Deloitte.

2024 Global Life Sciences Sector Outlook

Driving resiliency

Contents

Introduction

With the global pandemic firmly in the rearview mirror, life sciences companies are looking at key macro- and micro-economic drivers to guide their future growth. While the list of trends with wide-ranging global impact is broad, in this year, life sciences enterprises are paying particular attention to those more disruptive trends including increasing pricing pressures and changes in United States regulation, the acceleration of Generative AI (GenAI) adoption and impact, the geo-political environment, and as always, breakthrough science and outcomes. Companies are exploring how the evolution of GenAI can impact their operations and determining where to focus first and how to generate differential value. The potential of advanced technologies and these collaborations are directly integrated with life sciences companies' overall efforts to improve patient outcomes and inform their R&D decisions.

Companies are looking to the potential of GenAI to bring more value across the board—both in terms of cost reduction and revenue uplift. GenAI and other AI technologies, coupled with digital transformation tools, are poised to increase overall efficiencies and process innovation across many areas of the life sciences value chain. A top 10 biopharma company with an average revenue of US$65-75 billion could capture between US$5-7 billion of peak value by scaling the use of AI over 5 years.[1] The promise of AI and GenAI is expected to yield new partnerships in the rest of 2024 as large companies look to obtain technological capabilities, secure industry talent, and drive competitive advantage.

In the coming year, pharma companies will be finetuning strategies to create top-line value through strategic acquisitions with a cautious but active mergers and acquisitions (M&A) and capital environment expected as inflation is expected to lessen and interest rates likely stabilize. An active acquisition market may also offset loss of exclusivity patents, which could cost life sciences companies more than US$200 billion in revenue.[2] However, when it comes to M&A, companies should continue to expect regulatory scrutiny over antitrust concerns.

Partnerships and collaborations in conjunction with AI and GenAI are also driving new trends in accelerating the speed of time to value in R&D. With ongoing regulatory changes, pricing pressures, and loss of exclusivity in 2024, companies will need to harness the power of innovation[3] and leverage the potential of AI and GenAI to demystify complex disease biology, expedite drug discovery, cut study timelines, revitalize the clinical trial experience, and improve regulatory success. Leading biopharma companies are already adopting new AI/GenAI technologies and other data innovations across the value chain, while forming new partnerships, collaborating early with regulators, and outsourcing for cost and time savings.

Pharmaceutical trade started to rise in the third quarter of 2023,[4] and the global market for pharmaceuticals is expected to reach almost US$1.2 trillion in 2024.[5] During the pandemic, trade and supply chains were vital to increasing the production and distribution of medical supplies and vaccines,[6] however, in the past two years, global trade is noticeably more concentrated and geopolitically closed. This means major markets are increasingly relying on a smaller pool of trading partners[7] with attempts to protect and build local markets on the rise. As such, multinational corporations (MNCs) are lobbying government officials to find ways to temper the blow of export controls.[8]

MNCs are also working with governments to address drug pricing and value, which continue to come under scrutiny as pricing pressures are being felt globally.[9] While less-developed countries have voiced concerns over the unaffordability of medicines for decades, developed-world concerns around drug pricing are now pushing unaffordability to the top of the global health agenda.[10] In the rest of 2024, government-mandated pricing pressure and controls are expected to play an increased role in the affordability and accessibility of certain medicines.[11]

All of the above efforts underscore the foremost area of focus for life sciences companies: delivering better outcomes for patients. Companies have been focused on directly and indirectly improving patient experiences with the intent of ultimately improving their health outcomes. The data are bearing that out. Life sciences executives surveyed by Deloitte US believe that the leading action their organizations need to take in 2024 is "improving the patient experience, engagement, and trust."[12] With personalized care and treatments supporting better experiences, biopharma and medtech companies are exploring the many opportunities to improve touchpoints throughout the patient journey.[13] This includes a proactive and predictive approach to what patients need.[14] And as the process becomes more digitally enabled and personalized, it is also expected to become more "straightforward" and seamless. All of this will be to the benefit of patients and their long-term outlook.

In this outlook we examine what we see as disruptive trends like the impact of Gen-AI, the growth of the obesity market and treatment with GLP-1s, the IRA's first full year of impact as well as those trends which are more evolutionary in nature—like the continued complexity around navigating globalization in an uncertain geopolitical environment or the continue advancement of more personalized patient experiences. With geopolitical, economic, and regulatory landscapes still proving uncertain, life sciences will likely need to continue relying on innovation, agility, and collaboration as they build on their strong commitment to bettering the lives of patients.

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Value creation: M&A, partnerships, collaborations, new sources of capital, and shifting portfolios

Cautious optimism in 2024

The economic and geopolitical climate will likely continue to impact decision-making in 2024.

Over the past year, life sciences and medical technology (medtech) companies have been managing inflation, rising interest rates (which can curtail access to capital), and slower economic growth. However, in 2024, inflation seems to be lessening, rates appear to be stabilizing, if not dropping, and growth is likely to be moderate—setting up a cautious, but still active mergers and acquisitions (M&A) and capital environment.

M&A activity collectively in biopharma, platforms, medtech, and diagnostics was brighter than many expected in 2023—with 254 M&A deals and US$209.8 billion in total announced value—eclipsing 2022 figures of US$143.5 billion.[1] The overall sector fared better than the overall M&A market where US and global total deal value across all sectors fell 11% compared to 2022.[2]

Valuations grew for life sciences companies in most stages of their life cycles over the past year. In 2024, pharma companies will be finetuning strategies to create top-line value with strategic acquisitions, while also planning for long-term bottom-line improvements, including divestitures and cost reductions.

While glucagon-like peptide 1 (GLP-1) obesity drugs have been a boon for pharmaceutical companies, their rise, along with macroeconomic headwinds, are creating uncertainty for medtech valuations, which were down US$300 million in 2023. However, fundamentals are strong, and medtech leaders are bullish on growth in 2024, given the improving supply chain situation.

M&A: Creating momentum

Pharma's megadeals put buying power on display

A primary driver of strength in 2023 were large/mega cap pharmaceutical companies with undeployed capital (figure 1).[3] Dealmakers are paying healthy premiums for assets with high commercial potential with oncology being the strongest therapeutic area attracting investment.[4] The top 10 megadeals closed in 2023 were each worth more than US$4 billion, led by multibillion dollar deals by Pfizer/Seagen (US$43 billion) and Bristol Myers Squibb/Karuna Therapeutics (US$14 billion).[5] A number of the leading acquisitions involved medicines either nearing regulatory approvals or in advanced testing.[6]

In 2024, companies should continue to expect regulatory scrutiny for a variety of investment activities. To facilitate the Pfizer/Seagen deal and address antitrust regulators' concerns, Pfizer agreed to donate the rights of royalties from sales of cancer drug Bavencio to the American Association for Cancer Research.[7] At the end of 2023, the US Federal Trade Commission (FTC) also settled its Amgen/Horizon Therapeutics acquisition challenge.[8]

"Blockbuster and mega blockbuster product opportunities are getting the most attention in M&A, and that will likely continue over the course of 2024. Once the best late stage assets are picked up—we should start to see more partnering and M&A for earlier stage assets, as there is a lot of interest in accessing new product growth opportunities."

—**Daniel O'Connell**, CEO, Acumen

Figure 1. 2023 M&A deal characteristics in life sciences by buyer groups

	Small/mid-cap	Large/mega cap	Private equity	Private strategic
Pharmaceuticals	**Pre-clinical oncology;** milestone payments are common, contingent on commercialization + regulatory	Acquisitions of companied with **approved oncology assets,** particularly in the **ADC space**	Driven largely by one acquisition in the **antibiotics space** seen as a platform for further growth	Acquisitions of **approved and late-stage rare disease assets**
MedTech & diagnostice	**Geographic expansion i**n orthoperdics and **consolidate play in spine**	Tuck-in deals across various therapeutic areas, including neurovascular, diabetes, and spine	Minimal activity	Large transaction in interventional urology; otherwise, limited tuck-in activity
CRO/CDMO/supplier	Strength in **cell and gene manufacturing** and supportive AI tools for biological drug develop-ment	Considerable investments in products used in **protein-based drug therapy development**	Significant capital deployed into both **CROs and CDMOs**	Small asset acquisitions of life sciences suppliers

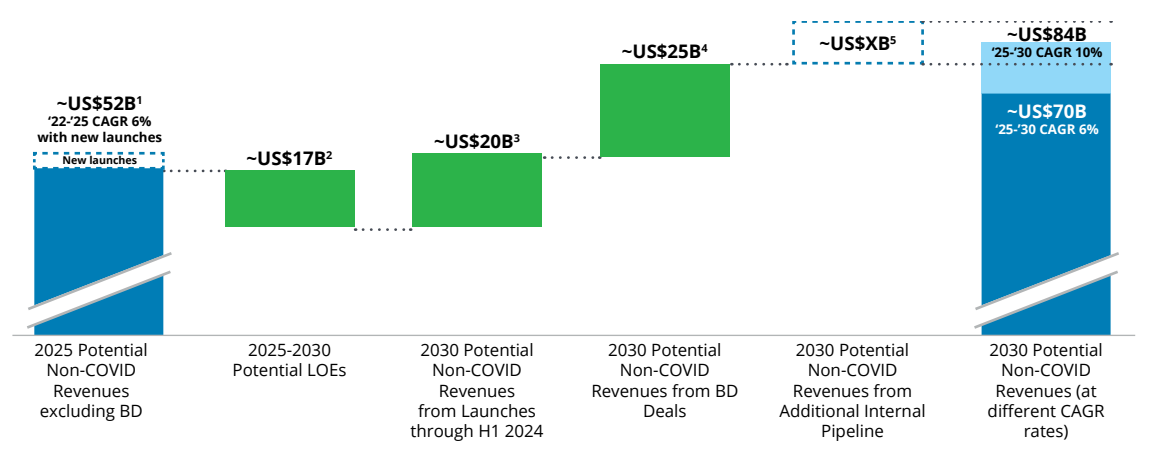
Over the next year, some big pharma companies will continue to look to M&A to plug portfolio gaps as a result of loss of exclusivity (LoE) across various therapeutic areas. In particular, late-stage development/early-stage commercial assets—that could contribute material revenue growth over the next few years—are expected to be attractive targets.[9]

Pharma M&A strategy highlight: Offsetting loss of exclusivity (LOE) with new acquisitions

Successful acquisitions may offset LOE patents for large pharmaceutical companies. Between 2022 and 2030, pharma companies will likely lose more than US$200 billion in revenue from the anticipated tectonic patent cliff.[10]

Pfizer, which faces US$17 billion in potential LOE between 2025 and 2030 and significant undeployed cash on their balance sheet from their COVID-19 portfolio, closed the largest M&A deal for biopharma in 2023. In its US$43 billion deal to acquire Seagen, Pfizer gained a market leader in antibody-drug conjugate technology to strengthen its position in oncology.[11] Pfizer projects an increase of US$3.1 billion in 2024 for top-line growth directly from the deal as well as bottom-line improvements over the long-term plan (figure 2).[12]

Figure 2. Pfizer's long-term plan to strengthen top-line growth after acquiring Seagen (illustrative)



Source: Pfizer, "Pfizer Invests $43 Billion to Battle Cancer," March 13, 2023

Pharma's near-term divestures/cost reductions

The immediate term may look bleaker as multiple pharma giants announce divestitures and cost reductions[13]—[14]including some work force cuts. Pipeline assets may be sold to other big pharma companies, while others sell to smaller companies and retain minority stakes. Given a few high-profile successes, this trend is likely to continue in 2024.[15]

As a result, freed-up capital may be deployed into accretive transactions.[16] While cautiously optimistic for 2024,[17] many experts expect that deal volume and value will pick up over the next year.[18]

Medtech returns to growth after 2023 divestitures

While pharma M&A activity was a bright spot in 2023, medtech and diagnostics M&A was not as strong. Over the past year, activity declined across M&A and venture, but the decline was not unexpected as medtech companies focused primarily on portfolio rationalization, divestitures, and cost transformation.[19] According to Deloitte US research, divestitures are being used to reduce debt and improve capital structures, generating improved balance sheets.[20]

Total deal value decreased nearly 45% year-over-year to US$13.5 billion, while deal volume actually accelerated. Some stakeholders continue to be optimistic about deal volume in 2024,[21] with companies targeting smaller deals in the US$200 million to US$800 million range.[22]

Regulators are also scrutinizing medtech deals. A protracted battle with regulators led to Illumina divesting its interest in Grail at the end of 2023.[23] Medtronic scrapped a US$738 million deal to buy South Korean-based EOFlow, an insulin patch-pump maker.[24]

In 2024, M&A is poised for a positive inflection point for improved activity as strategics and private equity alike re-enter the acquisition fold. M&A activity from medtech mega-cap players is likely to include high-growth small/mid-cap companies as well as emerging companies with interesting technology that could disrupt existing businesses.[23] Optimism is also being propelled by digital therapeutics and at-home diagnostics, growing use of biometric diagnostics, and speed to market.[24]

Private equity: Megadeals and tougher fundraising environment

More going private

More sponsor-backed companies may decide to go private instead of languishing at a below-IPO stock price in 2024.[27] Private equity (PE) investments in life sciences peaked in 2021 with 695 PE transactions totaling US$127.5 billion.[28] The space includes biotech and medical device companies as well as providers of related tools and services, like contract research organizations (CROs).[29]

Volume of P&E deals soars for life sciences suppliers

PE continues its interest in life sciences suppliers, deploying more than US$10 billion in capital into contract development and manufacturing organizations (CDMOs). M&A deal value across CROs/CDMOs/suppliers has jumped nearly 85% year over year to US$28.3 billion, while volume is up 50%. CDMOs are expected to attract more PE interest in 2024 and beyond as the need for highly specialized manufacturing facilities continues to increase.[30]

Tougher fundraising environment

Notable PE megadeals in 2023 included the US$7.1 billion privatization of biopharma CRO Syneos Health and the acquisition of veterinary drug maker Dechra Pharmaceuticals by Sweden's EQT for about US$6.1 billion, one of the biggest UK PE deals in 2023.[31] However, while EQT has been very successful in fundraising over the recent years, they are looking for new sources of capital, like private wealth, in a tougher overall fundraising environment.[32]

Venture capital: Billion-dollar fundraises amidst biotech challenges

Life sciences dealmaking in the startup space continues to decelerate after experiencing record highs in 2021 but is still above pre-pandemic levels. Venture capital (VC) remains active and resilient compared to many other fields,[33] and six funds that closed in the second half of 2023 now have more than US$6 billion to deploy into new investments in 2024.[34] A notable development to kick off startup investing in early 2024 is a US$3 billion raise by biotech creator Arch—a multibillion dollar deal that comes roughly two years after raising a similar amount.[35]

The pace of biotech IPOs stalled in 2023 with only 19 drugmakers pricing initial share sales.[36] Many experts are cautiously optimistic for 2024, and some anticipate a roller coaster year.[37] Six IPOs kicked off 2024, however, including a US$93.8 million deal for gene editing startup Metagenomi—one of the rare biotech companies to go public recently without a drug already in clinical trials.[38]

Biotech also hit a 10-year peak for bankruptcies with 18 companies filing for protection, preceded by 8 in 2022, and the next highest year in 2014, with 7.[39] Three companies already filed in early 2024, Humanigen, Athersys,[40] and Invitae (which is preparing for sale).[41]

Partnerships and collaborations: Expanding capabilities in tech and R&D

Integrating AI/ML

Representing a broader industry transition, there is a growing focus on precision medicine and personalized therapies that leverage advanced technologies, like artificial intelligence (AI) and machine learning (ML).[42] The promise of AI is expected to drive additional new partnerships in 2024 as large companies look to obtain new technological capabilities, secure industry talent, and drive competitive advantage.

Several AI-based drug development partnerships were signed in Q3 and Q4 of 2023.[43] The Verge Genomics/ Alexion (AstraZeneca Rare Disease) collaboration is worth US$42 million up front—consisting of a fee, equity, and near-term payments—and the potential for US$840 million in downstream royalties.[44] The collaboration will use CONVERGE®, Verge's AI-enabled approach for identifying novel drug targets for rare neurodegenerative and neuromuscular diseases.[45]

AbbVie made an upfront payment of US$30 million with potential milestone payments and royalties to AI/ML company BigHat Biosciences to commence an antibody research collaboration in oncology and neuroscience.[46]

Medtech companies continue to explore strategic collaborations across the health care ecosystem to leverage AI. GE HealthCare recently signed a US$44M contract with BARDA to develop AI-augmented ultrasound technology. A partnership was also formed with Mayo Clinic for innovation in medical imaging and theranostics—to enhance precision diagnosis and improve patient treatment using multi-modal data, AI, and digital health solutions.

Medtronic partnered with NVIDIA and Cosmo Pharmaceuticals to integrate NVIDIA's AI technologies into its GI Genius™ intelligent endoscopy module. They've also partnered with IBM Watson Health to develop AI tools for the diagnosis and treatment of heart disease.

R&D picking up steam and a multibillion-dollar deal

LoE is also driving market leaders to various types of partnerships. The top 20 highest value licensing, collaboration, and partnerships deals in 2023 were each worth at least US$1 billion—the total reaching about US$75 billion already by Q3 2023—with the largest transaction having a potential value of US$22 billion.[47]

Half the deals in the top 20 list for 2023 were around oncology assets and technology platforms, followed by cardiology and neurological diseases. In the booming area of antibody-drug conjugates, Merck and Co. and Daiichi Sankyo came together in a US$5.5 billion deal that has a potential lifetime value of US$22 billion.[48] The deal was the largesin a decade and unusual in that it involved a US$4 billion upfront cash payment. Daiichi Sankyo will retain rights for Japan, and the two giants will collaborate globally to develop candidates in other markets.[49]

In 2024, biotech companies with strong late-stage pipelines are ripe for acquisition and seeking exits.[50] But many small to mid-cap biotech companies facing a cash crunch are also looking to acquisitions, while a record number go bankrupt.[51] Partnerships are a growing trend and may be an alternative to M&A to boost values in 2024.

New sources of capital: Partnerships and strategic collaborations as alternatives to M&A for biotech

Tighter capital markets for small and midsize biotech companies in 2023 required many companies to find alternative ways of financing, including cutting costs and private investment. IPOs and public markets cooled, and venture funding investment was lower than in 2022 but still above pre-pandemic levels. At BIO Europe in late 2023, pharma companies made clear that substantial funding will be available for early-stage investment. However, biotech companies are still cautious and uncertain about how readily accessible funds will be.[52]

Addressing challenges with creativity and resourcefulness

Biotech companies are increasingly looking at partnerships and other creative collaborations as an alternative, or precursor, to M&A. The length of time to get regulatory clearances can be especially challenging, and many small to midsize biotechs have shorter cash runways for 2024 than in the past. In addition, prior to M&A, alliances and joint ventures may be used to demonstrate the viability of the business proposition, leaving regulators more comfortable with the arrangement.[53]

Reaping the benefits of partnerships and strategic collaborations

Some substantial benefits may be gained via joint efforts to acquire or have access to:

- New assets, like innovative science, platforms, and patents
- New capabilities and resources, like expertise, manufacturing, commercialization for large-scale indications, established infrastructures globally, and advanced technologies, e.g., AI
- New markets and patient populations
- Ecosystem-wide synergies and gap funding through public/private partnerships
- A trusted relationship that builds a pathway to future M&A

To find a symbiotic collaborator, companies need to first critically assess fit, complementary skills/resources, and the values/benefits that bring each partner to the table. But even when fit is determined and the deal has been structured and negotiated, the real work begins.

"Small to midsize biotechs may underestimate the resources and effort a partnership will take. When you have a limited resource base to start with, there are not a lot of departments to hand these things off to. Also, companies shouldn't underestimate the work it will take to build trust—and to stay true to the principles that were the basis for partnering in the first place,"

—**Renee Aguiar-Lucander,** CEO, Calliditas Therapeutics

Accessing new markets and new patient populations

For its first ever partnership, Calliditas Therapeutics set their sights on the world's second largest pharmaceutical market, China, in 2019. Calliditas entered into a licensing agreement with Everest Medicines to develop and commercialize its treatment for IgA nephropathy in Greater China and Singapore to address a huge patient need.[54] Chronic immune-mediated kidney disease is a major cause of kidney failure in China and other Asian countries, although considered a rare disease in the United States and Europe.

The partnership required Calliditas to remain agile—as clinical
trial plans were disrupted by the pandemic—and work on the relationship differences between its own Scandinavian culture and that of China. For example, CEO Renee Aguiar-Lucander says her Swedish colleagues had a reluctance to say "no" when something could not be done. In many cultures, saying no may be viewed as problematic or impolite.[54]

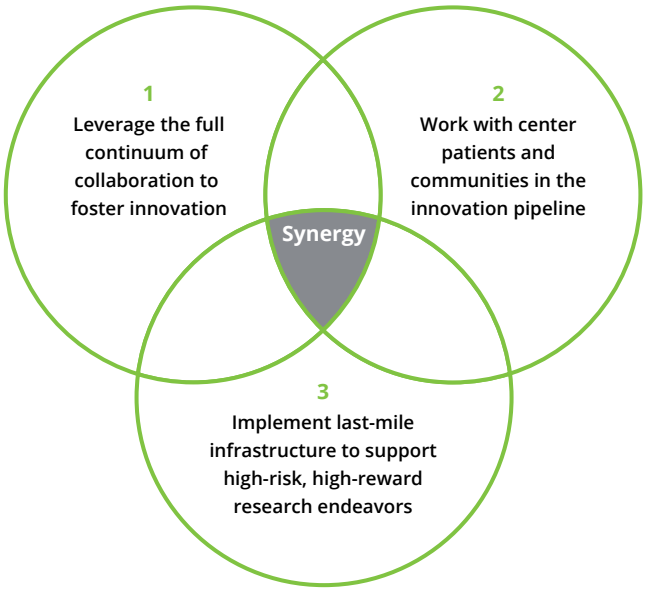
New sources of capital: Public/private partnerships for biomedical innovation

With tightened funding in the private sector, some companies find that government funding can become gap funding. COVID-19 provided an exemplary model for how governments can work with collaborators to advance care and treatment for all diseases, and, contrary to popular belief, government and nongovernmental institutional investment in biomedical areas does not reduce private spending on R&D.[56]

Beyond the pandemic, governments may continue to move disruptive ecosystem-wide solutions for biomedical innovation by:

- Prioritizing patients and communities in the innovation pipeline
- Leveraging the full continuum of relationships and partners
- Supporting funding and collaboration infrastructure for last-mile innovations[57]

Figure 3. Three synergy strategies for governments and collaborators



A government's ability to subsidize research and development in areas of unmet need may serve as a mechanism to drive research to the last-mile pipeline (figure 3).[58] Two mechanisms that some governments have used in the past could be key to de-risking high-risk research areas:

- **Push incentives** that reduce the cost of development by offering financial, tax, and technical incentives regardless of anticipated failure in the market

- **Pull incentives** that reward developments already considered relevant in the market and scientifically viable by helping ensure developers' financial viability into the future, even in inefficient markets[59]

Breakthrough biomedical innovations are not only possible but probable with government investment in the right infrastructure and incentives.[60]

New sources of capital: Medtech VCs launch new funds

After a downturn, VC investing in medtech started garnering renewed interest in mid-2023. Neuralink, Elon Musk's brain-reading startup (via implantable chips), and Beta Bionics, a low-touch automated insulin delivery system for diabetics, started an upturn with nine-figure deals.[61]

More selective investing

Venture capital investors are searching for visionary medtech founders to make more selective investments in 2024, and the digital health market could have promising opportunities for real innovators.[62] The most active category of medtech VC funding has been cardiovascular surgical devices. From 2020 through Q3 2023, Qiming Venture Partners is the leading medtech venture investor and Medtronic, the top acquirer (figure 4).[63]

Figure 4. Top medtech acquirers and VC investors from 2020 to 30 September 2023

Investor	Deal count	Investor type
Medtronic	5	Corporation
Boston Scientific	4	Corporation
Thermo Fisher Scientific	3	Corporation
Laborie Medical Technologies	3	PE-backed company
Philips	3	Corporation
Ottobock	3	PE-backed company

Investor	Deal count	pre-seed/ seed	Early-stage VC	Late-stageVC	Venture growth	Investor type
Qiming	49	0	25	22	2	VC
Hingshan	39	0	16	17	4	VC
Enterprise Ireland	34	3	7	14	10	VC
YuanBio Venture Capital	33	0	18	13	2	VC
European Innovation Council Fund	33	1	6	21	3	VC
Khosla Ventures	30	3	3	18	3	VC
Lilly Aisa Ventures	27	2	17	7	1	CVC
SOSV	27	6	2	18	1	VC
ShangBay Capital	26	3	14	7	2	VC
Johnson & Johnson Innovation - JJDC	24	0	7	13	4	CVC

Source: Pitchbook, Geography: Global

At the end of 2023, experts estimate the average cash balance at large medtech companies stood at approximately US$5 billion, up US$1.5 billion since early 2019.[64] Potential areas of M&A interest include mechanical circulatory support; transcatheter mitral and tricuspid valve repair and replacement; pulsed field ablation; peripheral vascular solutions; interventional devices to treat venous thromboembolism; and diabetes technology.[65] The left atrial appendage (LLA) closure market for reducing stroke is valued at US$1.4 billion and captured the interest of two companies, Johnson & Johnson and Medtronic, in separate deals. The LAA market is projected to reach US$6 billion by 2030.[66]

Tapping medtech giants' venture arms

Visionary startup founders may find opportunities through medtech giants' venture arms, like Boston Scientific and Johnson & Johnson.[67] For example, Johnson & Johnson Development Corporation (JJDC), Johnson & Johnson's venture arm, has innovation teams for early-stage startups around the globe—including in Shanghai, Boston, San Francisco, and London[68]—with its most notable exits including 23andMe, Nevro, and Grail.[69]

Intuitive Surgical's venture arm added a US$150 million fund in late 2023 bringing their total assets under management to US$250 million in 2024 across three investment areas:[70] Improving health care access and coordination; precision diagnostics and interventions; and secure, enriched digital health ecosystems.[71]

In addition to access and affordability, new business models that focus on early-detection and preventive care are drawing investment.[72] Also promising are digital health companies that focus on diagnostics to improve patient outcomes.[73]

New sources of capital: Medtech funding through government initiatives

The road to digital health and medtech innovation is being supported through many diverse economic initiatives with a growing focus on making medical services and devices for consumers more affordable and accessible.

Some examples of recent government biomedical or medtech initiatives around the globe include:

United States—The US administration recently designated 31 tech hubs across the country with 13 dedicated to either biomedical or medtech innovation. Some examples are the Greater Philadelphia Region Precision Medicine Tech Hub and Elevate Quantum Colorado.[74] Quantum computing has the potential to train AI in medical diagnostics more efficiently.[75]

Canada—Over CAD$2.1 million through PrairiesCan will help enable Alberta's health and medical technology sector to ramp up the commercialization of human mobility and home health innovations.[76]

Scotland—The Medical Device Manufacturing Centre (MDMC) has been awarded £3.35 million of additional funding from Scottish Enterprise to develop medical device innovation and improve the industry's sustainability.[77]

United Kingdom—The UK government is providing the National Health Service (NHS) with £21 million across 64 trusts to deploy new AI tools for the diagnosis and treatment of patients.[78]

Australia—The Australian government has set up an AUD$50 million fund for a combined AUD$115 million with Brandon BioCatalyst & ANDHealth towards a BioMedTech Incubator program.[79]

Shifting portfolios: Value creation in a new era of blockbuster drugs

Some companies are doubling down on oncology and specialty diseases, while others are committing to more prevalent chronic disease areas. In oncology, the Pfizer/Seagen deal escalated the excitement around antibody drug conjugates (ADCs), setting off a deal-making frenzy to snap up ADC assets and technologies.[80]

Merck, Daiichi Sankyo, BMS, and AbbVie all began making moves to access and/or expand their position in ADCs by the end of 2023. Japan's Daiichi Sankyo is also investing US$1.08 billion to create an "international innovation center" by 2030 in Germany and will equip the site to develop and manufacture future ADCs.[81] The size of ADC investments reflects a growing and increasingly valuable drug class that some proponents hope may eventually replace some forms of standard chemotherapy.[82]

Momentum is expected to continue, as the approach—using antibodies' specificity for targeted delivery of potent cytotoxic drugs—comes of age.[83] In 2024, deals from Johnson & Johnson/Ambryx and Roche/MediLink Therapeutics kicked off the year as well as smaller acquisitions and licensing.[84] Pharma and biotech interest is also attracting venture financing to ADC start-ups.[85]

In parallel, the market is rewarding those focused on more prevalent disease areas with the excitement over and growth of GLP-1 obesity drugs —a trend not seen in recent years. Those companies not active in either are finding themselves needing to explain their portfolio and scientific strategies.

At the 2024 J.P. Morgan Healthcare conference in January, Novartis found itself needing to explain the choice to double down on radioligand therapies (RLT), a platform where the company believes it can continue its established leadership for the long-term. Like ADCs, RLTs act like a guided missile but use a ligand to target cancer cells and kill them with a therapeutic radioisotope.[86] Novartis believes RLTs deliver better efficacy while producing less adverse events than ADCs.[87]

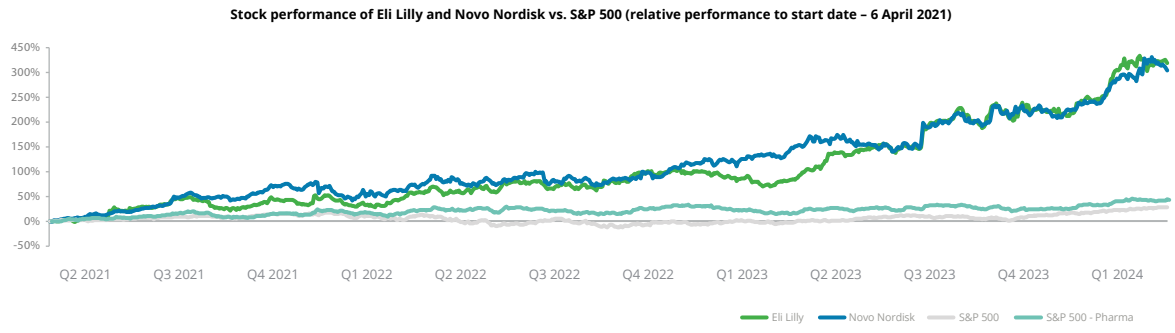
Rise of the GLP-1 weight loss boom, valuations, and market projections

Drugs originally developed to treat type 2 diabetes are now being formulated as popular weight loss drugs. Eli Lilly manufactures Mounjaro for diabetes (approved 2022) and its newly approved version for weight loss, Zepbound.[88] Novo Nordisk is also an obesity drug market leader with Wegovy (approved 2021) and Ozempic (approved 2022).[89]

Among biopharma market leaders, Novo Nordisk and Eli Lilly have some of the highest valuations due to long-term growth expectations and category leadership in metabolic diseases—including diabetes and obesity as the most prevalent. By the end of Q1 2024, Novo Nordisk's market capitalization reached a high of US$572.92 billion, rising from US$88.53 billion in late November 2016. Eli Lilly had a market cap high of US$740.30 billion, rising from US$74.1 billion in November 2016.[90]

The positive sentiment associated with the potential of their GLP-1 drugs is bringing Eli Lily and Novo Nordisk valuations on par with or greater than some leading tech growth stocks, like Tesla, as well as being disproportionate to the S&P 500 Pharma Index (figure 5). Analysts predict this upward trajectory to continue.

