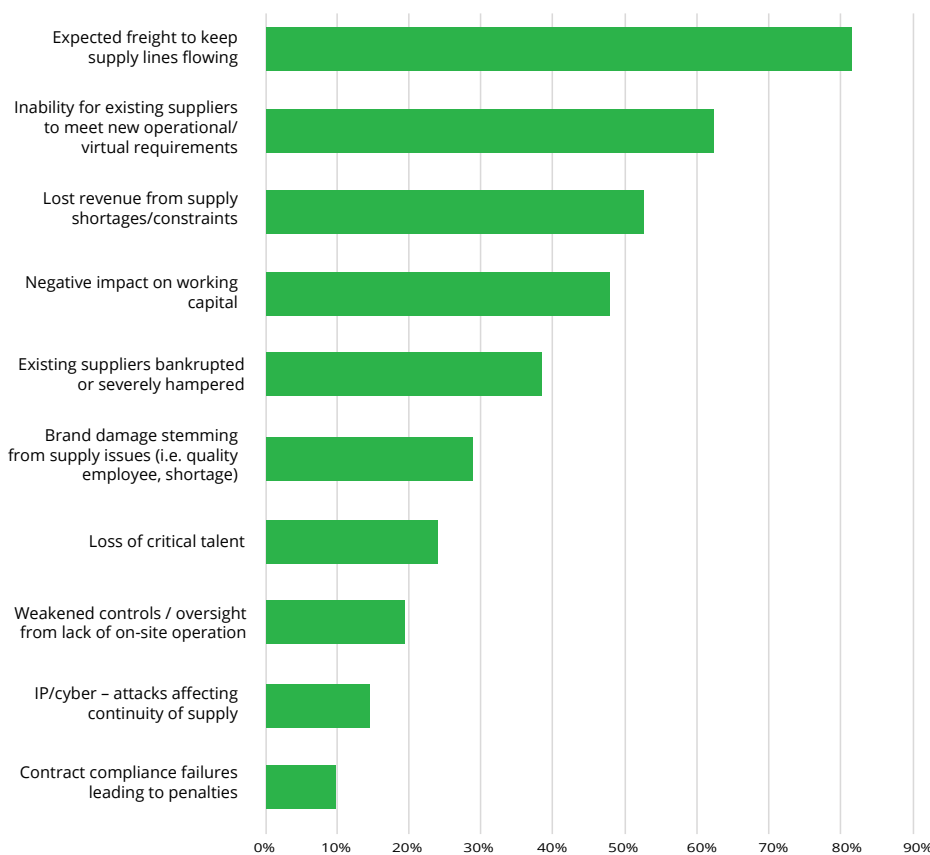
It took the chip shortages of 2020 and 2021 for semiconductors to cement their "critical" status. In 2022, Deloitte expects the global semiconductor chip industry to grow 10% to over US\$600 billion for the first time ever. Shortages and supply chain issues are likely to remain front and center for the first half of the year, hopefully easing by the back half, but with longer lead times for some components stretching into 2023, possibly well into 2023.⁵⁰

Whether explicitly or inadvertently, it is unknown which sectors could be prioritized if chip shortages persist. Many medical devices are chip-dependent, including ventilators and defibrillators; imaging machines; glucose, ECG, EEG, and blood pressure monitors; implantable pacemakers; and more. Patients who rely on these technologies for lifesaving and life enhancing care may be at risk.⁵¹

The issue is industry-wide for the hundreds of diagnostics, therapeutics, and capital equipment companies that produce essential medical technologies. An Advanced Medical Technology Association (AdvaMed) study conducted by Deloitte found that two-thirds of medical technology companies surveyed say semiconductors, firmware, and/or embedded software are required for at least half of the medical devices they produce for patients.⁵²

Deloitte found that half of semiconductors for the majority of those surveyed (mostly with over US\$1 billion in revenues) are single source—raising the stakes for supply chain disruption. All experienced chip supply chain disruption ranging from two weeks to more than a year, mostly from delays, order cancellations, and short orders.⁵³ Disruptions were all across the supply chain, many affecting the bottom line—e.g, increased shipping costs, decreased revenue from shortages, or negative impacts on working capital (see figure 7).⁵⁴

Figure 7: 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 Build Resilient Supply Chains,” AdvaMed/Deloitte, 2021.

