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# McKinsey on Life Sciences

Perspectives and research for the industry

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A note from the authors

# From productivity to performance: Growth, strategy, and the next chapter in life sciences

One year ago, the McKinsey Life Sciences Practice released our *RewiR&D* collection,[1] which explored how companies could "make more medicines that matter" through meaningful improvements in R&D productivity. That collection highlighted a long-standing truth: Progress across the industry—from medicines to devices, diagnostics, and digital tools—depends not only on efficiently translating science into solutions but also on ensuring those solutions endure and create sustained value. As we enter 2026, the value creation imperative has taken on new urgency—and with it, a renewed focus on growth and enterprise performance.

The operating landscape for life sciences companies is shifting in response to geopolitical and regulatory uncertainty, accelerating technological disruption—especially from agentic AI—and evolving investor and consumer expectations. In this environment, growth remains a decisive measure of strategy, execution, and resilience across biopharma, medtech, and the broader ecosystem. McKinsey analyses show that a one-percentage-point increase in revenue growth creates roughly eight times more shareholder value than the same gain in margin.

Alongside agentic AI, robotics and embodied AI are also advancing rapidly, reshaping how life sciences leaders design their operating models and rewire their enterprises for greater productivity and growth. We are already seeing examples of deeply embedded advanced robotic systems across life sciences manufacturing and R&D. Recent McKinsey Global Institute research indicates that humans, AI agents, and robots will increasingly work together across entire workflows—and that AI-powered automation could unlock $2.9 trillion in economic value in the United States alone by the end of the decade.[2] Life sciences executives and boards will play essential roles in guiding this transformation within their organizations—aligning strategy, rebuilding workflows, and establishing the necessary capabilities and safeguards.

Yet, even while the technologies and ways of working evolve, the fundamentals of outperformance remain the same: Winners turn scientific breakthroughs and technological disruptions into advantages, combining internal scientific excellence with external innovation and geographic expansion, even as policy, pricing, and geopolitical pressures intensify.

[1] *RewiR&D: Making more medicines that matter*, McKinsey, January 2025.
[2] "Agents, robots, and us: Skill partnerships in the age of AI," McKinsey Global Institute, November 25, 2025.

**Against this backdrop, several trends are poised to expand the strategic tool kit for growth in the new year:**

- **agentic AI,** which is beginning to transform enterprise performance by unlocking capacity across R&D, operations, and commercial—and shaping top-line growth by linking scientific, operational, and commercial workflows with unprecedented speed and coordination
- **a buoyant innovation ecosystem in Asia,** where scientific and process innovations are expanding rapidly, creating new hubs for manufacturing excellence, next-generation modalities, and emerging biotech breakthroughs
- **a new wave of consumerism and consumer channels,** with rising demand for health, wellness, and medical aesthetics—enabled by digital platforms, new brands, and shifting patient expectations
- **new operating models in biopharma and medtech,** centered on simplification, cross-functional agility, digital enablement, and enterprise-level scaling of automation systems

To bring these opportunities to life, this collection highlights some of the best-performing articles from 2025 that collectively illustrate how organizations can capture growth in this new environment. Among them are the following:

- **"Reimagining life science enterprises with agentic AI"** shows how AI can function as a collaborator—not just a tool—freeing 25 to 40 percent of enterprise capacity and capturing three to seven percentage points of incremental growth by rewiring workflows from discovery through commercialization.
- **"GLP-1s are boosting demand for medical aesthetics"** explains how this blockbuster therapy class is activating new consumer segments, driving entirely new patterns of demand, and reshaping growth in adjacent categories.
- **"The transformation imperative: Igniting value creation in medtech"** highlights how companies are reinventing their operating models to reignite growth, expand margins, and operate with greater commercial and organizational agility.
- **"The hidden traps of business building: A guide for life sciences CEOs"** examines how leaders can build new ventures—digital, consumer, and platform-based—that complement core portfolios and create new engines of growth.

The collection also features articles showing outperformers moving from AI pilots to full enterprise scale—accelerating early discovery, reshaping regulatory submissions, streamlining operations, and transforming commercial engagement—all with humans firmly in the loop. Importantly, technology alone will not deliver growth. Across the industry, companies are simplifying structures, redesigning processes, and sharpening their value-creation narratives to link strategy more clearly to performance. These stories are also told within this collection.

We hope this publication provides you with seeds of insight and inspiration, along with the tools to cultivate them. Because when science and strategy move together, when AI amplifies human expertise, and when purpose aligns with performance, the benefits extend across the ecosystem—to patients, physicians, health systems, and consumers worldwide.

Sincerely,

**Reinout Goedvolk**
Amsterdam

**Robert Linden**
Bay Area

Global Coleaders,
McKinsey Life Sciences Practice

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# 1

# Pioneering AI-Driven Transformation



# Reimagining life science enterprises with agentic AI

Agentic AI is poised to boost the benefits from AI by changing its role from tool to coworker and catalyzing an end-to-end reimagining of the life sciences value chain.

*This article is a collaborative effort by Chaitanya Adabala Viswa, Dan Tinkoff, Delphine Zurkiya, Eoin Leydon, and Jeffrey Lewis, with Lionel Jin and Meredith Langstaff, representing views from McKinsey's Life Sciences Practice and QuantumBlack, AI by McKinsey.*

**Life sciences companies** are facing margin pressures, higher R&D costs, and the need for continuous innovation amid increasing technological and operational complexity. They're also struggling to attract and retain talent. Externally, they are subject to heavy regulatory oversight and legislative uncertainty. For pharmaceutical companies, many blockbuster drugs are nearing patent expiration. For medtech companies, many devices in development, such as robotics and connected devices, are becoming complex platforms. For life science services companies, AI and the shift to cell and gene therapies are driving rapid technological changes. Factors such as global economic shifts, trade tariffs, most-favored-nation pricing policies, supply chain vulnerabilities, and geopolitical tensions further complicate the landscape. Meanwhile, the rapid progress of AI creates both opportunities and challenges. These combined pressures make it essential for life sciences companies to find new ways to boost growth, improve productivity, and increase operational agility.

Recent McKinsey research has found that nearly eight in ten companies use gen AI, yet 80 percent of them report no tangible bottom-line benefits.[1] Function-specific AI use cases have the greatest potential benefits, but companies face hurdles in expanding them past the pilot stage.[2] Think of it as the AI paradox—the technology has potential, but enterprises haven't yet adopted it nor seen its benefits at scale.

AI agents (for a definition, see sidebar "What is agentic AI?") have the potential to resolve this paradox by changing AI's role from tool to coworker. They can be combined into configurable networks that help employees by collaborating with them, performing tasks on their behalf, and handling activities that are currently low priority because of limited capacity, such as those related to the large volumes of lower-priority customers, contracts, and

[1] "Seizing the agentic AI advantage," QuantumBlack, AI by McKinsey, June 13, 2025.
[2] "Seizing the agentic AI advantage," QuantumBlack, AI by McKinsey, June 13, 2025.

invoices. In our experience, there are benefits to viewing AI as a coworker: People tend to be more patient with AI and invest their time to improve it through feedback; they become creative in finding more parts of their workflow that can be "agentified" once they see what is possible; and they proactively seek better ways to reorganize workflows once they understand how AI can help.

To understand how agents might change work and responsibilities in life sciences, we conducted a thorough, end-to-end, task-based analysis to evaluate the potential benefits of AI agents in specific workflows (see sidebar "How we determined the potential benefits of agentic AI in life sciences"). We analyzed 270 workflows and 1,200 tasks in 180 job families and found that agentic AI will transform workflows, change how work is done, and increase value by spurring growth and reducing costs in both pharma and medtech (Exhibit 1, parts 1 and 2). In pharma, 75 to 85 percent of workflows contain tasks that could be enhanced or automated by agents, potentially freeing up 25 to 40 percent of an organization's capacity. In medtech, the figure is 70 to 80 percent. These capacities are at the task level, so they may be fractions of employees' time. Organizations will need to make choices about how to redeploy this capacity, with implications for the shape of the organization and how work is conducted. Patients stand to benefit in various ways, including through quicker access to a wider range of new medicines, more personalized treatments developed using patient data, and improved matching of existing treatments to unmet needs.

We estimate that the full potential of agents could give companies incremental growth of five to 13 percentage points in pharma and three to seven percentage points in medtech. EBITDA would increase by 3.4 to 5.4 percentage points in pharma and 2.2 to 4.7 percentage points in medtech over the next three to five years, in addition to current initiatives focused on growth and margin expansion.

We found that the opportunities for agentic AI in the pharmaceutical and medtech sectors are similar in most domains, except in R&D, where their approaches differ significantly. This article presents the results for both sectors and highlights notable differences where relevant.

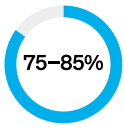
## What is agentic AI?

**AI agents** are goal-driven systems that operate independently by breaking down complex tasks, interacting with other systems, and learning in real time. They use machine learning and rules-based AI to enable reasoning, memory, and the capacity to interact with humans. Gen AI includes lower-complexity agents, sometimes referred to as "low-code" or "no-code," that employees with minimal coding experience can create and modify using natural language on various platforms. It also includes higher-complexity agents, sometimes referred to as "pro-code," which must be developed and fine-tuned by data scientists or engineers. Lower-complexity agents are well-suited for predictable tasks that can be chunked into subtasks, as well as for work with clean data, integrated systems, limited specialized knowledge, and lower-risk tasks. Typical uses include automated report generation and analyzing customer feedback. Higher-complexity agents are needed when those conditions aren't met, such as in predictive modeling for clinical trials or firmware development for medical devices. However, even no- and low-code agents require people to create, test, and tweak them and think through adoption and performance tracking. All AI agents should be part of broader business and talent changes that include training and incentives to promote adoption. As managers transition to overseeing a flexible network of agents that perform, adapt, and learn, the operations of life sciences organizations could transform fundamentally. Because the life sciences industry is strictly regulated, agents must consult humans before making important decisions or performing major tasks. Guardrails are set by the enterprise, a function or business unit, or the manager or supervisor overseeing that AI.

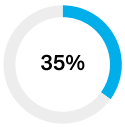
Exhibit 1, part 1

## There are several potential benefits of AI agents in pharma.

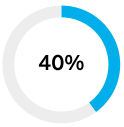
### Work will transform




**Agentifiable workflows**
Processes in life sciences where key activities can be augmented or automated by agents



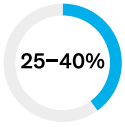

**Lower-complexity agents**
Agents that require minimal coding, with mostly business-driven build and oversight and rewiring mechanism for adoption




**'Superpowered' work**
Workflows can be extended by agents doing work that is currently too complex or costly for humans

### Roles will change


**Roles with AI sidekicks**
With agents as integrated teammates, employees' impact for patients can be amplified



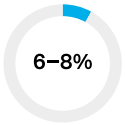

**Freed-up enterprise capacity**
Assigning agents to tasks where they excel (and humans don't) can free up time for where humans' unique abilities are needed most

**10+**

**New role types needed**
Agentic workforce can succeed with help from humans in new roles such as agent orchestrator and AI governance or quality manager

### Revenue will be affected


**Growth impact**
Expanded and better assets, more eligible patients reached, and revenue pulled forward within 3-to-5 year time frame, with potential for incremental 1% to 3% CAGR above baseline growth




**Cost efficiency**
Potential savings from increased productivity, reduced vendor spend, and optimized operations

**3.4–5.4 p.p.[1]**

**Impact to EBITDA**
Full potential enterprise-wide impact on EBITDA within a time horizon of 3 to 5 years

Note: Numbers do not include physical AI or growth from AI in products.
[1]Percentage points.

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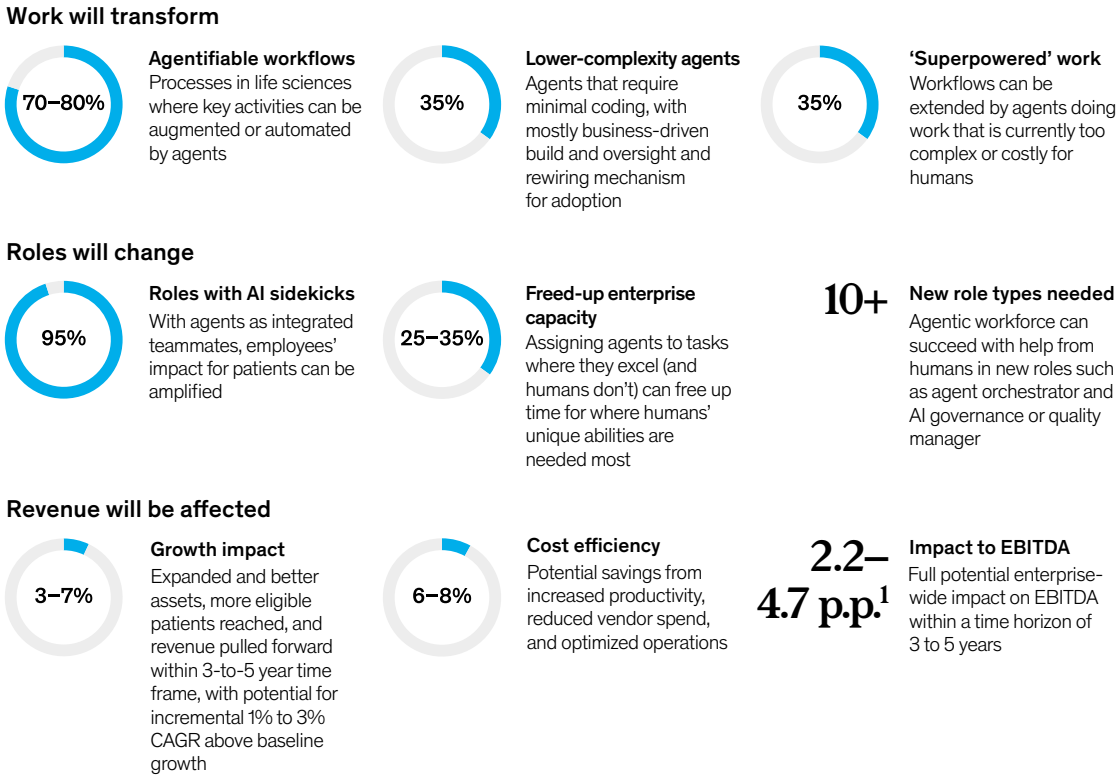
Exhibit 1, part 2

## There are several potential benefits of AI agents in medtech.




Note: Numbers do not include physical AI or growth from AI in products.
[1]Percentage points.