Figure 5. Stock performance of Eli Lilly and Novo Nordisk vs. S&P 500 and S&P 500 Pharma, Q2 2021 to Q1 2024



Source: Deloitte analysis

Experts say the treatment of obesity is on the verge of heading into mainstream primary care—comparable to the growth of hypertensive drugs that ballooned into a US$30 billion market in the 1990s.[91] The rising prevalence of lifestyle-related diseases is expected to continue to drive up overall GLP-1 agonist drug market projections. By 2030, the potential market is being priced anywhere from US$37 billion to more than US$100 billion.[92] While no one knows exactly how big it might be,[93] the surge is being driven by treatments for obesity and diabetes—a potential market of 30 million people in the United States alone by the end of the decade.[94]

In addition, GLP-1 agonists are being heralded as Science's "2023 Breakthrough of the Year" as potential new uses for the drugs emerge.[95] GLP-1s are showing promise for cardiovascular disease and investigations are underway for drug addiction, Alzheimer's, and Parkinson's diseases. These new uses may increase insurance coverage down the line.[96]

Growing high-quality concentrated revenue

Growing high-quality concentrated revenue, like Eli Lilly has achieved in the past four to six quarters, demonstrates an enviable road to value creation. Eli Lilly is making a long-term commitment in the obesity drug market with multiple obesity drug candidates in mid- and late-stage clinical development. At the end of 2023, the company also announced a multi-year partnership with startup Fauna Bio for obesity research with animal genomes, adding to the signs of a decade-long commitment to the market.[97] The result is Eli Lilly becoming the world's largest drugmaker by market cap—with 12% top-line growth and 20% bottom-line growth.

Addressing lack of reimbursement

Beyond the ability to meet the surging demand, another headwind to be navigated in 2024 and beyond is likely to be the lack of access and broader insurance coverage for obesity drugs. In the United States, lack of reimbursement for obesity treatments under government health care programs essentially makes these medications unaffordable.[98] Programs for low-income Americans do cover the drugs in some areas, but access is fragmented.[99]

Millions of older Americans on US Medicare cannot access the drugs, mostly because obesity drugs were originally classed as cosmetic in 2003; US lawmakers plan to push for a change in 2024.[100] If 10% of Medicare beneficiaries with obesity used a GLP-1, the annual cost to Medicare is estimated to be between US$13.6 billion and US$26.8 billion. But the total annual medical cost in the United States for obese adults averages US$1,861 higher than medical costs for people with healthy weight.[101]

Public and private payers could learn from guidelines in several EU countries, such as Norway, the Netherlands, Poland, and Italy.[102] These countries have reimbursement policies that may demonstrate a pathway to affordable coverage in the United States—slowing the progression of the disease. For example, some European coverage models deploy effective, but lower-cost medications for patients with lower BMI that do not meet the criteria for "obesity" but whose health could still benefit from treatment.[103]

Competition in weight loss market heats up, and digital health support services grow

Competitors and lower cost formulations that may also have potentially fewer side effects may be new entrants to the market. New products will need to distinguish themselves by clear advantages, and pharma companies have begun investigating:

- Novel molecular targets with alternate routes of administration

- Extended treatment intervals
- New double- and triple-agonist mechanisms[104]

Competition is already ramping up as Pfizer and Amgen are expected to release new data in 2024,[105] and several drugs in development may become attractive for acquisition. In late December 2023, Roche took over unlisted obesity drug developer Carmot Therapeutics in a US$2.7 billion upfront deal.[106]

Some smaller pharma companies are developing agents with novel mechanisms of action (MOAs), including Switzerland-based Aphaia Pharma and Japan's Shionogi.[107] Implications are expected for ingredients and support services. VCs are eyeing opportunities in weight care and management via both telemedicine and coaching as consumer interest soars (figure 6).[108]

Figure 6. Notable global VC deals for weight loss startups

Name	Close Date	Deal Size	Valuation	Deal Type	Location
Lark	10/13/2021	$100	$800.0	Late Stage	Mountain View
Calibrate	11/08/2022	$37.5	$365.0	Early Stage	New York
Zoe	11/01/2022	$34.8	$264.3	Late Stage	London
Nutrisense	06/28/2022	$25.0	$95.0	Early Stage	Chicago
Form Health	01/13/2023	$22.9	$6209	Early Stage	Boston
BooHee	11/21/2021	$15.6	$310.0	Late Stage	Shanghai
January AI	08/15/2022	$13.0	$28.8	Late Stage	Menlo Park
Nourish	01/20/2023	$9.3	$40.3	Seed	Austin
Intelliheath	02/15/2022	$8.5	$58.7	Seed	San Franciso
Veri	06/01/2022	$7.9	$12.5	Early Stage	Helsinki

Source: Pitchbook

GLP-1 proofing portfolios

While the rise of GLP-1 has created tremendous opportunities in obesity and obesity-related assets, some market leaders are also looking to GLP-1 proof their portfolios, flocking to "GLP-1-resistant" therapeutic areas like rare diseases, neurology, and oncology. Medtech companies may search for assets that are not impacted by GLP-1s or assets for which an increase in longevity could mean an increase in utilization.[109]

Extracting value from Generative AI and emerging technologies

Uncovering the realm of possibility

Generative AI (GenAI)'s release to the public quickly amassed adoption and delighted users, enchanted by chat-enabled interfaces and powerful new large language models (LLMs).[1] LLMs are foundation models—machine learning (ML) models pre-trained on a broad dataset that can be adapted to solve a range of problems, offering new ways to build applications or other foundational models.[2]

Early traction for GenAI was seen from consumer releases, but GenAI is quickly showing its potential to add contextual awareness and human-like decision-making to enterprise workflows.[3] This inventive era of GenAI advancement puts tremendous pressure on leaders to harness the technology's capabilities and promise, without being disrupted.[4] In the year ahead, extracting GenAI's value and managing its risks, while maintaining trusted enterprise status, are at the forefront of many leaders' strategic priorities.[5]

Amazon CEO Andy Jassy says that GenAI could be one of the most transformative technological transformations in decades,[6] while World Economic Forum (WEF) President Børge Brende, reminds leaders that the immense potential productivity gains underscore the need for responsible AI governance.[7]

The Winter 2024 Fortune/Deloitte CEO Survey of viewpoints—from the CEOs of some of the world's largest and most influential companies—shows there has been a marked increase in the adoption of GenAI.[8] The majority of CEOs (57%) intend to integrate new technologies into their business models to uncover growth opportunities, with a significant portion (56%) already leveraging GenAI to enhance efficiencies.[9]

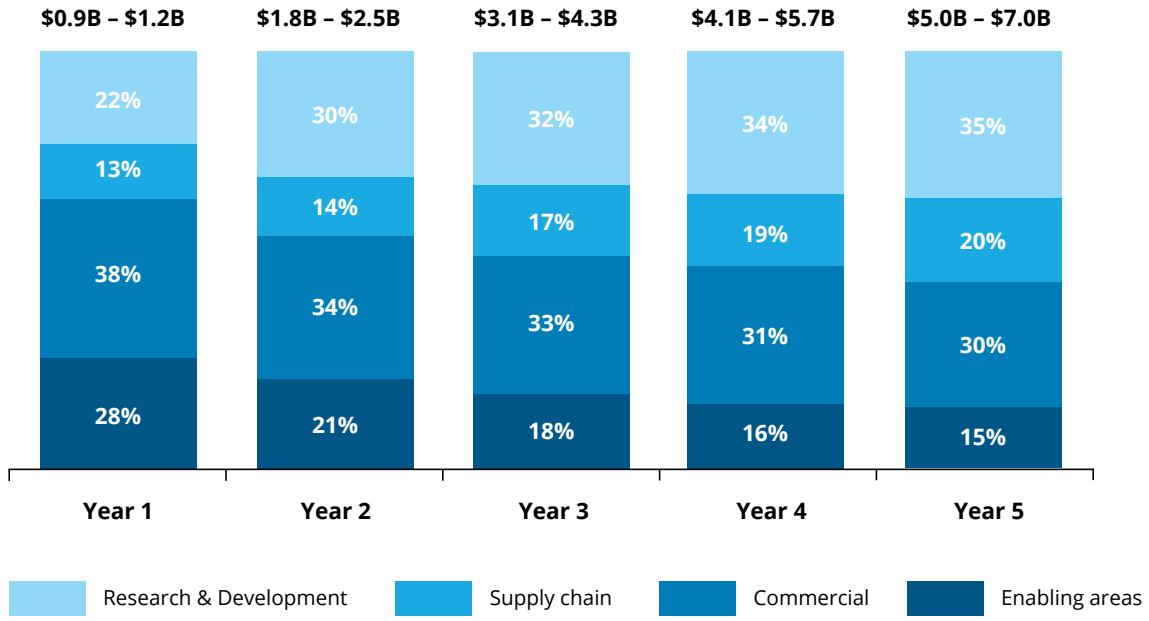
Creating competitive advantage

Increasing efficiencies and cost savings

In the next year, more than 90% of biopharma and medtech respondents surveyed by Deloitte say they expect GenAI to have some impact on their organizations.[10] GenAI and other AI technologies coupled with digital transformation tools are poised to increase overall efficiencies and process innovation across many areas of the life sciences value chain (figure 1).[11]

A top 10 biopharma company with an average revenue of US$65-75 billion could capture between US$5-7 billion of peak value by scaling the use of AI over 5 years. This varies depending on an organization's size.[12]

Figure 1. Average 5-year value accretion schedule of AI impact (percentage of peak value realized)



Assumptions:

01. Foundational data and infrastructure are in place to enable transformational use case development
02. Each function implements the full portfolio of transformational AI use cases (e.g., AI clinical trials, AI manufacturing, AI marketing)

Source: Deloitte, "Realizing Transformative Value from AI and Generative AI in Life Sciences," 2024.

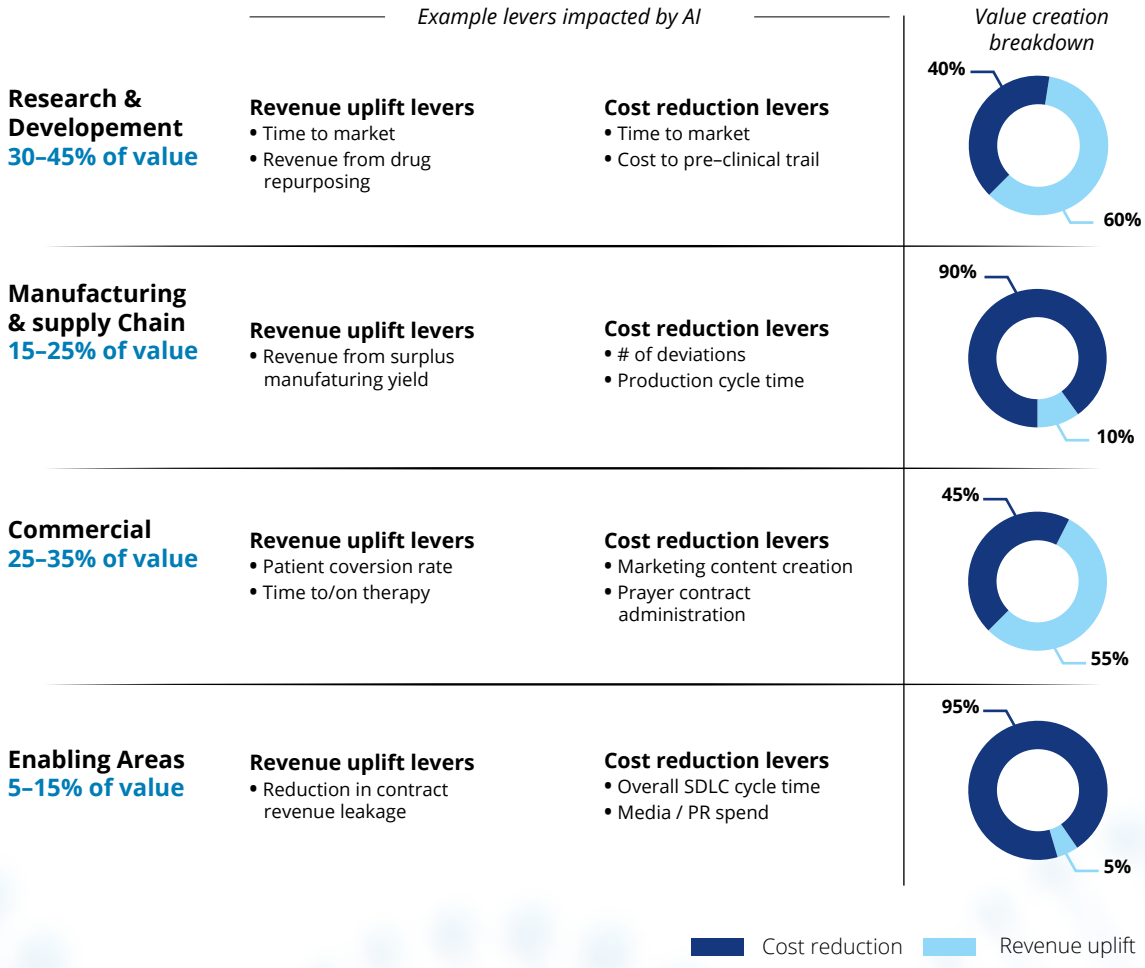
Creating value across the value chain

Are companies making choices for GenAI today that are going to create value and advantage? While it may be too early in the journey to declare, some approaches are gaining more traction and accelerating time to value vs. others.[13] Nearly 90% of value from the use of artificial intelligence in life sciences may be derived from three functional areas: research and development (R&D), manufacturing and supply chain, and commercial (figure 2).[14]

R&D represents the leading area for value opportunity at 30-45%. AI applied to novel drug identification and accelerating drug development could provide both cost savings and revenue uplift. Commercial may provide 25-35%, where marketing costs could be optimized and activities such as script utilization could be enhanced by AI. In manufacturing, supply chain, and enabling areas (including IT, HR, and finance) AI primarily provides opportunities for cost transformation through efficiency realization and vendor cost reductions.

How can organizations turn these impacts into competitive advantage? Greater speed and efficiency can enable redeployment of capital to other value creating areas. Greater effectiveness can help companies advance their science and engage their customers and patients comparatively with others. Ultimately, greater patient outcomes could be achieved.

Figure 2. Value creation breakdown by function



Source: Deloitte, "Realizing Transformative Value from AI and Generative AI in Life Sciences," 2024.

Finding synergies: Big pharma and big tech collaborating with GenAI

In 2024, many biopharma companies are looking for novel ways to marry the rich data sets of science with the latest GenAI technologies.[15] Alternatively, technology giants with advanced types of AI capabilities are looking to capitalize on the massive opportunities afforded by the life sciences and health care industry.[16] By 2025, 36 percent of the world's data is estimated to be generated by life sciences and health care.[17] Through GenAI, big pharma and big tech may be realizing these two sectors have more to gain from working together than by competing.[18]

Will GenAI create the trillion-dollar pharma company?

Evidence of tech titans' interest was on display with their formidable presence at the J.P. Morgan Healthcare Conference in early 2024.[19] Many tech company executives were looking to strike new deals with biopharma for GenAI/AI technologies, including NVIDIA, whose CEO attended the conference.[20] NVIDIA achieved a US trillion-dollar market cap status in 2023[21] and believes these generative technologies will also enable a drug maker to become the next trillion-dollar company.[22]

Pharma companies' collaborations with tech titans for GenAI

Tech titans are working with life sciences companies on more advanced GenAI in many areas that are constantly evolving, including the following:

NVIDIA: Provides a GenAI drug discovery cloud service, BioNeMo, to biopharma companies that want to create or customize their own generative models and then offer those as a Software-as-a-Service (SaaS) model to others via cloud APIs.[23] Some of NVIDIA's pharma relationships include Amgen, AstraZeneca, GlaxoSmithKline (GSK), and Roche subsidiary Genentech.[24,25]

Microsoft: Provides GenAI through Microsoft services, including Copilot, Microsoft 365 apps, Microsoft Azure, and Bing search engine.[26] Microsoft is collaborating on AI drug discovery with Novo Nordisk[27] and Novartis.[28] Some GenAI relationships in health care include Epic,[29] Siemens,[30] and health systems, like Mercy and Duke Health.[31]

Alphabet: Provides GenAI through Google services, including Gemini and Google Cloud. Its Target and Lead Identification Suite is designed to accelerate drug discovery and the Multiomics Suite to share mass amounts of genomic data in precision medicine.[32] Google Cloud is working on a GenAI relationship with Ginko Bioworks, for biosecurity and engineering biology,[33] and Insmed to bring about change in the drug development and commercialization process.[34] Insmed built a GenAI search capability for internal records leveraging Google Vertex AI Search that also allows categorized access to external medical articles.[35]

AWS: Gen AI on AWS Cloud allows integration with many leading foundations models—including Amazon, AI21 Labs, Anthropic, Cohere, Meta, and Stability AI—for uses such as generating new therapeutic candidates, better matching patients with the right clinical trials, powering patient engagement applications, and enhancing manufacturing oversight.[36] AWS is working with Novo Nordisk on protein structure prediction at scale; with Amgen on drug discovery and manufacturing;[37] and with Eversana to "pharmatize" AI across the life sciences industry, starting with a GenAI application for medical and regulatory content approvals.[38] AWS also worked with Pfizer on VOX, a proprietary GenAI platform for giving workers access to LLMs.[39] The company enhanced productivity by using GenAI to create first drafts of patent applications and medical and scientific content for human review and finalization.[40]

Democratizing a US$1 billion investment in phenomics with GenAI models

Founded in 2013, Recursion Pharmaceuticals is a leading AI-biotech company in what is now known as "techbio," advancing a clinical-stage pipeline in data-driven drug discovery.[41] Recursion uses its own operating system, Recursion OS, to turn drug discovery into a "search" problem—generating, analyzing, and deriving insight from massive biological and chemical datasets.[42] Its phenomics platform combines imaging and artificial intelligence for rapid validation and advancement of novel oncology targets.[43]

Looking to democratize its US$1 billion phenomics investment, Recursion is opening up access to years of proprietary work in hopes it will "move all of us forward faster."[44] The company's first in a potential series of GenAI foundation models—Phenom-Beta—is hosted on NVIDIA's BioNeMo platform.[45] In July 2023, Recursion also received a US$50 million investment from NVIDIA as part of a multi-year partnership to advance its AI technologies.[46] The aim is to leverage GenAI/AI technologies to benefit Recursion's own internal pipeline along with those of their partners, including Bayer for fibrotic diseases, and Roche/Genentech for oncology and neuroscience.[47]

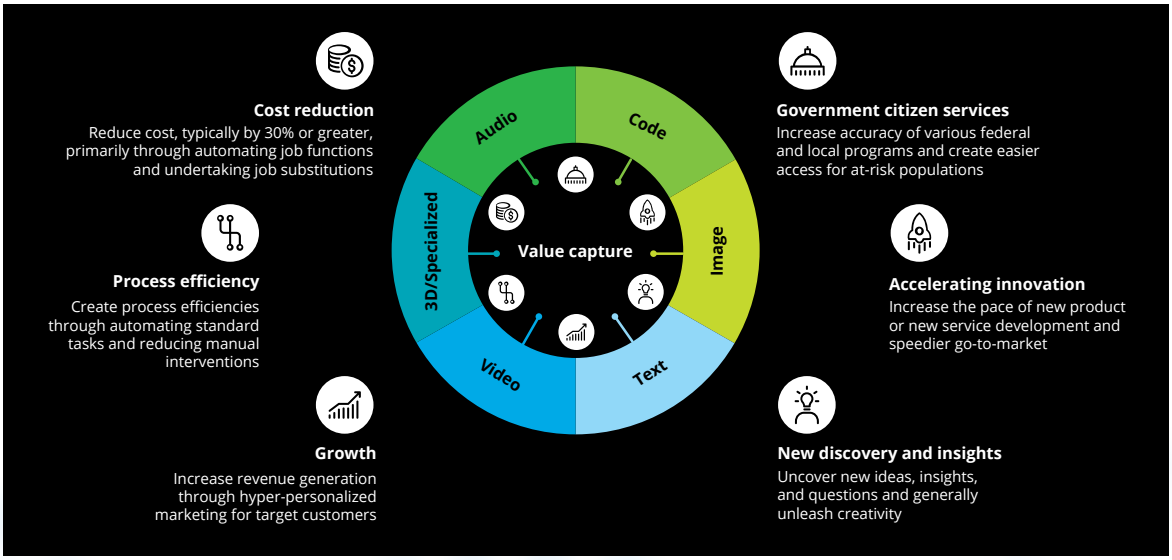
Understanding the technology to extract its value

Multimodal LLMs, the building blocks of artificial general intelligence (AGI)

Currently, multimodal LLMs are a step closer to mimicking human intelligence.[48] The ability to integrate audio, code, images, text, simulations, and videos with GenAI is already changing the way content is being generated and delivered and will likely remodel many types of consumer, business, and health care experiences (figure 3).[49,50]

Half of consumers surveyed by the Deloitte US Center for Health Solutions, report using GenAI in some capacity, and more than half believe GenAI could improve access to health care; 46% think it could make health care more affordable.[51]

Figure 3. Broad categories of value capture from GenAI



Source: Deloitte, "Realizing Transformative Value from AI and Generative AI in Life Sciences," 2024.

Simple uses of GenAI, like generating ideas and design artifacts, can be "no regrets bets" for organizations to de-risk investments and accelerate progress when kickstarting their GenAI programs.[52] More advanced use cases start incorporating more modalities and technologies.[53] Each modality, like text or video, is a potential value-driver for a use case; expanding modalities increases the potential benefits of a use case.[54]

For example, a use case for unlocking cures in drug discovery may provide value-drivers through both simulations and images (figure 4). The potential benefits in this use case are GenAI's ability to analyze and learn from vast amounts of data, including images, which can lead to more targeted and effective treatments. The ability to run simulations with GenAI to select the best potential drug candidates minimizes the need for real-world iterations.[55]

Because multimodal AI systems can interpret multiple types of data together, such as textual and image data, their development and validation require collaborative efforts between a number of disciplines.[56] Leaders should bring together a cross-disciplinary team of people with the domain knowledge to think creatively about potential use cases.[57] (See Deloitte's AI Institute's Generative AI Dossier to explore more use cases.)

Moving beyond use cases to a string-of-pearls strategy

LLMs and other foundation models are starting to unlock a slew of high-value applications. About two-thirds of life sciences companies surveyed say they are building GenAI use cases, and 36% say GenAI will impact their strategy in the year ahead.[58]

Vertical-specific use cases for life sciences are likely to command a premium due to the dependence on proprietary data. Incorporating proprietary content into a generative model can be accomplished by fine-tuning an existing LLM or training an LLM from scratch.[59] In 2024, new economies may be created for access to proprietary data and synthetic data.[60]

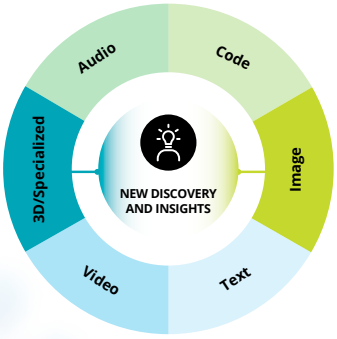
While each individual GenAI use case may generate some improvements, stringing together multiple use cases—along with other digital tools like machine learning and Internet of Things (IoT)—could transform entire processes, and that is where the value gets unlocked. This string-of-pearls strategy could be applied to everything from research to clinical development to customer engagement and patient experience. Each individual use case connects to another use case, and another, etc.[61]

Figure 4. Example of a use case in drug discovery to identify new drug candidates

Unlocking the cures

(New Drug Discovery/Generation)

Generative AI can be used to model the structure and function of proteins and biomolecules, accelerating the identification and validation of molecules and the creation of new drug candidates.



Issue/opportunity

Despite advancements in medical treatments, numerous diseases still lack effective solutions due to the complex, costly, and time-consuming process of drug discovery and verification. The challenge of drug development lies not just in iscovering potential treatments but also in the rigorous verification of their effectiveness, a process that is both costly and time-consuming. Compounding these issues are the unique complexities of clinical trials, which need to account for diverse populations, varied interactions with other treatments, and potential side effects. Furthermore, the rarity of some diseases creates additional hurdles due to limited data from fewer patients, making the development even more challenging.

How Generative AI can help

Cost reduction

The use of Generative AI in the verification of drugs during clinical development could significantly reduce costs. This is due to its ability to run simulations and select the best potential candidates for further testing, thereby minimizing the need for extensive real-world iterations.

Promoting public health

Generative AI has the potential to significantly improve public health by accelerating the discovery of better treatments and cures for diseases. Its ability to analyze and learn from vast amounts of data can lead to more targeted, effective treatments, directly benefitting patients and, by extension, society at large.

Enabling collaboration

Generative AI can facilitate improved communication and knowledge sharing across research groups. It can process and make sense of data from various sources, breaking down data silos and opening new opportunities for collaboration and innovation in experimentation.

Source: Deloitte, "The Generative AI Dossier," 2024.

String-of-pearls strategy in action, GenAI in scientific research

Thinking of use cases in the context of workflow, functional area, and greater mission to be accomplished can help assemble a string of use cases. Each "pearl" should have some major contribution that will make the main goal possible to achieve, thereby enhancing the power of the whole.[62]

String-of-pearls for expanding scientific research productivity and global collaboration

How can GenAI help?

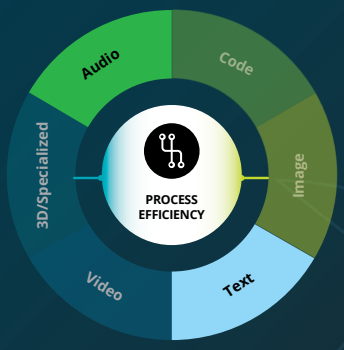
1. Serves as a brainstorming research partner, providing the ability to search a broader knowledge base, including proprietary data
2. Summarizes scientific literature for meta-analyses[63]
3. Processes and makes sense of data from various sources
4. Breaks down silos, to facilitate communication and knowledge sharing across research groups and geographies
5. Assists in writing research papers, grants, literature reviews, and non-technical summaries of data
6. Creates presentations in multiple modalities
7. Translates work, making it shareable across geographies (figure 5)[64]

Figure 5. One use case in the string-of-pearls for expanding scientific research collaboration

Language translation at scale

(Content localization)

Gen AI can be used to quickly and easily scale content across regions by translating and converting text and audio into regional languages.



Issue/opportunity
The ability to create and translate content at scale can be a competitive differentiator for multinational enterprises, but it can also command significant time and resources, and rapid, on-demand translation may be difficult to achieve.

How Generative AI can help

Tools for custom localization and quality assurance
Generative AI can be used to help organize and manage complex file types, analyze content before translation to optimize localization, and integrate glossaries, term bases, and language tools into workflow.

Content personalization across industries
AI-powered content personalization can supercharge localization efforts by improving engagement, building brand loyalty, and increasing conversions.

Speech recognition during translation
Generative AI can be leveraged to enable voice user interfaces (VUI), transcribe video and audio content into text, and simultaneously translate spoken content into the target language.

Source: Deloitte, "The Generative AI Dossier," 2024.

How can the language translation use case be expanded to provide more than two value-drivers of text and audio? GenAI could not only convert text to audio in multiple languages, but also generate a supporting video in another language—adding another value-driver to support sharing content across geographies and on more platforms.

Adopting an evolutionary AI mindset

As leaders start looking beyond siloed pilots and individual use cases, they could consider how GenAI can be part of an enterprise-wide transformation thatnot only fundamentally changes the way work is done and value is created, but also addresses compliance, privacy, regulation, and trust.[65] Successfully driving large-scale AI transformation requires an evolutionary mindset across the AI journey (figure 6).

Integrating GenAI into the enterprise tech stack

Ultimately, decision-makers should develop a strategy that harmonizes its existing AI enterprise strategy with GenAI, while considering GenAI's capabilities and limitations.[66] Getting the most from GenAI may require enterprise-wide infrastructure and platforms spanning the entire tech stack.

This includes secure cloud infrastructure, foundation models, modernized data platforms that manage high quality, context-rich data, and low-code/no-code platforms—to build and scale applications, in addition to establishing practices such as Large Language Model Ops (LLMOps) and Cloud Cost Management.[67]

Foundation models, the model layer of GenAI

Foundation models differentiate the GenAI tech stack from previous AI (figure 7).[68] Just as Microsoft's Win32 offers APIs for developers to access base-level hardware and OS functions, the model layer is designed to connect application developers to optimized hardware for adoption and democratization of GenAI.[69] Experts say foundation models will form the basis of GenAI's future in the enterprise.[70]

These foundation models are often available to developers via closed and open APIs, where developers can fine-tune them with additional training data to improve context, relevance, and performance for specific use cases and verticals.[71] In the model layer, closed-source model providers, like Cohere and Google host and manage models built on a vast data corpus and charge for consumption. Open-source models providers, like Meta and Stability.ai, are managed by communities and are monetized when they are fine-tuned or are based on usage costs as a function of the size of a company.[72]

Figure 6. AI value journey

Mindset evolution

Move beyond the end less cycle of near term proof of concepts, and place long term bets on AI in key areas

Leadership evolution

Goal leaders against measurable AI targets and value goals in order to drive AI evangelism and accountability

Investment evolution

Treat AI investments as core enablers of enterprise business strategies and not as experimental investments

Cultural evolution

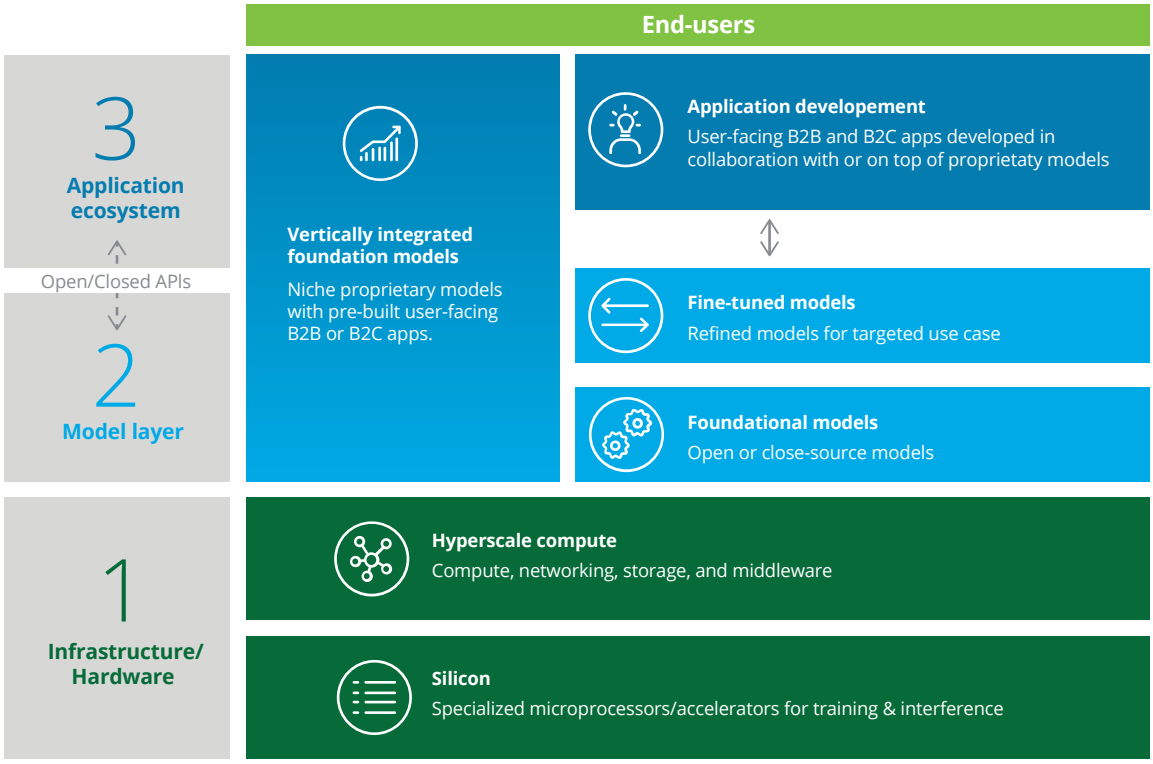
AI should not be looked at like a tool, but as a skill that all employees will need to possess to maximize efficiency

Execution evolution

Evolve beyond front and back office methods and adopt a "two in the box" approach where business & IT are goaled together

Source: Deloitte, "Realizing Transformative Value from AI and Generative AI in Life Sciences," 2024.