Medtech’s primary needs are 2nd or 3rd generation chips,⁵⁵ and the use of chips in life sciences and health care will likely grow. Regulators are approving new connected home health care devices such as wearables and smart patches whose use may span hundreds of millions of units, especially given the rise in virtual visits and decentralized clinical trials.⁵⁶

The United States is looking for companies to onshore larger portions of the semiconductor supply chain.⁵⁷ In October 2021, the US Department of Commerce established the Microelectronics Early Alert System to coordinate government resources and help companies resolve supply chain bottlenecks due to the chip shortage.⁵⁸ Intel is spending \$20 billion on a cutting-edge, 1000-acre chip manufacturing campus in Ohio which would make it one of the largest chip manufacturing facilities in the world. Production is scheduled to start in 2025.⁵⁹

In addition to the chip shortage there is a growing demand for software skills required to program and integrate chips—and an overall labor shortage—that will likely exacerbate the situation for the near future.⁶⁰

Growing popularity of RNA therapies and short-term plasmid shortage

Increased demand has led to an industry shortage of plasmid starting material, prompting a growing number of viral vector facilities to consider manufacturing plasmid in-house to avoid potential supply-chain issues. The shortage may continue for the next couple of years.⁶¹

Demand increased with the rise of viral vector and gene therapy facilities, and is further complicated by increased interest in mRNA manufacturing. Plasmids are the raw material for both viral vector and in vitro-transcribed (IVT) mRNA manufacturing.⁶²

Expanding the supply chain ecosystem in 2022

A business is only as strong as its chain of suppliers,⁶³ and the pandemic highlighted the need to transform traditional supply chain models.⁶⁴ According to a recent Fortune/Deloitte survey, the majority of LSHC CEOs say that supply chain disruption has resulted in higher costs of doing business and margin impacts,⁶⁵ and continued challenges will influence and disrupt business strategy over the next 12 months (see figure 8).⁶⁶

Figure 8: Winter 2022 Fortune/Deloitte CEO Survey, LSHC CEO responses

What supply chain challenges has your organization experienced?

Challenge	% of LSHC CEOs
Input/raw material shortages	33%
Labor shortages	92%
Maintaining quality standards	8%
Production and/or logistics issues	50%
Reduced logistics capacity (any mode)	33%
Reduced manufacturing capacity	0%
Other	8%

What supply chain actions do you expect to take in the next 12 months?

Action	% of LSHC CEOs
Change product portfolio and roadmap	25%
Change profit/pricing model (e.g., higher prices)	67%
Expand sustainability/climate change initiatives	17%
Expand the supply chain ecosystem with more partners	50%
Update/change the logistics network and modes	33%
Vertical integration acquisitions	25%
Other	8%

Source: Winter 2022 Fortune/Deloitte CEO survey, Deloitte, 2022.

According to the survey, half of LSHC CEOs plan to expand their supply chain ecosystem with more partners in 2022, with a majority planning changes to profit/pricing models (see figure 8).⁶⁷ The research further shows that a new normal appears to be setting in, wherein leaders expect new challenges to arise continuously, but are confident they can manage through them to achieve positive business results.⁶⁸



Environmental, Social, and Governance (ESG): Another CEO imperative

Life sciences companies face distinct challenges with their very visible role in drug pricing and access to medicines, and the pandemic only underscored this focus. During the pandemic, life sciences companies came closer to their purpose—expanding environmental and diversity/inclusion goals and recommitting to social issues and health equity.¹ ESG (environment, social, and governance) at large is growing in importance as investors, partners, communities, customers, and employees increasingly scrutinize the companies they support.²

In 2022, ESG performance is expected to come under even more monitoring, and life sciences companies will need to home in on the material factors affecting the sector.³ Work is also underway for new global ESG standards,⁴ and companies will need to determine how best to demonstrate their progress with robust measures and enhanced disclosures.⁵

Materiality, measuring what matters most

Materiality for life sciences

Materiality in ESG defines what is important to stakeholders as well as what is important for business success.⁶ Leading material factors for the life sciences sector include:

- Environmental sustainability, making medicines more sustainable and reducing greenhouse gas emissions, in particular, Scope 3 emissions of a company's supply chain⁷
- Drug pricing—balancing the need for innovation with the needs of policymakers⁸—and the broader effect from new ESG regulations⁹
- Access to medicines globally and supporting innovation in medicines and treatments with the greatest need¹⁰
- Health and race equity, including enhancing diversity in clinical trials¹¹
- Diversity in leadership and income equality, including a gender pay gap in scientific research and the pharmaceutical industry¹²

Material issues may sway public perception, ESG ratings, and company valuations,¹³ and companies that conduct materiality assessments have been shown to achieve significantly higher disclosure scores.¹⁴ In addition to positive societal impact, companies with strong ESG propositions and materiality may benefit from quantifiable business value.¹⁵

E, S, and G issues increasingly intertwined

Environmental, social, and governance issues are becoming progressively intertwined. For example, making medicines sustainable protects the environment and has a social impact on the broader access to medicines. As a result, more companies are realizing that ESG metrics and business metrics are inextricably linked.¹⁶

“

At the executive committee, when we review where we are and how we are progressing towards our objectives, we don't look at the ESG metrics separate from everything else, but rather, key elements of our ESG goals are an integral part of the broader set of operational goals and metrics that we review on a regular basis—they contribute to each other. For example, our ability to attract, retain and develop a diverse workforce contributes to our overall success and business results.