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## How we determined the potential benefits of agentic AI in life sciences

1. **We analyzed** each domain in biopharmaceutical and medical technology firms and deconstructed their workflows to generate a comprehensive map of all 270 workflows.
2. For each workflow, we examined more than 1,200 key tasks to assess whether they could be agentified, with simpler or more complex agents; the share of the task that agents could handle; and the time they could save.
3. We examined the roles responsible for those tasks and the amount of time each role spends on them. We analyzed 180 job families and identified ten new roles, such as agent orchestrator and AI quality manager, that will be needed to support agents.
4. This provided us with a bottom-up view of growth and productivity opportunities, which we analyzed at the profit and loss (P&L) level for each domain. A panel of technology and domain experts reviewed the benefits of each revenue and expense item and considered the costs to deploy and manage those agents.
5. We compiled those numbers by domain and functional area to assess the overall benefits to the P&L and the reduction in time-to-market for new medicines.

## Agentic AI is catalyzing three key shifts in life sciences

1. *Agentic AI can transform eight out of ten workflows*. Of the more than 270 life sciences workflows we analyzed, 75 to 85 percent of workflows in pharma and medtech have tasks that could be automated or augmented by agents (Exhibit 2). Nearly 40 percent of workflows are relatively standard and predictable and could be addressed by lower-complexity agents that business users could customize and implement themselves, possibly with minimal technical support. Another 50 percent are more complex, domain-specific workflows that companies could support with custom-built agents to help them differentiate from competitors.

2. *Up to 95 percent of life science roles may have agentic teammates*. Every functional area, domain, and job family has tasks for which agents could be deployed. Two-thirds of those roles will be involved in some combination of directly building, managing, and supervising lower-complexity agents, which they will orchestrate, tune, monitor, and maintain. New team roles, such as agent orchestrators, AI governance and agent quality managers, and agent supervisors, could also be needed to implement and support agentic workers.

   We expect this shift to free up 25 to 40 percent of enterprise capacity, allowing employees to focus on more strategic, value-adding, and productive work (Exhibit 3). At first, this additional capacity will free up employees for part of their work week, but we anticipate that over time, job descriptions, job families, and even organizational charts will evolve to replace certain roles entirely. This creates an opportunity for the leadership team—and especially human-resource officers—to rethink the shape of the organization. Management will have to decide what to do with freed-up capacity; this will likely depend on the domain. Some companies will reinvest it, some will grow into it—for example by freezing hiring—and some might take the margin improvement.

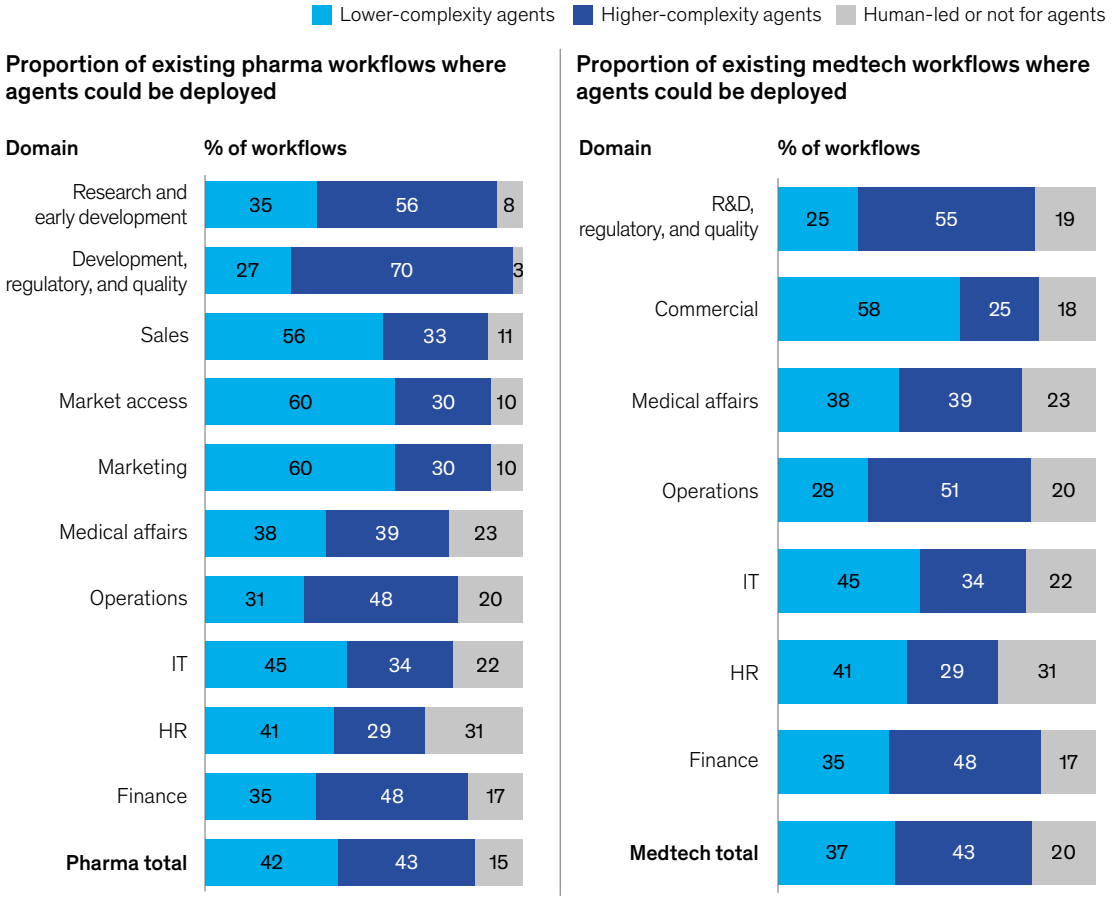
   The greatest productivity boost may come from agents performing tasks that humans are not currently doing; we found that 40 percent of workflows include tasks that are too complex or uneconomical for humans to perform, but that agents could handle at scale. Agents could find patterns that humans cannot, especially in complex, unstructured datasets. This could help researchers gather insights from diverse sets of scientific data and identify value leakage in the long tail of invoices, which are typically not a priority for human review. Agents could also collect and analyze data from a wide range of sources to continually monitor and report on a company's brand health, enabling always-on brand performance. These agent-specific strengths can create possibilities for new workflows, processes, and ways of working.[3]

3. *AI agents could boost growth and EBITDA*. They could lift growth by 5.0 to 13.0 percentage points in pharma and 3.0 to 7.0 percentage points in medtech, while increasing the EBITDA of pharmaceutical companies by 3.4 to 5.4 percentage points and medtech companies by 2.2 to 4.7 percentage points over the next three to five years (Exhibit 4, parts 1 and 2). Half of this increase would come from a boost in net revenue from acquiring more and better assets, reaching more eligible patients, and accelerating the time to market. The other half would come from greater efficiency in R&D and manufacturing and administration. As life sciences companies face margin pressures from portfolio crowding, policy changes, and pricing dynamics,[4] this potential margin boost is especially important. Capturing the full potential of agentic AI requires an enterprise-wide effort to which every domain contributes. This may be challenging for some companies, but even a subset of domains transformed by agents would yield significant benefits.

[3] "The future of work is agentic," McKinsey, June 3, 2025.
[4] "Simplification for success: Rewiring the biopharma operating model," McKinsey, March 21, 2025.

Exhibit 2

## Agents can augment 75 to 85 percent of today's workflows.




Note: Figures may not sum to 100%, because of rounding.

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Exhibit 3

## Agents could free up 25 to 40 percent of employees' workloads.


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## Reimagining work with agents

Agents can help tackle complex problems in life sciences, freeing people to develop more treatments and address other challenging problems. Here are six life sciences battlegrounds where agent-based AI can generate substantial benefits:

**1. Pharma research: Accelerating discovery and deepening scientific insight**

Research and early drug discovery involve complex processes, but agents can still enhance almost every workflow (Exhibit 5). The specialized data and expertise needed mean that nearly 60 percent of workflows will require custom-built agents. Once implemented, these agents can free up 21 to 30 percent of capacity in areas such as wet labs, data analytics, and regulatory support, which can be redirected to expand the research pipeline or accelerate the progression of candidate drugs to trials.

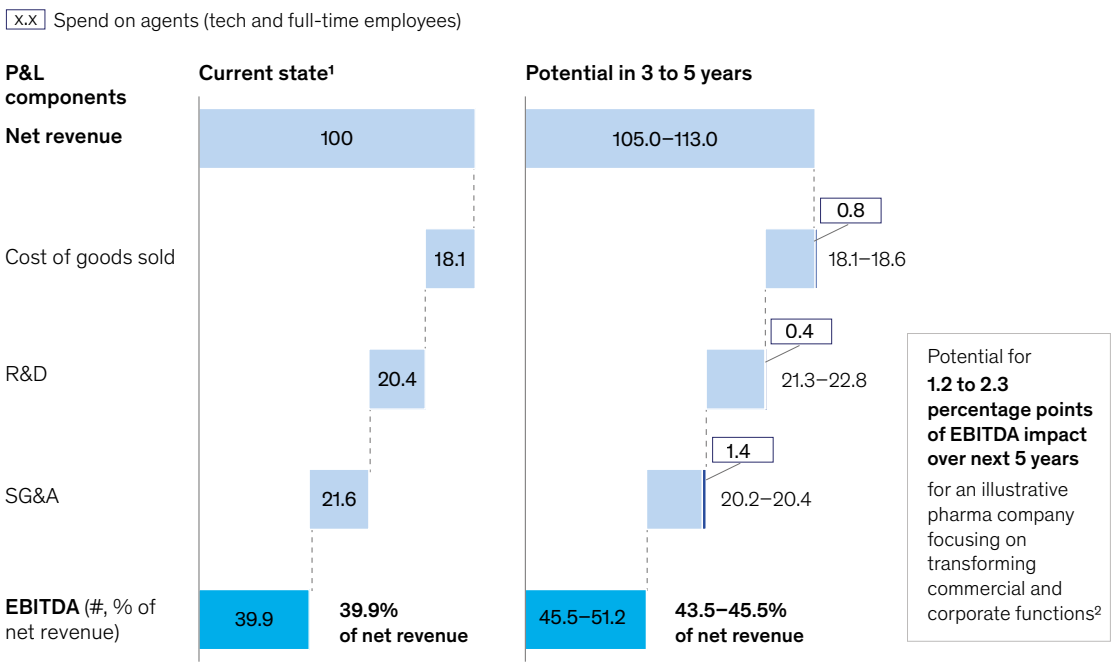
With agentic AI, work for early-stage drug discovery and scientific exploration can be reimagined in the following ways:

*Autonomous data analysis and insight generation*: An analytic agent can assist scientists by automatically preparing detailed data analyses of experimental data aggregated by a curator agent. The analytic agent would perform statistical analysis and visualizations, which are currently time-intensive tasks that require the expertise of highly trained scientific staff. The analytic agent can then work with a protocol-drafting agent, which suggests updates to the experiment protocols based on the latest findings. The human scientist reviews and adjusts these suggestions, enabling faster iteration and improved experiment design.

Exhibit 4, part 1

## The full potential of enterprise-wide agentic transformation could boost top biopharmas' EBITDA by 3.4 to 5.4 percentage points.

**Incremental profit and loss (P&L) impact for top pharma companies, not including baseline growth** (indexed to 100)




¹Based on aggregate level of 21 large-cap biopharma companies from FY2024 financial statements (Eli Lilly, Novo Nordisk, AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, GSK, Pfizer, Roche, Novartis, Merck & Co, Johnson & Johnson, Sanofi, Daiichi Sankyo, Gilead, Astellas, Takeda, Vertex Pharma, CSL, Biogen, and Regeneron); Johnson & Johnson, Merck & Co, Sanofi, and Roche based on only pharma business.
²Includes HR, legal, and tech delivery.
Source: Company financial statements; expert interviews; McKinsey Value Intelligence Platform

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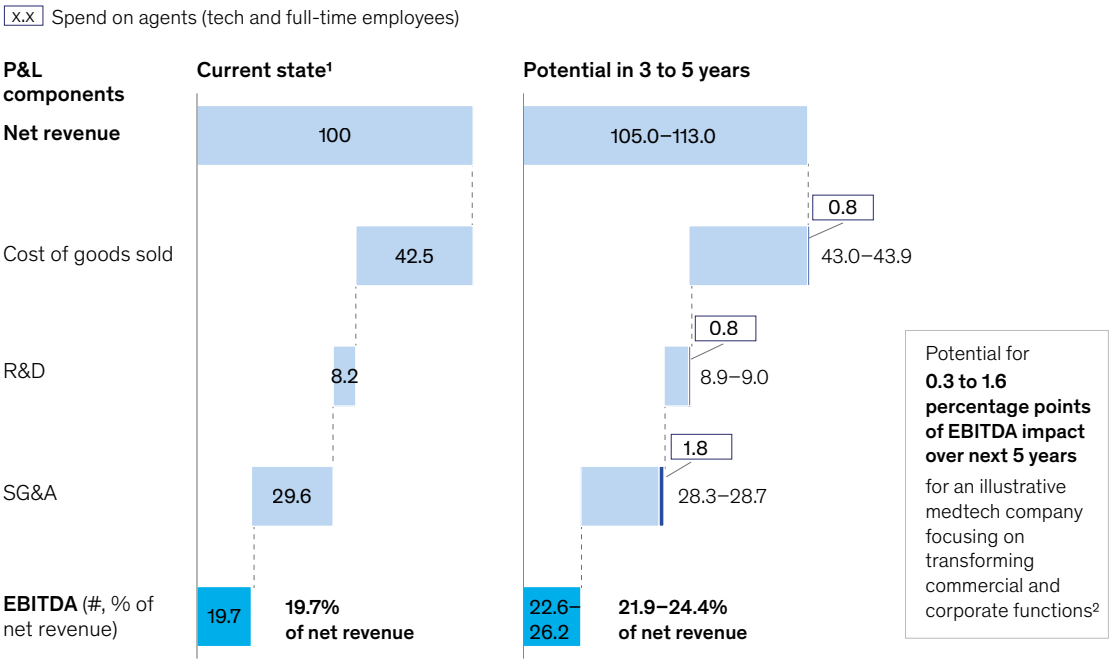
# Agent-based AI can generate substantial benefits in six life sciences battlegrounds.