Figure 7. GenAI Tech Stack



Source: Deloitte, "A new frontier in artificial intelligence," 2023.

Establishing operational efficiencies

Once these models are built, organizations need to establish operational capabilities around LLMOps. LLMOps focuses on unique needs of these models: compute, transfer learning, human feedback, tuning cost/performance, new metrics, prompt engineering, and building LLM pipelines. LLMOps tackles complexity of development of LLMs for efficiency, scalability, and risk reduction while scaling the applications into production.

In addition to LLMOps, another critical component is cloud cost management. This enables organizations to leverage the potential of GenAI while optimizing cloud resource consumption and maximize investments.

Managing risks, setting up the right base model

Deploying on premises (on-prem) and private LLMs

There are risks in deploying GenAI models across the enterprise, particularly LLMs, and there are several ways they can be deployed:

- Via a service provider, as a SaaS model, avoiding any configuration or installation issues
- Deployed on an organization's private cloud or network, "on-prem," enabling control and management of API configuration[73]

On-prem LLMs are installed on the organization's infrastructure and available to users who have access to the organization's network and the application. Some on-prem systems are isolated or "air-gapped" from open access to the internet but may be connected via secure means.

In 2024, some life sciences companies will also be looking to private LLMs for a walled garden to protect their data from going into the public domain and to control costs.[74] GenAI trained from a private LLM operates within a controlled environment and the dataset can be curated to align with specific guidelines, quality standards, and desired outcomes.[75] Companies that build solutions on private, rather than general purpose, LLMs could also have the most impact.[76]

Managing LLMs with orchestration startups

As more organizations put GenAI into action and face a myriad of choices, orchestration startups are predicted to play an outsize role in 2024. These startups are attracting significant venture capital interest[77] and designed to orchestrate the many tasks of managing LLMs, including:

- Simplifying model selection
- Choosing and fine-tuning models
- Integrating multiple LLMs into a single service
- Deploying applications at lower costs
- Creating platforms that democratize access to LLMs[78]

Managing regulatory uncertainty, instituting governance

Closing the AI trust gap

The capability many people find so captivating is GenAI's ability to mimic human thinking and behavior. Of course, human thinking and behavior aren't always perfect, predictable, or socially acceptable—and the same is true for technology.[79] Experts say keeping humans in the loop remains critical to check and validate the accuracy of AI and to address problems as they arise.[80]

Society expects guardrails to be in place so people can trust what AI has to offer.[81] Trust is not an inherent quality of AI but instead the product of AI governance, risk mitigation, and the intentional alignment of people, processes, and technologies across the enterprise.[82]

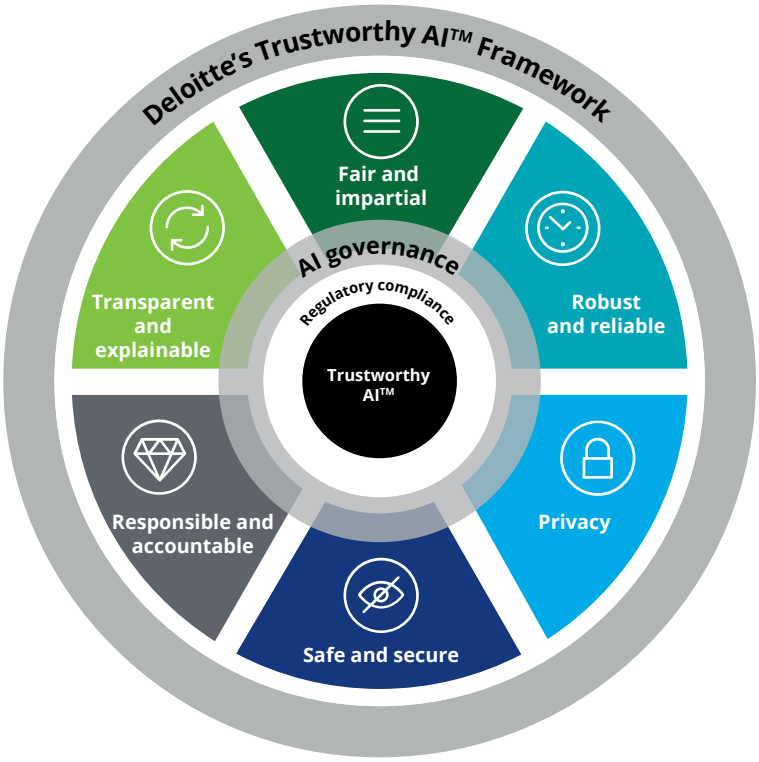
AI-experienced executives Deloitte surveyed across industries globally in December 2023 expressed a variety of concerns about GenAI risks, including the need to:

- Manage hallucinations and model bias,
- Assess potential intellectual property issues, and
- Ensure transparency and explainability.[83]

By 2026, more than 80% of enterprises are predicted to be using GenAI and/or deploying GenAI-enabled applications in production environments.[84] Business users should have a real understanding of GenAI and keep end users in mind--not rely solely on AI engineers and data scientists to contend with the risks and the consequences of trusting a tool.[85] Uncertainty around regulatory and legal challenges is expected to affect the development of the overall market.[86] According to one survey of technologists, 41 percent say that they are concerned about the ethics of AI tools that their company uses.[87] In another study of consumers and buyers in 25 countries, more than half of respondents don't trust their companies to use AI ethically.[88] Almost 70 percent of these respondents believe advances in AI make it even more important to be able to trust companies.[89]

Organizations can complement innovation with a strategy that also builds customer trust and brand equity. Deloitte developed its Trustworthy AI Framework to help organizations adhere to emerging regulations (figure 8).[90]

Figure 8. Trustworthy AI Framework



Source: Deloitte, "Trustworthy AI," 2022.

Private: Privacy is respected. User data is not used or stored beyond its intended and stated use and duration and users are able to opt-in/out of sharing their data.

Transparent and explainable: Users understand how technology is being leveraged, particularly in making decisions; decisions are easy to understand, auditable, and open to inspection.

Fair and impartial: The technology is designed and operated inclusively—for equitable application, access, and outcomes.

Responsible: The technology is created and operated in a socially responsible manner.

Accountable: Policies are in place to determine who is responsible for the decisions made or derived with the use of technology. Because an AI model has no autonomy or intent, it cannot be held accountable in any meaningful sense.[91]

Robust and reliable: The technology produces consistent and accurate outputs, withstands errors, and recovers quickly from unforeseen disruptions and misuse.

Safe and secure: The technology is protected from risks that may cause physical, emotional, environmental, and/or digital harm to individuals or communities.[92]

Appointing a chief AI officer (CAIO)

Forward-thinking enterprises are already appointing a chief AI officer (CAIO) to lead their business visions and manage reputational, regulatory, and legal risks.[93] An effective AI governance framework can help identify potential risks and gaps in capabilities, validate performance, and safeguard the business.[94]

While AI shares some practices with IT governance, it is a distinct discipline that benefits from both technical and non-technical stakeholders.[95] The US government is expecting US federal agencies to appoint CAIOs and introduce new governance approaches to ensure their use of AI is lawful, secure, and transparent.[96]

Of particular concern for life sciences is that LLMs have the potential to pose substantial risk with respect to proprietary or sensitive information that passes through these systems, despite current safeguards. Moreover, when existing foundation models are fine-tuned with a company's own data, experts say companies should double down on data governance, especially if an outside vendor is used for fine-tuning.[97]

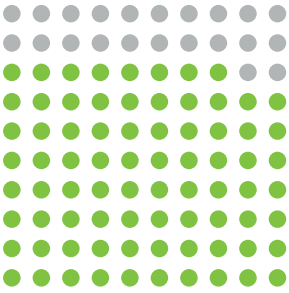
Companies may also consider creating a "sandbox," an isolated environment that allows employees to explore the capabilities of GenAI tools without sharing their prompts or the data with developers. Developers, as well as users, need to apply monitoring and feedback processes—helping ensure quality of the outputs generated and to encourage continuous improvement while companies determine what level of transparency is best.[98]

Anticipating future regulatory challenges

A string-of-pearls approach could also be utilized effectively in the context of regulatory—by aligning multiple technologies and geographies for a harmonized regulatory environment.[99] While a global set of regulations may not be feasible, the potential of global guardrails based on countries' regulatory approaches may provide regulatory clarity and could be beneficial.[100] A global collaborative and clarity of the regulatory environment can help accelerate the AI journey and adoption across regions.[101]

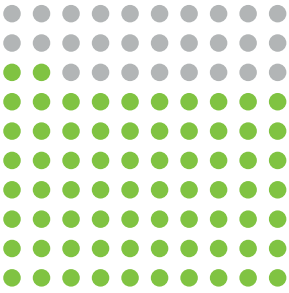
Research finds AI-experienced directors and C-suite executives are looking for more regulation and collaboration globally (figure 9).[102] A rapidly changing regulatory landscape and the speed of GenAI innovation can create a challenging environment for those building technologies and those looking to manage them.

Figure 9. Leader support for GenAI regulation and collaboration



78% more regulation

Agree the widespread proliferation of generative AI tools / applications will require **more regulation of AI** by governments



72% more collaboration

Agree there is not enough **global collaboration** with respect to ensuring the responsible development of all AI-powered systems

Source: Deloitte, "State of Generative AI in the Enterprise," January 2024.

Some LLMs and foundation models are already testing the limits of regulations, including the EU's Digital Services Act.[103] Companies can incur risks if they do not have safeguards that help ensure that these technologies are used effectively, responsibly, and legally.[104]

Almost half of organizations (47%) responding to the State of Generative AI in the Enterprise, survey report monitoring regulatory requirements as part of their risk management efforts. Many express concerns that widespread use of GenAI will concentrate power and increase economic disparity.[105]

2023 saw lawmakers agree on a vision. But in 2024 we can expect to see policies start to morph into concrete action and tech companies being held accountable. In particular, the emphasis is expected to be on content labeling, watermarking, and transparency.[106]

United States: The US set out its most sweeping set of AI rules and guidelines in an Executive Order (EO) issued by the US government on 30 October 2023.[107] In addition to AI safety and security, it includes a requirement that developers share safety test results for new AI models with the US government if the technology could pose a risk to national security. However, the EO lacks specifics on how the policies will be enforced.[108] Some highlights of the EO include:

- **Labeling guidance:** Requires the US Department of Commerce to develop guidance for labeling AI-generated content in hopes that labeling the origins of text, audio, and visual content will make it easier for consumers to know what's been created using AI online.
- **Labeling and watermarking tools:** Asks AI developers to develop labeling and watermarking tools that federal agencies may also adopt. Stakeholders say there are currently no fully reliable ways to label text or investigate whether a piece of content was machine generated. There is also no requirement to use these tools.[109]

In 2024, the new US Artificial Intelligence Safety Institute will be responsible for executing most of the policies called for in the order. Similar to the EU's AI Act, we are likely to see an approach that grades AI by type, uses, and the level of risk they pose.[110]

European Union: The world's first comprehensive law is the EU AI Act.[111] The new rules establish obligations for GenAI/AI providers and users depending on their level of risk. Many AI systems may pose minimal risk, but the European Parliament believes they need to be assessed.[112] Critical infrastructure and other high-risk organizations are required to do AI risk assessments and adhere to cybersecurity standards.[113]

AI systems that pose "unacceptable risk" are those that are considered a threat to people and will be banned (there may be some exceptions for law enforcement).[114] Critical infrastructure and other high-risk organizations will need to do AI risk assessments and adhere to cybersecurity standards.[115]

GenAI technologies that are general purpose, like Gemini by Google and ChatGPT, have transparency requirements to:

- Disclose that the content was generated by AI
- Design the model to prevent it from generating illegal content
- Publish summaries of copyrighted data used for training[116]

With limited-risk AI systems, transparency requirements call for providing enough information to allow users to make informed decisions. Users must be able to understand that they are interacting with an AI and have an opportunity to decide whether they want to continue using it or not.[117]

Most importantly, the EU AI Act ushers in binding rules on transparency and ethics.[118] Companies building open-source AI models are exempt from most of the AI Act's transparency requirements, unless their models

are as computing-intensive as GPT-4.[119] As other countries decide on policies, the EU's comprehensive regulations are poised to serve as a blueprint for overseeing the technology,[120] and tech companies are likely to have two years to implement the rules.[121]

Singapore: Another blueprint being looked at around the world is Singapore's approach to AI governance that was initiated in 2019.[122] IMDA, Singapore's Information Media Development Authority, recently developed "AI Verify," an AI governance testing framework and software toolkit to support the current state of AI.[123]

As governments continue to chart the course to mitigate AI's risk to society, enterprise-wide risk awareness—including AI literacy and individual responsibility—will play an increasing role in day-to-day operations with the advent of GenAI. To promote the necessary AI understanding, CIOs and business leaders could support business users with resources, enhance existing workforce training and learning sessions, and foster an enterprise culture of continuous learning.[124]

(See more at Deloitte's AI Institute.)

Looking ahead

To move beyond proofs-of-concept and scale, companies may need to upgrade enterprise technology and integrate GenAI into redesigned work processes. Organizations should identify where GenAI might make the most impact and build incremental digitization, moving beyond basic productivity use cases to higher order opportunities, such as new, differentiating services or business models.[125] In addition, a sound governance model can help drive adoption, ensure accountability for outcomes, and help to realize value.[126]

Strategy questions for life sciences and medtech stakeholders regarding GenAI

01. Does our organizational approach to GenAI have a value creation and advantaged mindset?
02. How can we best scale up and build a foundation for longer-term value creation?
03. Are we sufficiently diversified in terms of the ecosystem partners we are working with? There are multiple different solutions and capabilities—how do we balance focus and diversification?
04. What guardrails does our organization need to ensure responsible use of GenAI and how do we stay aligned with shifting societal expectations?
05. What do we need to do to ready our talent and organization to adapt to transformed ways and technologies?

Pricing pressures rising globally, threats of impacts on R&D innovation worldwide

Accelerating medicines spending

Drug spending and growth is expected to accelerate globally over the next few years but varies across countries.[1] Spending for medicines is largely correlated with degrees of economic development and should be considered in the context of a country's overall health care expenditures[2] and health expenditures in the context of GDP.[3] Use of medicines is typically higher in higher income countries than in lower income countries (figure 1).[4]

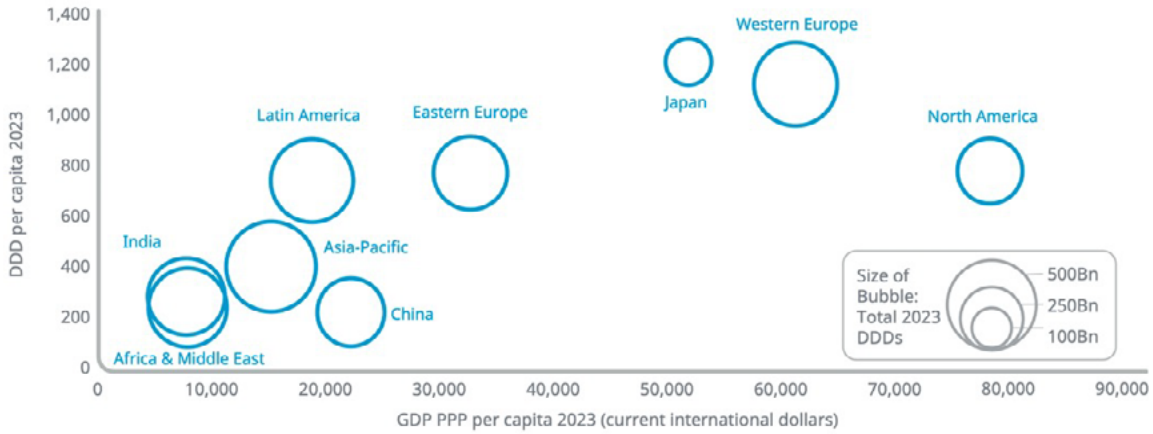
Some countries are more volume driven, while others are focused on the adoption of innovation in medicines.[5]

Specialty medicines are projected to represent more than 40% of global spending by 2028, with more than half of total spending in leading developed markets.[6]

Both population-driven volume growth—and a shift in the mix of medicines to higher cost products—is expected in North America, Eastern and Western Europe, Latin America, Africa, and the Middle East over the next five years. At the same time, China's drug spending looks to be less volume-oriented and more focused on expanding access to novel drugs, while Japan's spending is not likely to change as innovation is offset by annual price cuts.[7]

Figure 1. Per capita use of medicines

Defined Daily Doses (DDD) per capita by region compared to per capita gross domestic product (PPP), current international dollars



Source: IQIVIA Institute, December 2023; The World Bank, July 2023; International Monetary Fund, October 2023

Drug pricing pressures worldwide

Drug pricing and value continue to come under scrutiny as pricing pressures are being felt globally.[8] In 2024, government-mandated pricing pressure and controls are expected to play an increased role in the affordability and accessibility of certain medicines.[9] It's a complex topic, governed in wide ranging ways across the world, and requires taking multiple stakeholder perspectives in balance.

Direct drug pricing negotiations by the US government are underway for the first time in the US.[10] While the US government has a range of policy initiatives aimed at addressing drug pricing, the health care provisions of the Inflation Reduction Act (IRA)[11] are raising concerns among some drugmakers.[12]

In Europe, there is similar price consciousness. For example, in the UK, a new price regulation agreement–the voluntary scheme for branded medicines pricing and access (VPAS)—was reached to control the level of spending on innovative drugs.[13] VPAS sets a cap on the total allowed sales value of branded medicines to the UK National Health Service (NHS) on an annual basis.[14] The cap grows at an agreed rate of 2% per annum, but any medicine sales above the cap are required to be paid back to the UK Department of Health and Social Care (DHSC) via a levy.[15]

In Asia, Japan has steadily reduced prices every other year, ranging from around 2% to 9.4% after the latest fiscal year-over-year (FYoY) 2023 review.[16] China is leveraging its large population for its volume-based procurement strategy, significantly reducing prices while saving approximately US$36.3 billion at the end of 2021.[17]

Developed-world concerns around drug pricing are pushing the unaffordability of medicines to the top of the global health agenda as discussed at the World Health Assembly (WHA) in 2023.[18] Less-developed countries have voiced concerns over unaffordability of medicines for their health systems for decades. In 2024, the Access to Medicines Foundation is enhancing regulatory coordination in low- and middle-income countries (LMICs). The organization's updated biennial report is expected in 2024 and is expected to assess how pharma companies monitor the number of patients with access to their essential health care products in LMICs.

Implications of the US Inflation Reduction Act

The impact of pricing and access to medicines leads the list of concerns of more than half of US life sciences companies in 2024, according to a survey by Deloitte US.[19] Over the next five years, the IRA is expected to have implications for how the industry makes decisions and allocates resources in both research and development (R&D) and commercial efforts with corresponding implications for access to drugs across the world. The US holds almost a 43% share of the global pharma market and is home to some of the largest pharma companies worldwide.[20]

The IRA may have a positive effect for patient affordability given reduced out-of-pocket expenses for patients in Medicare Part D, and negotiated drugs are expected to be provided to patients at the negotiated price. Furthermore, smoothing is slated to begin in 2025, capping Medicare Part D out-of-pocket prescription drug costs at $2,000 annually.[21] As a result, it's anticipated that there may be major changes to commercial insurance design over the next few years, including pressures to incorporate patient out-of-pocket costs on net vs. list prices.

There can be material implications for drug companies with respect to gross-to-net, total molecule value—particularly for negotiated assets, price adjustments, and capital allocation for R&D and business development (BD).

A downstream effect is expected from the IRA on the operations and financials of health insurance plans, pharmacy benefit managers (PBMs), pharmacies, employers, hospitals, health systems, and other providers in the US. The price-negotiation provisions, for example, will likely impact the drug-acquisition price for providers and pharmacies and their reimbursement rates, in addition to rebates. Amongst all the players, the effects of lower negotiated prices put pressure on business practices.[22]

There may also be unintended consequences, such as differences for small molecule vs. biologic drugs as well as orphan drug dynamics (multiple vs. single orphan drug exclusion). Several negotiated drugs expect to have generics/biosimilars introduced within 12-24 months or less. In order to not create financial incentives that could deter biosimilars from entering the market, the IRA provides for a delay in selecting drugs for negotiation.[23]

Government's in-depth reviews on the drugs selected

An in-depth review of the first 10 drugs selected for negotiation is provided by the US Department of Health and Human Services (HHS)—the "Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs." Drugs selected represent nearly 20% of spending in the Medicare Part D drug benefit and were approved by the FDA more than seven years ago.[24]

According to the report, prices for the 10 drugs selected had more than doubled from 2018 to 2022, from US$20 billion to about US$46 billion, an increase of 134%.[25] In addition, the rate of growth in spending for these 10 drugs was more than three times as fast as for all Medicare Part D drugs over the same period.[26] List prices being negotiated factor into both insurance premiums and patient out-of-pocket costs.[27]

First 10 drugs selected for price negotiations

Drugs selected represent nearly 20% of spending in the Medicare Part D drug benefit and were approved by the US Food & Drug Administration (US FDA) more than seven years ago.[28] In 2024, the US administration is moving forward on seeking price cuts for 10 drugs covered by US Medicare that are commonly prescribed to older and disabled Americans; another 60 will be negotiated by 2029 (figure 2).[29] The first round includes medications for diabetes, heart-failure, arthritis, psoriasis, Crohn's disease, ulcerative colitis, blood thinners, and treatment for blood cancers. "Orphan" drugs for rare diseases, which treat conditions affecting fewer than 200,000 people, were excluded.

Drugs purchased at pharmacies under Medicare Part D are part of the first two years of negotiations, with Medicare Part B drugs, those administered by doctors, being added in 2028. Prices for the first 10 drugs are expected to be revealed by September 2024.[30]

In addition to the drug negotiation program, the IRA requires drugmakers that sell drugs through Medicare to pay rebates to the US government for drugs increasing in price faster than the rate of consumer inflation. As part of the rebate provision, prices for 48 prescription drugs included in Medicare Part B beneficiary coinsurances may be lower starting between 1 January 2024–31 March 2024.[31]

Government view, focus on cost savings

The drug negotiation program is estimated to potentially save Medicare US$100 billion[32] of the US$237 billion in overall savings projected for the IRA's drug pricing provisions over the next decade.[33] The US government believes Americans should not be paying two to three times more than what people

Figure 2. First 10 drugs up for Medicare price negotiation cuts in 2024

Drug	Type of medication	Pharma company
Eliquis	Blood thinner	Pfizer and Bristol Myers Squibb
Xarelto	Blood thinner	Janssen Pharmaceuticals, Inc., part of Johnson & Johnson, and Bayer
Jardiance	Diabetes, heart failure	Boehringer Ingelheim and Eli Lilly
Januvia	Diabetes	Merck & Co.
Farxiga	Diabetes, chronic kidney disease	AstraZeneca and Bristol Myers Squibb
Novolog	Diabetes	Novo Nordisk
Enbrel	Arthritis, psoriasis	Immunex, a subsidiary of Amgen
Stelara	Psoriasis, Crohn's disease, ulcerative colitis	Janssen Biotech Inc., part of Johnson & Johnson
Entresto	Heart failure	Novartis
Imbruvica	Cancers of the blood	Pharmacyclics, an AbbVie Company, and Janssen Biotech Inc., part of Johnson & Johnson

Source: US Department of Health and Human Services

in other Organisation for Economic Co-operation and Development (OECD) countries pay for the same drugs—even when accounting for rebates and discounts.[34]

A recent US Senate Health, Education, Labor, and Pensions (HELP) Committee staff report highlighted the high cost of drugs in the US compared to other countries.[35] The issue is complex, and there are many variables to consider. For example, HELP's focus is on gross prices that are part of the negotiations. Manufacturer gross drug prices for brand name originator drugs are significantly higher in the US than other countries—422 percent of prices in comparison countries in 2022.[36]

What the drug manufacturer receives, the "net" price, can be up to 75% less. Negotiated and statutory rebates to third-party payers are the largest share of gross-to-net differences.[37] In the first three quarters of 2023, net prices for brand-name drugs dropped for the sixth year in a row, with real, inflation-adjusted net prices falling -7.4% in 2023.[38]

Comparisons of gross prices shape public perception, and for 158 million Americans with employer-based plans, premium contributions and out-of-pocket costs, like those for prescription drugs, are taking up an increasing portion of US household budgets.[39] The US government increases demand for prescription drugs by subsidizing employment-based health insurance in addition to being the primary funder of basic research in biomedical sciences.[40]

Pharma industry view, focus on pharmacy benefit manager reform

Drug manufacturers point to PBMs as needing significant reform.[42] A concern for the Pharmaceutical Research and Manufacturers of America PhRMA is that the US government's policy presents barriers to transparency and accountability. Prescription drugs are the only part of the US health care system where the difference between list and net prices is monetized as rebates that are redistributed via intermediaries to payers.[43] PhRMA President and CEO Stephen Ubl says reforms should shift focus to ensure that rebates companies negotiate with intermediaries (like PBMs) are passed onto patients at the pharmacy counter.[44]

PBMs were introduced into the system to manage benefits for health plans, and while they were

Where does the money go? Gross-to-net price differences

A drug's net price represents the actual revenues that a manufacturer earns from a drug after paying rebates, applying discounts, and other reductions.[41] Gross-to-net price differences for brand-name drugs include:

- Rebates, discounts, and fees to commercial payers and plans
- Rebates and coverage gap discounts in Medicare Part D
- Rebates to the Medicaid program
- Discounts under the 340B Drug Pricing Program
- Manufacturers' payments to drug channel participants, including administrative and other fees to PBMs as well as fees and discounts to pharmacies, wholesalers, and other purchasers
- Patient assistance and copayment support funds

supposed to lower health care costs,[45] manufacturers' list prices actually increased to accommodate rebates.[46] PBMs' use of pharmaceutical rebates allows multiple players in the supply chain to potentially benefit financially at the expense of patients and control patients' access to certain drugs.[47] In addition, PBMs own their own pharmacies, and many believe this ownership creates huge conflicts of interest—hurting competition and distorting pricing.[48]

The US House of Representatives launched a report in 2023 that found:

- PBMs often require burdensome prior authorization that may cause lengthy delays to approve prescriptions.
- With lengthy delays, some patients may suffer, and even die, while they await authorization.[49]
- Some patients first have to fail to respond to a more expensive drug, even if a cheaper alternative exists because the PBM may have a financial incentive to compel the more expensive drug.[50]

Provisions in the US Department of Health & Human Services (HHS) November 2020 final rule on pharmacy benefit managers' rebates should eliminate rebates in favor of point-of-sale discounts in the Medicare Part D and Medicaid managed care organization programs.[51] Essentially, the rule is designed to remove the anti-kickback safe harbor for rebates.[52] However, implementation of the rule was deferred, and the IRA has extended the time to implement the rule until 2032. [53]

Industry stakeholders are also concerned about the disproportionate power and influence of the three largest PBMs that control over 80% of all prescription drug access and reimbursement in the US.[54] In 2022, these PBMs excluded more than 1,150 medicines from their standard commercial insurance formularies, representing a nearly 1,000% increase in exclusions since 2014, including medicines that would provide patients needed treatments at lower costs.[55]

Experts say out-of-pocket costs for many patients have risen as leading PBMs logged double-digit profit growth.[56] Enforcers, like the US Federal Trade Commission (FTC), and lawmakers in Congress have started focusing on PBMs with hearings and bills, and PBMs will likely remain on the hot seat.[57]

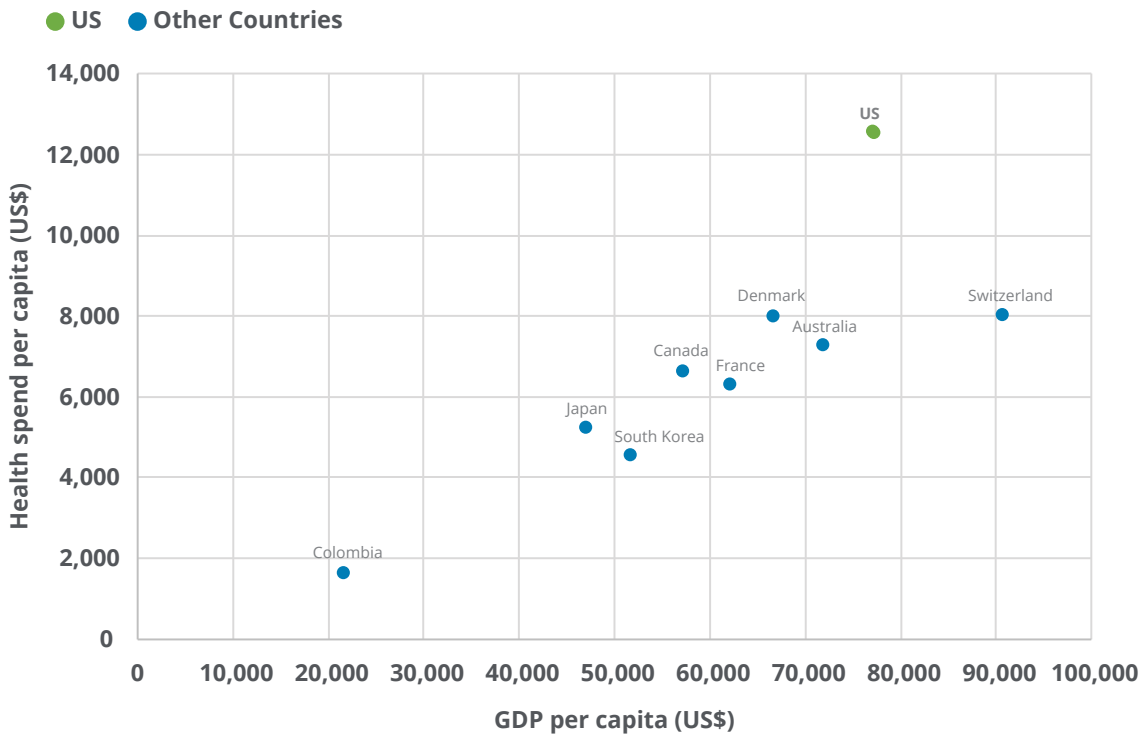
"The US is the only country where our members are capturing less than 50 cents on the dollar of the list price of the medicine, with the rest being absorbed very efficiently by other actors in the supply chain."