”

Anat Ashkenazi, CFO, Eli Lilly and Company¹⁷

Transparently tackling ESG challenges with stakeholders

Forward-looking companies should welcome diverse stakeholders and incorporate their perspectives into strategic decision-making to solve ESG challenges. Communicating challenges promotes transparency, and working together with stakeholders may provide:

- A better understanding of the implications of decisions
- Support that minimizes risk
- A social license to act
- More trust and a better reputation¹⁸

Biopharma companies are often held to an unparalleled standard when it comes to motive and profit, although continued innovation and product availability depend on it. Building trust is a vital pathway to demonstrating the true value that biopharma companies and the rest of the health care system bring to society while also being accountable to shareholders and stakeholders.¹⁹

While investor relations is available to communicate with shareholders on concerns, Jim Greffet says that a large part of his role, as Head of ESG for Eli Lilly, is determining what is important to stakeholders by having an open door for discussion.²⁰

“ The best way to understand what’s on your stakeholders’ minds is to talk to them. ”

*Jim Greffet, Head of ESG, Eli Lilly and Company*²¹

Climate disclosure mandates ramping up

The impacts of the environment and climate change are increasingly viewed as a growing financial risk—both in terms of a company’s exposure to impacts as well as their contribution to increased global warming.²² As more robust data is being sought on environmental issues,²³ climate mandates are ramping up, especially in Asia.²⁴

In 2021, New Zealand became one of the first countries to formally legislate the mandatory assessment and reporting of climate change risks by publicly listed companies, banks, investors, and insurers.²⁵ The Securities and Exchange Board of India rolled out a series of rules in 2021,²⁶ and Thailand’s SEC (Securities and Exchange Commission) will soon require companies to annually disclose ESG impacts and policies, including the level of greenhouse gases emitted.²⁷

Non-financial ESG reporting is further along in the European Union, but the first set of reporting standards—the Commission’s proposal for a Corporate Sustainability Reporting Directive (CSRD)—is expected in October 2022.²⁸ In the United States, the SEC recently proposed [new rules to standardize climate-related disclosures](#) for US-listed companies.²⁹

Growing focus on Scope 3 emissions

Investors are particularly interested in “Scope 3” disclosures—greenhouse gas emissions (GHG) that also include a company’s suppliers and other partners. Under the US SEC’s new proposed rules, registrants would be required to disclose Scope 3 GHG emissions, if material or if the registrant has set a GHG emissions target or goal that includes Scope 3 emissions. The proposed rules would provide a safe harbor for liability from Scope 3 emissions disclosure and an exemption from the Scope 3 emissions disclosure requirement for smaller reporting companies.³⁰ Digital solutions for measurement and optimization (that include Scope 3) are a core component of a successful Net Zero strategy.

Some life sciences companies are setting ambitious Scope 3 targets led by AstraZeneca (see figure 1).³¹ In addition to its long-term target, AstraZeneca commits to reducing absolute scope 3 GHG emissions from fuel and energy related activities, upstream leased assets and downstream leased assets—80% by FY2030; from use of sold products—95% by 2030; and from upstream transportation and distribution, waste generated in operations, business travel, employee commuting and end of life treatment of sold products—46% by FY2030. All commitments are from a 2019 base year. AstraZeneca also commits to science-based targets by FY2025 for 95% of its suppliers by spend covering purchased goods/services and capital goods, and 50% of its suppliers by spend covering upstream transportation and distribution and business travel.³²

Figure 1: Life sciences companies’ absolute Scope 3 GHG Net-Zero commitments

Company	Target	Target Year	Base Year	Notes
AstraZeneca	90% reduction	2045	2019	Long-term target in addition to other shorter-term targets
Illumina, Inc.	46% reduction	2030	2019	From purchased goods and services, capital goods, upstream transportation and distribution, business travel, employee commuting and investments
Novartis	35% reduction	2030	2016	
Merck & Co., Inc.	30% reduction	2030	2019	Target boundary includes biogenic emissions and removals from bioenergy feedstocks
Pfizer Inc.	10% reduction	2025	2019	10% from upstream transportation and distribution
	64% reduction	2025		64% of its suppliers by spend covering purchased goods & services
				Target boundary includes biogenic emissions and removals from bioenergy feedstocks
Johnson & Johnson	20% reduction	2030	2016	Target boundary includes biogenic emissions and removals from bioenergy feedstocks
GlaxoSmithKline	16% reduction	2030	2017	
Takeda	15% reduction	2025	2018	Through educating and influencing suppliers ³³ and commits 67% of its suppliers by emissions covering purchased goods and services, capital goods and upstream transportation and distribution will have science-based targets by 2024
Sanofi	14% reduction	2030	2019	Target boundary includes biogenic emissions and removals from bioenergy feedstocks

Source: Science-Based Targets Initiative, 2021.