Exhibit 4, part 2

## The full potential of enterprise-wide agentic transformation could boost top medtechs' EBITDA by 2.2 to 4.7 percentage points.

**Incremental profit and loss (P&L) impact for top pharma companies, not including baseline growth** (indexed to 100)




¹Based on aggregate level of 10 large-cap medtech companies from FY2024 financial statements (Medtronic, Boston Scientific, GE Healthcare, Edwards Lifesciences, Stryker Corporation, Intuitive Surgical, Abbott, Phillips, Baxter, and Johnson & Johnson); Johnson & Johnson based on only medtech business.
²Includes HR, legal, and tech delivery.
Source: Company financial statements; expert interviews; McKinsey Value Intelligence Platform

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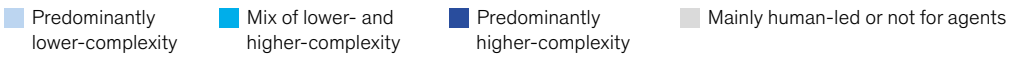
*Data-driven drug-candidate selection*: A key function of the drug discovery team is to evaluate drug candidates for a specific target. Traditionally, these decisions relied heavily on early preclinical efficacy experiments and expert opinions. With AI agents, the team can benefit from a much richer set of inputs. AI agents can synthesize insights from the latest literature and trial data compiled by a literature-explorer agent, perform in silico modeling of success probabilities using real-world data, multiomic analyses from the data-science agent, and endpoint simulations from the feature-generation agent, creating a prioritized list of potential drug candidates. With the help of these agents, the team can efficiently review and approve this list for the next stage of screening and testing, significantly improving and hastening the decision process.

*Accelerated regulatory submission preparation*: A regulatory-drafting agent could autonomously compile the latest efficacy and toxicology testing data into a submission-ready document. What once took a week or two of manual effort now only requires the scientist a few hours to review and finalize. By automating the drafting process, the regulatory-drafting agent not only reduces timelines but also ensures compliance with regulatory standards, allowing the scientist to focus on higher-value tasks, such as strategic innovation and building relationships.

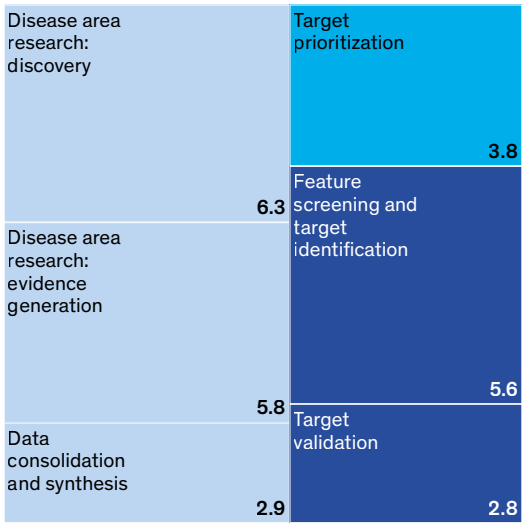
Exhibit 5

# Most workflows in research and early development can benefit from agents.

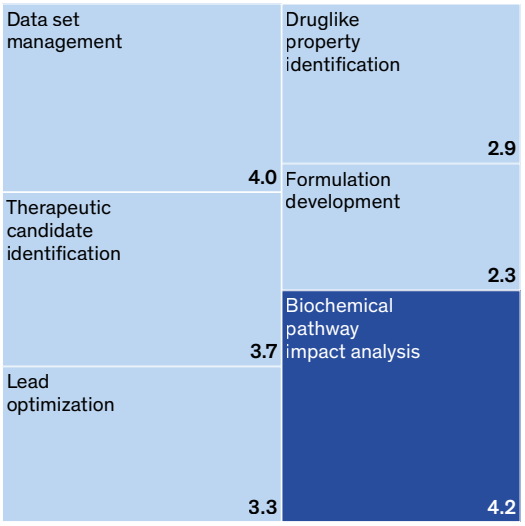
## Relative value at stake by workflow, with type of agent



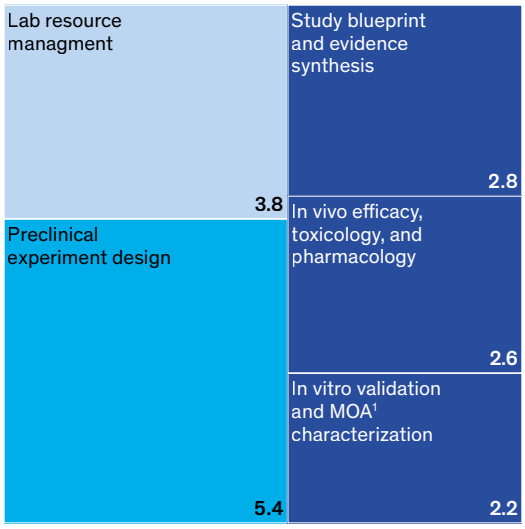

### Disease understanding and target identification



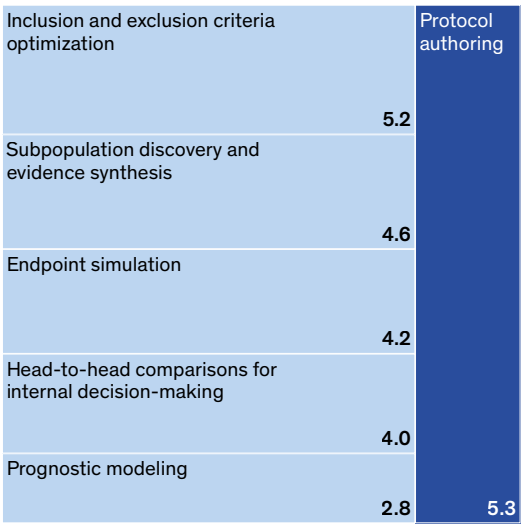

### Compound identification and optimization




### Preclinical evidence generation




### Clinical trial preparation




[1]Mechanisms of action.

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Several large pharmaceutical companies are actively leveraging AI, including agentic AI, to speed up various stages of drug discovery and development. One has a collaboration with a company that integrates AI and robotics for drug discovery. It uses AI-powered platforms for molecular modeling, crystal structure prediction, and screening to identify and improve small-molecule drugs. The AI autonomously performs complex calculations and predictions to reduce the list of potential drug candidates and optimize workflows.

**2. Pharma development: Accelerating clinical trials and enhancing patient journeys**

Agentic AI can help companies conduct clinical trials faster, more efficiently, and with higher quality while also improving the patient experience. Although study teams have already been working toward these goals using digital tools, AI, and gen AI, we expect a major shift to come about once agents are more fully implemented. Agents are no longer just tools for study teams; they are evolving into intelligent partners that collaborate with teams throughout the clinical trial process and can operate semiautonomously to handle a wide range of workflows. Over the next five years, we expect this to lead to a 35 to 45 percent boost in productivity in clinical development that will benefit every function (Exhibit 6).

Agents can also shorten timelines, delivering medicines to patients more quickly and accelerating revenues, and enhance decision-making and execution, thereby increasing the likelihood of demonstrating the efficacy and safety of novel treatments.

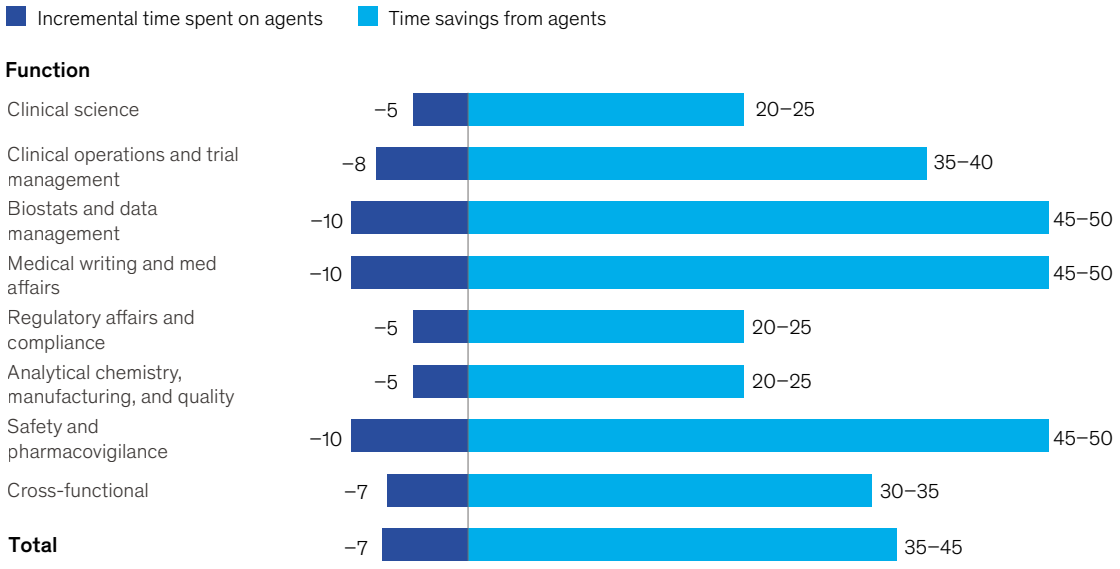
We see agents performing seven key roles in development:

1. optimizing trial designs informed by agentic retrieval of benchmarks and data, with scenarios designed using machine learning (ML)
2. orchestrating sites, vendors, and sponsors for site start-ups
3. managing clinical data from one-click electronic data capture design through anomaly detection and query triage
4. engaging sites and principal investigators with hyperpersonalized, multimodal messages

Exhibit 6

## Agents can benefit roles in every clinical development function.

**Work hours shifted by agentic workforce,** % of function capacity




McKinsey & Company

5. managing trials, including root cause investigations and next-best-action recommendations

6. assembling submission materials informed by regulatory intelligence

7. automating document production throughout the trial life cycle

Here is how three of these would work in detail:

*Trial design*: A clinical-trial benchmarking agent identifies similar trials and establishes benchmarks for key metrics such as enrollment rate. Meanwhile, a literature-explorer agent evaluates the competitive landscape and unmet needs. Both agents send their outputs to a trial-optimizer agent that uses ML and simulation tools to refine the trial design, under the supervision of a human clinical scientist. Once the design is finalized, a document-generation agent generates a draft of the protocol in minutes, using a library of design elements such as endpoints, and refines the draft through feedback from a critic agent and a human clinical scientist. This approach could enable companies to design trials 50 percent faster with 25 percent fewer amendments.

*Study start-up*: A site feasibility agent creates site questionnaires based on the trial protocol and compiles the responses. The start-up selection agent then uses ML-based site selection to produce a prioritized site list of predicted high-performing sites for the study start-up team to review and confirm. A site contracting agent then automatically drafts "first time right" site contracts based on fair market value benchmarks, site potential, and site-specific precedents, speeding up contracting processes. The process then moves to the document drafting agent, which automatically drafts site-specific documents such as the investigator brochure and site initiation visit materials, enabling the start-up team to quickly activate the sites. This agentic approach could double site activation rates with 30 to 50 percent fewer staff.

*Clinical data flow*: At the beginning of trials, the case report form (CRF) design agent extracts structured protocol metadata to create annotated CRFs, which are then provided to the electronic data capture configuration agent to support quicker database setup. During the trial, the data entry agent flags delays in data entry and involves clinical research associates to ensure CRFs are completed. Meanwhile, the query generation agent detects anomalies in the data and automatically raises relevant queries. These queries are handled by a data cleaning agent, which flags complex queries for human review. Once the database is locked, the programming agent produces analysis datasets and results tables from the collated data, with a human biostatistician providing input for nonroutine datasets. This process could boost productivity in data management and programming by 60 percent, while reducing database build timelines from two to three months to under two weeks.

One major pharmaceutical company has adopted a multi-agent trial copilot to improve its oversight of the development process. The clinical operations team works with a supervisor agent that manages a group of specialized agents focused on site activation, subject enrollment, data management, and analyzing longitudinal trends. These agents use data from the company's clinical control tower, including portfolio, trial, and site information, to provide real-time, actionable insights and initiate proactive interventions to support on-time trial completion. The company plans to give its agent teams more independence in the future, including engaging principal investigators and clinical research associates for routine tasks.

**3. Medtech research and development: Accelerating innovation and prototyping**

By automating complex tasks such as prototyping, design controls, patent filing, and risk management, agents could free up 15 to 20 percent of capacity for R&D teams, allowing them to focus on higher-value activities, including strategic innovation, partnerships, and designs centered around patients and healthcare professionals (HCPs). This acceleration would shorten the time to market for life-saving medical devices. Also, improved decision-making and risk mitigation could lead to safer, more effective devices that better meet patient needs, boosting clinical and commercial success.

Agents could support medtech R&D teams in a variety of ways:

*Prototyping and design controls*: Prototyping is essential in medtech R&D, where engineers

improve device designs and manufacturing to meet requirements. Agents could transform this process and assist teams by autonomously creating and testing virtual prototypes. A design-simulation agent could analyze specifications, simulate performance, identify flaws, and suggest improvements early. A compliance agent could compare prototypes to standards and flag noncompliance in real time.

*Innovation mapping and patent filing*: In the medtech sector, it is crucial to stay at the forefront of innovation. Agents can transform how R&D teams identify opportunities and safeguard intellectual property. An innovation-mapping agent could scan defined sources of patents, industry literature such as journals, and trade publications to discover emerging technologies and trends, then compare these to existing products and solutions to identify unmet needs and opportunities for research. This agent could generate a prioritized list of opportunities along with competitive analyses, which could be designed and prototyped with agentic assistance. Once a concept is developed, a patent-drafting agent could prepare the initial submission, ensuring legal and technical compliance. Automating these tasks would help R&D teams find high-value opportunities more quickly and better secure their IP.