—**Stephen Ubl**, President and CEO of PhRMA[58]

Drug pricing in the context of per capita health expenditures and GDP

The US spends considerably more per capita on health expenditures than peer nations, spending about US$12,500 in health expenditures per capita, with a GDP per capita of approximately US$77,000 in 2022 (figure 3).[59] Switzerland and Germany have the next highest health expenditures per capita, at about US$8,000 each per capita in 2022; GDP per capita in 2022 was higher for Switzerland at about US$90,000, and close to US$67,000 in Germany.[60]

Figure 3. GDP per capita and health consumption spending per capita, US dollars, 2022 (current prices and PPP adjusted),



Source: Petersen KFF Health Tracker, analysis of OECD data

As an example of the wide range in prices paid for essential medicines across the world, n 2019, the median price paid for 60 tablets of the blood thinning medication Eliquis by a sample of private health insurers was US$440 in the US, US$162 in Switzerland, and US$96 in Germany in 2019 (figure 4).[61] The price in the US was 4.5 times more than in Germany.[62]

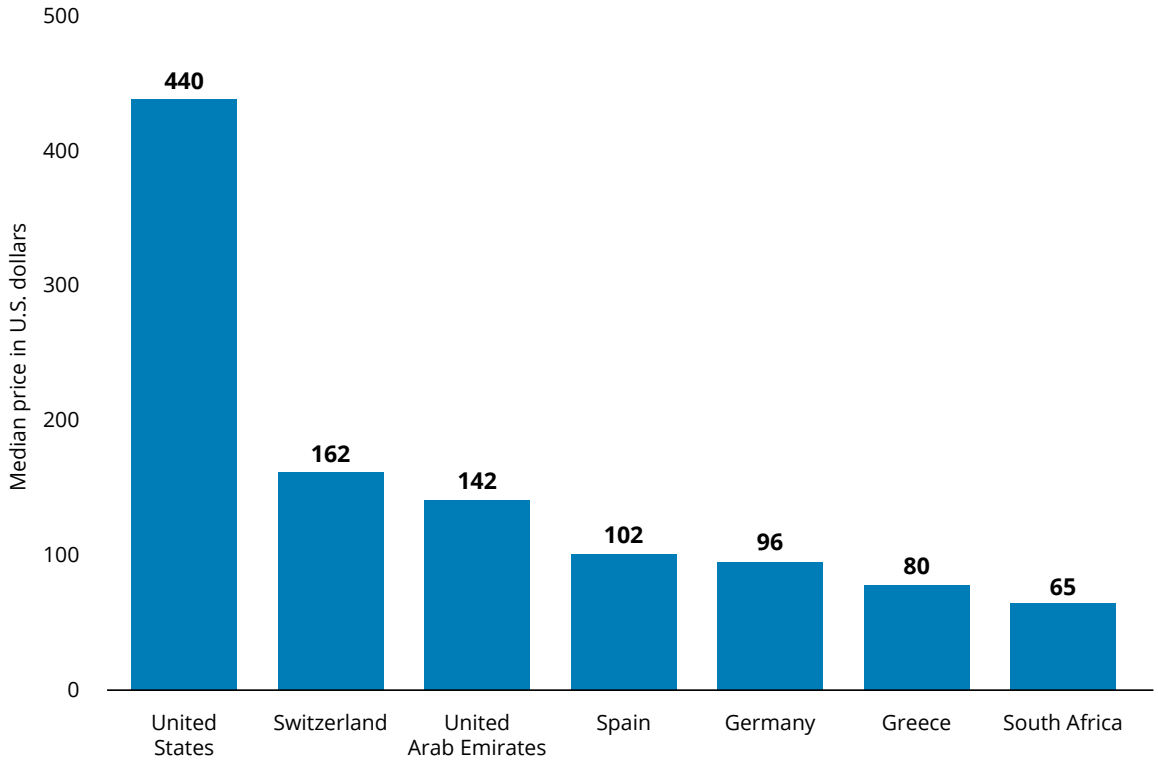
The Bristol Myers Squibb (BMS) customer savings and support webpage promotes that Eliquis is covered by 90% of commercial and Medicare Part D plans, but out-of-pocket copays vary. The webpage offers a US$10 copay card to apply towards any copay for patients deemed eligible to receive it, which could be those who have insurance and still have a copay or those without insurance.[63]

Discounted prices advertised for 60 tablets of Eliquis by GoodRX, available to consumers from leading pharmacies in the US, are in the range of about US$592 to US$626—a savings of 9% to 17% off the retail price.[64] GoodRX's discount and coupon prices are

based on contracts between a pharmacy (or pharmacy purchasing group) and a PBM that provide the prices and are a best estimate.[65] Some patient assistance programs (PAPs) also provide those with limited incomes access to free or low-cost prescription drugs from the drug manufacturer.[66]

As we point out in the patient section of this outlook, some patients do not even know who manufactures their drugs, and more than one company is associated with many drugs. Finding the best available price and discount is not just a patient problem, it can become an administrative cost and burden on health care professionals (HCPs), pharmacists, communities, and the health care system as a whole if patients cannot afford the medicines they need and risk suffering additional health consequences.[67]

Figure 4. Median prices paid for Eliquis by a sample of private health insurers in select countries in 2019



Notes: Prices are for Eliquis (apixaban 5mg) – 60 pills. The source compared the median prices paid by a sample of private health insurance companies for 34 specific health care services in 11 countries in 2019. Health cost comparisons among various countries are complicated by differences in sectors, fee schedules, and prices may not be representative of prices paid by other plans in that market. The limitations were minimized by selecting services with very specific definitions and wording survey questions to match the procedures that are the basis of the US payment system.

Source: Statista, 12 August 2022

CMS hosts patient "listening sessions" in support of Medicare negotiations

Concern about high copays were expressed at the patient listening session for Eliquis—hosted by the US Centers for Medicaid and Medicare Services (CMS)—and open to the public online.[68] These live-streamed listening sessions are opportunities for patients, patient advocacy groups, caregivers, and others to provide feedback on the values of particular drugs.[69] Ten sessions were held in Q4 2023, one for each drug being negotiated.[70]

Transcripts for the sessions are available on the CMS website,[71] including a transcript for the Eliquis session.[72] One medic, representing Doctors for America as its Vice Chair for Access to Affordable Care, points out that high copays for Eliquis are not insignificant for seniors on a fixed income.[73]

Area of high public interest and opinion

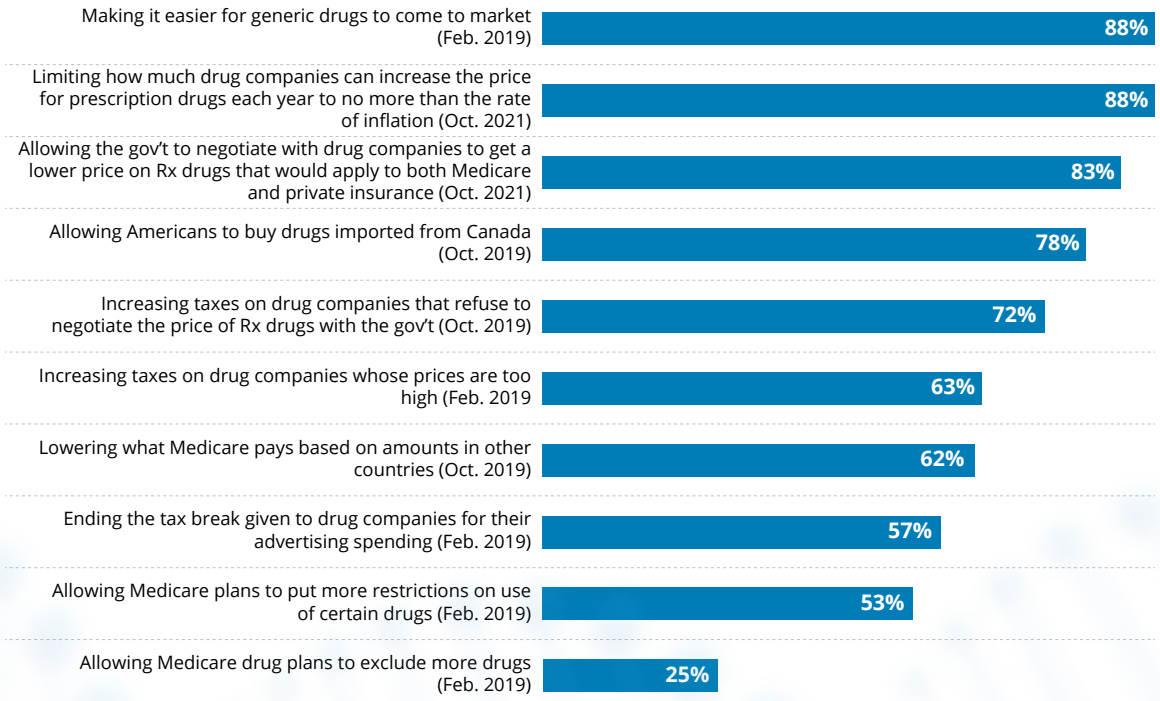
The pharma sector faces growing public scrutiny and media attention regarding drug pricing transparency and affordability.[74] More than 900 name brand drugs have price increases taking affect at the beginning of 2024.[75] But the median wholesale acquisition cost (WAC) increase of 4.7% is now the lowest percentage increase in more than a decade, down 0.1% from 2023.[76]

Many believe the pharmaceutical industry is viewed unfavorably due to the rising (and total) cost of prescription drugs.[77] Research organizations have been polling public opinion in the US for decades,[78] and 93% of Americans feel drugmakers would still make enough money if prices were lowered.[79]

A 2023 poll found that 82% say the cost of prescription drugs is unreasonable, and almost three-quarters of Americans feel there should be more regulation to limit the price of drugs.[80] An end of the year 2022 poll queried Americans regarding support of various proposals for lowering drug costs (figure 5).[81]

Figure 5. Tracking US public opinion on drug cost regulation, November-December 2022

Percent who favor each of the following actions that would keep prescription drug costs down:



Source: KFF Health Tracking Poll (29 November-8 December 2022)[82]

Reducing the price differences between the US and other countries

Reductions in administrative burdens and drug costs could substantially reduce the difference between US and peer nation health spending.[83] While drug manufacturers say price cuts can negatively affect innovation,[84] the US government's view is that companies spend more on stock buybacks and dividends than they do on research and development (R&D).[85] Accordingly, the IRA has tax implications, including a 1% share buyback excise tax and a corporate alternative tax of 15% for companies meeting the thresholds.[86]

Pharma industry view, focus on innovation

According to PhRMA, members want to get patients access to the medicines they need, but believe the IRA is a threat to innovation and collaboration.[87] PhRMA member companies have more than doubled their annual investments in the search for new treatments and cures over the last decade.[88]

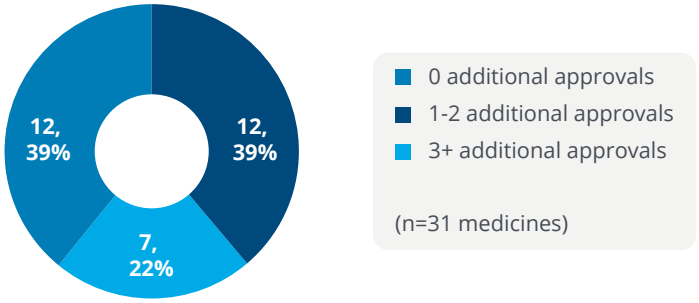
From discovery to launch, drug manufacturers spend an average of US$2.3 billion to bring a new drug to market.[89] The top 20 global pharmaceutical companies collectively spent US$139 billion on R&D in 2022.[90]

PhRMA states that the IRA ignores the nature of the R&D process by not considering:

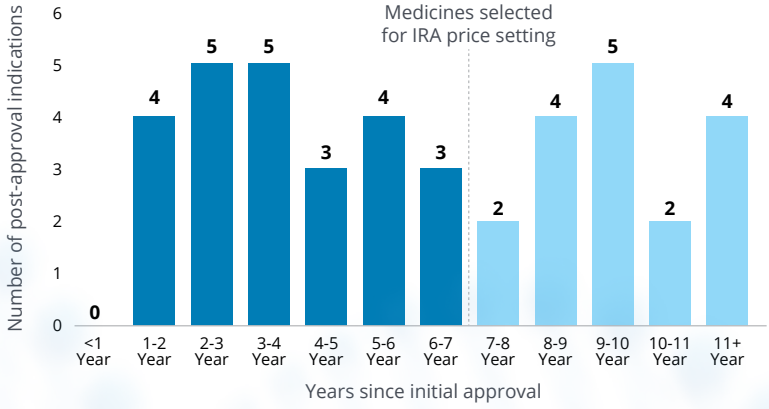
- Innovations that occur past the time of their first USFDA approval (figure 6)—new uses for medicines, new patient populations, new formulations, and new dosage forms.
- The real-life impact new drugs and treatments can have on patients.
- The increase in therapeutic value over time as medicines are approved for new uses—such as in new patient populations, for use with new diseases or new stages of disease.[91]

Figure 6. IRA's price setting impact on cancer medicines, research from the Partnership for Health Analytics and Research (PHAR)

Number of cancer medicines by number of post-approval indications
For small molecule oncology medicines receiving initial FDA approval between 2006-2012



Timing of post-approval indications
For small molecule oncology medicines receiving initial FDA approval between 2006-2012



Source: PhRMA, research from PHAR

Lawsuits argue the constitutionality of the pricing negotiation framework

As part of the IRA, a new US excise tax, ranging from 65%-95% on all US sales by a pharmaceutical manufacturing company, may potentially be applicable to pharmaceutical manufacturers who do not enter into a negotiation program with the US government to determine maximum prices.[92]

While all the companies representing the first 10 drugs selected signed agreements to negotiate,[93] PhRMA, drugmakers, some patient advocacy groups, and others, initiated lawsuits against the constitutionality of the measure. [94] The Global Colon Cancer Association (GCCA) joined PhRMA's lawsuit because it believes that the IRA could thwart progress in colon cancer research that is affecting more Americans under 50.[95] According to GCCA Executive Director Andrew Spiegel, "The IRA is implementing a process where patient voices and concerns have no real seat at the table." [96] He says patients deserve better, and that's why GCCA joined in the lawsuit.[97]

As of 1 May, the courts have rejected the PhRMA lawsuits including one brought by AstraZeneca[98]—signaling that the pharmaceutical manufacturers may not secure legal protections. However, PhRMA filed an appeal,[99] and a federal judge in New Jersey is permitting four other drugmakers—BMS, Novo Nordisk, Novartis, and Johnson & Johnson—to combine their arguments.[100] Additional lawsuits are still pending.[101]

Impacts on portfolio strategies

Will less revenue mean less drug innovation?[102] Lowering US drug prices may impact incentives to innovate because drugmakers are likely to be less profitable.[103] The IRA is already affecting R&D decision-making and portfolio strategies as there is uncertainty around planning. Some companies are rethinking R&D investments—shifting away from small molecule investments.[104]

In a survey of 25 participating PhRMA members, three-quarters say early-stage pipeline projects are likely to be cancelled and two-thirds say pipeline projects that are planned, but not yet in clinical development, will likely no longer be pursued. More than half expect to reduce spending on new scientific platforms that may take many years to develop.[105]

Nonetheless, recent research by the Congressional Budget Office (CBO) expects that about 13 out of 1,300 new drugs, or 1%, over the next three decades would not make it to market as a result of changes brought about by the IRA.[106] Other experts say novel discoveries are mostly the result of taxpayer investments in academic research and startups.[107] However, how those new discoveries are accelerated and studied is predominantly funded by the pharma sector, not biotechs, given the cost.

Acumen Pharmaceuticals is an innovative biotech company specializing in novel Alzheimer's disease therapeutics, with a focus on toxic amyloid beta oligomers. Acumen received funding from the US Department of Health & Human Services (HHS),[108] and recently was awarded "[the 2023] Monoclonal Antibody Solution of the Year" by the BioTech Breakthrough Awards program. [109] Acumen CEO Daniel O'Connell says that in order to really bring attention to Alzheimer's disease, and meet the market's needs, it will require the support of large pharma companies.

"We are in the early days of launching disease modifying treatments for Alzheimer's disease patients. Large pharma companies, like Biogen, Eisai and likely Eli Lilly are helping to establish the market. Over the next few years, with additional data and time, opportunities will start to open up. Buyers are trying to assess how big the Alzheimer's market is really going to be. Large pharma companies, like Biogen and Eli Lilly have added to the mix. Depending on the drug growth trajectory with those initial products, companies like Merck, maybe AbbVie and BMS, will be looking for their play. That is going to contribute to some level of partnering and M&A that will further catalyze growth of the Alzheimer's space.

Knowing the mindset within the business leadership of these big pharma companies right now, there is a "wait and see, show me" kind of attitude for Alzheimer's disease. For Acumen, and our mAb (monoclonal antibody), it's a greenfield; there is no prior precedent. The field is in the process of establishing the patient journey, the infrastructure, etc. It's going reasonably well, and by this time next year, we're going to be convinced that the commercial possibilities are very real and growing. It'll be an important time for us to continue to position our asset and program as one with attractive differentiation and long-term potential. And there's an important role for the larger pharmaceutical companies to play in bringing these innovations to commercialization and ultimately have the envisioned patient impact."

—**Daniel O'Connell**, CEO at Acumen Pharmaceuticals
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IRA impact requires a balanced view from stakeholders

In 2024, pharmaceutical leaders should consider ways to make products more commercially accessible through different payment schema. In the next few years, patients may lose out for niche indications as the IRA is discouraging the development of some types of medicines and treatments for certain patient populations. These effects are likely to spread throughout the world as the US leads transformative innovation.

No doubt the impacts of the IRA will be profound in the US as well as globally, but the precise impact and timing is still unfolding. All sides present strong arguments. Pharma wants to keep innovating—and be incentivized to do so. Patients want fair prices and HCPs want patients to be able to afford their necessary medicines. And the US government wants more equitable prices—as it is carrying a large share of the burden to make these drugs available globally.

Pricing pressures challenge Japan's innovative reputation in medicines

While Japan is known for developing innovative medicines, recent pricing pressures, akin to those in other parts of the world, are also driving reforms.[111] Reforms are creating uncertainty for pharmaceutical companies in the world's third-largest pharma market as well as concerns over the future of innovation.[112]

The Japanese government reimburses patients for drugs at prices specified in the Drug Price Standard (DPS). The DPS covers all medications dispensed by the National Health Insurance (NHI) and stipulated by Japan's Ministry of Health, Labour and Welfare (MHLW).[113]

Health care funding sources, public vs. private

Health care in Japan is publicly funded, while health care delivery is primarily done through private institutions.[114] In the UK, the health care system is mostly public, while predominately private in the US (figure 7).

Japan's health care system is known for maintaining relatively low health care costs compared to other developed countries.[115] In 2022, its health expenditure per capita was US$5,250, less than half of that for the US.[116] While patients in Japan have copays, there are caps on out-of-pocket expenses.[117]

Figure 7. Countries' health care service provider and its financial resource

Country	Primary service provider	Financial source*2
	Private (Public: 5%)*1	**Public** (Public: 84%)
	Private (Public: 23%)*2	**Private** (Public: 51%)
	Public (Public: almost all)*2	**Public** (Public: 79%)
	Private (Public: 45%)*2	**Public** (Public: 77%)
	Private (Public: 25%)*2	**Public** (Public: 78%)

Note: *1=Japan's MHLW data, 2021; *2=OECD, data, 2020
Source: Deloitte analysis

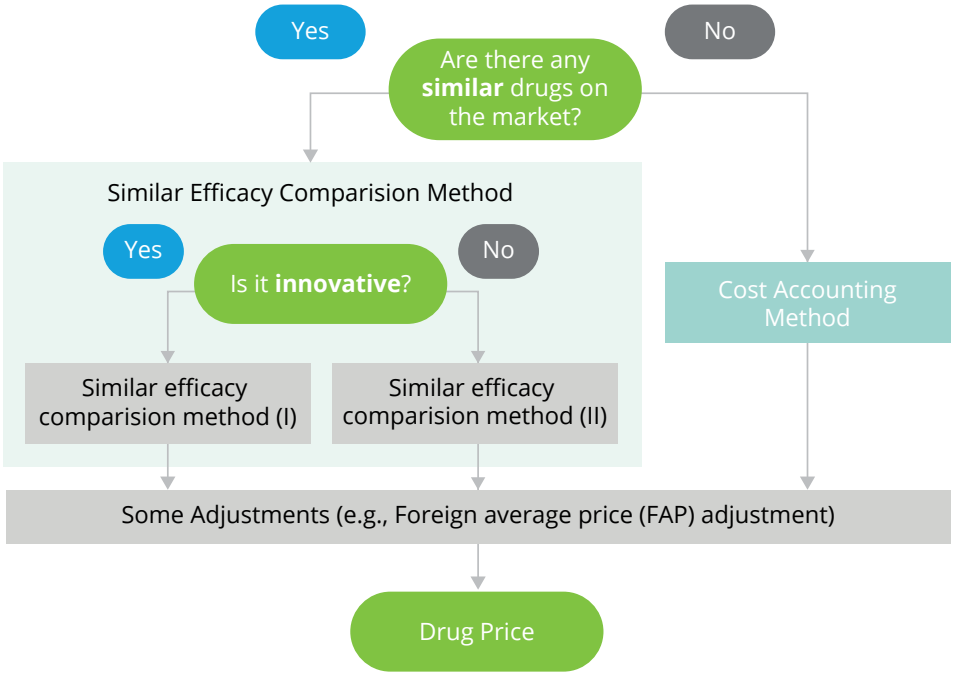
In FY2023, Japan's average drug price decreased 9.4% for 2,000 drugs in the DPS,[118] accounting for 36% of products increased in the FY2023 DPS.[119] This 9.4% decrease in 2023 for Japan's drug prices is twice the size of the 4.7% drug price increase in the US for 2024, reflecting some of the differences between countries with publicly funded health care systems and private.[120]

A new layer between market access and reimbursement

While the US government recently started considering value assessments through price negotiations, Japan was one of the first countries to introduce cost-effectiveness data for pricing new pharmaceutical products in 1992.[121] But a new Cost-Effectiveness Analysis (CEA) implemented in 2019 is testing the country's reputation for innovation.[122]

In a simplified overview, new drugs and treatments are originally evaluated for their similarity to other products in the market (figure 8). If similar and "innovative," the new product is priced comparably, according to Japan's Similar Efficacy Comparison Method (SECM) I. For less innovative products, SECM 2 adds premium adjustments for various values, like marketability and specific use. If there are no comparable drugs, a cost accounting method is used.[123] After the drug standard listing, drugs may be subject to a CEA or repricing over time.[124]

Figure 8. Pricing methods for new drugs in Japan



Source: ISPOR Asia Pacific, CRECON Medical Assessment Inc.

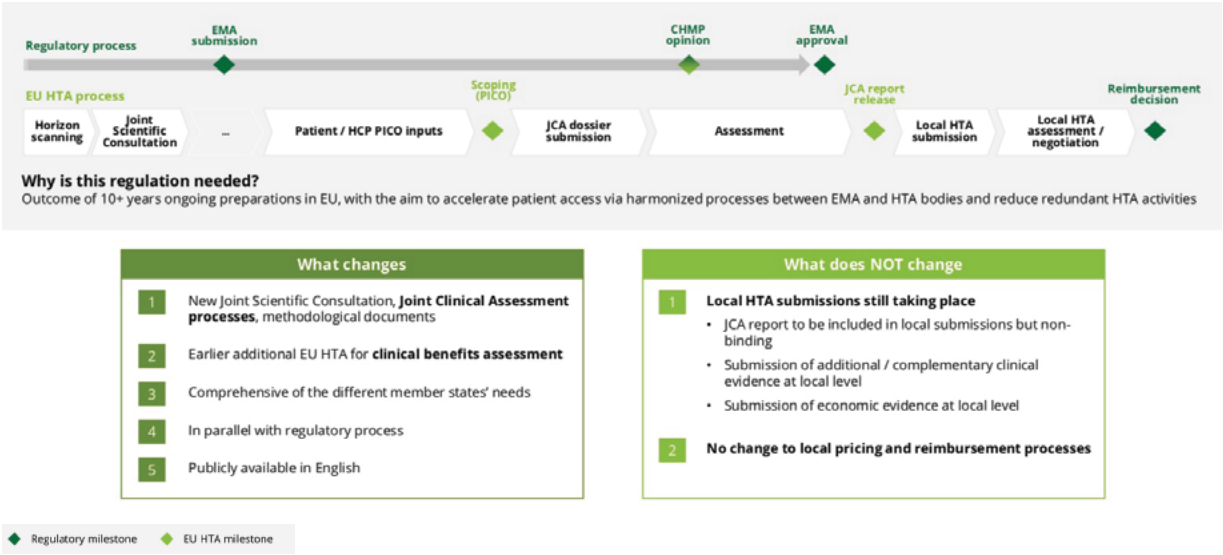
Drug manufacturers may be required to undergo a CEA for certain medicines and medical devices as part of the Health Technology Assessment (HTA) process.[125] HTAs aim to inform decision makers about relevant aspects of new health technologies, including pharmaceuticals, medical devices, surgical procedures, and other health care interventions.[126]

Experts say some of the challenges for drug manufacturers include assessing whether they will be subject to a CEA, and then ensuring they have the capabilities to show they meet CEA requirements. This extra step presents a delay in reimbursement and market access challenges.

Cross-country HTA collaborations, and value in the European Union (EU)

In many countries, HTA is used to inform reimbursement and pricing. New technologies, like Generative AI (GenAI), have the potential to improve HTA submissions. In the near future, cross-country HTA collaborations are expected to require more comparative clinical data for pricing and reimbursement decisions (figure 9).

Figure 9. Overview on European Union (EU) HTA process in parallel with European Medicines Agency (EMA) submission process*



Note: * Process and timeline are not final and expected to change until 2025

Source: Deloitte analysis

Providing evidence for value in the EU

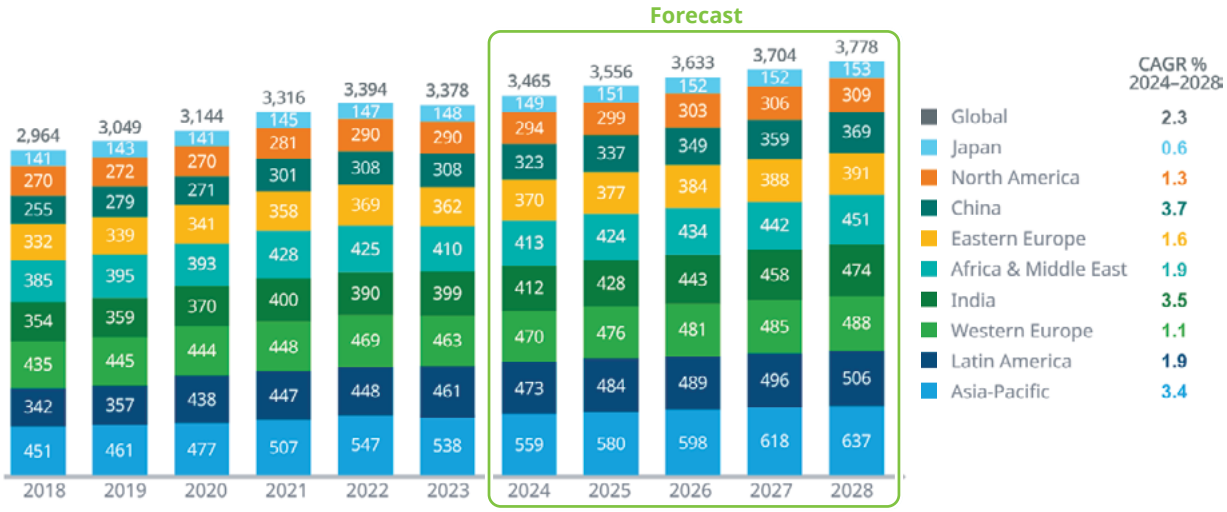
Evidence for a value-based system already has precedent in many other countries, particularly throughout the EU. Collectively, the EU plus the UK represent the second largest pharma market (33%), even though China is the second largest by country.

For example, Norway currently has a system that gives a drug its cost based on the patient's quality-adjusted life year. Their approach seeks to control costs by negotiating the prices of new drugs based on their cost-effectiveness and how health benefits are distributed.[127]

Rising use of medicines and calls for global pricing transparency

A good balance—between pharma cost containment measures, innovative medicine, and affordability—is critical to achieving optimal pricing and reimbursement, as the use of medicines is only expected to rise globally (figure 10)[128] along with global calls for pricing transparency. Many countries already require their manufacturers to declare ex-factory pricing—the manufacturer's selling price—in their initiatives (figure 11).

Figure 10. Historical and projected use of medicines by region, 2018–2028



Note: Forecasted Defined Daily Doses (DDF) in billions

Source: IQVIA, "Global Use of Medicines 2024, Outlook to 2028", January 2024.

Figure 11. Approaches used for drug price transparency by various countries

	Approach used on drug price transparency to government (through price declaration practices of pharma companies)				Drug price setting mechanism		Governing bodies for price setting mechanism
	Report other countries' price	*Ex-factory price*	*Distribution/ logistics fee/ wholesale*	*Pharmacy retail price/reimbursement list (RL)*	*Price referencing*	*Price negotiation*	
	✓	✓		✓ (RL)	✓	✓	*Patented Medicine Prices Review Board*
		✓	✓	✓	✓	✓	*National Development and Reform Commission*
	✓	✓	✓	✓ (RL)	✓	✓	*Ministry of Health*
		✓	✓	✓ (RL)	✓	✓	*Pharmaceutical Price Regulation Scheme, Department of Health*
	✓	✓		✓	✓		*Ministry of Health, Welfare and Sports*
		✓		✓ (RL)		✓	*Medicare, Department of Veteran Affairs, Medicaid, Health Maintenance Organization and Pharmacy Benefit Managers*

*Drugs covered under Medicare, Department of Veteran Affairs' health plans and Medicaid Best Price Program

Source: Deloitte analysis

In 2024, the US joined attempts by health systems around the world to control spending on new drugs, while also ensuring and improving access to innovative medicines for their populations. The IRA in the US is expected to have significant implications on how some of the largest pharma companies allocate funds for R&D and commercialize their drugs. Impacts on innovation and access could be felt globally.

In Europe, Japan, and China, the focus on how to evaluate the cost benefit of new medicines will likely continue—with new challenges. In particular, they will need to focus on how to value and price the benefits for cell and gene therapies as a class of expensive drugs with patient benefits over multiple years. Only through collaboration between industry and the health ecosystem can patients be assured that there is a win-win for finding cures and preventing and treating the diseases that affect all of us.