Broader effects on the supply chain and drug pricing

Additional costs are typically involved with meeting ESG criteria, and changes may have an effect on pharmaceutical pricing policies. Drug pricing is increasingly becoming a broader ESG topic, cutting across corporate governance, the investment community, and global access to medicines. But new ESG requirements may focus on the degree of influence a supplier has within the supply chain beyond Scope 3 greenhouse gas emissions.³⁴

For example, the recently approved Supply Chain Due Diligence Act in Germany introduces new obligations for German companies with regard to protecting human rights in supply chains globally. The entire supply chain, from the extraction of raw materials to the delivery to customers, is covered by the new act—which will apply to companies with at least 3,000 employees in Germany in 2023, and those with at least 1,000 employees in 2024.³⁵

Statutory health insurance funds in Germany are also introducing ethical considerations into pharmaceutical supply contracts. One tender for the supply of five antibiotics was part of the discount contract system that included a number of ESG conditions—including protections for workers' rights and environmental standards. Those with higher environmental standards had a better opportunity to win the contracts, while in the past, the main criteria was price.³⁶

Collectively making medicines sustainable

The non-profit Sustainable Medicines Partnership (SMP) endeavors to bring the biopharma industry together on a single initiative—reducing waste in medicines. The biopharma industry produces 4.5 trillion medicines annually—and many are never used. For example, US\$37 billion in medicines are lost every year due to failures in cold chain logistics alone.³⁷

Another reason for waste is shelf life given to a medicine is typically based on the information available when it went through the approval process. But it may actually be twice as long before it is no longer effective.³⁸

“

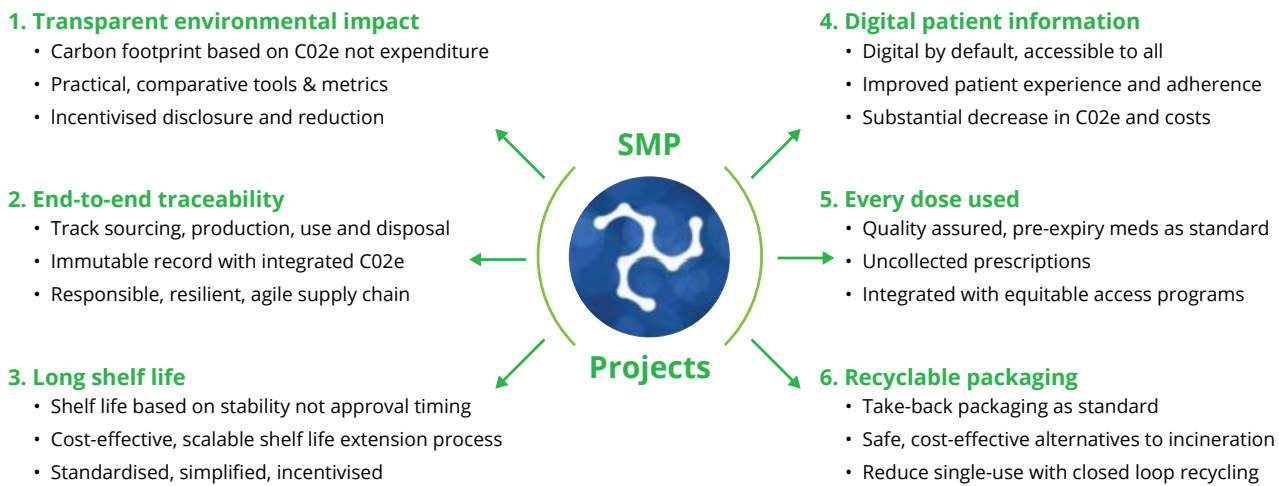
I saw the magnitude of the problem as well as the opportunities to deal with it. I wanted action

”

*Dr. Nazneen Rahman, Founder, YewMaker and Sustainable Medicines Partnership,
Non-executive Director, AstraZeneca³⁹*

SMP is a four-year program designed to deliver evidence-based, scalable, and sustainable solutions that address six pillars to make medicines sustainable (see figure 2).⁴⁰ The organization is not only looking to rally the biopharma industry, but also collaborating with the 'Big 4', the NHS, health care, the medicines supply chain and packaging, government bodies, academia, researchers, designers, entrepreneurs, and patient groups.⁴¹

Figure 2: 6 pillars of the Sustainable Medicines Partnership



Source: Deloitte analysis

Improving access to medicines

Overall, pharmaceutical companies are making incremental progress in improving access to medicines globally and supporting innovation for treatments with the greatest need.⁴² But the impact of these ESG factors was clearly highlighted by the pandemic.⁴³

According to the Access to Medicines Foundation, 5 billion people have access to medicines, but there are 2 billion people to go.⁴⁴ The Access to Medicines Index is a tool designed to drive change in the pharma industry by tracking its progress.⁴⁵ The Foundation's new strategic direction for 2022-2026 expands the range of companies and healthcare sectors to mobilize in the fight against health care inequality.⁴⁶

2021 Access to Medicines Index results

The 2021 Index analyzed how the world's top 20 pharmaceutical companies addressed access to medicine in 106 low- and middle-income (LMIC) countries for 82 diseases, conditions, and pathogens (see figure 3).⁴⁷ Companies were measured and ranked overall and in individual categories for:

- Governance of access
- Research & development
- Product delivery⁴⁸

Of the 20 companies analyzed in 2021, GlaxoSmithKline (GSK) took first place overall as well as first place in the governance

of access and research and development categories. GSK leads governance due to its clear access-to-medicine strategy embedded in its overall corporate strategy and CEO remuneration tied to access objectives. In R&D, GSK is undertaking 22% of the total number of priority R&D projects, followed by Johnson & Johnson with 13.6%.⁴⁹

Novartis was the first to begin mainstreaming access planning across its pipeline⁵⁰ and attained first place for product delivery in the 2021 index, leading consistently across all access strategies.⁵¹ In 2021, 8 companies adopted processes to systematically address access to medicine for all new products, and 12 out of 20 make access to medicines a direct board level responsibility. Sanofi was recognized for its approach to access strategies for supranationally procured products (procured through international organizations like The Global Fund).⁵²

“ Large research-based pharmaceutical companies have a critical role to play in preparing for the next pandemic. While academic groups and small biotechs can pioneer new research ideas, big companies are essential in ensuring rapid development and access. ”

Access to Medicines Foundation⁵³

Figure 3 :Access to Medicines Index 2021, top 20 pharma companies



Source: "Access to Medicine Index 2021," Access to Medicine Foundation, 2021.

Taking actions to improve access performance

Pfizer's performance in planning for access improved from previous years, helping the company move into a top 5 overall position for the 2021 Index.⁵⁴ Some actions Pfizer took to improve access include:

- Expanding access planning during development from vaccines to all products
- Launching a Global Pricing and Access Strategy that requires access planning for all products to commence two years pre-launch
- Sharing many IP assets with third-party researchers, e.g. for malaria and TB via research institutions and via the COVID-19 Therapeutics Accelerator
- Completing a sustainability bond whose proceeds are used for social (e.g. for COVID-19 and AMR Action Fund) and environmental projects⁵⁵
- Reaching nearly 700,000 patients in 2020 through its ex-US patient assistance programs, some of whom may not have otherwise been reached through traditional commercial channels⁵⁶
- Linking CEO remuneration to access performance.⁵⁷

The [Methodology Report](#) for the 2022 Access to Medicines Index lays out the metrics by which companies will be assessed this coming year.⁵⁸ A greater weight will be put on R&D in 2022, focusing on indicators that measure outcomes, rather than policies and processes.⁵⁹ The 2021 Access to Medicines Index found that despite major gaps in the pediatric drugs pipeline, only 6% of R&D projects targeted children under 12 years of age.⁶⁰

Leading health equity

Strategies for enhancing diversity in clinical trials

A material factor for life sciences under the social umbrella, or "S" in ESG, is diversity in clinical trials. COVID-19 brought existing social inequalities to the fore, and ensuring clinical trials better reflect patient populations will expand access to potentially life-saving therapies, build trust, and promote innovation.⁶¹

In the report, *Five Key Strategies for Enhancing Diversity in Clinical Trials*, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Deloitte US Center for Health Solutions (CFHS) outline five critical strategies for enhancing diversity in clinical trials during the research and development of new medicines.⁶²

- **Create a network of clinical trial sites in underserved communities.** Establish research sites in locations where potential participants already receive care, including non-traditional locations such as community health centers and pharmacies.
- **Develop a racially and ethnically diverse pool of investigators and staff.** These key community ambassadors can ensure that trials are culturally competent and mindful of unconscious/implicit bias.
- **Establish long-term relationships and invest in the community.** Prioritize long-term and sustainable community building efforts, like investing in health education or supporting the next generation of diverse health practitioners and investigators.
- **Engage the community in conversations.** Sponsors should communicate and work toward shared understanding with the community and seek input into the elements of design that might impact community members' ability to participate.
- **Provide sustainable support and standardized platforms.** Build a data infrastructure that leverages real world data and includes baseline measurements to improve data on race and ethnicity.⁶³

A community-based clinical trial infrastructure may be the most effective way to sustainably accomplish the goals of enhancing access to clinical trials and promoting health equity. Shifting the paradigm will likely require substantial cross-stakeholder commitment and collaboration.⁶⁴

Principles of health equity for medtech

Medtech makes the technologies and tests that are responsible for the accurate diagnosis of disease and improved patient outcomes. AdvaMed (Advanced Medical Technology Association) is a global trade association advancing the interests of the medtech industry and is working to ensure the industry is doing its part to mitigate the adverse impacts of health disparities among people and communities of color.⁶⁵

AdvaMed's board-created and board-approved set of principles are designed to guide the industry in addressing racial health disparities. The principles call on industry to:

- **Promote inclusion and equity and health care.** Promoting unbiased treatment of patients likely requires partnerships to educate the industry and others on identifying, acknowledging, and addressing bias.
- **Partner in education with stakeholders.** Outreach to, and partnership with, clinicians to educate them regarding disparate trends in patient care, including access technologies.
- **Advocate for and facilitate patient access to innovative technology.** Develop and disseminate materials for use by patients, providers, and facilities.
- **Promote research equity in the medtech industry.** Require engagement and partnership with other caregivers and groups to bridge the gap, and promote the need for, involvement in studies and research to include more diversity among investigators.⁶⁶