*Design controls and regulatory readiness*: Once a design has been finalized, a documentation agent could generate design-control files based on specifications, reducing design time. Risk management is vital in medtech R&D to ensure device safety and efficacy. Agents could streamline this by automatically identifying, assessing, and suggesting mitigations for risks throughout the product life cycle. A risk-assessment agent could analyze design inputs, manufacturing, and post-market data to create a risk profile. A risk mitigation agent could recommend design or process changes using predictive modeling. And for regulatory readiness, a submission agent could compile the necessary documents, reducing risk-management efforts by 15 percent.

As an example, a leading medtech company is already leveraging agentic AI to transform its product and software development processes. The company has implemented a multi-agent system to tackle key challenges such as managing interdependencies between systems and teams, tracking delivery, and consistently maintaining quality in more complex products and devices. Specialized agents now oversee critical tasks, including software testing, design iteration, and risk mitigation, while a central AI supervisor with human oversight coordinates these efforts to ensure smooth integration among teams and systems. By automating routine tasks and providing real-time insights, the company has greatly enhanced its ability to manage complexity and deliver high-quality products on schedule.

**By automating certain complex tasks such as prototyping, agents could free up 15 to 20 percent of capacity for R&D teams.**

**4. Commercial pharma and medtech: Elevating customer engagement and market success**

Commercial organizations in both pharma and medtech are grappling with rising complexity in engagement, increasing demands for personalization from HCPs and patients, an evolving policy environment, and cost constraints. Internal processes from brand planning to field enablement remain fragmented and inefficient, burdened by manual workflows and legacy systems. In pharma, companies' growing dependence on a sprawling network of external vendors is making cost structures unsustainable.

Agentic AI can help by taking on time-consuming activities like drafting brand plans or preparing contracts, freeing up teams to focus on strategic execution. They can also unlock new capabilities that were previously out of reach, including real-time insights for decision-making; self-service content creation; automated first-pass medical, legal, and regulatory reviews; and personalized pre-call planning for field representatives. These initiatives could translate into a 4 to 8 percent increase in revenues and a 5 to 9 percent reduction in commercial spending over the next five years.

Here are three transformations that can be enabled by agentic AI in commercial:

*Sales engagement*: Agentic AI can transform sales operations in life sciences. Intelligent assistants can redefine account representative engagement by supporting pre- and postcall activities, such as HCP and territory planning, capturing insights from individual interactions, automating follow-up tasks, and providing personalized coaching feedback to reps. These tools can help identify trends early and enable personalized, data-driven engagement by synthesizing clinical evidence, product info, and engagement data in a conversational format. Virtual sales platforms can extend reach to hard-to-access territories and HCPs in a compliant, scalable way, adding value to the HCP experience. These innovations could reduce the burdens of sales representatives by 15 to 25 percent and increase revenue by up to 3 percent through improved targeting and stronger relationships.

*Marketing*: Agentic AI is revolutionizing marketing workflows in strategic planning, content creation, review, campaign development and execution, and performance tracking. Self-serve platforms let marketers produce content independently, reducing their reliance on agencies and speeding up turnaround times. Automated pre-MLR (medical, legal, and regulatory) review systems identify common issues before formal review, decreasing cycle times and improving compliance. Unified platforms that aggregate internal and external data, with conversational interfaces, help marketers understand brand performance and patient and HCP needs. These tools automate tasks, speed execution, and provide intelligence to enhance responsiveness to changes in the market.

*Market access and payer engagement*: Agentic AI can enhance market access and payer engagement through increased automation, better decision-making, and minimized value leakage. Advanced gross-to-net optimization can simulate complex access scenarios at brand and portfolio levels, helping to inform trade-offs that were once difficult to make. A contracting-intelligence platform can enable smarter contract decisions by analyzing past deals, modeling potential outcomes, and guiding negotiation strategies. Several manual tasks can also be automated, including creating initial contract drafts, monitoring performance, and tracking compliance. Automated invoice auditing can ensure contract terms are upheld and identify discrepancies early. Together, these innovations can reduce manual workload, boost financial results, and support more strategic, data-driven decisions while fostering more consistent and effective engagement with payers.

**5. Pharma and medtech operations: Accelerating execution and decision making**

Life sciences operations face many challenges, including high interdependence between subfunctions and the need for time-critical decision-making and extensive quality and compliance documentation. These issues can be addressed with tailored agents or groups of agents, which can speed up processes and boost efficiency by improving metrics like service levels, forecast accuracy, manufacturing throughput, deviation rate, and cycle time for document creation. Agent-based AI could help with 75 to 85 percent of workflows in operations, reducing the time required for key tasks in supply chain, procurement, manufacturing, product development (CMC), and quality by 25 to 35 percent (Exhibit 7).

Here are three ways in which agentic AI can improve operations:

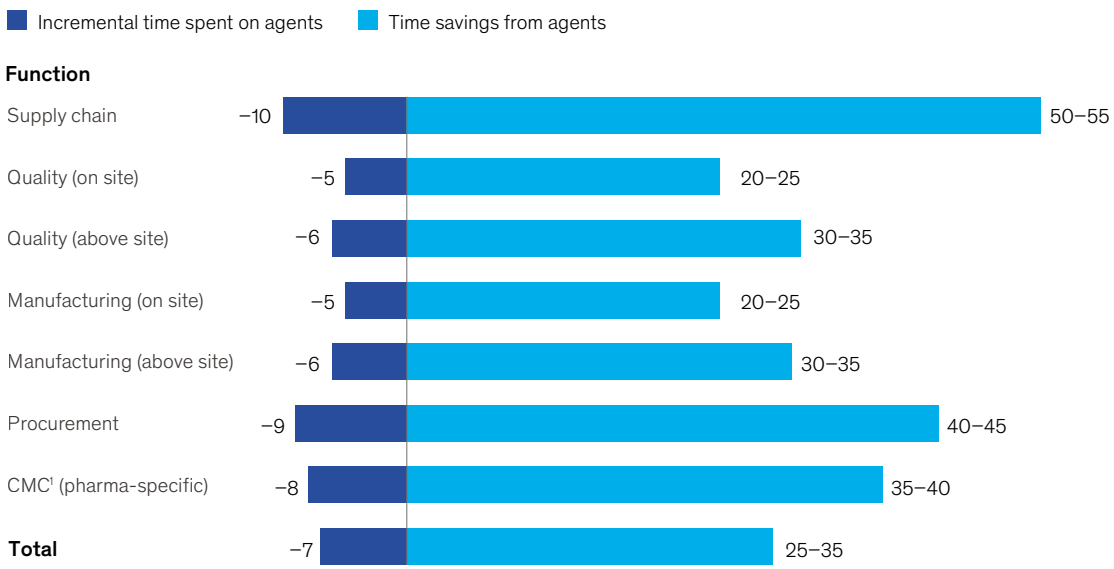
*Solving interdependencies with cross-operations planning*: Integrated end-to-end operations planning—which is essential to optimizing production and ensuring product availability—requires alignment among enterprise functions. Orchestrating agents can enable multifunctional interactions, eliminating delays from inefficient communication and approval processes. Agents can connect components such as supply planning, raw material supply, and manufacturing by reacting to external factors such as demand fluctuations. This integration transcends boundaries, providing teams with visibility into inputs, outputs, and decision-making. For example, a supply chain planning agent can ingest demand signals to simulate scenarios and create forecasts, which a production planning agent can then use to schedule batches. A raw materials agent can monitor inventory levels to trigger reorders, ensuring the availability of raw materials.

*Automating decision-making*: Agentic AI tools can improve decision-making and accelerate processes in all operations. To improve decision-making, multicomponent platform servers can be set up as middleware that allows agents to access data in a structured way, providing better contextual awareness of multistep tasks. Agents help identify changes in signals to process inputs and execute optimization decisions.

Exhibit 7

## Agents can shift workforce hours across operations functions.

**Work hours shifted by agentic workforce,** % of function capacity




[1]Chemistry, manufacturing, and controls.

McKinsey & Company

For example, in plant operations, by directly connecting to manufacturing execution and process-information systems, agents can detect and respond to deviations in real time. They can increase yield and product quality by adjusting bioreactor parameters such as pH and $O_2$ and modifying machine settings like pressure, temperature, and linear motor speed for fully automated medtech manufacturing lines.

Procurement category management agents can track changes in raw material supply and commodity prices to initiate targeted negotiations. Negotiation agents can coach procurement managers to negotiate with suppliers. Supplier management agents can observe suppliers' performance metrics and detect negative trends, such as in service levels, before they significantly affect operations.

*Accelerating document generation*: Operations teams spend a lot of time manually drafting good manufacturing practice documents for on-site and above-site workflows. Two types of documentation agents can help ease this burden.

The first type creates templates for standardized documents by using historical reports and good documentation practices requirements to draft initial versions of standard operating procedures, deviation and corrective and preventive action reports, validation protocols and reports, change control impact assessments, and technology transfer documents, drastically reducing the labor hours needed. These agents can also generate engineering and maintenance reports, such as equipment failure mode and effects analyses and preventive maintenance plans, along with procurement documents such as contracts and requests for proposals.

The second type of document agent connects to data sources, such as laboratory information management system testing results and manufacturing execution system process parameters, to generate near-final drafts of documents such as supplemental biologics license application filings for technology transfers.

Pilots and early assessments show that documentation agents can achieve 75 to 80 percent productivity gains for initial document generation. Additional benefits are possible through collaboration with document review agents that ensure compliance with regulatory and quality standards. End-to-end document generation and review agents can cut turnaround times from weeks to hours, enabling cross-functional teams to concentrate on final review and approval.

**6. Information technology: Transforming IT operations and driving innovation**

Agentic AI can revolutionize how IT organizations develop and manage technology.

*Agent-powered application development*: The integration of agentic AI into software development is transforming how digital products are designed and built. Instead of relying on product analysts to write user stories, designers to create mockups, and QA analysts to develop test scripts, agents can generate all these components with less oversight. Developers can assemble code using natural language commands rather than traditional programming languages. AI can handle routine coding tasks efficiently, analyze design patterns, and suggest improvements, allowing human designers to focus on creativity and strategic planning. This streamlined process accelerates development and improves the quality of new software products.

*Automation of IT operations*: As AI technology advances, traditional IT operations will experience significant changes. Tasks such as issue detection, event correlation, and service-request fulfillment can be fully automated. Agentic AI systems can update continuous integration and continuous delivery pipelines enterprise-wide as policies evolve, disseminate insights from new software updates to every deployed system, and perform automated threat monitoring. AI-driven systems can predict and resolve issues before they affect operations, ensuring smoother and more reliable IT services. This automation can save costs, improve service quality, and increase user satisfaction.

*Accelerating legacy system migration with intelligent automation*: Agentic AI can streamline the migration process to modern enterprise systems by automating complex and time-consuming tasks for development teams. Migration agents can analyze legacy systems, map data structures, and identify dependencies to ensure a

# Unlocking the full potential of agentic AI in life sciences requires a strategic, organization-wide approach that redefines workflows, roles, and human–agent collaboration.

smooth transition. These agents can also verify data integrity, detect inconsistencies, and automate data cleansing, reducing errors and manual effort. Using AI-driven insights, organizations can accelerate their migration timelines, minimize disruptions, and achieve a seamless transition to the new environment, enabling faster realization of business value. As many organizations rely on systems that are nearing the end of their life cycles—such as enterprise-resource planning—this acceleration is critically needed.

While the opportunity to transform IT with AI is real, so too is the burden it will create for IT. Business units and functions are deploying new AI faster than ever and are increasingly experimenting with new technology that is easier to build and deploy. This could create a complex technology landscape that, if left unmanaged, will become the next tranche of legacy systems that will be challenging to operate and keep up-to-date.

A Fortune 500 company launched a $600 million initiative to upgrade its aging systems, which included 400 applications, but faced challenges due to slow manual coding processes and inconsistent coordination. AI tools were used to automate code conversion, but they did not significantly accelerate the process. Human workers migrated to supervisory roles, managing teams of more than 100 AI agents responsible for documentation, coding, and testing. This change cut time and effort by over 50 percent. Specialized teams of agents worked on specific features, with their work reviewed and coordinated by other agents. Human supervisors ensured the smooth execution of these agent-managed tasks.

## The path to implementation

Unlocking the full potential of agentic AI in life sciences requires a strategic, organization-wide approach that redefines workflows, roles, and human–agent collaboration. Our Rewired framework offers a concrete foundation to approach this.[5] To ensure successful implementation at scale, organizations must focus on several critical enablers:

1. *Guide from the top*: A clear, top-down mandate from leadership is essential. Leadership's focus should be on aligning agentic AI's value-creation potential with corporate strategy rather than on technology challenges. Leadership must steer clear of small, incremental improvements by championing a bold vision, setting ambitious goals, and ensuring accountability across functions.

2. *Reimagine workflows*: Operational leaders should strive to reimagine work in their domains. This involves identifying high-value workflows that can incorporate agents, providing every user with intelligent interfaces to access agent capabilities, and encouraging a culture of innovation and experimentation. A thorough understanding of current processes and the capabilities of agentic AI is essential, from leaders down to the front line.

[5] "Rewired and running ahead: Digital and AI leaders are leaving the rest behind," McKinsey, January 12, 2024.

3. *Invest in people*: Many roles will change from doing manual and repeatable tasks to setting goals and steering AI agents. Traditional process and people management will migrate toward supervising hybrid teams, leading to changes in organizational structures. Employees will need new skills and tools to activate and supervise agents and overcome the cultural and organizational barriers to adoption. Additionally, new business processes will be needed to measure, monitor, and improve the performance of the agentic workforce. The talent function will play a significant role in managing these transitions and can begin exploring the implications now.

4. *Build scalable foundations*: To maximize the benefits of AI agents, organizations can invest in flexible interconnected networks of AI agents that enable their rapid development, deployment, and management.[6] These "meshes" include modular, cloud-based architectures that can handle increasing complexity and volume, as well as lower-complexity agents that empower nontechnical users to create and customize agents. Agent-to-agent interoperability and the ability to coordinate multiple agents will be key to success. Scalability also requires a robust data infrastructure to ensure agents have access to high-quality, real-time data. Managing data well is key to success and includes aligning the organization on data ontologies and ownership. Strategic partnerships with technology providers and start-ups can provide access to cutting-edge innovation.