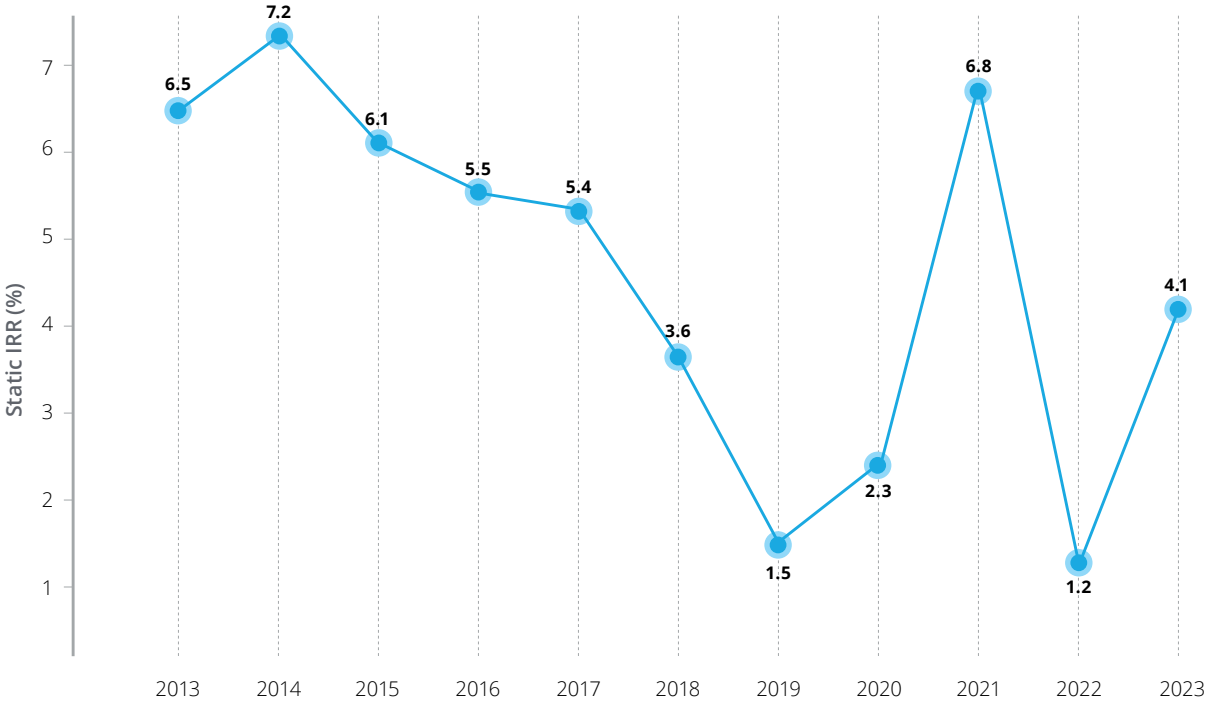
Accelerating speed of time to value in R&D

Large pharmaceutical companies account for almost two-thirds of total pharma research and development (R&D) investments[1] and spent a record total of US$161 billion in 2023—an increase of almost 50% since 2018.[2] As a percentage of companies' net sales, spending reached a historic high of 23.4%.[3]

Since 2010, Deloitte's series on Measuring the return from pharmaceutical innovation has provided insights into the productivity of biopharma R&D and has now evolved to include the top 20 pharma companies by R&D spend (determined in 2020).[4] For this cohort, R&D spend increased 4.5% from 2022 to 2023, while the average R&D cost to progress an asset from discovery to launch remained flat in this period at US$2.284 billion per asset.[5]

This year's modeling, based on a dataset that includes an expanded scope of assets and line extensions, shows the internal rate of return (IRR) rising to 4.1% in 2023 from 1.2% in 2022—the lowest point for the cohort since our analysis began (figure 1).[6]

Figure 1. Internal rate of return of the late-stage pipeline



Source: Deloitte, "Unleash AI's potential: Measuring the return from pharmaceutical innovation – 14th edition," 2024.

In 2024, ongoing regulatory changes and loss of exclusivity of an unprecedented number of high-value assets are expected to challenge the existing biopharma operating model.[7] Pricing pressures from the Inflation Reduction Act's (IRA's) health provisions are already impacting R&D decision-making and portfolio strategies.[8] Ten R&D leaders interviewed by Deloitte expressed more concern about changing regulations than cycle times or R&D costs.[9]

Scientific and technological advancements present a significant opportunity for those willing to harness the power of innovation, but the rapid pace of innovation can also be a challenge.[10] Advances in AI, including Generative AI (GenAI), have the potential to demystify complex disease biology, expedite drug discovery, cut study timelines, revitalize the clinical trial experience and improve regulatory success. Realizing productivity improvements and unleashing AI's value could provide new sources of value.[11]

Not just speed to market, but accelerating time to value

Speed to market has long been a leading priority for drug developers to accelerate patient access to life-saving therapies.[12] Since Deloitte first started analyzing pharmaceutical innovation in 2010, still only about one in ten new drugs entering human trials obtains regulatory approval.[13] Despite many advances in science and technology, this remains one of the leading challenges for the biopharma industry.[14]

"When you're facing an illness like cancer or heart disease, you don't want therapies 20 years from now—you want them now."

—**David Reese**, Executive Vice President, Research and Development, Amgen [15]

Speed to market is only part of a success formula; companies should also be looking at ways to accelerate time to value.[16] Leading biopharma companies are adopting new GenAI/AI technologies and other data innovations across the value chain, while forming new partnerships, collaborating early with regulators, and outsourcing for cost and time savings.

"Twenty-five percent of our projects entail working with partners, which has doubled research productivity as measured by dollars spent per clinical candidate and doubled our first-in-human entries."

—Paul Hudson, CEO, Sanofi[17]

Adopting a more agile mindset

Accelerating people and processes

By adopting strategies to accelerate time to value, companies can start on their individual path to potential cost savings and competitive advantage[18] even if small gains are made in each step of the process.[19] With the pace and development of AI-enabled digital solutions only expected to accelerate, leaders should start reengineering with an agile mindset.[20]

Accelerating time to value in an agile manner means having the people and processes in place to change and adapt swiftly in response to market forces.[21] Successful companies are building strategies to reduce the time it takes to advance across the stages of R&D, commercialization, and post-marketing surveillance. [22]

"We are applying speed levers in multiple areas, from digital technology and innovative study designs to regulatory partnerships. Our goal is to help each drug development team integrate as many of these levers as possible to accelerate progress."

—Kimberly Clemenson, Vice President, R&D Transformation, Amgen[23]

Snackable AI for improving business functions

At the BioCentury China Healthcare Summit in late 2023, Sanofi CEO Paul Hudson discussed how Sanofi uses "snackable AI" to get rapid access to data by providing many people across the organization with "bits" of AI for real-time decision-making and reporting. He says snackable AI offers radical data transparency and may provide immediate and trustworthy feedback without hesitation or sugarcoating–unlike managers who may delay delivering data to leaders when uncomfortable with the results.[24]

Use of AI in R&D expected to grow 106%

While the pharma industry is innovative in R&D, it is also true that it is often slow at embracing technological revolutions.[25] However, GenAI has brought more widespread attention to the current state of AI and jumpstarted many new initiatives.[26] Research shows that AI currently accounts for approximately 16% of drug discovery efforts and is

predicted to grow by 106% over the next three to five years.[27] It is the combination of domain specific LLMs, GenAI, AI/ML, deep learning, and data analytics that is positioned to accelerate time to value across biopharma R&D.

The R&D function represents the top value opportunity for large biopharma companies representing 30-45% of value creation. AI applied to novel drug identification and accelerating drug development could provide both cost savings and revenue uplift.[28]

Combining next-generation AI technologies with rich multi-omics data may close the loop across the R&D pipeline with rapid, automated generation and testing of hypotheses from bench to bedside.[29] Currently, GenAI may reshape the way life sciences organizations decide:

- Which disease areas to invest in,
- Which targets to pursue, and
- Which molecules to develop.[30]

Incorporating GenAI in R&D, from novel target identification to regulatory approval

Experts have ambitions to apply GenAI technologies to novel target identification through to regulatory approval, and into commercialization.[31] To kickstart their GenAI programs, organizations should employ "no regrets bets" that can deliver value in a relatively short timeframe (figure 2).[32] These types of low-risk activities can accelerate progress, while de-risking investments.[33]

Figure 2. GenAI's "no regrets bets" in R&D

	DESCRIPTION	VALUE TO THE BUSINESS UNIT	VALUE TO THE ENTERPRISE	WHY THIS IS NO REGRETS
Research & Development	**Scientific literature summarization**			
	Generates easy-to-consume summaries of scientific literature	**Greater productivity** from faster hypotheses testing	+ Cost reduction + Revenue uplift	GenAI can cut through research noise and go straight to insights with **minimal resource investment**
	Intelligent study deliverable authoring			
	Automate the drafting of clinical study report (CSR) deliverables	**Greater speed** from less rework and automated drafting	+ Cost reduction + Cost avoidance	Companies have a massive **treasure trove of past documents** that can be tapped into to automate creation

Source: Deloitte, "Realizing Transformative Value from AI & Generative AI in Life Sciences," 2024.

The following model illustrates three horizons of innovation in pharma R&D with the development of GenAI (figure 3). Throughout the evolution of GenAI, experts say that keeping a human-in-the loop where possible will be critical to maximizing productivity gains without significant risks, even in high stakes applications.[34]

Figure 3: R&D transformation horizon

Areas of Change	Horizon 1 Today	Horizon 2 18 Months	Horizon 3 5 Years
How Is data managed and accessed?	**Disjointed ecosystem of non-standardized data sources** aligned to specific business processes *Example: RWE for omics analysis; CTMS for clinical study conduct processes etc.*	**Amazon-like marketplace** where purpose-built R&D data products or extracts can be searched and accessed *Example: Research scientists can search for biomarker analysis data from past studies clinical trials data and request access*	A **dynamic data fabric** that seamlessly connects data assets across functions to provide a single source of truth *Example: Clinicians can readily leverage real-time data from safety, commercial, and regulatory systems to meet their business needs*
How are insights curated and consumed?	Insights are generated from discrete analytical models and **interpreted by data analysts** to support clinical processes Scientists **manually review and synthesize** scientific literature (e.g., publications, patents) to create research insights *Example: Clinical study managers rely on data analysts to contextualize outputs of site selection analytical models*	Business users leverage **GenAI to interpret outputs** of complex analytical models that provide them with more flexibility and context Scientists can access **summary insights** from vast amounts of scientific literature enabling them to rapidly adapt research priorities *Example: Clinicians can interact with GenAI chatbots to understand population health insights to optimize inclusion criteria*	Insights are **readily-embedded into business workflows** with little to no-need for human intervention Insights from external research are **rapidly contextualized and disseminated** across the enterprise *Example: Research, Clinical, Finance, Commercial, Regulatory teams are provided with contextualized impact summaries of a competitor's patent*
How are research operations conducted?	Experiments are highly manual and expensive due to **iterative hypothesis development and compute-intensive validation** *Example: Scientists manually create and test hypothesis, going back to the drawing board only after confirming failed hypotheses*	Scientists use **AI-powered simulations** to parallelize generation, testing, and optimization of thousands of hypotheses *Example: Scientists generate 3D biomolecular structures by rapidly testing and optimizing new molecules to treat breast cancer*	Research scientists prioritize leads by **amplifying decisions** with impact on downstream functions *Example: Researchers prioritize leads for treating breast cancer based on likelihood of regulatory approval and commercial viability*
How are clinical trials managed?	Complex trial processes and systems result in **highly manual, linear, and siloed decision-making leading to suboptimal outcomes** *Example: Disjointed decisioning around study design and site selection lead to expensive delays in trial execution*	Clinical **processes are streamlined & simplified** through AI / GenAI automation to deliver efficiency and experience gains *Example: GenAI copilots optimize study design decisions by incorporating insights from downstream patient enrollment and site selection processes*	Clinical trials are autonomously run through GenAI copilots that **optimize outcomes across the end-to-end value chain** *Example: Real-time participant attrition insights generate recommendations to modify upstream study design choices*
How does R&D interact with other functions?	**Operations within different part of R&D are often siloed** and insights are not shared across all R&D teams *Example: Clinical data and analytics are rarely readily available to upstream research scientists*	**Seamless data and insight connectivity** enables greater collaboration across all R&D functions *Example: Research, clinical, and regulatory teams work together to solve problems and create new products*	Hyper-connected enterprise where all **enterprise functions work together** to optimize enterprise outcomes *Example: R&D, regulatory, commercial, and manufacturing functions collaborate to seamlessly launch new drugs*
How do R&D organizations navigate regulatory landscapes?	Diverse regulatory rules are **manually interpreted** by local market and process teams in non-standardized, highly manual review cycles *Example: Regulatory teams spend weeks manually reviewing new clinical regulations in EU and assessing impact on ongoing and upcoming trials*	R&D teams leverage **GenAI capabilities** at scale to automate monitoring, synthesis, and impact assessment of regulations *Example: GenAI copilots identify and synthesize trial diversity requirements in the US and flag impacted studies*	Business processes limit human error and regulatory cycle time by building **AI-enabled regulatory checks** into processes *Example: GenAI copilots ensure new protocols are compliant with the latest regulatory policies during the drafting process*

Source: Deloitte analysis

Low-hanging fruit, GenAI replacing many manual processes

Google demonstrated the capabilities of its multimodal platform, Gemini, to aid research scientists in extracting data from scientific literature, often an arduous, time-consuming process done by hand.[35] In one example, Gemini read through 200,000 papers, filtered relevant studies down to 250, extracted the key data needed, annotated, and created graphs—and the entire process took about an hour.[36] In the near term, the ability to access knowledge rapidly and transform manual processes opens up an opportunity for GenAI in clinical trials.[37]

"The clinical trial space is an area where we have a lot of repetitive and very time-consuming tasks. GenAI is really a tool that enables an acceleration in some of these tasks, where before it would be a very manual prolonged process for both sponsors and sites."

— Silvia De Carvalho, Clinical Studies lead at AXON

To achieve the necessary increases in R&D productivity, some of the sweet spots are drug discovery and early clinical development, from target selection to clinical proof-of-concept.[39] Synthetic data is one way to accelerate access to data to start prototyping models quickly, and generative chemistry combined with a platform of tools and human expertise may help speed up drug design and identify better candidates. Work is being done with GenAI in de novo protein design, such as antibody design.[40]

GenAI model, SyntheMol, creating recipes for chemists to synthesize drugs in the lab

Researchers at Stanford Medicine and McMaster University are utilizing a new GenAI model for synthesizing molecules, dubbed SyntheMol.[41] The model created structures and chemical recipes for six novel drugs aimed at killing resistant strains of Acinetobacter baumannii, one of the leading pathogens leading to antibacterial resistance-related deaths.

Older computational models were able to yield some results by sifting through 100 million known compounds. However, this only scratched the surface in finding all the chemical compounds that could have antibacterial properties—estimated as close to 10^{60} possible drug-like molecules. The work is being expanded with other research groups, using the model for drug discovery for heart disease and to create new fluorescent molecules for laboratory research.[42]

While a number of biotech companies are developing AI-designed drug molecules, none have received US Food & Drug Administration (FDA) approval.[43] It will take time to collect and analyze the data needed to demonstrate the safety and efficacy of these drugs through clinical trials.[44]

Accelerating clinical trials with GenAI

As it develops, GenAI offers several possibilities for accelerating clinical trials, including:

- Automating document generation activities to increase velocity,
- Increasing study retention by amplifying patient engagement, and
- Improving regulatory engagement with tailored submissions.[45]

Tracking speed, productivity, quality, and sustainability of GenAI applications

Reviews of potential applications for GenAI along the R&D pipeline should consider linking strategic value to metrics in speed, quality, productivity, and sustainability.[46] Use cases that improve the quality of data, assets, and decision-making have the potential to reduce failure rates across R&D phases.[47]

Productivity and quality may offer the largest gains provided by GenAI in the near term, followed by speed, then sustainability over the next decade.[48] Considering individual use cases along these metrics may help determine an optimal string-of-pearls strategy—where use cases are combined to unlock the full value of GenAI.[49] Strategic applications of AI can be found all across the R&D value chain (figure 4).

When developing the business case for investment in digital and AI, the short-term costs need to be balanced against the long- term efficiency gains. Executing large-scale strategies requires setting up a governance function for making investments, assessing value realized, and monitoring ethical and legal risks from the use of AI.[50]

For more information on the string-of-pearls strategy, read the **Extracting value from Generative AI and emerging technologies** section of the 2024 Global Life Sciences Sector Outlook.

Figure 4. Strategic applications of AI across the R&D value chain

	Role of AI	Value levers
Drug repurposing	Perform meta-analysis of clinical trial and research data to generate high quality hypothesis for drug repurposing	• Reduced pre-clinical costs • Reduced time to market • Higher NDAs
AI-driven drug discovery	Optimize target and biomarker identification and shortlisting candidates while assessing toxicity and therapeutic efficacy	• Improved clinical success rate • Lower failure rates • Higher number of NDAs
Rapid design and setup	Automated protocol generation, drafting of study documents (consent form, agreements) and regulatory submissions	• Lower average protocol authoring time • Lower average time to first enrollment
Digital data flow	Collate and standardize trial data elements to create analysis-ready data sets and to auto-populate tables and charts in trial artifacts (e.g., case report forms)	• Reduced total time per phase • On-time database lock • Faster documentation creation
Regulatory intent and submission excellence	Identify regulatory requirements across geographies, generate drafts of dossiers, and understand competitor regulatory strategy	• Higher regulatory success
Participant experiences	Enhancing participant experiences with strategic nudges to revolutionize recruitment and retention strategies	• Reduced drop out rate • Faster recruitment • Lower terminations for insufficient recruitment

Source: Deloitte UK, "Unleash AI's potential - Measuring the return from pharmaceutical innovation," April 2024.

Setting near-term GenAI objectives

Small molecule de novo generation is already delivering value, and the next wave of opportunities being developed are in the clinical arena, from operations and delivery to patient experience.[51] In the near term, organizations should look to organize data more effectively, in addition to identifying early wins from productivity gains across functions.[52] The quality and comprehensiveness of proprietary data that these algorithms are trained on are expected to be a differentiator. As GenAI becomes a core capability within R&D data science teams, organizations should also have strategies in place for developing their future workforce.[53]

Accelerating speed in clinical trials

The pace for scientific and technological advancements is accelerating, from gene therapy to AI, but challenges in clinical research remain, including:

- The ability to recruit and retain a representative patient population
- The delayed response to operational problems
- The reliance on incomplete or un-insightful data sources

Ultimately, transforming clinical trials could require companies to work in very different ways, drawing on change management skills as well as partnerships and collaborations. This may require companies to develop highly skilled interdisciplinary leadership and AI experts who can innovate, organize, and guide others as well as AI-friendly CEOs and board members to push for the adoption of AI.[54]

Strategic CGT partnerships trigger speed to value

Discovering how fast novel treatments can reach rare disease patients

In late 2023, the US FDA approved the first cell and gene therapy (CGT) treatment using CRISPR gene-editing technology to treat sickle cell disease—Vertex Pharmaceuticals' Casgevy.[55] The treatment is being viewed as a test case for how fast these trailblazing medicines can reach patients (in 2024, experts will be tracking the results).[56] Some suggest that if more than 2%, or about 2,000 US sickle cell patients, benefit from CGT over the next year, it may be a marker of progress for the disease. [57] There are 100,000 sickle cell disease patients in the US.[58] Tracking the speed at which revolutionary medicines reach patients may provide new insights and value.[59]

> "I think this is a pivotal moment in the field. It's been really remarkable how quickly we went from the actual discovery of CRISPR, the awarding of a Nobel Prize, and now actually seeing it being an approved product."
>
> **— Alexis Thompson,** M.D., Chief of the Division of Hematology at Children's Hospital of Philadelphia[60]

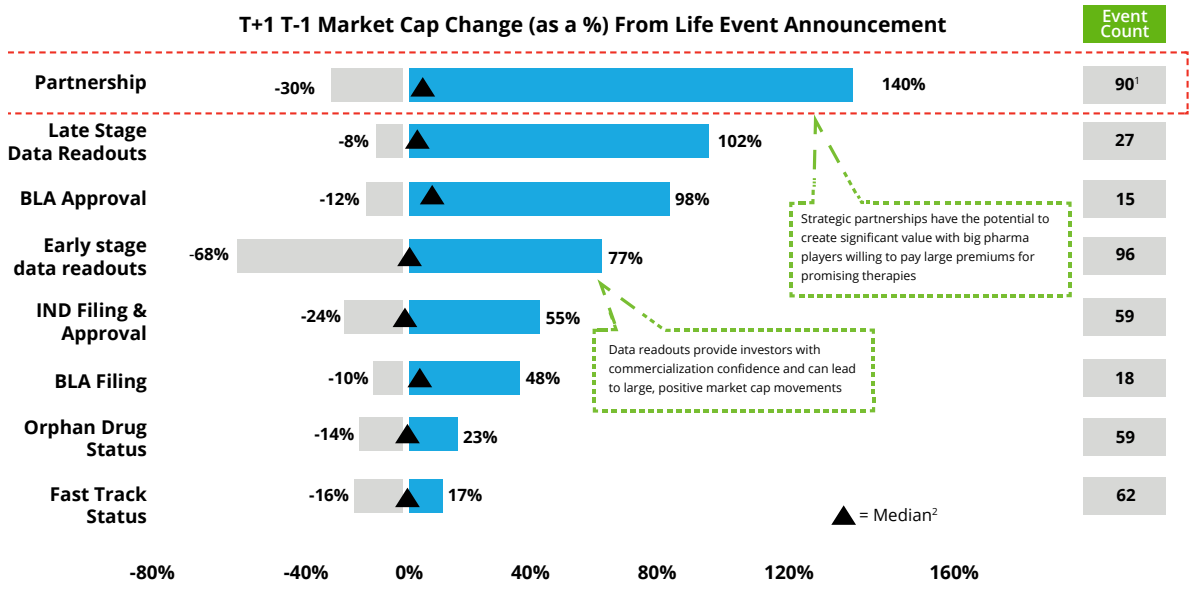
The Casgevy approval was quickly followed by another CGT approval for sickle cell disease, Bluebird Bio's Lyfgenia.[61] In 2023, Bluebird Bio said that its study for Lyfgenia was the longest follow-up of sickle cell patients to date—following 47 patients over 5 years[62]—and the National Heart, Lung, and Blood Institute (NHLBI) points to its transparency and collaboration as laying the groundwork for other technologies to follow.[63] The company says a validated access and reimbursement strategy is driving a favorable insurance coverage landscape.[64]

Successful partnerships involve a combination of commercial and R&D arrangements

What moves the needle for CGT investors after regulatory approvals is what happens when a company is closer to having a commercial product, according to Deloitte US' CGT Market Index research team.[65] Strategic partnerships top the list of triggers, with market cap increasing by as much as 140% for companies announcing partnership arrangements with another, typically large pharma company (figure 5).[66]

Figure 5. Deloitte CGT Market Index™ value triggers

Limited number of triggers correlate with an increased market value for CGT companies, data as of 2023



Source: Deloitte US analysis

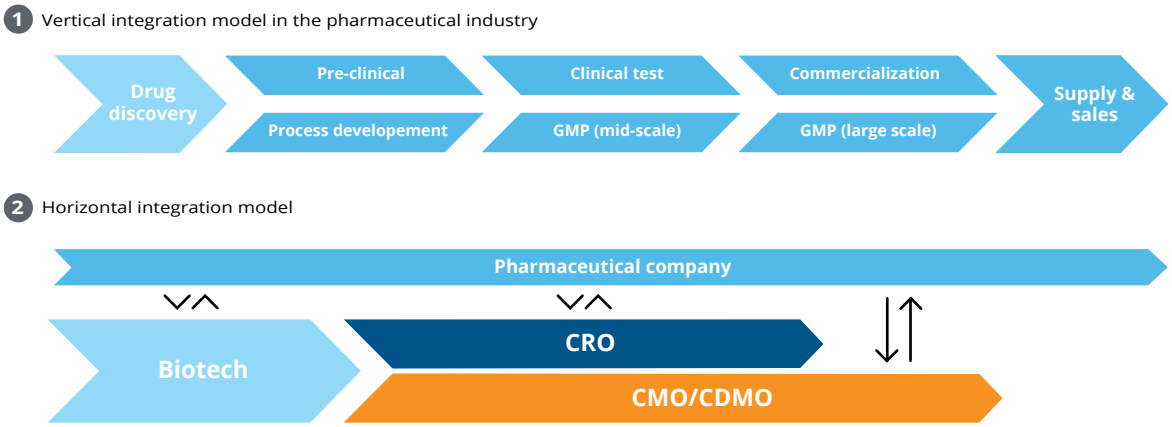
Research demonstrates that the most successful partnerships involve a combination of commercial and R&D arrangements, not one or the other. These partnerships typically combine the technological expertise of CGT companies with the asset development experience, clinical trial know-how, market access, and distribution channel infrastructure of larger companies.[67]

On the other hand, manufacturing partnerships did not trigger positive results, while contract manufacturers did derive more value than a company undertaking construction of its own costly facility.[68] Overall, companies stringing together multiple milestones realized continued high-impact value creation multiples over those hitting just one milestone and then moving on.[69]

Outsourcing for time and cost savings

Outsourcing is on the rise for both biotech[70] and pharma companies to accelerate speed to market.[71] Like the semiconductor segment, the pharmaceutical ecosystem has a mature horizontal division model of drug discovery and manufacture by biotech and pharmaceutical companies (figure 6).[72]

Figure 6. Horizontal division of roles in pharma



Source: Copyright © 2022 Kurata, Ishino, Ohshima, and Yohda, "CDMOs Play a Critical Role in the Biopharmaceutical Ecosystem," Frontiers in Bioengineering and Biotechnology, 21 March 2022.

As many pharma companies adopt digital practices to shorten development timelines and reduce R&D costs, more are forming strategic alliances, outsourcing, or acquiring early and late-stage capabilities. There appears to be proliferation of collaborative research agreements/partnerships in the early drug discovery and preclinical drug development stages. In clinical trials, patient recruitment and clinical lab and diagnostics testing areas are seeing more outsourcing.[73] The number of contract research organizations (CROs) are growing,[74] and pharma companies are turning to flexible manufacturing in response to changing regulatory and market needs.[75]

Proliferation of CROs facilitate experimentation

CROs and other contract service firms allow chemical expertise to be acquired rather than developed, which may enhance speed to market.[76] These molecule-on-demand firms have altered experimentation as artificial intelligence and machine learning help to design new drugs.[77]

The growth in CROs is behind a renaissance in small molecule discovery with developers learning novel ways to use small molecules to target disease.[78] In 2023, sales of the top 10 selling drugs were split 40/60 between small molecules and larger, more complicated biologics where sales were dominated by a few biologic blockbusters.[79]

Globalization of contract development organizations (CDMOs)

Life sciences and medtech companies are considering new ways of working to help ensure product safety and quality without sacrificing speed. Companies adopting cutting-edge technologies, employing advanced process automation/continuous manufacturing, and incorporating real-time monitoring and modular facilities designs, may quickly and efficiently adapt production processes to accommodate varying product types, volumes, and customer demands.[80]

While some pharma companies in Europe favor regional CDMO services for close proximity to markets, innovation capabilities, and talent, CDMO services are being globalized by China and India. These two countries are projected to experience the largest CAGR growth in the CDMO industry—9.63% in China and 11.34% in India.[81]

C "R" DMO outsourcing model emerges globally to accelerate therapies

As drug makers seek to increase efficiency and productivity and gain access to advanced technologies, there is a growing demand for outsourcing technology solutions that provide more integrated end-to-end services.[82] Drug makers are starting to seek out contract research development manufacturing organizations (CRDMOs). These operators consider

themselves science and technology platforms that also bring the "R," or research, into the CDMO mix.[84]

CRDMO facilities are starting to spring up around the world—including in China, Singapore, the US, and Italy. By consolidating and unifying the CRO and CDMO models, companies see an opportunity to accelerate the time it takes to bring new therapies to market.

"Building end-to-end capabilities and offering integrated solutions in the small molecule space is our vision. Clients and the market want a one-stop shop and a partner who can take care of the entire project."

—Giovanni De Filippo, Fine Chemicals Sales & BD head, Angelini Pharma SpA[85]

New drug approvals and launches

A total of 69 novel active substances (NASs) were launched globally in 2023,[86] led by the US, with 55 compared to 37 in 2022.[87] Over the past five years, NAS launches around the globe totaled 362.[88] The tally of NAS launches in China is on the rise, but an increasing number are not available outside China, reflecting an increasingly domestic industry.[89]

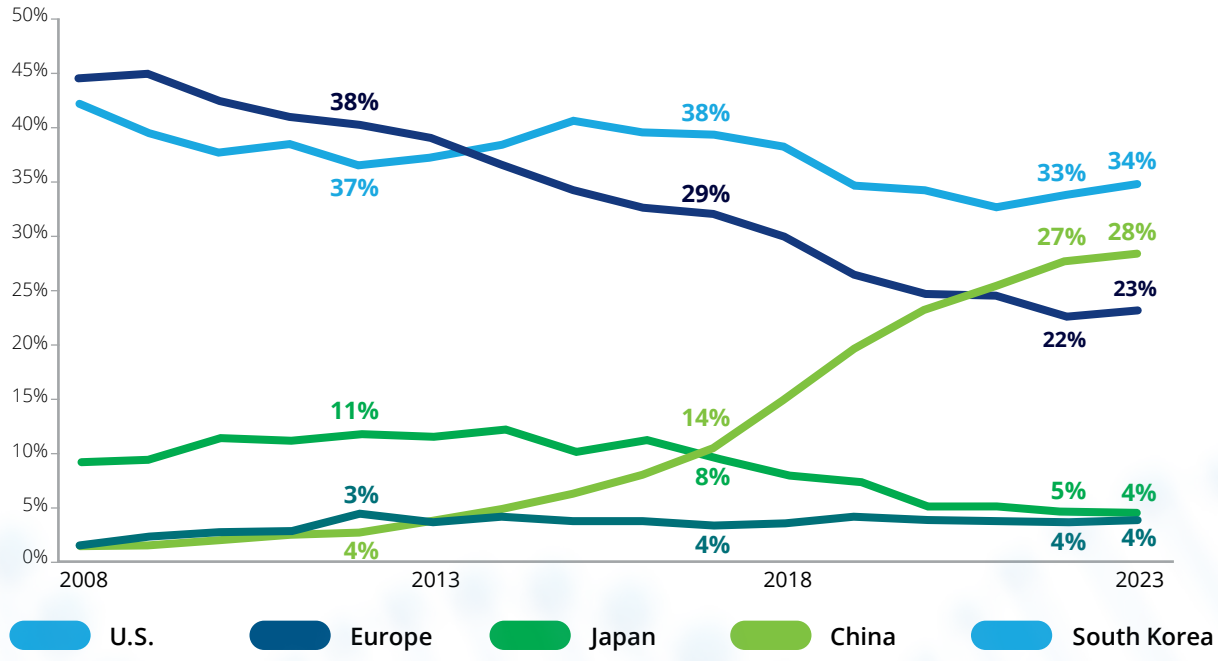
China eclipsing Europe and gaining on the US in R&D

Clinical trial starts are increasingly global with Asia experiencing the largest growth in recent years. China moved ahead of Europe in NAS launches as well as in clinical trials to reach the number two spot behind the US globally.[90] While China's NAS launches are domestic, China's clinical trials are increasingly global.