Health equity is covered extensively in Deloitte's [2022 Global Health Care Sector Outlook](#).⁶⁷

Advancing diversity and women in leadership

Women appointed CEOs globally rose to 13% in 1H 2021, compared to 6% in the previous 6-month period.⁶⁹ In the Fortune 500, there were 41 women CEOs in 2021, an all-time record, but just 8.1% of the total.⁷⁰ In the Fortune Global 500, women accounted for 23% of the chief executives in 2021, including 6 women of color, also an all-time high.⁷¹ As of January 2022, women hold 31 (6.2%) of CEO positions at S&P 500 companies.⁷² Women of color hold only 1 percent of CEO positions across the Fortune 1000.⁷³

Some notable new CEO appointments in 2021 for Life Sciences and Health Care include: Karen Lynch, CVS Health (the \$268 billion health care giant is now the largest company ever to be run by a female chief executive); Roz Brewer, Walgreens Boots Alliance (the only Black woman currently running a Fortune 500 company); Reshma Kewalramani, Vertex Pharmaceuticals,⁷⁴ and Tan Sin Yin (Jessica Tan), co-CEO, Ping An Insurance.⁷⁵

China capitalizes on digital platforms for health equity

For decades, China has strived to achieve health equity nationwide. During the pandemic, with many outpatient clinics closed and medical supplies low, patients with non-COVID-19 symptoms were among the hardest hit groups. Digital health care proved to be a promising solution to this issue, and the pandemic accelerated the development of many digital health platforms, including WeDoctor and Alibaba Health. These platforms facilitated online health care consultations and the delivery of medicine from health care institutions to patients—providing more accessibility. Digital accessibility was also encouraged in rural regions, where more patients delayed treatments than in urban areas.⁶⁸

“

We're seeing more intentionality. We're seeing a focus on women of color. And we're seeing a recognition that diversity and women in leadership is even more important.

”

Lorraine Hariton, CEO, gender equality organization Catalyst⁷⁶

Research shows that efficiency gains from having a larger female representation in firm leadership can be quite large.⁷⁷ Women CEOs exhibited a different leadership style than men during the COVID-19 crisis—leaning toward empathy, adaptability, accountability, and diversity.

Women's more positive communication style scored higher for words expressing trust and anticipation, according to S&P Global.⁷⁸ They report that female CFOs are more profitable and have produced superior stock price performance compared to the market average. Women may be the most underutilized source of growth.⁷⁹

According to the Women Business Collaborator, there are 10 accelerators for advancing women to the CEO role:

1. Recognize women's experience, talent and acumen to be CEO Leaders
2. Generate board support for women in the pipeline
3. Create shareholder and stakeholder value
4. Sponsor and advocate for women leaders
5. Include diverse women
6. Celebrate and affirm the men who are building pipelines
7. Use successful Women CEO role models as examples and advocates
8. Pay equal or better compensation
9. Search Firms to include women in their slates
10. Join and support women's organizations focused on position, pay and power for all women⁸⁰

There is also a gender pay gap that needs to be addressed in the overall scientific research community and pharmaceutical industry.⁸¹ A significant imbalance between genders was found by the British Gender Pay Gap Report.⁸² It is interesting to note that GSK, the leader in access to medicines, had no gap in distribution of pay—and also appointed the first female to CEO of a leading pharma company, Emma Walmsley in 2016.⁸³

In 2022, companies are expected to face continuing external pressures from institutional investors, activist shareholders, potential employees, and customers to increase the representation of women on corporate boards, in C-suite positions, and across executive leadership, as well as equal compensation and mobility for women and people of color.⁸⁴ If life sciences companies are to be truly understanding of the diverse patient population they seek to serve, executive and board members should also be truly representative.⁸⁵

ESG ratings and raising levels of public trust

More than 150 ESG ratings and data providers

Rating agencies and data providers are useful tools for measuring an organization's positive or negative impact on ESG issues. But the sheer number of firms to consider—each using its own methodology—is often a challenge.⁸⁶

There are at least 600 products from more than 150 organizations providing ESG data to corporations and asset managers. Leaders in the field include MSCI, Sustainalytics, ISS ESG, Bloomberg, and S&P Global (TRUCOST). Some data providers are specific to industries—like the Access to Medicines Index.⁸⁷ Chinese ratings providers come from many diverse viewpoints, ranging from traditional index/data providers, fintech companies, asset managers/owners and academic/non-profit institutions to consulting companies.⁸⁸

As a result, rankings from the many data firms assessing ESG performance vary.⁸⁹ Novartis, an ESG leader in the sector, publishes its performance ratings provided by various agencies (see figure 4).⁹⁰

Figure 4: Novartis performance ratings across ESG ratings providers, updated January 2022