5. *Establish robust change-management to ensure adoption and value at scale*: The transformative potential of agentic AI requires a robust and sustainable change-management strategy. Efforts should include role modeling by executives, a compelling change story, training, ongoing coaching, and incentives to encourage and reward adoption. It should also involve integrating agents into existing business processes, such as management reviews, quarterly business reviews, and sales performance evaluations, along with mechanisms to gather and incorporate feedback.

6. *Set risk management and governance guardrails*: As agentic AI becomes embedded in critical workflows, it's best for organizations to establish strong governance frameworks to ensure ethical use. These include clear accountability for decisions made by agents, guardrails to prevent unintended consequences and ensure compliance with regulatory requirements, regular audits, and bias-detection mechanisms.

7. *Foster a culture of continuous learning*: The implementation of agentic AI is a long-term learning challenge for employees and companies. Leaders should establish a strategy for continuous learning and adaptation, including a safe environment for experimentation and a structured approach to skill-building. Organizations must continuously monitor technological advancements, assess new capabilities, and improve their own implementations.

8. *Mobilize an agent factory*: A small, centralized group with leadership support can ensure agentic AI is deployed toward the most impactful use cases. The group can facilitate the process for reimagining workflows in collaboration with domain leaders, contribute relevant technology expertise, monitor impact and adoption metrics, and help remove roadblocks to deliver the transformational potential of agentic AI.

By addressing these dimensions holistically, life sciences organizations can harness the transformative power of agentic AI to propel innovation, achieve sustainable competitive advantage, and, most importantly, improve patient outcomes.

[6] "Seizing the agentic AI advantage," QuantumBlack, AI by McKinsey, June 13, 2025.

## Defining tomorrow

The true power of agentic AI lies in its ability to amplify human ingenuity, freeing teams from mundane tasks and unlocking entirely new possibilities for discovery and value creation. By embracing these systems, life science companies can redefine the limits of innovation, accelerate breakthroughs, and deliver life-changing therapies to patients with unprecedented speed and precision. We anticipate that pharmaceutical and medtech companies that embrace this transformation will operate radically differently and more competitively five years from now, with benefits accruing in the meantime. Are you ready to reimagine what your organization could achieve with an agentic workforce alongside your people?

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# How scientific AI is unlocking hidden value in drug repurposing

AI is transforming drug repurposing by quickly identifying new uses for existing medicines, accelerating patient access to therapies, and creating cost savings.

*by Alex Devereson, David Champagne, Emily Briggs, Ian Lyons, Jennifer Hou, Alexander Aranovitch, Chris Anagnostopoulos, Maren Eckhoff, and Valmir Selimi*

**In pharmaceuticals,** strategically identifying new uses for existing drugs—in other words, drug repurposing or indication finding—can accelerate the delivery of therapies to patients and offer substantial cost savings compared with developing novel compounds. However, traditional methods of indication finding have often been slow and limited, relying on expert opinions, literature reviews, and chance observations. Now, AI is stepping in and offering a transformative approach, as explored in the paper *Indication Finding: A novel use case for representation learning* (https://arxiv.org/pdf/2410.19174).[1]

In the paper, researchers from McKinsey; Quantum Black, AI by McKinsey; and the Ellison Institute of Technology demonstrate how a specific type of AI, known as "representation learning," can analyze real-world data to identify potential new uses for existing drugs. This AI technique enables the system to learn complex relationships within vast data sets of patient information. Rather than simply examining individual data points, AI generates "embeddings," which can be visualized as maps. On these maps, diseases and treatments are positioned near each other based on their similarities and connections. This allows researchers to recognize diseases that might be effectively treated by drugs already used for related conditions.

The researchers focused on anti-IL-17A drugs, which are used to treat inflammatory conditions. They provided the AI with a massive data set of real-world data from more than 17 million patients and asked it to create maps. It then identified diseases that were closely related to the diseases that anti-IL-17A drugs are known to treat.

The AI showed a striking ability to identify diseases such as rheumatoid arthritis, rosacea, and hidradenitis suppurativa for which anti-IL-17A drugs have already shown positive results in clinical trials. In the top 50 indications that the AI ranked, 60 percent were conditions with positive trial results, and none were from conditions for

[1] Maren Eckhoff et al., "Indication finding: A novel use case for representation learning," QuantumBlack, AI by McKinsey, October 24, 2024.

which the drug had failed. In the top 200, all positive-validation conditions were ranked, compared with only 20 percent of those with failed trials. The AI also ranked diseases for which anti-IL-17A drugs have previously failed to demonstrate efficacy, such as Crohn's disease and atopic dermatitis, much lower on its list. Additionally, it surfaced some diseases for which anti-IL-17A drugs' efficacy has not yet been tested, pointing to potential new research avenues. This level of accuracy demonstrates that AI can significantly assist in identifying new applications for existing therapies.

While this research is still evolving, the implications for the pharmaceutical industry are profound. By using AI-driven indication finding rather than pursuing lengthy and costly searches for completely new drugs, companies can efficiently identify opportunities to extend the utility of their existing portfolios. This more informed, data-driven decision-making results in faster time to market for new treatments and reduces R&D costs. Furthermore, such strategies can significantly enhance the product life cycle management of existing assets, maximizing their commercial value. Those interested in diving deeper into this research can find the complete paper here (https://arxiv.org/pdf/2410.19174).

The original paper was authored by **Alex Devereson** and **David Champagne** of McKinsey and **Matej Macak** of the Ellison Institute of Technology, with **Emily Briggs**, **Ian Lyons**, and **Jennifer Hou** of McKinsey and **Alexander Aranovitch**, **Chris Anagnostopoulos**, **Maren Eckhoff**, and **Valmir Selimi** of Quantum Black, AI by McKinsey.

# Scaling gen AI in the life sciences industry

Gen AI pilots have shown promise, but for the technology to deliver transformational business value in the life sciences industry, organizations need to rethink how they scale it.

*by Chaitanya Adabala Viswa, Dandi Zhu, Delphine Zurkiya, and Joachim Bleys*

**Back in July 2023,** researchers at the McKinsey Global Institute estimated that gen AI could unlock between $60 billion and $110 billion a year in economic value for the pharmaceutical and medical products industries, boosting productivity and innovation in domains across the industry's value chain—from the way new treatments are discovered to how they are marketed and administered by physicians. Six months later, McKinsey experts dug deeper into those numbers, uncovering more than 20 use cases with the greatest potential for near-term impact.

Now, with gen AI use cases proliferating across the business community, we decided to find out how much progress life science organizations have made in capturing this value. In late summer 2024, we surveyed more than 100 pharma and medtech leaders responsible for driving their organizations' gen AI efforts. All respondents report having experimented with gen AI, and 32 percent say they have taken steps to scale the technology. But only 5 percent say they have realized gen AI as a competitive differentiator that generates consistent and significant financial value (Exhibit 1). Nonetheless, companies remain optimistic about gen AI, with more than two-thirds of respondents saying they plan to significantly increase investment in the technology (Exhibit 2).

Why do so many life science organizations struggle to realize results from their gen AI deployments? And what are the minority of top performers doing differently? This article reveals the most common pitfalls life science companies are facing—and offers solutions that can help organizations move from pilot purgatory to driving real business value at scale.

## The key challenges to scaling gen AI in life sciences

Based on our survey and our experience, we have identified five key areas that pose challenges for life science companies attempting to realize company-wide value from gen AI: gen AI strategy, talent planning, operating model and governance structure, change management, and risk (Exhibit 3).

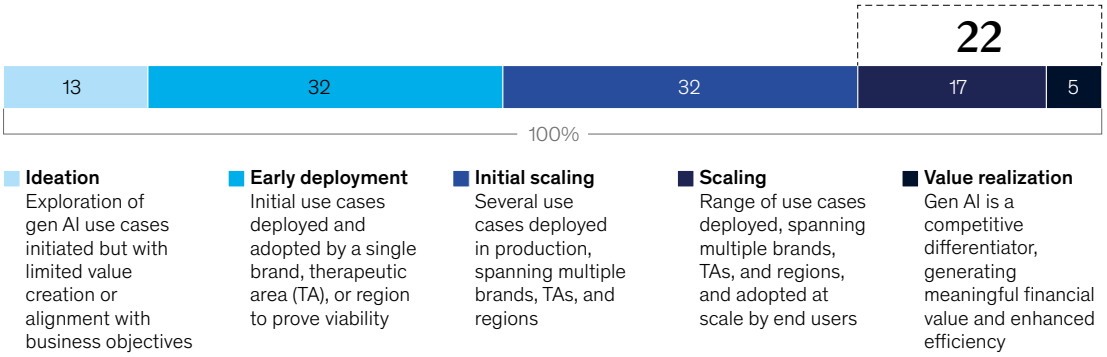
### Challenge 1: Ambiguous, shortsighted, or nonexistent enterprise gen AI strategy

About 75 percent of respondents say that their organizations lack a comprehensive vision for gen AI or an intentionally designed, strategic road map with clearly defined success measures linked to business priorities. Instead, they tend to proceed in a decentralized manner, use case by use case. This instinct to capture short-term value through experimentation, coupled with the federated/function-led structure of many life science organizations, explains many of the challenges organizations encounter when it comes to scaling.

Exhibit 1

## Nearly a quarter of life science organizations have deployed gen AI at scale.

**Reported level of gen AI maturity at organization,** % of respondents




Note: Figures may not sum to 100%, because of rounding.
Source: McKinsey State of Gen AI in Life Sciences Survey, Aug 23–Sept 18, 2024 (n = 82)

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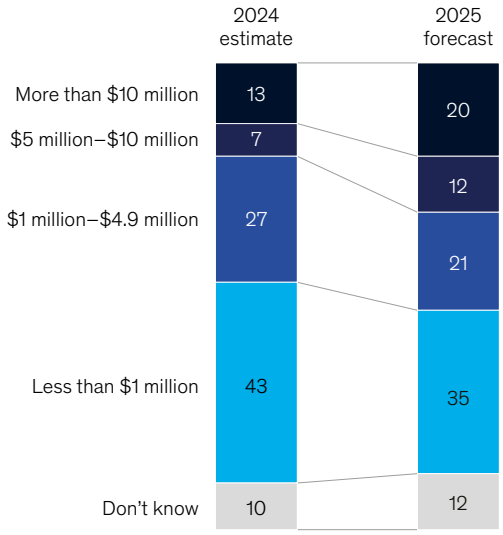
Exhibit 2

## Life science organizations are boosting their gen AI budgets in 2025.

**Reported gen AI budgets,**
% of respondents



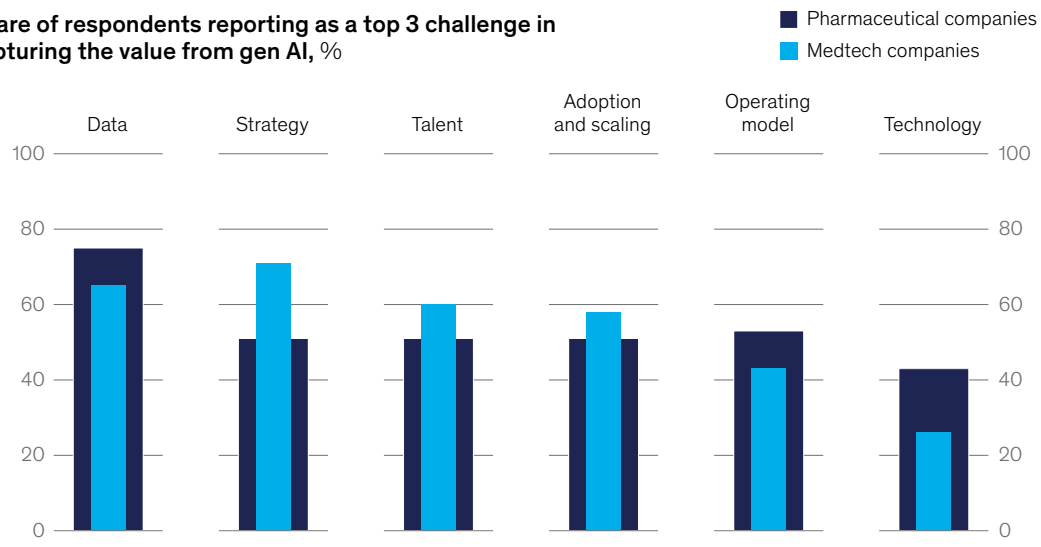

Source: McKinsey State of Gen AI in Life Sciences Survey, Aug 23–Sept 18, 2024 (n = 82)

McKinsey & Company

Exhibit 3

## Issues relating to data and strategy stand out as the top challenges in realizing gen AI's potential.

**Share of respondents reporting as a top 3 challenge in capturing the value from gen AI,** %




Source: McKinsey State of Gen AI in Life Sciences Survey, Aug 23–Sept 18, 2024 (n = 82)

McKinsey & Company

McKinsey research has found that digital transformations seldom succeed unless C-suite leaders are aligned around a business-led road map. Without an intentional strategic posture toward gen AI—whether a top-down mandate or a coordinated enterprise road map driven by a center of excellence—individual business units are left to navigate the ever-evolving technology landscape on their own, pursuing a multitude of new use case ideas that, no matter how compelling, often fail to add up to a strategy that delivers actual value.

### Challenge 2: Lack of talent planning and upskilling

At most life science companies, the existing pool of tech talent presents a traditional tool kit for IT, data science, and product development. Unfortunately, traditional approaches to tech talent are unable to deliver the quality and performance of enterprise-grade solutions needed for gen AI, for example, agent-based architecture, model validation, large language model (LLM) operations, and the fine-tuning of models. But only 6 percent of survey respondents report having conducted a skills-based talent assessment to determine how to evolve their talent strategy into one that considers gen AI priorities.

Prompt engineering has emerged as a key gap, especially for more complex gen AI applications. One life science company, for example, was attempting to use gen AI to draft regulatory documents, only to discover that prompt engineers required a unique combination of regulatory domain knowledge and engineering rigor to craft scalable prompts that generate submission-ready output—a specialized necessity that made the role especially challenging to fill.