Only about a third of all clinical trials are being held in the US as the US clinical research footprint shifts overseas.[91] China is only a few points behind the US, with 28% of all clinical trial starts from China-headquartered companies in 2023—a significant jump from only 3% a decade ago (figure 7).[92]

Notably, China also reached the number two spot for worldwide R&D expenditures across all industries, surpassing the EU (17.5%) with 17.8%, mainly as a result of its tech sector.[93] For China's pharma companies, high expenditures on R&D and procurement are shrinking profit margins.[94]

Figure 7. Number of Phase I to III trial starts based on company headquarter location, 2008-2023



Source: IQVIA, "Global trends in R&D 2024," 2024.

Currently, the US leads biopharmaceutical innovation, supported by its large domestic market, IP protections, limits on government drug price setting, supportive science policies, and supportive innovation clusters.[95] However, the US is experiencing rising drug pricing pressures and US policies may weaken foundational IP protections.[96]

Critics point to lessons learned as a result of the US decline in semiconductors and telecommunications, where the US originally held leadership positions. Policy analysts suggest policymakers should not attack pharmaceutical companies but focus more on how to win the global battle for pharmaceutical sector competitiveness.[97]

Funding biopharma R&D

How biopharma R&D unfolds depends on the ability to effectively partner across geographies and between the public and private sectors. This highly collaborative process can affect decision-making about R&D investments.[98] Ultimately, financing for R&D can play a major role in whether the medicines and treatments that patients need are developed.[99]

Researchers recently explored how pharmaceutical R&D is financed and how this may evolve in the future.[100] Of the total US$300 billion spent on pharmaceutical R&D, large pharmaceutical companies represent almost two-thirds of investments.[101] Public and not-for-profit sectors contribute a quarter of the total (US$75 billion).[102] These essential scientific advances may then flow downstream for private R&D sector investment.[103] Venture capital currently accounts for about a tenth of the total investment.[104]

Calls for more research into drug development productivity/value creation

Some AI researchers say that more funding should go to academia to study ways to cut costs and improve pharmaceutical R&D productivity as there is scant research on how value is actually created.[105] The US Congressional Budget Office (CBO) also recently called out a need for more research.[106]

The CBO uses a simulation model of drug development to analyze legislative proposals and incorporates feedback from academic and industry experts to inform its model. Life sciences and medtech leaders should be aware that the agency recently expressed interest in researching:

- How changes in the future profits of pharma companies might affect the development of drugs with differing characteristics (e.g., small and large molecules),
- How changes in the number of new drugs can affect health outcomes, and
- How policies—such as price negotiation or accelerated drug approvals—could affect companies' decisions about which indications to target for approval.[107]

Shifting trends in openness: Globalization vs. localization and impacts for multinational companies

Life sciences and medtech companies are increasingly global, and the global economy is moving toward a new normal—a shift away from peak globalization.[1] The United Nations' latest "World Openness Report 2023" shows "world openness" falling 0.4%—a downward trend amidst a growing move away from openness between countries, sectors, and regions.[2] Declining interdependence between countries may have negative consequences for global trade and overall prosperity.[3]

The Asia-Pacific (AP) region is expected to yield among the highest growth over the next several years—due to its sizable consumer base, increasing disease incidence, and supportive regulatory frameworks[4]—and China and Japan are among the largest economies in the pharma and medical device markets (figure 1). In AP we see two understandable but diverging approaches being taken by the second and third largest life sciences countries in the world. China is advancing policies that prioritize its own national interests and technologies,[5] while Japan's trade openness is at its highest level historically—at almost 47% and up about 10 points from 2021 to 2022[6]. The multiple factors driving these diverging models include trade corridors, macro political dynamics, access to talent, views on growth, and IP protection.

Figure 1. Top pharma and medical devices markets by country, growth forecast 2019 to 2028

	Top 5 Pharma Market by Country			Top 5 Medical Device Market by Country		
Country	2019 Sales (US$ B)	2023 Sales (US$ B) E	2028 Sales (US$ B) F	2019 Sales (US$ B)	2023 Sales (US$ B) E	2028 Sales (US$ B) F
US	**453**	**571**	**704**	**165**	**205**	**262**
China	**121**	**165**	**237**	**30**	**43**	**61**
Japan	**106**	**100**	**163**	**33**	**33**	**43**
Germany	**77**	**87**	**111**	**32**	**37**	**46**
France	**41**	**47**	**57**	**18**	**20**	**24**

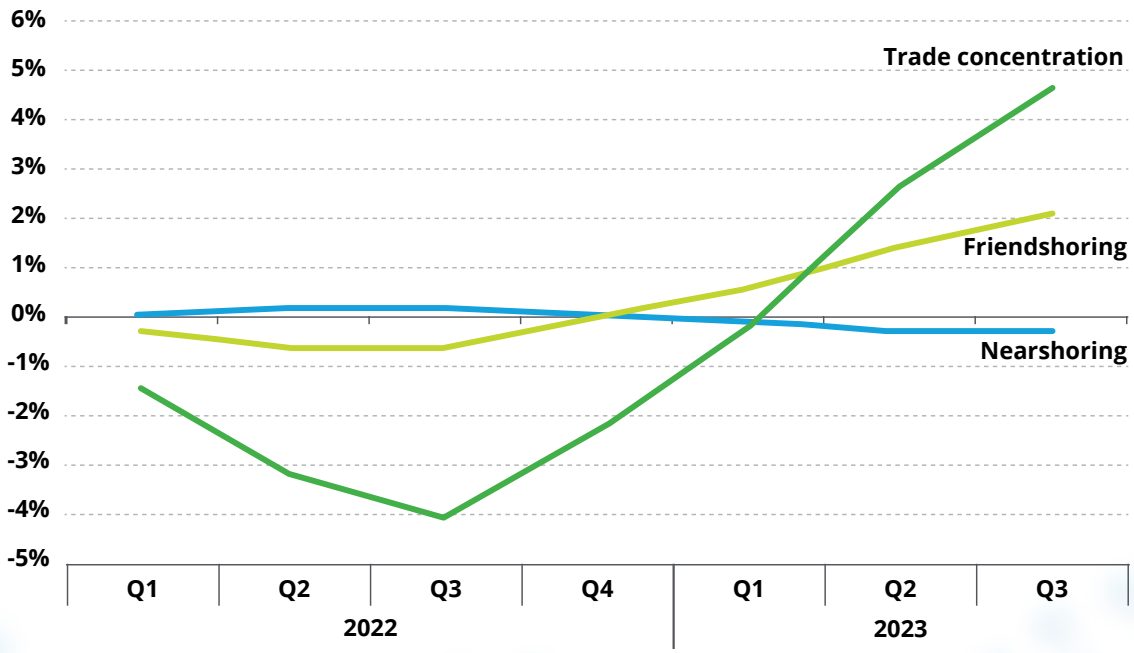
Source: EIU and Statista Market Insights

Globalization is not dead, but changing

Global connectedness may be measured by the flow of trade, capital, information, people, technology, and ideas—and while globalization is not dead, it is changing.[7]

During the pandemic, trade and supply chains were vital to increasing the production and distribution of medical supplies, including vaccines.[8] However, in the past two years, global trade is noticeably more concentrated and geopolitically close, relying on a smaller pool of trading partners (figure 2).[9]

Figure 2. Global trade patterns' geopolitical turn, bilateral trade changes since Q1 2022



Source: UNCTAD, United Nations Trade Update 2023

On the whole, international trade flows are still proving resilient, while some stakeholders question the threat of *deglobalization*.[10] The volume of cross-border engagement is a valuable measure for economic growth,[11] and the World Trade Organization (WTO) believes recent trends need monitoring.[12]

In 2024, marked difference in growth among regions is expected to continue,[13] part of the glocalization trend—a blend of *globalization* and localization, involving:

- shorter supply chains,
- an emphasis on re-establishing domestic manufacturing capacity, and
- a more strategic role for government.[14]

Tracking trading patterns

After a dip in 2023, the expectation for growth in global trade is rising—3.3% growth is projected for 2024.[15] The two emergingly divergent models in China and Japan, highlighted earlier, are also demonstrated by their current trading patterns.

Experts say China is likely to remain the world's leading exporter for the near future, but its export dominance in the global economy may be peaking.[16] Between EOY 2022 and EOY 2023, China's exports decreased by US$10.4 billion or -3.39%, primarily impacted by a decrease of over 20% in exports from China to the US.[17] However, the US remains China's top trading partner in exports followed by Hong Kong, Vietnam, South Korea, and Japan. China increased imports in 2023, with the US, South Korea, and Australia as leading partners[18] China's growth objectives point to becoming a high-income economy, rather than simply raising GDP.[19]

Japan is the fourth largest economy by GDP, as Germany moved ahead of Japan in 2023 to claim third place behind the US and China.[20] Almost a quarter of Japan's trade is with China,[21] and Japan's export of goods and services is on the rise—climbing 4.1% in 2022 above pre-pandemic levels.[22] Japan exports almost equal to both the US and China.[23]

Pharmaceutical goods import and export ratios

Pharmaceutical trade started to rise in the third quarter of 2023,[24] and the global market for pharmaceuticals is expected to reach almost US$1.2 trillion in 2024.[25]

Japan, the third largest pharmaceutical market, imports about three times the pharmaceutical products it exports (figure 3)[26] and is a critical export market for US pharmaceuticals.[27] Historically, Japan has accelerated economic growth with "external" globalization through expansion of trade and outward foreign direct investment (FDI).[28] As of 2021, Japan is the largest source of overall FDI into the US, with an FDI stock of US$721 billion.[29]

China has a relatively equal level of pharmaceutical product imports and exports.[30] Currently, the US and China are relying more on each other for pharmaceuticals, with the US exporting semi-finished/end products and China exporting API.[31] The US imports US$10.2 billion in pharmaceutical goods from China, while exporting US$9.3 billion to China, driven by advanced medicines such as cancer treatments and antibiotics.[32] Despite progress in some areas, barriers for trade with US companies remain challenging.[33]

Figure 3. Comparison of 2021 pharmaceutical imports and exports, China, and Japan

Pharmaceutical Goods	China	Japan
Imports	US$34.1B	US$30.3B
Exports	US$36.0B	US$10.2B

Source: OECD (Organization for Economic Co-operation and Development)

US-China tech wars continue to affect medtech and technology companies

Revenue in the medical device market is projected to reach US$182 billion for the US and US$36.38 billion in China, in 2024.[34] The US is the top exporter and importer of medical instruments; China is fourth in imports, fifth in exports; and Japan is fifth in imports.[35]

China and Japan lead exports for semiconductor devices that are essential for therapeutic medical devices; Hong Kong, China, and the US lead imports.[36] Integrated circuits dominate the semiconductor market, and China experienced sharp declines in these imports—a drop of 15.3% in 2022 and 15.2% through Q3 2023 YoY in the number of units.[37]

Domestic production and exports are starting to show more resilience. In 2024, China is expected to lead chip recovery mid-2024, but the US plans more export controls on high-end AI chips.[38] In 2023, Japan also introduced export controls, limiting 23 different types of chips sales to China.[39]

The demand for chips that are optimized for Generative AI and investment in AI-supporting servers is bolstering demand in Japan, according to the Semiconductor Equipment Association.[40] Despite being down at the beginning of the year, Japanese chip gear sales are forecast to climb 27% in the fiscal year[41] that starts in April 2024.[42] Japan's new industrial policies are aimed at restoring the international competitiveness of its semiconductor industry.[43]

China's "new whole-nation system" was also put into place to advance its R&D, including spurring its semiconductor industry to catch up with global competitors.[44] Some believe current US tech bans are stimulating a domestic ecosystem[45] and motivating China to deliver on its own technological breakthroughs.[46] But China still lags two to three generations behind Taiwan and South Korea in manufacturing the most advanced chips.[47]

Multinational corporations (MNCs)—like Intel, GE, NVIDIA, and Qualcomm, among others—are lobbying government officials to find ways to temper the blow of export controls.[48] For example, NVIDIA introduced less powerful chips in China in December 2023 to comply with US export restrictions.[49]

> "MNCs need to monitor the global and China local environment closely, continue to leverage industry associations to influence government policy, and keep their China strategy adaptable to external changes."
>
> —**Medtech** CEO of MNC operating in China[50]

Heightened scrutiny for biotech foreign investments

China and the US share ties in biotech R&D and commerce, and the Committee on Foreign Investment in the United States (CFIUS) is increasing scrutiny of Chinese investment in the US biotech industry. Companies with "critical technology" or "sensitive personal data" are at greater risk and should be prepared for potential CFIUS challenges in 2024, related to foreign transactions for investment.[51]

Market leaders remain committed to business in China

As geopolitical tensions rise, many top life sciences and medtech MNCs report they remain committed to China in 2024, but expect more regulatory scrutiny and market access challenges.[52] Pharmaceutical MNCs are reworking business models[53] as they watch price cuts play out and internal priorities shift.[54]

Medtech and technology companies operating in China are also monitoring the macroeconomic situation as they remain susceptible to disruptions in supply chains.[55] Global political tensions in 2024 are the primary concern of 90% of US medical device executives in a survey of C-suite executives by the Deloitte Center for Health Solutions.[56]

> "The China pharma market will remain a very important focus for us, as its size and scale will continue to rise. The growth will be slower going forward (although we have the ambition to grow double digits in 2024). Currently our HQ leadership team has a very 'balanced' view on China—neither bullish nor negative."
>
> —**Pharmaceutical** CEO of MNC operating in China[57]

Opportunities in the China market

For pharmaceutical MNCs, the vast size and scale of the China market is a magnet for expanding global plans,[58] and China is raising R&D investment by 10% in 2024 to speed up scientific and technological breakthroughs.[59] There is an opportunity to make considerable progress in the development of treatments for chronic as well as rare diseases.[60] For the treatment of rare diseases, drug cost and affordability are in need of further legislative and policy support.[61]

China is also an attractive market for medical device companies looking to strengthen their industrial and supply chain resilience.[62] Since Q3 2023, Medtronic started showing stronger-than-expected recovery for its procedure volume in China.[63] The company reports that the impact of value-based procurement (VBP) is "largely behind us as the majority of its product portfolio has been repriced."[64] Medtronic CEO Geoff Martha says that the company is continuing to invest in China because "it's a big market, and it's growing."[65]

Acceleration of centralized anti-corruption efforts

Medtronic says it has not been affected by anti-corruption issues, which are expected to continue to be a factor in 2024.[66] China's latest anti-corruption campaign by the central government in China includes rectification efforts by 14 government agencies, including China's National Health Commission (NHC).[67] Research shows bribery has been the most common form of corruption in the medical sector, and new policies reflect a "zero-tolerance attitude."[68] While healthcare providers are most often cited as taking bribes, pharmaceutical and medical equipment suppliers are also said to be paying the bribes.[69]

China's rectification efforts are not likely to be short-term in duration or impact—possibly lasting for five years followed by rigorous and regular enforcement, according to recent research into the anti-corruption campaign by Deloitte China.[70] With tightened pharmaceutical regulation, pharmaceutical companies should urgently construct comprehensive and effective corporate systems to facilitate compliant business operations.[71] In the context of rectification, product R&D can help pharmaceutical companies improve their competitiveness in China's health care system.[72]

Operating in China is complex

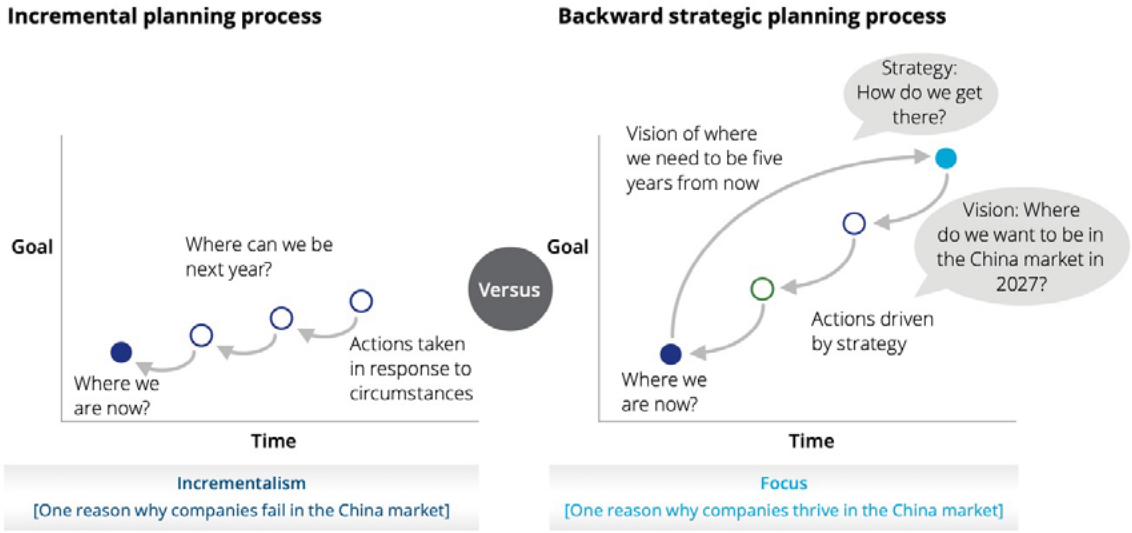
Changes in geopolitics, technology, regulations, and local competition makes operating in China challenging for MNCs. But addressing these challenges may open up new markets and opportunities.[74] From the experiences of successful and unsuccessful MNCs in China, Deloitte China finds that it may be better to implement a strategy that is focused, as opposed to one that is reactive and incremental (figure 4).[75]

Meeting the challenges of the China market

Alongside opportunities, MNCs operating in China face challenges, especially due to growing local competition. China's use of intellectual property (IP), forced technology transfer, and many market access matters may still impede multi-national firms from operating on equal footing with local Chinese firms.[76] Since the government of China introduced the "Made in China 2025" strategic plan in 2015, China has had its sights on capturing a much larger share of the biopharma and advanced medical device markets.[77]

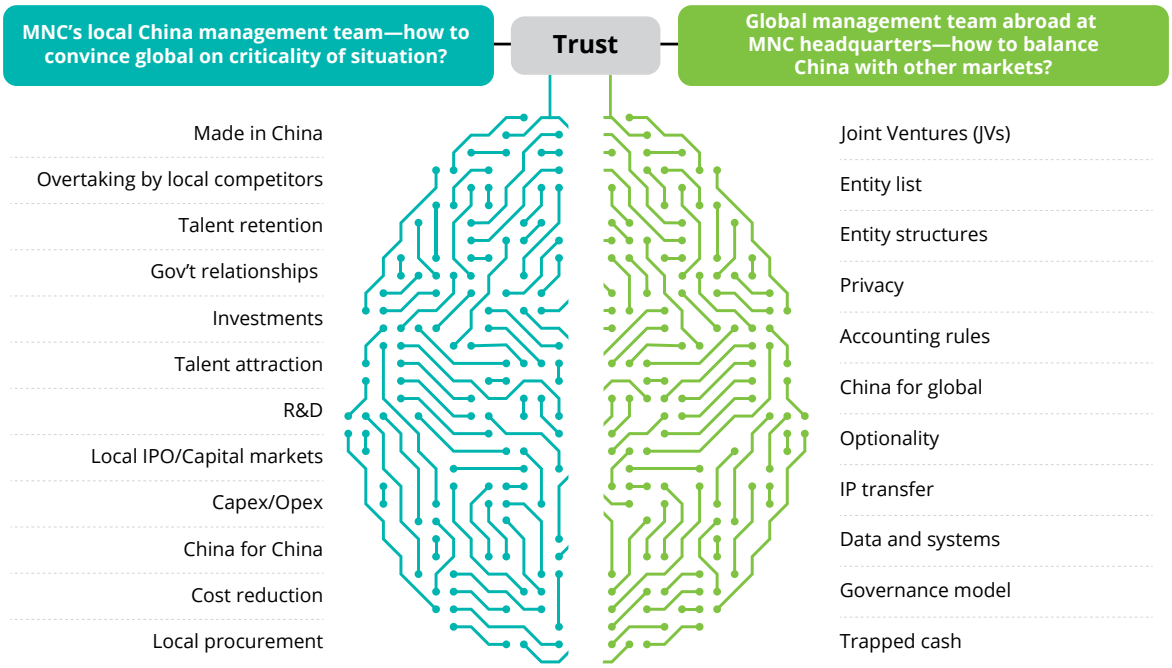
In recent years, alignment between an MNC's corporate office in China and its global headquarters outside of the country has been tricky. During the COVID-19 pandemic, MNCs' global leadership teams were unable to visit China, and without face-to-face interaction, some found challenges in effective communication. To bridge trust and improve communication between global and local management teams often includes balancing China with other markets, while also understanding the critical needs of local management in China. (figure 5).

Figure 4. Incremental vs. focused strategy



Source: Deloitte China, *MNC Localization 2.0*, 2022

Figure 5. Bridging trust between global and local management teams



Source: Deloitte analysis

China expects foreign MNCs operating in China to become more localized and support local growth.[78] Toward the end of 2023, Pfizer, Sanofi, and Biogen all tapped local collaborators to help commercialize their products in China.[79] As marketing responsibilities shift to other firms, job cuts are expected at each of the leading drugmakers.[80]

"MNCs need to work out a balanced action plan to address the short-term challenges—geopolitical conflicts, volume-based procurement (VBP), diagnosis-related group/diagnosis-based intervention packet (DRG/DIP), 'buy local'—while also seeing China's long-term opportunities, like 'Healthy China 2030,' therapy penetration to cover a broader population, and the potential growth in health care expenditures as a percentage of GDP, from about 7% in 2020 to 9% in 2030."

—**Medtech** CEO of MNC operating in China[81]

Drug and device pricing impacts in China

China's regulatory changes have been altering portfolios and business models for MNCs, and in particular, go-to-market strategies.[82] China's VBP, DRG (fixed payment), and DIP (price-adjusted payment) pricing plans seek to reduce the cost of drugs and devices by awarding large volume sales to tender winners with the lowest price in cities, provinces, or the country.[83]

As the Chinese government sees the benefits of these price cuts, it has expanded product categories.[84] At the end of 2023, China rolled out its fourth national high value consumables VBP, and tenders expect to be carried out in mid-2024. Some medtech devices saw dramatic price reductions—11 artificial intraocular lens products averaged 58% in price cuts, and 19 sports medicine products averaged 72% in price cuts.[85]

Drug products also underwent price cuts in late 2023, averaging 58% as part of the ninth national pharma VBP. Of more than 260 drug products undergoing preliminary bids, only five are supplied by four foreign companies.[86]

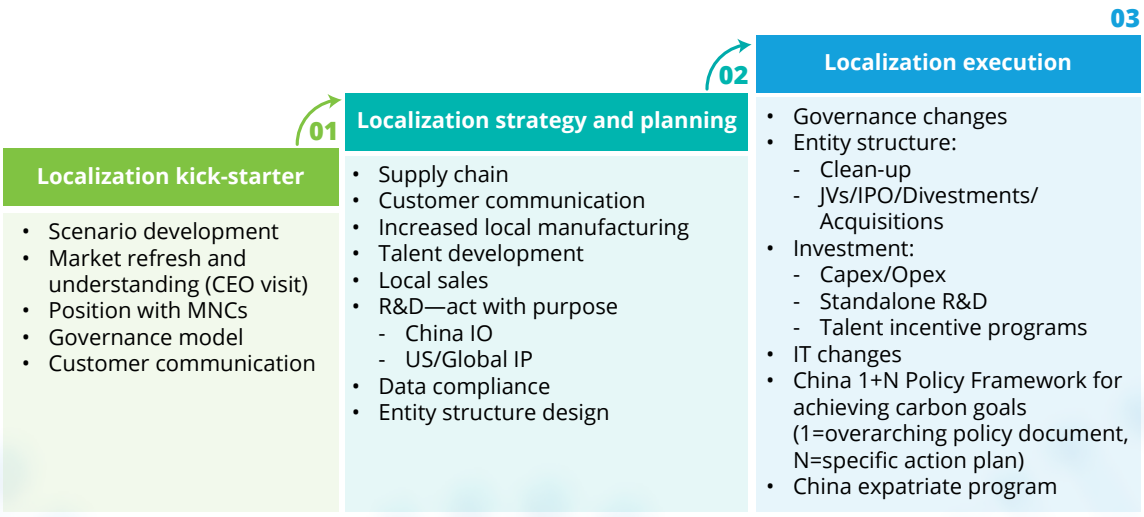
"By 2024, about 80% of high-value consumables will go through VBP, and VBP-winning products are the major products that China patients can have access to under the current policy. We saw there are clear needs from China patients for differentiated, better quality, and more advanced technology/innovation products. MNCs need to continue to influence the government to enable this offering to patients through the public hospital evaluation system, DRG/DIP payment exception, and commercial insurance, etc."

—**Medtech** CEO of MNC operating in China[87]

Advancing a localization strategic plan

Localization has been a continuous theme in the evolving China market, and MNCs should be advancing their localization plans—to not just be competitive in the China market but also to address the increasing risks surrounding supply chain disruption and technology and data sovereignty. There is no one-size-fits all formula, and each company is at a different stage (figure 6).

Figure 6. Stages of advancing a localization plan in China for MNCs



Source: Deloitte analysis

Building local support in China

Life sciences and medtech MNCs are expected to show support for local initiatives.[89] The Healthy China 2030 initiative is China's health reform to improve the country's public health services, medical industry, and food and drug safety. Its focus is on prevention rather than treatment.[90]

Recently, Pfizer demonstrated its support of Healthy China 2030 by signing an agreement with China to cooperate on improving the country's health coverage. The memorandum of understanding with the Health China Research Center plans to support public health research and improve the health of rural populations.[91]

Bringing talent back home, attracting new sources of R&D innovation

Over the last 25 years, China's R&D spending to GDP share has risen from 0.56% to 2.4% and is likely to surpass Japan and Germany in the next decade, given its current momentum.[92] Local Chinese companies have been spending relentlessly on R&D and, as a result, are making advances on the technology front.[93]

To capture its share of biopharma and medical device markets, China knows it must innovate, not just copy, to succeed. In recent years, it launched more than 200 talent recruitment programs to attract high-caliber scientists globally. China's Thousand Talents Program (TPP) recruits Western-educated Chinese STEM researchers back to China. A recent study found TPP to be successful in attracting promising young scientists with cash and lab support, but less successful in luring high-caliber researchers. These more established researchers prefer the West for less "administrative intervention."[94]

However, the research also shows that over time, the support has enabled returning foreign-educated researchers to surpass their peers who stayed abroad in publishing productivity. Productivity rose 27%, including publication in high-caliber journals.[95]

There are more than 1,600 MNC R&D centers operating in China, and more than US$38 billion worth of intellectual property has been imported.[96] Currently, China is encouraging foreign investors to establish R&D centers in China to undertake major scientific research projects.[97]

In August 2023, the China State Council released "*Opinions to Further Optimize the Environment for Foreign Investment and Increase Efforts to Attract Foreign Investment*".[98] The opinions in the policy call for relevant departments to develop a convenient management mechanism for cross-border data transfer security. The policy also conveys that the Chinese government intends to facilitate the entry-exit and residence of foreign executives and technical personnel (and their families) from foreign-invested enterprises.[99, 100]

China CEO insights on innovation in 2024

In surveying CEOs from MNCs operating in China,[101] many identified innovation as a primary driver for success in China, but there were various views on the state of innovation and how to generate true innovation. Some felt that digital innovation has been applied widely, while others say that the state of AI and "the tools available are behind what is done elsewhere in the world." One pharmaceutical CEO says that the "vibrant growth of domestic innovation injects new vitality into the China pharmaceutical market, but also intensifies competition." Another believes that "the most important initiatives for 2024 will be around 'education and engagement' of patients and health care providers in China."

> "MNCs need to continue to accelerate innovative product launches in China while at the same time creating differentiation and value propositions in specific areas, striking a better balance between price and quantity, and exploring various payment methods in order to maximize the value of innovative drugs."
>
> —**Pharmaceutical** CEO of MNC operating in China[102]

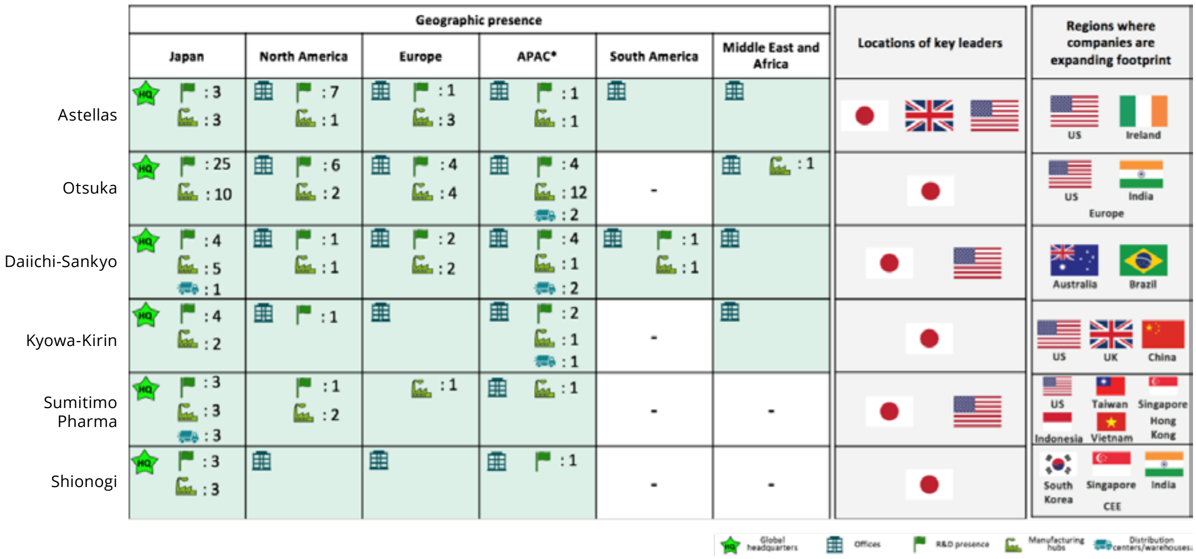
Active globalization efforts in Japan

Expanding footprints of Japanese pharma companies

The Japanese pharmaceutical industry has been actively participating in globalization efforts and activities—increasing their global presence through M&A, collaborations, broader R&D, and expansion into emerging markets. They are less dependent on local revenue, generating more than half of their revenue outside of Japan. Takeda, the largest pharmaceutical company in Japan and currently 17th largest in the world, leads in its globalization efforts with a global presence in more than 80 countries.[103] With over 20 years of a deliberate strategy to expand and serve globally and more recently- 10 years of comprehensive transformation already underway, Takeda is an 'exceptional' Japanese head quartered company but one which is really a globally "headquartered" across Japan, the US and Europe (Switzerland). Takeda has been led by Christophe Weber, its first non-Japanese CEO, for almost 10 years. He shared in an interview in 2021, "When I joined the company in 2014, the ambition was to make two big changes. One was to transform the R&D capabilities so we could improve productivity. The second was to globalize the company, to increase scale, so we could be more competitive."[104] During this journey, Takeda has acquired multiple other multi-national pharmaceutical companies (e.g., Millennium Pharmaceuticals, Shire Pharmaceuticals among others) and committed to a global enterprise business model and strategy. Its early commitment to a comprehensive globalization path is distinctive in the Japanese pharmaceutical market.[105]

After Takeda, Astellas Pharma has the maximum presence outside Japan, both in terms of facilities and leadership locations, and conducts business in approximately 70 countries around the world. In contrast, Shionogi has a more limited presence outside Japan, as its R&D centers are concentrated in Japan. However, most of the Japanese pharmaceutical companies are expanding their presence in the US followed by Asia-Pacific (APAC) and Europe (figure 7).