Agency	Rating	Current	Previous	Industry perspective
Access to Medicine Index¹	Score	4.18 ▲	3.2	2 / 20
CDP²	Climate score	B ▼	A-	Management band B/B- ⁹
	Water score	A- ▼	A	Leadership band A/A- ⁹
FTSE4Good²	ESG score	4 ▼	4.7	n/a ¹⁰
ISS ESG^{2,3}	ESG score	B ►	B	4 / 473
MSCI^{2,4}	ESG score	A ►	A	Best rated peers: AAA (3 PharmaCos), AA (10 PharmaCos)
	MSCI Global Compact	Pass ▲	Watchlist	
	Controversy ⁷	3 ▲	1	
S&P Global^{2,5}	ESG score	83 ▲	73	5 / 91 in Pharmaceuticals (97th percentile)
Sustainalytics^{2,6}	Risk score	17 ▲	21	1 / 432 in Pharmaceutical subindustry group ¹¹
	Controversy level	3 ►	3	

1. Published every 2nd year. Result shown shows 2020/20218 scores 2. 2021/2020 scores 3. Published every 2nd year. Updated December 2021. 4. Updated December 2021 5. Updated December 22, 2021. Novartis has been a DJSI World member since 2022 6. Updated April 2021 7. 0-10 scale, 0 being most severe controversy 8. Leadership as defined by rating agencies 9. Climate: Novartis received a B (Management band), same as the Biotech & pharma sector average, Water: Novartis received a A-(Leadership band), higher than the Biotech & pharma sector average 10. Novartis is in the top 5 Pharmaceuticals 11. Pharmaceuticals subindustry group.

Source: Novartis, January 2022.

“ ESG is central to the Novartis strategy and is critical to delivering on our purpose to reimagine medicine to improve and extend people’s lives. Looking ahead, we are renewing our focus on our ESG material topics, redoubling our efforts on improving access to medicines and accelerating our journey toward a zero-carbon future. ”

Vas Narasimhan, CEO, Novartis⁹¹

Bridging the ESG perception/reality gap

There is an overuse of cliches in ESG reporting, and stakeholders expect to see evidence of action, not empty words.⁹² However, despite actions, more than 90% of 250 public companies studied by data company RepTrak have a perception/reality gap between public opinion and ESG actions/ratings.⁹³ With this gap, a company may be judged more harshly in a crisis scenario,⁹⁴ and the pandemic demonstrated the importance of anticipating and managing risk.⁹⁵

To mitigate this risk, biopharma companies might consider working together on specific ESG initiatives to build more trust and raise public opinion of the industry⁹⁶—especially since biopharma ranks as one of the least trusted industries according to many consumer polls.⁹⁷ While public opinion improved during the pandemic, recent Deloitte research found the lowest levels of trust for biopharma to be in the United States and the highest in India.⁹⁸

Preparing for new global standards

A significant challenge—for ratings' agencies, asset managers, and companies themselves—is that ESG information is not reported in a standardized way.¹⁰¹ The IFRSF (International Financial Reporting Standards Foundation) formed the International Sustainability Standards Board (ISSB) to provide the global financial markets with high-quality disclosures on climate and other sustainability issues. Consolidation of several standard-setters is expected by June 2022, with the release of the first batch of climate-related disclosure standards.¹⁰²

The World Economic Forum's International Business Council welcomes the arrival of the new IFRSF standards that the IFRSF has indicated¹⁰³ and suggests companies consider its Stakeholder Capitalism Metrics framework to prepare.¹⁰⁴ Life sciences companies should not wait for mandates and can begin by:

- Identifying the metrics most relevant to their own company's strategy and stakeholders as well as those relevant to the life sciences sector¹⁰⁵
- Identifying a full list of individuals and groups whose interests are affected or could be affected by its company's activities¹⁰⁶
- Monitoring and evaluating how new and existing third-party relationships impact the company's ESG priorities
- Collaborating across the ecosystem to simplify data collection, synthesis, and reporting
- Looking for ways to transform business models and innovate solutions to move toward goals
- Communicating the company's ESG vision and strategy early to win support¹⁰⁷

Gathering data for better ESG reporting

It is important that corporations measure and report on the results of their ESG efforts to live up to the purpose set for the enterprise. This enhances integrity and authenticity of the environmental and social goals.¹⁰⁸ Selective reporting that does not connect narrative information and financial information can lead to greenwashing.¹⁰⁹ The temptation can be great for being seen as ethical, as this may drive profitability. But the risks remain, even if unintentional, with bad data and communications.¹¹⁰

Watchdogs are analyzing ESG reports, questioning the substance of companies' pledges and looking for evidence of greenwashing.¹¹¹ By utilizing better data and analytics, companies can have a more systematic, quantitative, objective, and financially relevant approach to key ESG issues—providing ESG reporting with data integrity.¹¹²

Demonstrating performance for ESG reporting starts with:

- Knowing what needs to be collected
- Knowing who needs to be involved in the process
- Knowing where the data is in the business
- Developing a robust, future-proof data collection process¹¹³

In addition to data management, Deloitte research finds that organizations could likely improve the efficiency and effectiveness of ESG reporting processes with an integrated and automated platform approach. Strong governance and internal controls in ESG measurement and disclosure are part of establishing a comprehensive strategy for integrating ESG considerations into business processes.¹¹⁴