### Challenge 3: Loosely defined operating model and governance

One common challenge leaders face is creating the right operating model for gen AI transformation, often choosing between one of two extremes. At one end of the spectrum is a highly decentralized approach, in which the organization simultaneously launches multiple use case pilots. While this allows companies to move fast, it also leads to

quality, cost, and sustainability challenges and creates operational silos that inhibit the sharing of knowledge and the ability to capture cost synergies. At the opposite end is a top-down approach, with centralized decision-making and a phased rollout of use cases. This approach can be slow and often frustrating, destroying momentum.

One company swung between the two. It began its gen AI efforts by launching 1,500 different use cases. When that proved unwieldy, company leaders imposed a top-down governance structure that led to a different set of issues, constricting the innovation pipeline with projects requiring an arduous approval process that stretched some two to three months.

**Challenge 4: Underestimating the process rewiring required to drive scale**

To succeed with gen AI, companies must integrate the technology across complex workflows to promote adoption and impact—a reality that highlights the need for effective change management. McKinsey has found that 70 percent of digital transformations fail not because of technical issues but because leaders ignored the importance of managing change. In fact, for every $1 spent on technology, $5 is required for change management to successfully drive capability building, adoption, buy-in, and value capture over time.

One company launched a center of excellence function to initiate a broad gen AI platform for a range of use cases but failed to communicate a compelling change story to accompany those initiatives. That failure, coupled with the lack of holistic, end-to-end planning and thinking, resulted in a collection of gen AI tools that almost no one ended up using.

**Challenge 5: Inadequate understanding of risk**

Gen AI introduces unique risks, from hallucinations and accuracy to bias and intellectual property protection. But 35 percent of survey respondents report that they spend fewer than ten hours with their risk counterparts, limiting the degree of collaboration with these crucial functions. This dynamic needs to evolve to scale gen AI. Successful scaling requires business leaders, technology teams, and risk management professionals to communicate from the outset; the absence of such collaboration can lead to issues being raised late in the game, when they are much more difficult to fix, or a lack of adherence to the risk and compliance guardrails that are critical to building trust in the organization.

One company, for example, spent several months developing an external-facing gen AI solution, only to be forced to withdraw the launch due to a lack of alignment with its digital, medical, and legal teams—which raised significant risk issues after the tool had been developed. This resulted in a severe setback for the gen AI team's agenda, morale, and momentum.

## The solution: A five-point plan to realize value from gen AI

Successfully scaling gen AI and capturing its value potential requires more than just a technological rollout. An effective gen AI strategy is fundamentally different from traditional tech projects. Given the rapid pace of innovation, a gen AI strategy must be dynamic, scenario driven, and focused on how to engage with the broader ecosystem. Scaling gen AI involves comprehensive change across the organization, encompassing strategy, talent, governance, and risk management.

Based on our experience, we have identified five key strategies to move from gen AI use cases to enterprise-wide adoption. These actions ensure that organizations not only experiment with the technology but also fully integrate it into their operations to drive measurable business value.

— *Adopt a domain-driven approach.* Successful AI strategy cannot be based on a slew of disconnected use cases, which often leads to fragmented efforts and missed opportunities. Instead, the focus must shift to domain-driven transformations, where gen AI is applied to fundamentally reshape critical areas of the business, such as the commercial, medical, or R&D domains. Thirty-eight percent of the life science organizations surveyed cite research as their leading strategic priority in their gen AI journey, followed by the commercial domain, at 28 percent (Exhibit 4).

Exhibit 4

## The research and commercial domains are leading strategic priorities for gen AI initiatives.

**Biggest strategic priority for organization's gen AI efforts,**
% of respondents


Note: Figures may not sum to 100%, because of rounding.
Source: McKinsey State of Gen AI in Life Sciences Survey, Aug 23–Sept 18, 2024 (n = 82)

McKinsey & Company

This domain-driven approach ensures that gen AI isn't just another tech solution but a core enabler of business transformation. Rather than focusing on technology for technology's sake, organizations that prioritize domain transformations are better positioned to capture the full value of AI. Crucially, there is no such thing as a stand-alone gen AI strategy. The real focus should be on deploying gen AI to support broader business objectives, drive strategic goals, and create differentiation in the market. Organizations that view the technology through this business-first lens have found greater success in scaling AI initiatives.

— *AI transformation encompasses more than just tech.* Scaling gen AI isn't simply a matter of implementing a new technology; it's about rewiring the organization's operating model and culture to support new AI-driven ways of working. This extends to talent strategies: the workforce must evolve beyond traditional IT data science roles to include new skills—AI engineering, large language model fine-tuning, and business translation—to bridge the gap between technical execution and business value capture. Without a comprehensive talent realignment, organizations will be less successful in scaling their gen AI efforts. Further, gen AI implementation needs to drive measurable value. This requires a clear up-front agreement on how value will be captured, say, through acceleration of time to market, productivity increase, or improved probability of success.

**Rather than focusing on technology for technology's sake, organizations that prioritize domain transformations are better positioned to capture the full value of AI.**

One life sciences company, for instance, launched an enterprise talent upskilling and planning program, with targeted initiatives for business and technical roles. The program also introduced dedicated gen-AI-focused leadership roles in critical functions to drive sustained organizational change. With the appropriate talent—and leadership—in place, the company's gen AI initiatives proceeded much more smoothly than they would have otherwise.

— *Adopt an ecosystem approach.* In the rapidly evolving AI ecosystem, an externally focused partnership strategy is critical. Given the speed at which AI technologies and methodologies are advancing, life sciences organizations should consider cultivating a network of low-cost, high-optionality partnerships. These partnerships can provide flexibility and give organizations the ability to quickly pivot and seize opportunities as they arise. Organizations should also establish clear "triggers" that indicate when it's time to move from exploratory partnerships to larger strategic bets. This ensures that the business remains agile and can scale up or shift its AI investments based on real-time insights and market movements.

Engaging with the broader ecosystem—including academia, tech, and venture capital—is also essential to staying on top of the latest developments. Relying solely on internal capabilities is no longer enough to stay competitive in AI. A dynamic, externally focused lens ensures that companies stay ahead of the curve and capture the full value of gen AI innovations.

— *Deploy a platform-driven approach from the outset.* A platform-driven approach is key to ensuring that gen AI initiatives are scalable, sustainable, and reusable across various business domains. A scalable AI platform allows organizations to standardize infrastructure, data pipelines, and development processes, ensuring that each new use case builds on the previous one. This can also help reduce duplication of effort, encourage collaboration across business units, and foster consistency in AI performance across the organization. Moreover, a platform-driven approach ensures that AI models are not developed in isolation but are integrated into a unified framework, allowing them to be adapted and reused across various business domains. This not only reduces costs but also accelerates time to value, as insights from one domain can be applied to another.

One life sciences company found success by adhering to a mantra: "Slow down to speed up." The company spent three months defining a detailed blueprint for insights and document platforms. This enabled the reuse of components within each platform, enabling rapid scaling across use cases.

— *Embed risk management in the full product development life cycle.* One of the common mistakes organizations make with gen AI is treating risk management as an afterthought or as an obstacle to innovation. In fact, risk management must be embedded throughout the entire AI product life cycle. Gen AI introduces unique risks—such as hallucinations, bias, data security, and intellectual property issues—which require careful oversight.

To ensure these risks are managed effectively, business leaders and risk and compliance functions should collaborate regularly. Organizations should establish clear governance frameworks early on and ensure that ethical guidelines are in place to address concerns about AI fairness, transparency, and accountability.

Given the high regulatory requirements in life sciences, organizations should place greater emphasis on risk management. One organization proactively identified the guardrails necessary to address evolving regulations (for example, the EU AI Act) and technology limitations (for example, the probabilistic nature of models). The organization established clear, responsible AI requirements, including mandatory observability, validation protocols, and human-in-the-loop guidelines, which were defined prior to the start of product development.

## What a holistic transformation can look like

What does a successful gen AI initiative look like? Consider one life sciences company that recognized the gen AI opportunity early and embarked on a holistic transformation across domains. Company leaders convened a C-level task force to steer the overall gen AI strategy, set up governing bodies across the R&D, commercial, medical, and operations domains, and asked each domain to prioritize one use case with high-value potential for C-level sponsorship.

The company then ran proofs of concept with an eye toward scaling, using its early experiences to organize reusable components into domain-specific platforms. The technology and business teams partnered from the outset, ensuring that all gen AI solutions addressed priority business needs and helped drive the process changes needed to spark adoption and deliver value.

In the meantime, the company engaged ecosystem partners to bring in learnings and assets from across the life sciences industry and beyond and built stage gates to focus resources on partnered solutions that were ready to scale across therapeutic areas and geographies.

Leaders shaped a compelling change story focused on how gen AI solutions were intended to augment rather than replace employees, for example, by helping them deal with increasing workloads, and used change management teams to help drive a successful rollout. They provided white-glove support for initial users and deployed these early adopters as change ambassadors to build bottom-up momentum. Impact metrics were defined, tracked, and reviewed at regular governance meetings to ensure gen AI initiatives remained on track to scale and deliver business impact.

This kind of experience does not have to be an outlier. Leaders of life science organizations should understand that capturing the potentially transformative value of gen AI requires more than experimentation and individual use case deployment. It demands strategic integration into the organizational fabric. In the next chapter of the gen AI story, organizations should take an intentional approach to driving alignment with business strategy, scalability, and sustainability. This pivotal moment is an opportunity for life sciences leaders to lead transformative change, revolutionizing drug discovery and patient care, as well as driving meaningful bottom-line results.

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# How pharma is rewriting the AI playbook:

## Perspectives from industry leaders

*by Alex Devereson and Navraj Nagra*

AI-powered data analysis is accelerating pharma R&D, from discovery to clinical trials, leaders from across the pharma industry shared.

**If we assume** artificial intelligence (AI) will be a game changer for almost all industries, how will companies turn that potential into returns? In the pharmaceutical sector, simply bolting AI onto business as usual likely won't deliver tangible results, industry leaders said on McKinsey's Eureka! podcast.

Investment in AI is increasing at a fast clip. Companies invested more than $250 billion in it last year. In the pharma industry alone, the AI market is projected to grow from more than $4 billion this year to a whopping $25.7 billion by 2030. Amid this surge, medicine makers have yet to see substantially shorter development timelines or improvements in preclinical or clinical success rates.

What will drive success? Pharma leaders told us AI deployment in their industry isn't just about adding the technology to accelerate existing processes. The effort will require a complete reimagining of drug discovery and development workflows. But leaping headfirst into AI—the classic "move fast and break things" mindset of start-up culture—won't work in a highly regulated industry that touches patient lives.

Each podcast guest described what makes AI rollouts effective—insights that align with McKinsey's principles for implementing AI successfully. They center on culture, technology, and talent.

**Listen to the Life Sciences Eureka! Podcast on Apple Podcasts, Spotify, or your preferred podcast app.**

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# The six enablers of successful AI deployment

## 1. A successful AI rollout is the result of clear goals and a rethink of the process. It's more than just tech—it's part of a strategy focused on business value.

You can't drop an AI model into an existing workflow and expect transformation to happen. Companies need to take a big-picture view and think through how AI fits into their broader strategy. Key questions include: What problem are we solving? What's the blueprint for capturing value? How do we define and measure return on investment?

AbbVie's Howard Jacob noted that success with AI comes from rethinking processes and building new capabilities, not layering tools onto legacy systems. "Inside AbbVie, we have begun to look at everything within the past year—early target discovery, target development, biologics design, and patient recruitment and engagement," Jacob said. "The uptake is just extraordinary, and I'm glad we put the infrastructure in place so we could start running fast."

"The uptake is just extraordinary, and I'm glad we put the infrastructure in place so we could start running fast."

**Howard Jacob**, vice president of genomics research and head of data integration at AbbVie

## 2. Analytics and AI models can turn data into insights that inform decision making and accelerate R&D.

Use-case-related algorithms and models help companies transform data sets into insights that advance business and scientific objectives. These include drug discovery and development and clinical trial design and data.

For example, Ashita Batavia at Johnson & Johnson Innovative Medicine (J&J) said the company is using algorithms that review diagnostic test images to find patients that might be a good match for new treatments. The company also uses deep-learning algorithms to prescreen tissue samples from bladder cancer patients to help determine if they might qualify for clinical trials.

"We were able to prescreen and accelerate the time to an answer or a screening decision for some patients."

**Ashita Batavia**, head of hematology and oncology data sciences, R&D, at Johnson & Johnson Innovative Medicine

"[To a] digital pathology image we could apply an algorithm that we built and validated to predict the presence or absence of a qualifying mutation for a trial, which pathologists are unable to do," said Batavia. "With the algorithm . . . we were able to prescreen and accelerate the time to an answer or a screening decision for some patients."

Boehringer Ingelheim is applying AI to rethink trial design. Lykke Hinsch Gylvin, its chief medical officer and head of global medicine, pointed to the company's use of digital twins—virtual patient models that help simulate outcomes and reduce reliance on placebo groups.

"These tools help us to accelerate speed while minimizing the number of patients on the placebo control arms, which is a win-win for us and the industry," she said. These models speed up trials and reduce patient burden without sacrificing data quality.

# The six enablers of successful AI deployment (continued)

## 3. A robust tech stack is essential to provide computing power, data infrastructure, and tools for model development.

As outlined in our report published early this year by Jeffrey Lewis, Joachim Bleys, and Ralf Raschke, a modern tech stack allows for insights, workflows, data collection, storage, transfer, and processing of data throughout the discovery, research, and clinical-development stages. It's made up of four layers: infrastructure, data, application, and analytics.

A well-integrated stack doesn't just enable AI—it determines whether those tools can scale. Pharma organizations that rely on siloed systems and point-to-point integrations often struggle to move beyond isolated pilots. By contrast, a modular setup with well-organized data and systems that work together can support the deployment of AI tools across discovery and development. This structure helps teams use AI more effectively—making it easier to access clean data, automate research and trial operations, and apply models to tasks like identifying eligible patients for trials, designing molecules, or preparing regulatory submissions. The tech stack therefore becomes the foundation for moving from experimentation to enterprise-wide AI adoption.

## 4. The right data is critical.

Problem-specific data is an essential part of successful AI deployments. The nature of that data is also changing, and it's now being generated specifically to feed and improve algorithms. For example, when designing a clinical trial, electronic health records can help identify patients who aren't responding well to treatments. During drug development, practitioners need to match the data to the problem they're trying to solve and build a strategy around it.