Figure 7. Geographic presence and expanding footprint of Japanese pharma companies (beyond Takeda)



Source: Deloitte Japan analysis

Notes: 1. APAC—Asia-Pacific, includes all of Asia and Oceania, except Japan. | 2. CEE—Central and Eastern Europe. | 3. Firms have multiple offices across regions.
4. For Otsuka and Sumitomo Pharma, some of the R&D facilities are combined with manufacturing hubs.

Making progress in the globalization journey

US and EU pharmaceutical companies utilize a functional management approach in managing business functions, organized by disease region (figure 8). Early-stage pharmaceutical companies in Japan are managed by region. By prioritizing regional business expansion, these companies are looking at increasing market share in a region or country.

More advanced pharmaceutical companies in Japan have started the move towards managing by global function, rather than region. This approach is more centralized where multiple regions are managed by the headquarters across an optimal distribution of tasks and resources.

To increase R&D productivity, some companies are looking at moving more R&D functions outside of Japan, but talent is scarce. In 2024, these companies can expect increased competition for talent with global expertise.

Growing optimism for growth through collaborations

In 2024, as leading life sciences and medtech companies look to balance both a global and local perspective in Japan, more are exploring collaborations to drive growth.[106] Bristol Myers Squibb (BMS) aims to double the size of its Japan business over the next decade, driven not only by its internal products and pipeline but also through partnerships.[107] Currently, as much as 60% of the drug giant's development pipeline is externally sourced, with BMS poised to further promote collaborations that bolster its portfolio.[108]

BMS in Japan generated sales of approximately US$1.4 billion in 2022, and the company's "Japan Moonshot program" is designed with the aim of doubling this revenue over 10 years by:

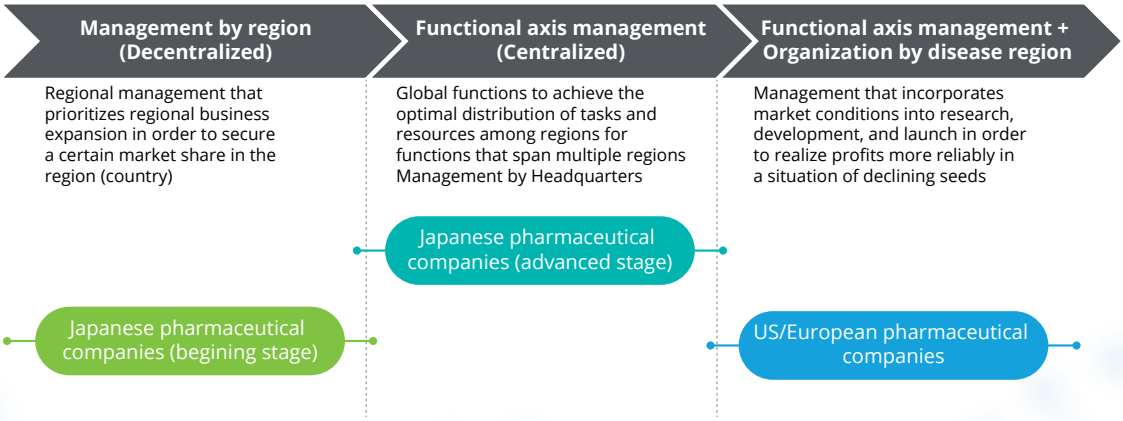
- Gaining new drug approvals
- Growing existing products including through label expansions
- Accessing external innovation[109]

A string of product launches are also part of the doubling plan.[110] Of nine new medicines already approved by the US FDA, three have attained the green light in Japan, and others are either under regulatory review or in mid- to late-stage clinical development.[111] There are more programs underway pursuing regulatory approval in Japan as well as plans to expand access to existing products.[112]

BMS's R&D strategy in Japan is leveraging new uses for AI/ML, focusing on three areas:

- Identifying new molecular candidates to improve the odds of success
- Tapping into AI/ML to accelerate clinical trials and create better programs
- Incorporating new technologies into patient outcome studies[113]

Figure 8. Approaches between US/EU and Japanese companies as they globalize



Source: Deloitte Japan analysis

Takeda's expansion into emerging markets

Already Japan's largest and most global pharmaceutical company, Takeda is moving forward on a plan to grow its emerging market business to US$9 billion by 2030.[114] Its regional strategy includes delivering health care and medicines to 85% of the world's population.[115] The World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE) recently recommended Takeda's dengue vaccine, QDENGA, for introduction in areas with a high dengue disease burden.[116]

Dengue fever is among the most common mosquito-borne viral disease, causing more than 390 million infections per year, and is endemic in more than 100 countries.[117] Brazil was the first country to make Takeda's vaccine available in the public health system for children and adults.[118] QDENGA is also currently available in countries in Europe, Indonesia, Thailand, and Argentina.[119] Argentina is currently undergoing its worst dengue outbreak in 20 years with over 100,000 infections registered in 2024 alone.[120]

Expanding R&D in Japan and international collaborations

The biopharmaceutical industry has invested more than US$92 billion in R&D in Japan over the last decade, developing over 1,500 new medicines and supporting over 140,000 jobs in Japan.[121] As of Q1 2024, 70 research-oriented pharmaceutical members make up the Japan Pharmaceutical Manufacturing Association, whose "Industry Vision 2025" is to provide innovative drugs to 8 billion people worldwide by 2025.[122]

Embarking on a strategic turnaround for innovation

Japan has an internationally unique innovation system in which all new drugs were created by incumbent pharmaceutical companies, like Takeda, which has the largest R&D budget of the Japanese pharma companies.[123] There is a shift taking place with the rise of personalized medicine towards first-in-class drugs for orphan diseases,[124] with the establishment of start-ups as an important pathway for new drug R&D.[125] The start-up sector in the life sciences has been historically weaker in Japan than elsewhere.[126]

Japan has started a strategic turnaround for the biopharmaceutical market with the "*Japan Bioeconomy Strategy*," which aims to transform Japan into the world's most advanced bioeconomy society by 2030.[127] The government of Japan has allocated funds to promote biomanufacturing technologies with significant investments in biopharmaceuticals, regenerative medicine, cell, and gene therapies (CGTs) and advanced therapy medicine products (ATMPs).

The Bioeconomy Strategy encompasses a broader spectrum than the "*Vision Plan*," spearheaded by the Ministry of Health, Labor, and Welfare (MHLW), which is focused specifically on revitalizing Japan's pharmaceutical sector with particular emphasis on innovation, global competitiveness, and R&D investment.[128] Strengthening collaboration with biology research in academia is a way to improve the drug discovery competitiveness of Japanese companies.[129]

Attracting new talent and researchers

The Japanese market for new and patented pharmaceuticals is expected to reach more than US$72 billion by 2027, making it the second largest in the world after the US.[130] In 2023, the Japanese government committed to investing circa US$75 billion in an endowment fund for select universities to produce world-class research and compete globally. Other organizations are also creating novel funding opportunities.[131]

"We specialize in young researchers, especially those who have returned from abroad and need funding for start-ups. We are trying to nurture those that will become excellent researchers in the future, with a small budget."

—Yukihide Hayashi, head of the **Life Science Foundation of Japan**

Scientists, like biophysicist Kazuhiro Maeshima, benefited from years of research overseas before returning to Japan. Maeshima joined the Genome Dynamics Laboratory at the National Institute of Genetics (NIG), based in Shizuoka, with one attraction the level of academic freedom. "Essentially, we can do what we want. This may be pretty rare in Japan, but we believe it's a critical factor in performing exciting research," he says.[132] Maeshima is also interested in collaborating internationally, and currently is working with colleagues in Australia because of their relatively small, high-quality research community.[133]

Focus on R&D hiring in Japan

Japan's human capital for R&D has been growing more slowly than its peers.[134] In 2024, R&D now accounts for 40% of jobs for new grads hired at pharmaceutical companies, according to responses by 52 companies surveyed in Japan.[135] The trend was more evident at top-tier companies, like Chugai Pharmaceutical, where R&D dominated with 80% of new hires; Chugai also had the most hires with 155.[136] At Daiichi Sankyo and Ono Pharmaceutical, R&D jobs were also the majority, accounting for 60% of hires.[137] For all companies, new sales jobs accounted for just 20%.[138]

The generics manufacturer Nichi-Iko Pharmaceutical resumed hiring new grads for FY2024 after a two-year drought.[139] All 25 new hires were assigned to the production and quality team. [140] Others leading increases in the number of jobs YoY included Nippon-Kayaku (+42), Eli Lilly (+17) and Mitsubishi Tanabe[141, 142]

Looking back at FY2023, Chugai hired the most mid-career personnel in R&D, accounting for 40% of jobs, and no sales hires were made. About 20% of Ono Pharmaceutical's mid-career hires were for R&D jobs.[143]

Microsoft to invest approximately $2.9 billion to boost AI and jobs in Japan

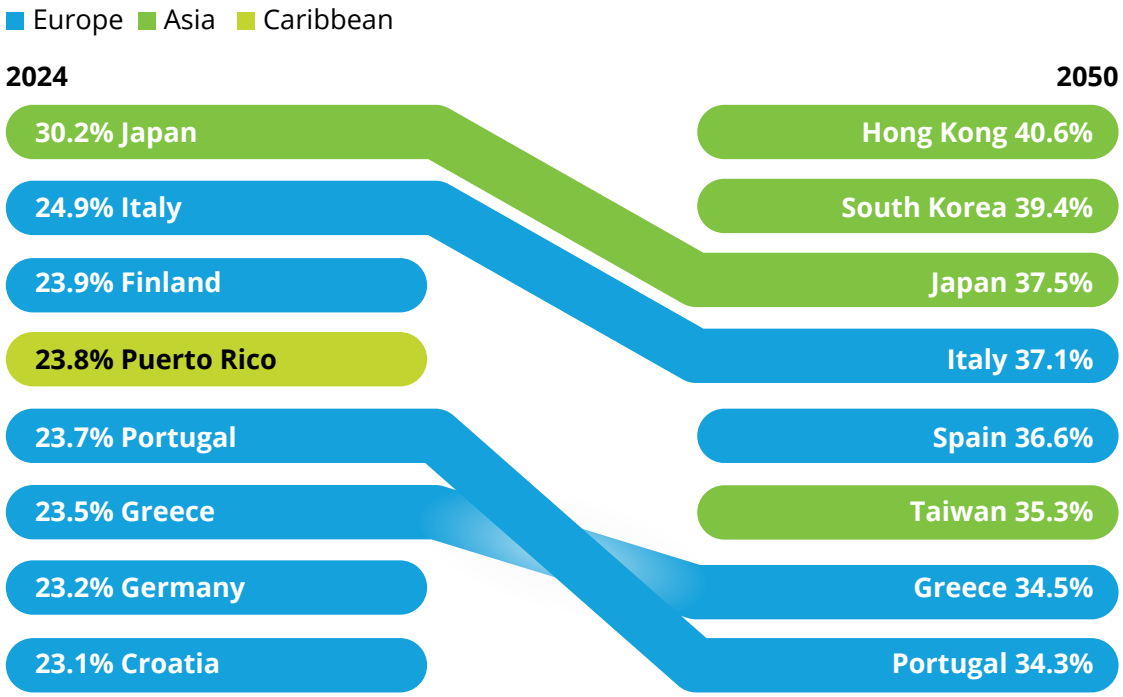
Microsoft is planning an AI-related reskilling program in Japan that will train 3 million workers over three years. The investment also includes setting up a new Tokyo-based lab for R&D in robotics and AI.[144] Under the plan, Microsoft plans to install advanced AI semiconductors at two existing facilities in eastern and western Japan.[145]

Meeting the challenges of an aging population in Japan and risks to society

One of the biggest challenges facing Japan is the rise in its aging population—one in 10 people are over 80 years of age.[146] Japan currently has the highest percentage of citizens aged 65 or older among countries or territories with over a million people (figure 9).[147]Around the world, aging is becoming a leading issue for governments and health care ecosystems as the number of people worldwide over 60 years of age will rise to reach nearly 2 billion by 2050.[148]

Figure 9. World's oldest populations

Estimated share of a population in countries and territories with over a million people aged 65 or older, in 2024 and 2050.



Source: Statista, United Nations Population Division

Births dropping, companies making shifts to address aging market

As more people age, the number of births in Japan dropped to new lows in 2023, and leaders are assessing the demographic crisis as well as the future impacts to society with an aging population.[149] China also released data showing that its population shrank in 2022—for the first time in six decades.[150]

Companies are starting to address these shifts. For example, Oji Holdings, a maker of diapers in Japan, is wrapping up its domestic output of infant diapers later this year to boost production of sanitary items for adults, mainly in nursing homes.[151]

The demand for elderly care is driving the development of innovative technologies, like automation for managing care.[152] These advancements support independent living and can help reduce the burden on caregivers and nursing staff by using tools to monitor and address senior's needs.[153] In 2024, companies at the forefront of such technologies are poised to benefit from the growing demand. [154]

New digital and AI technologies for assisted living and elderly care

Lifelens, created by Panasonic, allows tech-enhanced rooms to automatically monitor patients. Hitowa Care Services' newest retirement home is a Lifelens partner

in Japan and uses cameras in each of its rooms to record patients while an AI system analyzes the data.[155] The technology also uses sensors that report whether a person is in bed or not and can keep track of the patient's heartbeat.[156]

The Japanese market for diagnostic and therapeutic AI health care tools is projected to be worth around $114 million by 2027.[157] Entrepreneurial physicians in Japan are helping to develop new AI health care tools for improving the speed and accuracy with which doctors can make diagnoses.[158]

For example, Japanese companies hold a 98% share of the global market for endoscopes but diagnosing cancer from images captured by endoscopy is highly challenging.[159] Japanese startup AI Medical Services (AIM) has developed an AI tool to improve diagnostic accuracy by training on more than 200,000 high-resolution videos of the stomach.[160] Gastric cancer remains the third leading cause of death worldwide, and its incidence is particularly high in Asia.[161] Asian-Americans are also more affected.[162] Japan and Korea have national stomach cancer screening programs because the incidence of gastric cancer is so high.[163]

Digital therapeutics are also seeing more adoption as chronic diseases rise.[164] US-based Welldoc and Japan's Astellas Pharma are collaborating for a clinical trial using Welldoc's BlueStar digital health app for diabetes management.[165]

More opportunities for digital services to promote a healthy life expectancy

Increasing adoption of technology among the older generation presents opportunities for businesses to reach a wider customer base through digitalization, including managing their health.[166] By helping people stay mobile and free of debilitating age-related diseases, they can enjoy a better "healthy life expectancy."[167]

However, when life expectancy grows faster than healthy life expectancy, the result is often lower quality of life and higher medical and social security costs.[168] MNCs, like Swiss pharma company Novartis, are looking for ways to lower costs in Japan by collaborating within the health care ecosystem as it faces the challenges of an aging society.[169] Novartis is working to raise awareness and improve management of cardiovascular disease—one of Japan's top social burdens affecting its middle-aged to elderly population. The Swiss company is collaborating with academia, local government authorities, and industry partners in various regions within the country.[170]

In Japan, the senior life environment is built on an outdated model of life span, instead of extending health span.[171] To deal effectively with its aging society, Japan should consider a new socially inclusive system for people expected to live into their nineties or more.[172] Extending healthy life span is further discussed in the patient section of this outlook, "*Achieving better patient outcomes with personalized experiences and authentic shared decision making*".

Moving forward amidst shifts in openness

To flourish in a hypercompetitive global environment and achieve leadership in life sciences requires sustained supportive policies and investment in R&D.[173] Shifting trends in openness— and how a country views its place in the world—are expected to continue to influence internal and external innovation and quality of care. Successful life sciences and medtech companies are paying attention to these shifts and remaining equipped with geopolitical expertise, while also developing strategies and actions to adapt to the challenges of this changing landscape.[174]

Achieving better patient outcomes with personalized experiences and shared decision-making

Life sciences and medtech organizations are increasingly focused on achieving better patient outcomes, not only through more rigorous science, but through better patient experiences.[1] Life sciences executives surveyed by Deloitte US believe that the leading action their organizations need to take in 2024 is "improving the patient experience, engagement, and trust"—and the trend is now a higher priority for more companies than it was in 2023.[2]

Personalized care and treatments support better experiences, and there are many opportunities for life sciences and medtech companies to improve touchpoints throughout the patient journey.[3] However, effectively and positively influencing a patient's journey requires a thorough and specific understanding of that patient's journey in order to be proactive and predictive about what patients may need.[4] As the process becomes more digitally enabled and personalized, it is also expected to become more "straightforward" and seamless.

Every patient's experience is different, and a patient's lived experience in a fragmented health care ecosystem may cause frustration.[5] The process of shared decision-making (SDM) can better illuminate what patients may prefer. According to the UK's National Health Service (NHS), SDM is a process that involves selecting tests and treatments based on evidence, while also considering the person's individual preferences, beliefs, and values.[6]

Studies show that there is continued need for improvement between the theory and practice of SDM.[7] Practicing SDM can improve patient-reported outcomes[8] and is also a possible link between the best of patient-centered care and evidence-based medicine.[9] The process is ripe for more personalization to deliver the right solution at the right time.[10]

Personalization through technology

In 2024, life sciences and medtech organizations are considering novel ways to make experiences across the patient journey more customized for patients through technology.[11] Many are experimenting with advancements in artificial intelligence (AI) all across the patient journey—from prevention to diagnosis, treatment, and monitoring.[12]

A patient's journey may start even before a patient contacts the provider.[13] For example, by identifying which patient types are more likely to have a certain disease, AI can raise awareness of the clinical journey that undiagnosed patients may undergo and potentially expedite progress in the journey.[14]

Early interventions are also being made possible through wearables, predictive and propensity modeling (using past data to predict the next action),[15] health assessment tools, and new types of biomarkers and screenings. With more data, health care providers (HCPs) can have a more granular view of the patient.[16]

Growing focus on the patient journey

New patient and provider needs are emerging

In medtech, successful organizations are embracing a more holistic view of the patient care journey beyond the physical device.[17] More patients are taking an active role in their health care journey and turning to health solutions and services tailored to their prevention and wellness preferences over treatment alone.[18] Patients are also demanding customized and convenient care adapted to personal behaviors and routines, with greater ownership of their secure health data.[19]

This engaged patient persona creates a powerful market segment of active consumers with distinct health demands, willing to consider solutions that may better meet their specific needs.[20]

Changing role of chief patient experience officers

Some health care companies have added a chief patient experience officer to their C-suite, and their focus is evolving from the inpatient experience to improving the patient's entire health care journey.[21] Lisa Allen, Ph.D., chief patient experience officer at Johns Hopkins Medicine says she came from the world of quality, statistics, and research, but her passion was really being patient- and family-centered.[22] "A lot of people were just studying the disease process, and I was asking how it was affecting people's lives," she says.[23] Patricia Rosello, M.S.N., R.N., chief patient experience officer at Baptist Health South Florida, says it is crucial to have a passion to see things from a patient's perspective and look at the whole patient journey.[24]

> "Your ability to influence and be very collaborative is going to be key because it takes all these different relationships to make any journey a better journey for a patient. You have to have that broad perspective and a high level of empathy and understanding."
>
> —**Patricia Rosello**, M.S.N., R.N., Chief Patient Experience Officer, Baptist Health South Florida[25]

With more focus on the patient journey, the role for chief patient experience officers is evolving and becoming increasingly strategic.[26]

Integrating patient preferences and values in decision-making

Care collaboration, where patients feel respectfully engaged in the evaluation of their health, is inconsistent.[27] While it is expected that patients should be informed and understand any risks, benefits, and possible consequences of different options through discussion and information sharing,[28] it is less understood how to integrate an individual patient's values and preferences in the process of SDM.[29]

Making SDM "collaborative"

Making SDM collaborative means there is a bidirectional exchange of information between patients and providers that helps patients make individualized, informed decisions about their care.[30] The process should consider a patient's desired level of involvement and autonomy[31] as well as an individual patient's values, goals, concerns, and desired quality of life (QoL).[32] But the path to values integration is not well defined.[33]

While SDM practiced collaboratively can improve informed consent and patient trust, as well as benefit many stakeholders,[34] its application in daily practice is still limited—even in the Western world, where collaborative SDM is championed as an ideal.[35]

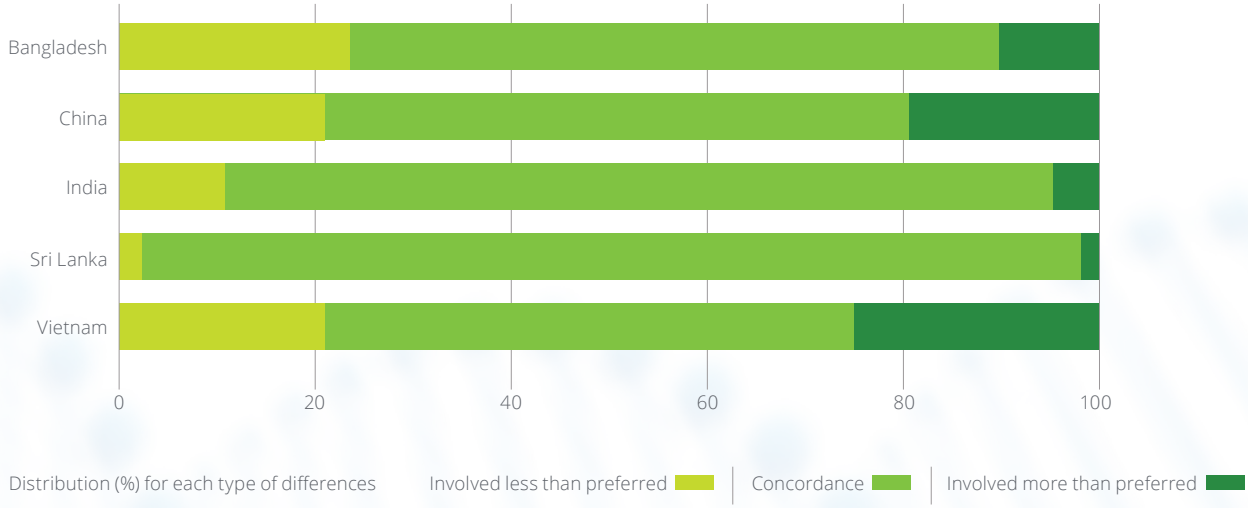
Researchers say that providers should not make assumptions about a patient's desired role in decision-making and stress the importance of clarifying patients' desires.[36] Even characteristics such as age, education, and health literacy skills may not be consistent indictors for how involved a patient wants to be,[37] and cultural and generational preferences vary.[38]

Balancing views for patient-led vs. provider-led care

On one end of the spectrum, some patients want a more active, or "patient-led" form of decision-making, researching their conditions and treatments available.[39] On the other end, patients may prefer a more traditional "physician-led" style, assuming the doctor knows best.[40] But how providers can balance these needs also depends on the providers' own views, which are equally as varied.[41]

In Ethiopia, researchers identified a gap between patients' expectations and providers' perception of the patient's role,[42] showing that providers also exist somewhere on a spectrum between person-centered care and paternalistic care.[43] A multi-country study in Asia found varying degrees of "concordance" between countries over the amount of involvement patients prefer (figure 1).[44] Researchers found this to be the first study to examine the associations of perceived roles in decision-making and patient outcomes among advanced cancer patients in low- and middle-income countries. Joint decision-making was associated with higher well-being and perceived quality of care.[45]

Figure 1. Distribution of discordance/concordance between perceived and preferred roles in decision-making in five Asian countries



Source: Semra Ozdemir, et al., "Patient-Reported Roles in Decision-Making Among Asian Patients With Advanced Cancer: A Multicountry Study," 18 November 2021.

Opportunity for education in a new paradigm of care

One step forward may be gaining a better understanding of various providers' perceptions of patient involvement in SDM.[46] A small study of medical residents in the Netherlands found that young doctors preferred more traditional, physician-led, decision-making.[47] Their decision-making appeared to be affected by contextual factors—their medical knowledge and knowledge about SDM—and by their beliefs and convictions about their professional responsibilities as a doctor.[48] While trying to provide patients with the best possible evidence-based treatment, these residents confused SDM with acquiring informed consent for their recommendations.[49]

Education can be an important part of a new paradigm of care, and the international coproduction health network (ICoHN) is an initiative supporting learning in different communities of practice with patients, practitioners, students, and researchers to explore coproduction in SDM.[50]

Bigger opportunities for life sciences in SDM

Life sciences companies are increasingly focused on "informed" decision-making to support SDM.[51] A well-informed patient is more likely to actively participate in the decision-making process and better understand the potential outcomes and risks of any treatments.[52] In addition, informed decision-making may help build trust, as even patients who ultimately opt to defer a final treatment decision to a provider are still interested in quality information.[53] There is an opportunity to increase awareness about the role of SDM,[54] and evidence shows that SDM can promote appropriate care, decrease overtreatment, meliorate health outcomes, and thereby, may reduce health care costs.[55]

The use of patient decision aids (PDAs) can help patients participate in decisions to improve both the quality of the decision-making process and satisfaction with their choices.[56] Life sciences companies that develop PDAs with information on treatment alternatives, potential risks, and benefits might consider how a patient's preferences and values could be addressed.[57]

By championing SDM and facilitating collaborative PDA development with clinicians and decision-makers, patient advocacy groups, and patients, life science companies have an opportunity to show support for strategies that further respect patient rights and responsibilities in the decision-making process.[58]

Some AI tools may prove beneficial to increasing the practice of SDM—but the design and use of these tools should also incorporate patient preferences.[59] McGill University in Canada, which has been a leader in AI and machine learning (ML) research globally,[60] conducted a scoping review of AI interventions that were used to facilitate SDM across several countries.[61] Researchers observed a lack of emphasis on patients' values and preferences in the studies.[62]

McGill researchers found none of the studies on SDM included health care providers or patients in the design and development of the AI interventions. They suggest further research should be conducted to strengthen and standardize the use of AI in different steps of SDM and to evaluate its impact.[63]

While AI in SDM is in its infancy, there are multiple advances in AI and Generative AI (GenAI) that focus on improving patient journeys across multiple disease areas—from better diagnostics and use of visualization and characterization functionality to support HCPs, faster reimbursement, and more. See the GenAI section of the Outlook for further elaboration on the power and growth of GenAI/AI.

Optimizing touchpoints in the patient experience

A patient experience touchpoint is any point at which a patient interacts with the health care ecosystem as they manage a given condition/affliction, whether through an in-person service or online, through a website, platform, or app.[64] The sum of all these touchpoints influences a patient's perception of the care they receive and the patient journey.[65]

Strategies to optimize the patient journey should integrate the patients' perspective at each touchpoint.[66] Specifically and accurately mapping the patient journey can also help identify new opportunities to improve a patient's quality of life (QoL), not limiting actions to acute needs.[67]

Every patient journey can have several stages that are considered inherent to a specific disease.[68] For example, cancer can present suddenly and decisions regarding treatment can be time sensitive, causing a patient's emotions to run high.[69] Chronic diseases, like diabetes, typically progress gradually and may often be preventable or mitigated with lifestyle changes.[70] Every patient's individual journey can also differ within their disease, and care should be holistic and able to adapt to needs as they change over time.[71]

In 2024, as person-centered care continues to be a priority, strategic leaders should be looking at possibilities for their organization to improve patient experiences[72]—even one touchpoint improvement may make a difference in someone's life.