Financial vs non-financial ESG communications

Sustainability reporting is expected to be a trusted, credible, and relevant resource for stakeholders—making a clear link between financial and non-financial information.⁹⁹ Some companies may create problems by repurposing technical financial investor information into other public communications geared to a less technical audience. While at times this may be a matter of resources, life sciences companies should consider the effects on public perception, and opt for more authentic messaging targeted to each specific audience.¹⁰⁰

“ As a board member, it’s also my responsibility to ensure that ESG reporting is not a marketing exercise but one that transparently lays out a set of goals that leadership is measuring its performance against. ”

Jamere Jackson, CFO of AutoZone, Audit Committee Chair, Eli Lilly and Company¹¹⁵

Investor focus on ESG reporting

ESG now accounts for 10% of global fund assets, and 2021 was a record year for investment. US\$649 billion poured into ESG-focused funds worldwide thru 30 November 2021, up from US\$285 billion in 2019.¹¹⁶ Experts say US\$4 of every US\$10 moving into global equity funds is being diverted to ESG funds.¹¹⁷ From the US\$6.1 trillion held in ESG funds, 59% is held in Europe, Middle East, and Africa, according to Refinitiv Lipper Research.¹¹⁸

While inflows in European ESG funds decreased in 2021, this was more than offset by rising flows into US and Asian ESG funds. In China, RMB 250 billion (US\$39.3 billion) was invested in ESG funds through Q3 2021,¹¹⁹ and the number of funds surged to 48—close to the total of the previous 5 years.¹²⁰

Foreign investors in Chinese assets have to meet their fund domicile standards on ESG when investing in China, which is driving improved reporting by Chinese firms.¹²¹ Researchers studied a novel dataset that showed ESG performance in China positively associated with the short-term cumulative returns of CSI 300 stocks around the COVID-19 crisis. They concluded that investors may interpret ESG performance as a signal of future stock performance and/or risk mitigation in times of crisis.¹²²

Investors are looking for demonstrative ESG reporting to compare a company’s ESG risks and opportunities to their business strategy, operations, and financials.¹²³ In 2022, as the velocity of ESG investments rise¹²⁴ and investor focus on ESG practices grows, more board members are considering whether ESG measures should be incorporated into executive incentive plans to hold management accountable for ESG results.¹²⁵ ESG is expected to remain front and center for 2022.¹²⁶

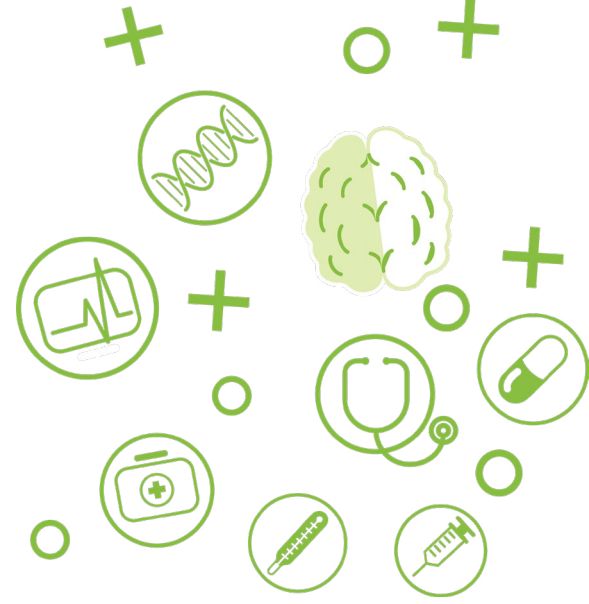
New sustainability-linked bonds (SLB) tied to climate, access to medicines, biodiversity

Since Novartis became the first pharma to create an SLB in 2020, SLBs have become a growing trend.¹²⁷ In November 2021, Teva Pharmaceuticals linked both climate and access to medicine targets to an SLB. Their US\$5 billion bond is the largest of its kind from any sector and the first issued by a generic medicines company. They are committing to access to medicine targets with a 150% increase in both the number of registrations and products provided through access programs in LMICs.¹²⁸

In addition to access to medicines and other ESG concerns, part of Eli Lilly’s sustainability bond is tied to a specific category addressing terrestrial and aquatic biodiversity conservation—using their skills in genetic engineering and recombinant technology to avoid testing on animals. Since 7 out of 8 manufacturing plants have transitioned, there is larger effect on the environment and conservation. For example, by eliminating testing on horseshoe crabs, an endangered species, Eli Lilly also protects the birds that feed on the crab’s eggs.¹²⁹

In 2022, companies can expect more scrutiny for SLBs. While SLBs are linked to Key Performance Indicators (KPIs), there are no standards. Penalties for missing KPIs are often less serious. Another issue is that the maturity date of the bond and the measurement of the KPIs often coincide, potentially enabling the issuer to redeem early if KPIs are going to be missed.¹³⁰

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The digital enterprise at scale: A CEO imperative for 2022

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