> "The big thing for us was generating data with the explicit purpose of building models, because we believe that's a source of advantage."
>
> **Kim Branson**, senior vice president and global head of AI and machine learning at GSK

"The big thing for us was generating data with the explicit purpose of building models, because we believe that's a source of advantage," said Kim Branson of GSK, which invested in a robust global team called Onyx to carry out data engineering at scale. The team's mandate is to ensure scientists have the right data and insights.

Data quality is also important, as poor quality inputs can result in unreliable models, ineffective R&D efforts, and regulatory risks.

For AI systems to effectively analyze data, it needs to be organized, which can be a challenge for large organizations that use legacy infrastructure.

## 5. AI rollouts require multiple talent streams.

Companies must adopt a flexible and horizontal approach to talent management—through upskilling and reskilling—and maintain a team with a range of skills. GSK's Branson emphasizes the importance of cross-functional teams as a foundation for successful AI initiatives. "Domain knowledge absolutely matters for assessing how the data is generated," he said. "We have people that are both machine learning [specialists] and deep experts in some of these domains." In clinical imaging, GSK assembled a team of people who have PhD and postdoctoral qualifications in clinical imaging, alongside those with machine learning expertise, he added.

J&J's Batavia emphasizes the importance of what she calls "trilingualism" in skills proficiency, including in data science, science and medicine, and business strategy. "It's rare to find a person who has, say, practiced medicine, has been a trialist who understands data sciences, and has a business strategy lens," she said. "But if a candidate has a couple of those skills, they can upskill and learn the rest."

Organizations also need to be open to collaboration when building in-house is not practical. "You need all those different elements—the technical expertise; the biological, chemical, and clinical insight; and the compute infrastructure—and you need to be able to incorporate them together sensibly," Genentech's Marioni said. "One company is unlikely to have all those elements in-house, so we collaborate closely on the compute side with Amazon Web Services and NVIDIA to accelerate how quickly we can train and deploy the models we're coming up with together."

"Don't underestimate that holistic approach—80 percent of the challenge related to many of these efforts is the people part."

**John Marioni,** senior vice president and head of computational sciences, Genentech Research and Early Development

## 6. A flexible change-management approach helps meet the evolving needs of both business and scientific stakeholders.

AI is set to transform how organizations create and manage processes. A rigid, linear product development model is being replaced by an iterative cycle of prototyping, feedback, and continuous improvement. AI tools can accelerate product prototyping, allowing for faster testing and refinement. In addition, AI agents can autonomously lead or own parts of a process, raising new governance questions. For example, should organizations centrally control AI agents or allow teams to decide how independently they operate? For AI adoption to succeed, companies need to identify change champions across the organization, with clear KPIs.

At Genentech, Marioni's team has embedded AI directly into experimental workflows through a "lab-in-the-loop" model. Rather than using AI as a passive analysis tool, Genentech uses it to actively guide experiments—particularly in molecule design.

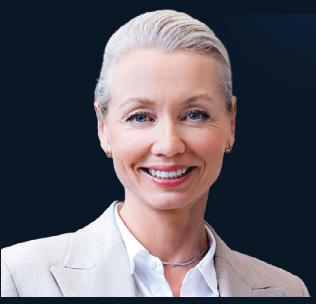
"We start with the model, receive a prediction, validate it, and then improve the model," Marioni said. "It's a virtuous circle . . . you keep doing that until the model can generate good predictions that can complement and guide the next experiments that are being done."

While overcoming technological obstacles is always important, addressing the people element—the cultural issues—is often a critical enabler for success. Most of the challenges related to AI rollouts are people related, he argues.

"Don't underestimate that holistic approach—80 percent of the challenge related to many of these efforts is the people part, so getting that to work makes an enormous difference," Marioni said. "If we do that right, the rest follows."

# The six enablers of successful AI deployment (continued)

Boehringer Ingelheim is also reshaping how teams work to support AI integration at scale. The company introduced a set of "new behaviors" designed to encourage entrepreneurial thinking across teams. These include collaborating with purpose, delivering to win, and innovating—behaviors that are not only encouraged but actively rewarded, said Hinsch Gylvin.



> ". . . collaborating with purpose, delivering to win, and innovating—behaviors that are not only encouraged but actively rewarded."

**Lykke Hinsch Gylvin,** chief medical officer and head of global medicine at Boehringer Ingelheim

## Facing the risks in pharma

As organizations train AI models on patient data, they face a range of risks—including privacy concerns, data misuse, and regulatory compliance challenges. According to our *The state of AI* report from March, 47 percent of organizations using generative AI experienced one negative consequence, with cybersecurity being a top concern.

Working with patient data means companies need to take a layered, deliberate approach to protection. As we noted in our November report *Harnessing AI to reshape consumer experiences in healthcare*, companies need to map out risks and develop mitigation plans. They should develop governance processes anchored in algorithm transparency and continually monitor AI-specific regulations.

Ultimately, the effectiveness of AI outputs depends on the quality of the input data. The data must also be representative of the domain it aims to model. Skewed data sets—where certain segments are disproportionately represented—pose a significant risk, alongside issues like longitudinal data gaps and AI model hallucinations.

Firms should also ensure that AI models are explainable. As J&J's Batavia noted, explainability "doesn't get as much airtime as it should . . . knowing what the data is, what the AI application is doing, why it's doing it, and how we're able to use it."

## The road ahead

AI investments in pharma will soon face heightened pressure for returns, and the race will ultimately result in winners and losers:

- The **redesigners** fundamentally rework their operating models, embracing automation, computer-generated simulated trials, and AI embedded across the value chain.
- The **tinkerers** dabble in discrete, one-off efforts, rolling out isolated pilots that may fail to scale. As a result, they may find that their investments yield low returns, harming their long-term competitive advantage.

The winners will be the firms—the redesigners—that weave AI into all of their workflows, not the tinkerers who layer it on top of existing processes.

Successful AI deployment will depend on how strongly company leadership embraces the technology to fundamentally shift how organizations work. Hinsch Gylvin of Boehringer Ingelheim pointed out that the key is having a clear strategy and goal for where, how, and when you apply AI and digital tools.

We know AI will transform drug discovery and development and could make real differences in patients' lives. Experts told us success using AI depends on a focused approach and a redesign of processes to support both iteration and a rethink of the way we work. In short, redesigning and experimenting are essential to innovating with AI. Companies that do both well will be positioned to come out ahead.

Podcast guests also highlighted the importance of creating an adaptive culture, with the goal to gradually build confidence across organizations.

"Building trust is the key," said AbbVie's Howard Jacob. "We have to elevate the conversation to focus on what AI and [machine learning] outputs do well and how we can leverage them to continue to get better. I saw the same thing when genomics was first coming out. People felt it was a waste of money. We don't have those conversations anymore."

# 2

# Optimizing Operations and R&D for Efficiency



# Rewiring pharma's regulatory submissions with AI and zero-based design

Six building blocks could help pharma organizations slash filing timelines from months to weeks, potentially unlocking as much as $180 million in net present value for priority assets.

*This article is a collaborative effort by Anton Mihic, Gaurav Agrawal, Lotte Berghauser Pont, and Rosa Poetes, with Giulia Ferretti and Ralf Raschke, representing views from McKinsey's Life Sciences Practice.*

**Biopharmaceutical companies** have set bold ambitions to reduce regulatory-submission timelines for new products. This is part of broader efforts and ambitions over the past decade to compress clinical timelines and revitalize stagnant R&D productivity in the industry. Among the many steps required to deliver new medicines to patients, the often-time-consuming submission process presents an exceptional opportunity to accelerate the drug development period.

Faster and higher-quality submissions during drug development can provide substantial benefits to patients, pharma companies, and other stakeholders. For example, it would provide patients with earlier access to potentially life-saving therapies. Additionally, per our analysis, a pharma company making an improved submission for a $1 billion asset one month more quickly than typical would unlock roughly $60 million in net present value (NPV).

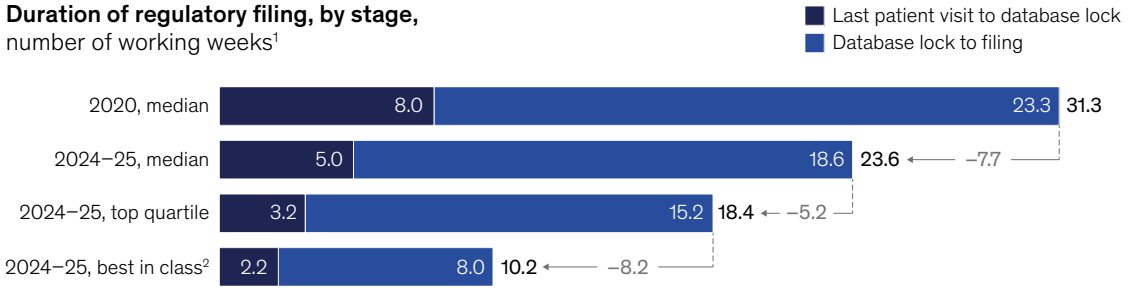
In the past five years alone, the pharma industry has made impressive progress in reducing filing timelines. Per McKinsey's benchmarking data, some leading companies have accelerated their overall submissions by up to three times over the 2020 industry average, and others are now sustainably delivering filings eight to 12 weeks after database lock (DBL), cutting historical timelines by 50 to 65 percent (Exhibit 1). Our estimates show that companies that achieve this feat could extend patent exclusivity during peak revenue years and, in doing so, obtain roughly $180 million in NPV for a $1 billion peak sales asset.[1]

Almost all top pharma companies have set ambitious filing timeline targets—the most ambitious are aiming to file in fewer than eight weeks. Yet many companies struggle to transform their submission processes at scale. Key obstacles include the complexity of digital integration, diverse therapeutic modalities, and internal capability gaps, all of which have led to inconsistent execution across the industry.

[1] This estimate assumes the acceleration from the median timeline in 2020 to the top quartile's timeline in 2024 (an acceleration of roughly 12 weeks), with an NPV of roughly $60 million per month.

Exhibit 1

## Today's leading pharma companies are filing regulatory submissions up to three times faster than the industry average in 2020.




[1]From benchmarking of 62 pharma companies. 2025 data as of Q1.
[2]Speed of top 2 or 3 fastest submissions in benchmarked data set.

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We propose a path forward that draws from our work with several top 20 global pharma companies. This article describes the six building blocks of successful submission excellence transformations—approaches that consistently produce high-quality submissions. It also explores technologies that can enable faster submission, including automation and gen AI, and offers three implementation approaches for companies to revamp their submission journey.

## Six building blocks of submission excellence

The six elements of successful submissions span three core areas: strategic and process foundations (simplified filing strategy and redesigned zero-based process), organizational transformation (radically changed operating model), and technology enablement (modernized core systems, scaled task automation, and scaled, AI-enabled content generation). Together, they create a comprehensive approach to achieving sustainable submission transformation (Exhibit 2). Although companies may choose to implement the six building blocks in varying combinations and sequences, the most successful transformations pursue all of them.

### Block one: Simplification of filing strategy

Organizations should start with a filing strategy that's built on rigorously defining and targeting the desired product label. This approach promotes collaboration across different teams, such as biostatistics, clinical-development, marketing, regulatory, and safety groups. As a result, the study designs meet all requirements while focusing on critical-path activities. Clinical programs designed by regulatory strategists with a laser focus on efficiently demonstrating a product's benefit and risk profiles can be combined with proactive education and engagement from health authorities.

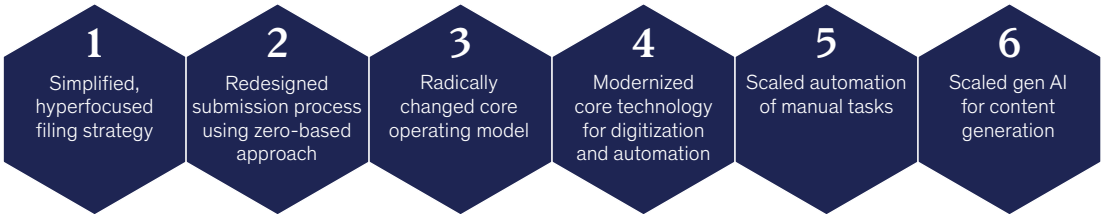
### Block two: Zero-based redesign of submission process

Several top pharma companies have taken steps to fundamentally redesign their entire submission process, starting with the last patient's last visit and extending all the way to filing. Some have taken a gradual approach by applying lean principles to improve each step. Others have achieved faster results by conducting a zero-based redesign of core processes and automating key aspects of their operations.

Exhibit 2

## Pharma companies see faster results from submission excellence transformations when they implement all six building blocks.

**6 building blocks of submission excellence**

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They have employed such strategies as bold decision-making, front-loading, "parallelizing," and removing nonessential dossier activities (table).

Redesigning core processes can alleviate the substantial workload placed on global regulatory teams caused by inefficiencies in responding to health authority queries (HAQs). These inefficiencies can slow the correspondence between pharma and health authorities and, by extension, the resolution of HAQs. This problem is magnified when companies file submissions simultaneously in multiple countries to reach a larger patient population faster.

**Block three: Radical change of core operating model**

A successful process redesign requires a fit-for-purpose operating model that aims to deliver faster, more sustainable submissions. As such, organizations should embrace a paradigm shift in their submission process and be prepared to acquire the capabilities needed to scale the adoption of new processes. Lasting success depends on adequate training, focused capability building, strong leadership commitment, and clear expectations across the product portfolio.

Pharma leaders should target these important outcomes for their operating-model overhauls:

- *Autonomous, small cross-functional teams.* The teams should include biostatistics, regulatory, and medical-writing groups and be empowered with clear goals and incentives to work in sync.
- *Rigorous planning and sustainable execution of the filing process.* A submission manager leading the team needs to initiate early filing preparations, have full accountability for the critical paths, and ensure that no detail gets overlooked.
- *Faster, focused decision-making.* Leaders should be able to make bold, early decisions on high-value assets.
- *Culture of bold innovation and collaboration.* Team members should be encouraged to push boundaries within and beyond their functional roles.
- *Stronger vendor partnerships.* There needs to be real-time collaboration with external vendors to provide seamless execution and prevent last-minute delays.