What can't be measured, can't be improved

The health care industry generates a tremendous amount of real-world data (RWD) that provides valuable insights on patients, their diseases, and their patient journeys and care.[73] But up to 80% of health outcomes can be driven by nonclinical factors, such as access to transportation, education, job opportunities, nutritious food, and safe housing.[74]

This nonclinical data—referred to as social determinants of health (SDoH)—aren't typically captured in traditional RWD.[75] SDoH are the environmental conditions where people live, learn, work, play, and worship that affect a wide range of health and quality-of-life outcomes and risks.[76]

These factors need to be better understood to more effectively enhance a patient's journey, which is why, for example, Deloitte has invested in combining Komodo's Healthcare Map with its HealthPrism SDoH data set—one of the largest SDoH data sets in the US—to develop a more comprehensive view of patients, their care journeys, and their outcomes.[77]

For example, digital health technologies and the widespread use of mobile phones can enable, those in low- and middle-income countries, and other disadvantaged patients, to actively participate in their care, despite transportation challenges, through home monitoring devices, health care apps, wearable technology, and telehealth services.[78]

Finding opportunities for digital touchpoints

Because patients have individualized needs and concerns, life science organizations should respond to patients with a personalized engagement approach that put them at the center of care and connects them digitally.[79]

Digitally powered personalized health care plays a part in helping improve access to treatments.[80] Deloitte's ConvergeHEALTH ConnectTM creates enhanced digital touchpoints across patient journeys.[81] In a stylized manner, you can observe the differences in patient journeys for cancer and chronic disease (figure 2)[82]

Touchpoints in the patient journey for rare disease

In rare diseases, patients may endure challenging diagnostic journeys and often require multifaceted treatment plans.[83] The process typically requires a patient navigate a convoluted system of specialists, testing restrictions, and reimbursement hassles before they're even diagnosed, much less treated.[84] Some companies are working to make a difference by mitigating the burden and personalizing the experience. For example:

- **PANTHERx** streamlines the process associated with getting rare disease medications to patients and incorporates patient education and adherence plans. RxARECARE teams specialize in unique disease states and the select medications patients will receive. Personalized care teams work to ease a patient's burden by taking care of the billing process from start to finish and handling contingencies, like getting a damaged refrigerator replaced, and getting costs reimbursed so a patient won't miss a treatment due to improper storage.[85]
- **MMIT** provides patient access data and analytics to pharmaceutical and health care companies. Carolyn Zele is a rare disease survivor that now works as a market access specialist for the company. She says that she advocates daily for manufacturers to understand the plight of patients. "When patients are at their weakest and most vulnerable, they shouldn't have to fight for a diagnosis or help coordinating their own care. They shouldn't have to file multiple appeals to a payer or manufacturer to help pay for their treatment," she says. Zele advises manufacturers to map the twists and turns of the patient journey to become deeply familiar with the existing access barriers. Pharmaceutical companies may improve access to treatments with a deeper understanding of the patient journey.[86]

Figure 2. Comparison of patient connect across oncology and diabetes patient journeys

Source: ConvergeHEALTH by Deloitte

Touchpoints in the patient journey in oncology

Amidst a mounting need for care services, the cancer burden is growing globally. For 2022, the World Health Organization reports that an estimated 20 million new cancer cases were diagnosed, and it projects 35 million new cases will be diagnosed in 2050.[87]

Approximately one in five people develop cancer in their lifetime, but people are living longer after cancer.[88] Data shows an estimated 53.5 million are still alive five years following a diagnosis,[89] but many aren't getting the follow-up care they need and face continued health challenges.[90] Of those that die from the disease, about one in nine are men, and one in 12 are women.[91] Lung, breast, and colorectal cancer are the most prevalent cancers.[92]

Improving early diagnosis in cancer

To improve the lived experiences of cancer patients, person-centered care should be more than a "nice to have."[93] Patients want to be able to navigate all stages of their cancer care easily and efficiently, and personalized patient journeys should include a needs-based approach for the patient as well as their loved ones.[94]

Early symptoms and indications of cancer with prompt presentation are key to early diagnosis.[95] When cancer care is delayed or inaccessible, chances of survival are lower, more problems are associated with treatment, and costs are higher.[96]

In the UK, the majority of cancers are diagnosed in an emergency room.[97] Only breast and cervical cancer, and to a lesser degree, colon cancer, are found during routine screenings.[98] Macmillan Cancer Support, a leading UK charity organization,[99] is introducing the electronic risk assessment for cancer (ERICA) trial.[100] ERICA is testing six tools as part of Skyline software for clinical effectiveness in improving referral rates particularly in early stages of diagnosis.[101]

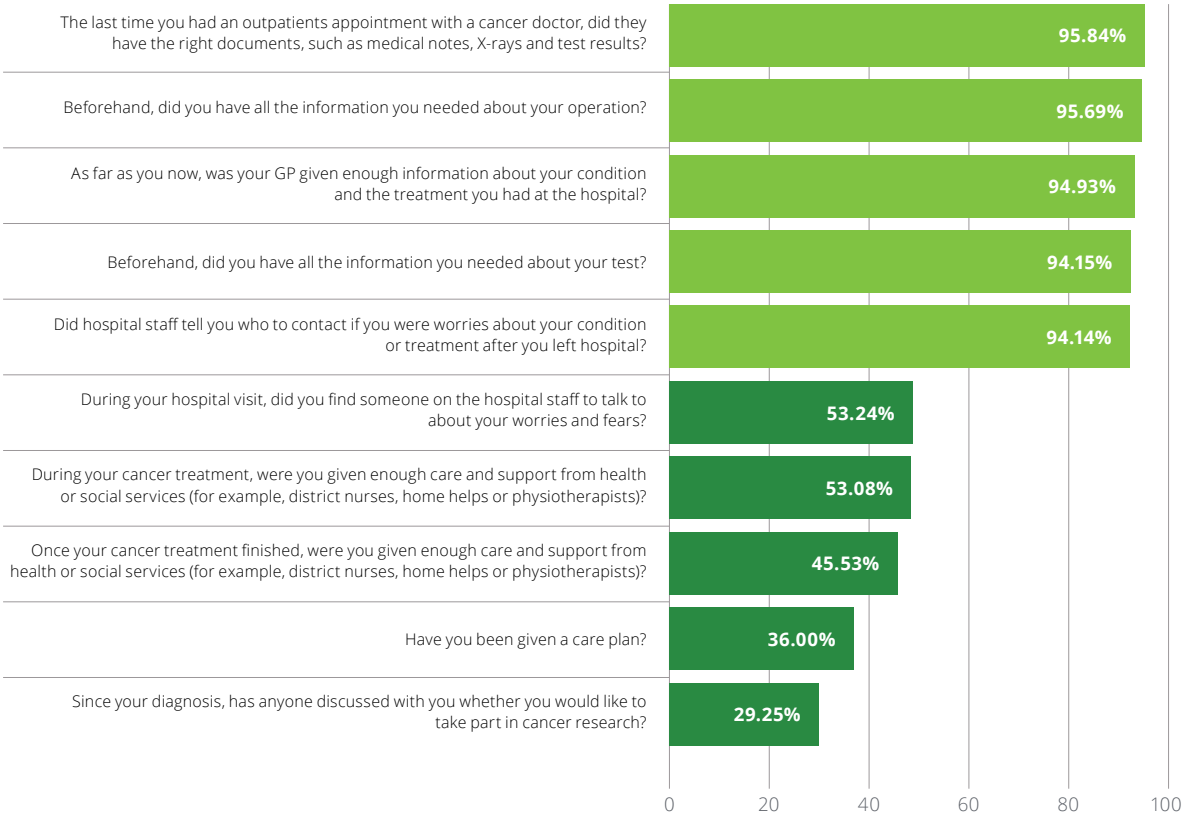
Improving the lived experience with cancer

In a national survey of cancer patient experiences in the UK (figure 3), the NHS fell below 54% in meeting patients' needs for emotional support during hospital care and subsequent treatment (figure 3).[102] Less than half of the patients surveyed felt they had the care and support needed after treatment, including only one-third saying they were given a care plan. An opportunity appears to exist to discuss participation in cancer research as less than 30% say this was discussed with them at any time following diagnosis.[103]

As many people are living longer with cancer, a future vision relies upon ongoing support for people living with cancer during treatment and beyond.[104] People with cancer should always be able to live life fully—in a way that is meaningful for them.[105]

Deloitte UK and Macmillan Cancer Support conducted research in the UK on shaping the future health care experience for people with cancer.[106] One forecast of the January 2023 report was the future ambition related to the lived experience of cancer patients, including where the system is failing and where action is needed (figure 4).[107] Organizations may want to engage this vision for scenario planning to help make a better future of health for cancer patients a reality.[108]

Figure 3. Patient experience survey, National Health Service (NHS) England cancer care



Source: Picker, National cancer patient experience survey, 2021. Data and tables: 2018

Figure 4. The future of health and the lived experience in cancer, strategies for action

People's understanding and awareness of cancer risks and symptoms

- More people will have a **better understanding of cancer risk and their own health generally**. This will likely mean more people are **seeking action sooner over cancer signs and symptoms**, as they have increased access to screening tests which are accepted widely.
- A **customized/localized** approach will be taken to **increase health literacy and raise understanding, awareness, and trust**, particularly in less represented communities.

Person-centred care (including well-being)

- People will have equitable access to a personalized care experience.
- There will be greater **emphasis on the needs of the individual and measuring outcomes that matter to people living with cancer**.
- The use of **digital tools** at scale will complement the workforce to support people and meet their holistic needs. A greater range of technologies will allow support to be tailored to each individual's needs, maximizing the impact for people living with cancer and the people that matter to them.

Living with and beyond cancer and end of life care*

- As people live longer with cancer alongside other long-term conditions, primary, **community and secondary care will coordinate better to provide holistic support**.
- There will be **big shifts away from siloed working** to a more multidisciplinary and cluster medicine way of working.
- **A large part of end-of-life care will move** from secondary/tertiary centres **to community/home settings.** There will be a **cultural shift regarding death and dying**, and people living with cancer will expect to have **open conversations about end of life and their choices**.

Location of care

- **Community diagnostics –** including blood tests and local diagnostics – **will play a much greater role in diagnosing cancer.**
- There will be an increased role for **community and home-based care** to support treatment for less complex cases of cancer care, including innovative solutions (e.g., chemotherapy buses, virtual wards) underpinned by increased cancer knowledge in the generalist workforce.
- This will decrease reliance on specialist centres and increase their capacity to **deliver novel therapies** to treat complex cancers.
- **And there will be a reduced requirement for patients to travel long distances to specialist centres,** with virtual multidisciplinary teams (MDTs) connecting specialists in tertiary centres with the wider workforce locally.

Source: Deloitte UK and Macmillan Cancer Support, "Shaping the future of cancer care," January 2023.

Navigating cancer care, including after treatment

Cancer care navigation is growing in importance and is a strategy for helping cancer patients overcome barriers across the cancer care continuum.[109] Emerging evidence suggests that providing patients with navigation services improves quality of life and patient satisfaction for care in the survivorship phase and reduces hospital readmission in both the active treatment and survivorship care phases.[110] Palliative care data is limited.[111]

Other programs help to address the significant racial, ethnic, and socioeconomic disparities in cancer, including access to screenings.[112] After treatment, survivorship programs also help improve quality of life and help patients find resources and a community.[113] Examples of these programs include:

- **Patient navigation services:** In the US, the Biden Cancer Moonshot program is prioritizing supportive services for people affected by cancer, including championing the importance of expanding patient navigation services.[114] The program is providing personalized assistance to patients, caregivers, and families to help identify and resolve barriers to high-quality and timely cancer care through care coordination and advocacy, even after treatment.[115]
- The first patient navigation program in the US was launched in 1990 by Dr. Harold Freeman to improve health outcomes in marginalized communities in New York.[116] In late 2023, the US Centers for Medicare & Medicaid Services (CMS) finalized codes for Principal Illness Navigation (PIN) services so providers can receive payment for navigation services. In early 2024, seven large private health insurance companies also agreed to cover the cost of cancer navigators.[117]
- **Collaborating for health equity:** The American Cancer Society (ASC) and Pfizer launched a three-year initiative targeting improvement in health outcomes in medically underrepresented communities across the US. Efforts are underway to enhance awareness of and access to cancer screenings, clinical trial opportunities, patient support, and comprehensive cancer navigation.[118]
- **Collaborating for health equity with non-clinical support:** In late 2023, the ACS launched ACS CARES (Community Access to Resources, Education, and Support), a new multi-channel, customizable program to deliver non-clinical patient navigation support to cancer patients and caregivers. For those not as comfortable with digital tools, the program also places trained college and graduate student volunteers in oncology clinics to help patients and caregivers receive non-clinical, individualized in-person support. A US$1 million commitment from the Deloitte Health Equity Institute (DHEI) is helping to expand the program.
- **Cancer survivorship program:** Physical activity is an important part of cancer recovery.[119] In the US, the "LIVESTRONG at the YMCA" cancer survivorship program organizes small groups of people living with, through or beyond cancer to improve their strength and fitness, while also gaining emotional support from peers.[120] According to research from the Yale Cancer Center and Dana-Farber/Harvard Cancer Institute, participants in the specialized program experience improved fitness and quality of life, as well as significant decreases in cancer-related fatigue.[121] The 12-week program is offered at over 790 YMCAs and serves 400 communities around the country.[122]

Life sciences and medtech companies might consider creating, sponsoring, or otherwise getting involved with these types of programs to gain a better understanding of the cancer survivor's journey and ongoing needs. For example, some opportunities might include engaging wearables as part of activities in the fitness program, providing transportation to and from facilities for cancer survivors, and hosting events that raise awareness of mental health support resources or answer questions about clinical trial participation.

Growing demand in diagnostics for early detection, rehabilitation, and prevention

More younger people getting cancer

Survival rates for some cancers have improved dramatically since 1975, rising to 68% from 49%.[123] For example, people with non-Hodgkin lymphoma now have a 74% survival rate compared to 47%, 50 years ago.[124] Improved screening has also led to detection and diagnosis of cancers at earlier stages, when treatment has a higher chance of producing a positive outcome.[125]

But cancer is starting to affect more adults younger than 50 years of age, with an 80% rise in the cancer rate from three decades ago.[126] One US oncologist started noticing the trend 10 years ago. She was asked to treat a teenager that flew in for treatment from China for a gastrointestinal disease typically found in people 65 years or older, but the cancer was too advanced to treat.[127]

Oncologists around the world are seeing more younger patients with cancers uncommon for young people.[128] Worldwide, the most common cancer for young adults under 40 is breast cancer,[129] and more than 90% of women under 40 in the US are diagnosed between 30 and 39.[130] More than a dozen types of cancers are rising in multiple countries.[131] In the US, colorectal cancer has become the leading cause of death for men under 50.[132] There is a growing need for better screening, awareness, and treatments.[133]

Patients with certain cancers, like ovarian cancer and leukemia, also often experience ongoing recurrence and remission,[134] and these diseases may be managed like a chronic illness.[135] As people live longer with various cancers, and the number of people with chronic disease increases, reevaluating the role of patient autonomy in chronic disease and cancer may prove beneficial in rebuilding trust and advancing patient-centered care.[136]

New biomarker research underway for earlier diagnosis of Alzheimer's disease

China has become the country with the largest number of Alzheimer's patients with nearly 10 million cases.[137] However, more than 21% are under the age of 60 and are working age, creating a demand for earlier screening and diagnosis.[138] Currently, Alzheimer's disease (AD) affects nearly 7 million people in the US and approximately 32 million people worldwide.[139]

The development of more biomarkers offers one of the most promising paths to early diagnosis for AD.[140] Beyond imaging and cerebrospinal fluid (CSF) tests, an urgent need exists for simple, inexpensive, noninvasive, and easily available diagnostic tools such as blood tests to diagnose the disease.[141]

> "The biomarker space right now is advancing rapidly. Plasma and blood biomarkers are moving beyond what we've seen—more highly correlated with stage of disease and presence of pathology and will contribute to improved and earlier detection and the possibility of tailoring treatments for patients."
>
> —**Dan O'Connell**, CEO, Acumen Pharmaceuticals[142]

Acumen's sabirnetug program (ACU141193) is developing a deeper understanding of key biomarkers related to AD.[143] A humanized monoclonal antibody (mAb), sabirnetug (ACU193) was discovered and developed based on its selectivity for soluble amyloid-β oligomers (AβOs).[144] By selectively targeting toxic soluble AβOs, sabirnetug aims to directly address a growing body of evidence indicating that soluble AβOs are a primary underlying cause of the neurodegenerative process in Alzheimer's disease. One of its distinguishing factors is the potential for cognitive improvement, in addition to slowing the disease progression.[145] Acumen recently announced the first patient dosed in the company's ALTITUDE-AD study a Phase 2 trial evaluating sabirnetug in in early AD patients.[146]

Other emerging biomarkers include retinal imaging and skin and saliva tests. Tests with these types of biomarkers are exploratory.[147]

Smart devices for more personalized care and rehabilitation

Smart devices are being used for quicker diagnosis and rehabilitation by enabling remote collection of user data and providing health-related feedback for faster, more personalized, and more accurate health care conclusions.[148]

- **Smart implants:** Persona IQ "The Smart Knee" by Zimmer Biomet is being used to detect if a patient is progressing as expected through rehabilitation by remotely tracking range of motion, gait disturbance, function, pain, etc.[149] The goal is to reduce readmissions and revisions. The software provides personalized post-operative smart metrics that connect patients through a care management platform and automated data flow.[150]
- **Computer vision:** Senseye's novel diagnostic platform for mental health uses digital biomarkers for mental health expressed by eye physiology.[151] The brain-based methodology uses computer vision and a proprietary machine learning algorithm that works on any smartphone.[152] The company's first target is post-traumatic stress disorder (PTSD). The device was designed to help clinicians personalize care and diagnose PTSD with a 15-minute ocular test, rather than over months using other forms of evaluation.[153]

Preventative care and direct-to-consumer diagnostic services

As some patients strive for more autonomy, life sciences companies are exploring new channels and partners to engage directly with patients rather than relying solely on HCPs.[154] More direct-to-consumer (DTC) health services are launching to address patient concerns and preferences more expeditiously.[155] As these services become more prevalent, effective, safe, and cost effective, it's likely that they will grow in popularity.

There are blood tests and screening procedures that many feel are informative and preventative, but they may not be covered by insurance, or alternatively, consumers may not want to wait, or pay, for a doctor's appointment to get access.[156] Patients may be told that a test is not necessary, when it might prove lifesaving,[157] and others may be a waste of time.[158]

- **DTC MRI:** On **Prenovu's** website, consumers are called to "put their health in their own hands," so they can catch conditions before they are a crisis.[159] Prenovu offers AI-assisted scans, including a Whole-Body MRI scan, that screens for 500 conditions.[160]

  Actress and television host Maria Menounos is now one of the rare pancreatic cancer survivors after her cancer was detected early—at stage 2—with a Prenuvo scan.[161] With US Food and Drug Administration (FDA)-approved scans and other screenings, most pancreatic cancer is not typically discovered until stage 4, and diseases discovered at this stage commonly have a prognosis of a 1% survival rate at five years after discovery.[162] However, at USD$2500 and up, the access to such scans are extremely limited and there's some debate about the risks of these scans, including false positives which may lead to unnecessary procedures and costs.
- **DTC lab testing:** Direct access testing (DAT) or DTC lab testing enables individuals to order their own medical tests directly from a clinical laboratory, which assigns their own HCP to the order.[163] DAT is subject to a fragmented regulatory landscape and may not be available in some jurisdictions.[164] The DTC lab testing market is projected to reach a hefty US$1.59 billion by 2030, signifying a paradigm shift in health care dynamics due to personalized diagnostics.[165] Forecasts for the period, 2023 to 2030 show a Compound Annual Growth Rate (CAGR) of 10.8%.[166] Some drivers include the rising incidence of chronic as well as sexually transmitted diseases and the increasing penetration of pharmacogenomic testing within the DTC laboratory testing realm.[167] Challenges include genetic data privacy, the potential for misinterpretation of test results, and the need for professional medical counseling.[168] Other issues—like sample integrity, regulatory concerns, limited test portfolios compared to conventional laboratory testing, and the lack of reimbursement schemes—are likely to be headwinds to growth.[169]

Managing the chronic disease journey in Type 2 diabetes

Diabetes is a worldwide epidemic and an expensive chronic condition that continues to increase faster than many HCPs can manage.[170] Healthy eating and physical activity are critical to diabetes management, and while some interventions have proven effective at changing certain behaviors, there are still challenges in achieving sustainable long-term results.[171]

The patient journey in diabetes has changed over the last decade and is now part of digitally powered personalized health care. Many digital solutions include combinations of remote patient monitoring, behavior and lifestyle modification, coaching support, and nutritional ketosis.[172]

The growth of the GLP-1 class of medications for the treatment of obesity and pre-diabetes will also play a disruptive role in the management of Type 2 diabetes. For further insights on the growth of GLP-1 diabetes drugs, see the Value Creation section of the Outlook.

More evidence-based research needed for diabetes digital management tools

Recent research is calling into question the effectiveness of digital management tools used to track and manage patients' Type 2 diabetes.[173] Peterson Health Technology Institute (PHTI) conducted research that asserts that the leading tools evaluated do not deliver meaningful clinical benefits and increase health care spending relative to usual care.[174] PHTI says users of these tools achieve only small reductions in hemoglobin A1c (HbA1c) compared to those who do not use the tools.[175]

PHTI hopes to raise the bar on expectations and evidence, and some agree that there needs to be a more rigorous assessment of solutions.[176] But many, including the Digital Therapeutics Alliance, pushed back on conclusions drawn or the methodology used for the study.[177]

Initial data in the research showed that one "promising solution," Virta Health, might be more likely to deliver clinically meaningful benefits.[178] The digital health care company aims to reverse Type 2 diabetes through personalized nutrition therapy and remote medical care, including telehealth, while also controlling prescription costs for patients.[179] PHTI affirmed that glycemic control and remission are more likely with Virta Health if patients can maintain the rigorous dietary requirements of the intervention.[180]

In addition, Virta Health recently published its own research on its nutritional therapy in Diabetes Therapy showing it to be a potential off-ramp to GLP-1 drugs.[181] Many face the prospect of regaining weight after stopping GLP-1 medications, and Virta Health's results potentially have major implications for employers and plans looking to improve members' health outcomes.[182]

Supporting patient autonomy in chronic disease

An important part of managing a chronic disease is patient autonomy.[183] Diabetes self-management often requires personal autonomy and a supportive social environment to influence outcomes.[184] Researchers in China found that supporting patient autonomy in Type 2 diabetes could help patients achieve glycemic control—not only at the end of intervention but up to six months after.[185]

Patients' personal experiences concerning everyday life with disease or disability shape their knowledge and understanding.[186] Respecting and supporting patient autonomy may not mean providers agree with or confirm a patient's different beliefs and perceptions, but it may be necessary to inform or develop that patient's understanding. Being respectful and seeing the patient view as an expression of their autonomy helps to build trust.[187]

Regulators heightened interest in measuring what matters most to patients

Because patients often live with their disease or condition for long periods of time, and clearly understand the intricacies of their symptoms, the US FDA is increasingly looking to understand how patients describe their health status and assess their outcomes without interpretation from others.[188] Input from patient-reported outcome measures (PROs) and clinical outcome assessments (COAs) can then be used to help select or develop tools to measure what matters most to patients as well as shape future policy.[189]

To date, health-related quality of life (HRQoL) is assessed inconsistently and there is no validated method to integrate HRQoL data into the assessment of therapeutic agents.[190] Including HRQoL as an endpoint may offer crucial information on functional abilities and treatment side effects from the patient's perspective.[191]

Utilizing PROs and HRQoL as standard practice in the clinical trial setting could provide a more comprehensive, patient-centered assessment of therapies under development and help guide patient-provider discussions around treatment options in clinical care.[192] Leading pharma companies like Gilead, Sanofi, AstraZeneca, Biogen and Eisai are starting to include newer methods to assess HRQoL for clinical trials in HIV, COPD, diabetic neuropathy, and Alzheimer's disease.[193]

Advancing the future of health with quality of life in longevity

The importance of quality of life is expected to expand as more people live longer,[194] and people's preferences for quality of life versus longer life as they age may influence their longevity.[195] Breakthroughs in the study of longevity—why humans age, how they age, and interventions to slow the aging process—suggest the possibility of some humans significantly surpassing current life expectancies.[196]

Extending health span, not just life span

A paradigm shift is underway—from disease-focused treatments to those that address the underlying mechanisms of aging, biological systems, and wellness.[197] The goal is to extend health span, not just life span.[198]

The number of aging adults is on an increasing trajectory.[199] Some people may be living longer, but they are doing so with less physical function and a reduced quality of life.[200] Also, a digital life has led many to a sedentary life resulting in an increased risk of disease.[201]

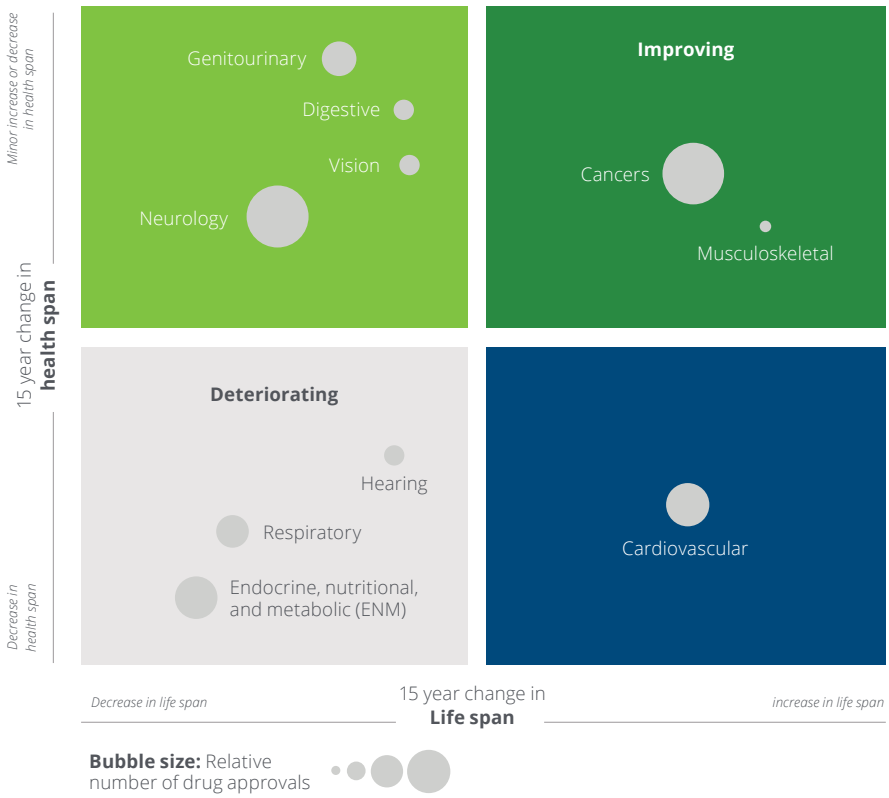
Can longevity-focused concepts help improve the current status quo? Deloitte US analyzed 10 therapeutic areas to uncover two extreme scenarios—disease areas that are deteriorating and those that are improving (figure 5).[202]

In tracking life span over a period of 15 years, deteriorating therapeutic areas saw reduced health span and life span, signifying more years of life with a disability as well as premature death, driven by worsening lifestyle behavior (obesity, Type 2 diabetes) and the growing elderly population.[203] Aging is the leading risk factor for neurological and musculoskeletal disorders. Treatment advances for cancer and cardiovascular disease have been the primary contributors to life span improvement.[204]

Emerging longevity ecosystem

A growing ecosystem of life sciences, health care, and health tech companies is emerging focused on solutions that address underlying drivers of disease and aging (figure 6).[205] Globally, venture capital funding is increasing support for the immense potential of innovative solutions aimed at extending human life and improving health during aging.[206] For example, LEAPS by Bayer, headquartered in Leverkusen, Germany, has invested about US$1.5 billion as of 2023 in various biotech and health-related companies and is dedicated to propelling advancements in aging and age-related diseases.[207]

Figure 5. Longevity disease matrix



Analysis explained

Health and life span

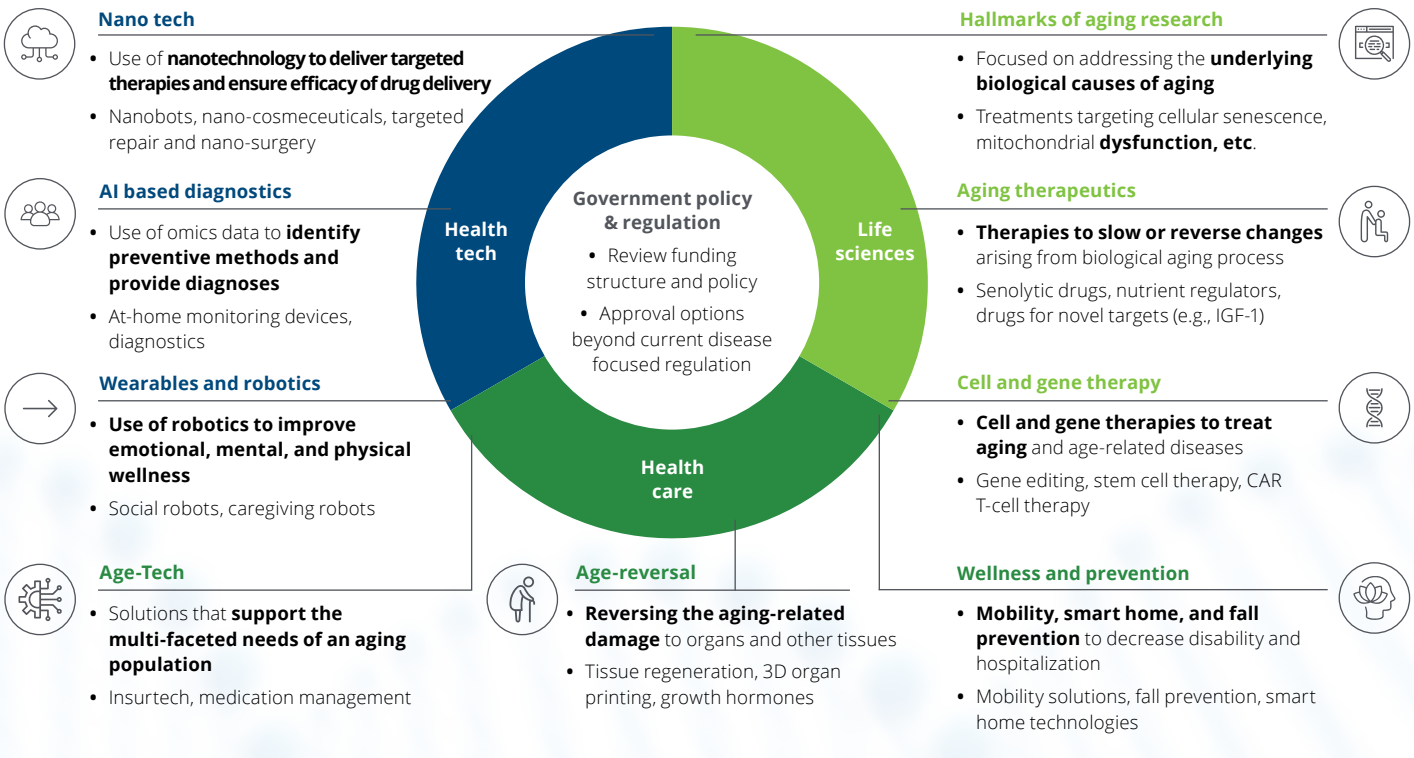
- Chart illustrates the difference of a patient with a disease in 2000 vs. 2015 and whether they experience a better health or life span in the latter.
- For example, the average cancer patient experienced a materially longer health and life span in 2015 (vs. 2000).

Drug approvals

- Number of drug approvals was used as an analogue for the life sciences industry's concentration on a given therapy area.
- No statistical correlation exists between disease area concentration and improvement in health and life spans.

Source: Deloitte US, "Living a 140-year long and healthy life," 2021.

Figure 6. The longevity ecosystem



Source: Deloitte US, "Living a 140-year long and healthy life," 2021.

Life sciences

We expect the convergence between technology, life sciences, and health care to continue supporting a growing ecosystem in pursuit of extending human longevity. Longevity research is poised to revolutionize the therapeutics market, and life sciences companies that opt to embrace a forward-thinking longevity mindset recognize that the future of health is one where therapeutics enable prevention and well-being over treatment-based reactionary care.

Health care

Health care providers should prioritize patient wellness and create hyper-personalized preventative solutions. Because personalized medicine enables a patient-centric approach to well-being and care delivery that has the potential to improve outcomes and reduce cost, personalized medicine is highly likely to continue gaining traction as a prominent feature of the future of health care.

Insurers

Public and private insurance payers should reexamine their offerings and consider adding services and products that also support populations with longer, healthier life spans.

Health Tech

Health tech is rapidly advancing as companies leverage real-world evidence and data and capitalize on the shift to well-being and personalized medicine. Emerging technologies and data-driven decisions are starting to accelerate rapid diagnosis, treatment selection, and delivery. The many benefits of these technologies on the aging population, especially, should not be underestimated.

Patient

Healthy aging varies according to social systems, education, and knowledge about lifestyle behaviors and health care.[208] Few studies have recognized the potential of self-care behaviors among older adults to prolong independence later in life, and the role of motivation has largely been ignored with regard to longevity.[209] Research from Cardiff University in Wales finds that choiceful behavior, self-reflection, and supported autonomy helped to predict who would live longer.[210] As companies invest in longevity research, they might also more deeply consider the role of patient autonomy in healthy aging.[211]

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Acknowledgements

We would like to thank the following individuals for their contributions to this report: Angela Dunn, Karen Taylor, Emily May, Jake Zhao, and Zara King, Terry Koch, Tapsi Bansal, Pallavi Shirsat, Dorin Shah, and Ketaki Soman.

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Endnotes

Value creation: M&A, partnerships, collaborations, new sources of capital, and shifting portfolios

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