Table

## Pharma companies can accelerate submissions by optimizing processes across seven categories.

| Category | Examples |
|---|---|
| Data preparation optimization | • rigorous and cautious collection of data about and samples of last patients' last visits<br>• unbatched sample analyses for last patients' samples<br>• automated cleaning of data and issuing of queries<br>• preblocked time with principal investigator for sign-off and e-signature |
| Predrafting of lean clinical reports and chemistry, manufacturing, and control reports, with hyperfocus on label | • early alignment on key messages for studies and label<br>• scenario-based front-loading of draft reports<br>• application of lean writing principles by trained writers across modules |
| Batch generation and tables, listings, and figures (TLF) standardization | • early alignment on and commitment to key TLF data<br>• fixed number of TLF data sets<br>• preprogramming off the critical path<br>• dry runs executed before database lock (DBL )<br>• standardized templates<br>• prioritized table delivery in batches |
| Strategic review in 24 hours, with a single round after DBL | • fixed document review time<br>• restricted access to sections<br>• condensed reviewer matrix and training of reviewers<br>• early-stage strategic reviews conducted to allow a single round after DBL |
| Submission publication around the clock | • around-the-clock publication, using offshore capability<br>• cloud-based publication<br>• rolling publication<br>• sections locked after publication |
| Clinical-pharmacology-process optimization | • sample analysis prioritization<br>• early release of pharmacokinetic and pharmacodynamic data to clean team<br>• models developed for population pharmacokinetics and pharmacodynamics, based on earlier data<br>• writing of final population pharmacokinetics and "parallelized" summary of clinical pharmacology<br>• Optimized vendor capacity |
| Automation | • automated and restrictive workflows<br>• collaborative, structured, and gen-AI-enabled content writing<br>• automated checks of TLF quality and writing style |

**Block four: Modernization of core technology for digitization and automation**

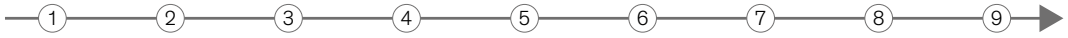
Technology is critical in sustainably accelerating regulatory submissions. Modern, integrated core systems, such as regulatory-information-management systems (RIMS), enable seamless workflows, embedded automation, and data-centric approaches that replace document-heavy processes. According to data from McKinsey's 2025 regulatory affairs benchmark, roughly 80 percent of top pharma companies said that they were modernizing their RIMS. Some had automated core processes beyond basic writing tools, quality controls, and publishing by applying structured content and collaborative authoring within a data-centric submission workflow (Exhibit 3).

Leading pharma companies are investing in scaled workflow automation and digital data flow, integrating technology from protocol development to submission. Their biggest challenges are navigating the complexity of available solutions, prioritizing high-impact investments, and building internal capabilities to adopt and scale automation. Some industry leaders are laying the groundwork for real-time data updates and automated exchanges with health authorities, thanks to the emergence of next-gen RIMS platforms and external initiatives that have focused on building technology bridges between sponsors and regulators. The widespread adoption of this workflow is still to be fully realized. To achieve the full potential of a data-driven regulatory future, companies should develop a clear strategy, scalable technology road map, and structured implementation plan.

Exhibit 3

## Use of an automated, data-centric submission workflow is crucial for pharma companies to submit faster regulatory filings.

**Example of a data-centric submission workflow**




1. **Data generation**
   Real-time regulatory intelligence hub knowledge base capability, with latest global and regional health authority requirements; end-to-end digital data flow, from protocol to submission
2. **Data preparation**
   AI-assisted clinical data cleaning, review, query generation, and reconciliation; automated data transformation (eg, study data tabulation model, analysis data model)
3. **TLF[1] generation**
   Predefined, set number and type of TLFs in workflow; gen-AI-assisted TLF programming, generation, formatting, and audit trails
4. **Drafting and labeling**
   Gen-AI-assisted drafting, automated formatting, and style guide checking; structured content management; digitized label platform, including automated propagation of changes from company core data sheet to local template
5. **Review**
   Auto-suggestions for initial drafts and auto-consolidation of comments
6. **Quality control**
   Automated quality control and source data validation of in-text TLFs; automated validation of compliance with controlled terminologies, abbreviations, and CDISC[2] standards
7. **Publication**
   Enhanced, continuous publication, leveraging regulatory intelligence hub and automated publishing tools
8. **Local translation**
   Real-time population of local templates; automated translation for "rest of world" filings from electronic common technical document
9. **HAQ[3] management**
   Real-time population of HAQ repository; integrated HAQ workflow, with AI-assisted response drafting based on HAQ repository

[1]Tables, listings, and figures.
[2]Clinical Data Interchange Standards Consortium.
[3]Health authority query.

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### Block five: Scaling of automation for manual tasks

Automation promises to be a game changer for the submission process, yet it remains largely underused beyond core tasks, such as dossier writing and validation (Exhibit 4). For example, internal benchmarking reveals that only 13 percent of companies automate the time-consuming formatting of tables, listings, and figures at scale. Likewise, the global workflow associated with the HAQ process—a major contributor to the workload—remains largely unautomated. The opportunity exists for organizations that successfully scale automation in these areas to make considerable gains in filing speed and workload efficiency.

### Block six: Scaling of gen AI for content generation

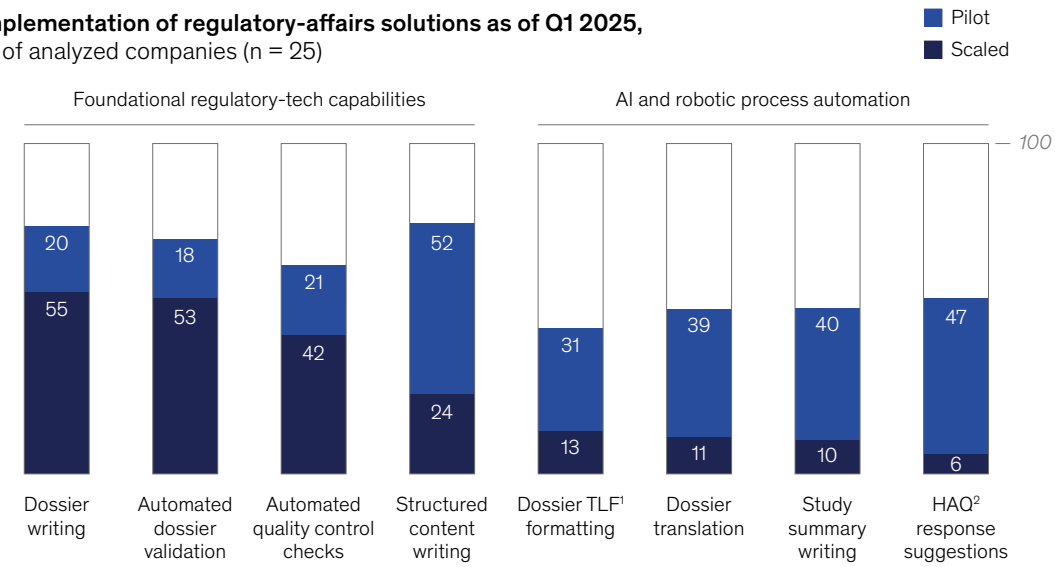
Gen AI is emerging as a major disruptor in regulatory and medical writing. Early pilots show that gen-AI-assisted medical writing can help reduce the end-to-end cycling time for authoring of clinical-study reports (CSRs) by 40 percent.[2] And more recently, McKinsey and Merck codeveloped an AI-powered platform that reduced first-draft CSR writing time to 80 hours, from 180 hours, and cut errors by 50 percent.[3] Many companies are now expanding into other regulatory document types, including safety and efficacy summaries, labeling, and even clinical pharmacology, to enable further submission timeline compression. Gen AI could also be used to generate HAQ responses, which could streamline that time-consuming task, including for situations when multiple health authorities submit queries simultaneously. Also, we're observing meaningful advances with agentic AI, which could be used as a virtual content challenger alongside a human in the loop who reviews the submissions to anticipate lines of questioning and improve the overall quality of a dossier during the internal review and quality control process.

[2] "Unlocking peak operational performance in clinical development with artificial intelligence," McKinsey, January 9, 2025.
[3] *New at McKinsey*, "With gen AI, Merck and McKinsey transform clinical authoring," blog entry, McKinsey, June 27, 2025; "Merck expands innovative internal generative AI solutions helping to deliver medicines to patients faster," Merck press release, June 25, 2025.

Exhibit 4

## Many pharma companies have yet to scale their automation and AI pilot projects that aim to accelerate filings.

**Implementation of regulatory-affairs solutions as of Q1 2025,**
% of analyzed companies (n = 25)




[1]Tables, listings, and figures.
[2]Health authority query.

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Leading companies are already developing technology plans and building AI-ready capabilities to stay ahead in this transformation. To overcome scaling challenges and capture gen AI's full benefits across entire pipelines, leaders should prioritize four actions:

— Modernize core clinical-data systems to support AI-driven automation.

— Build state-of-the-art gen AI authoring platforms with reusable components that balance flexibility and precision for high-stakes documents.

— Invest in AI adoption with well-defined workflows that secure compliance and high quality.

— Upskill talent, including by training employees in the effective use of these tools and broader AI adoption strategies.

## Submission transformation over three horizons

Although companies choose to take their own approach to accelerating filing, we have observed that successful submission transformations follow a sequence across three discrete horizons. Within each horizon, companies typically choose one to three high-priority assets to hasten through the filing process while they adjust their underlying processes for sustainability. This strategy can yield early, tangible benefits to top-line revenue and resource capacity while systematically addressing fundamental governance, processes, systems, and ways of working.

*Horizon one:* Revamp the operating model and processes (Exhibit 5A):

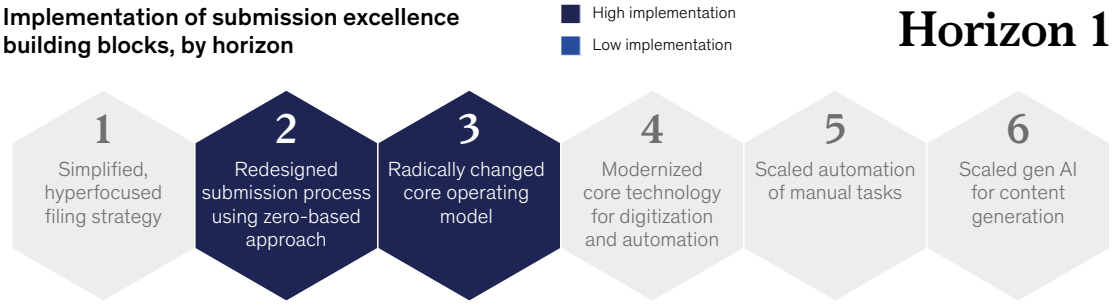
— Using building blocks two and three, this horizon primarily involves the execution of a zero-based redesign of the submission process and radical changes in the core operating model.

— Examples of outcomes include more flexible governance, improved execution rigor, and basic technology improvements, such as workflow automation.

— The DBL-to-filing timing is approximately 12 to 14 weeks.

Exhibit 5A

**A staggered approach to submission transformation allows pharma companies to adjust and streamline underlying processes more efficiently.**

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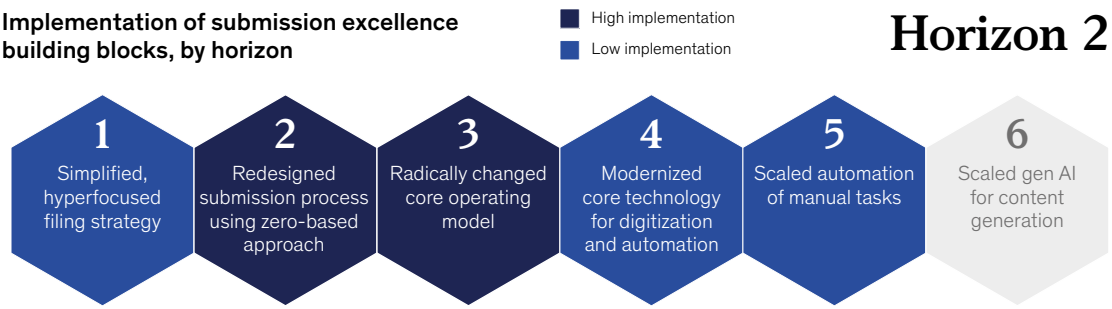
*Horizon two:* Perform a zero-based redesign of the operating model and experimentation with emerging technology (Exhibit 5B):

— Using building blocks one through five, this horizon involves the execution of a laser-focused filing strategy and a full revamp of the operating model and processes, including a zero-based design of all core processes and entirely new ways of working.

— Examples of outcomes include automation integration for structured content authoring, source updates, and translations and the use of gen AI for generating content, such as clinical-study reports.

Exhibit 5B

## A staggered approach to submission transformation allows pharma companies to adjust and streamline underlying processes more efficiently.

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— The DBL-to-filing timing is approximately eight to ten weeks.

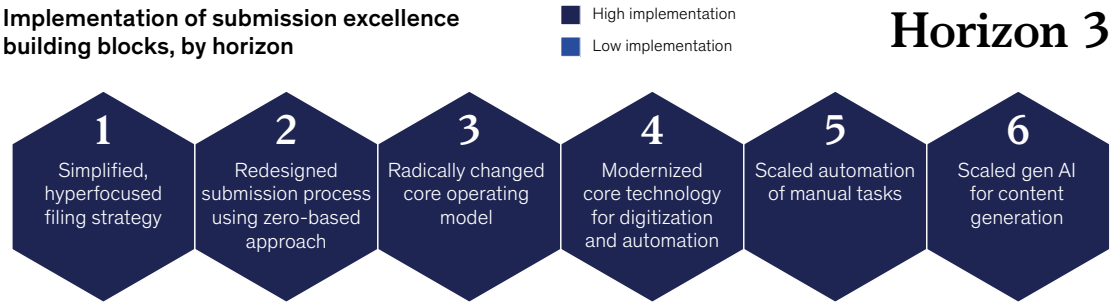
*Horizon three:* Shift the paradigm from scaling technology to submission (Exhibit 5C):

— Using building blocks one through six, this horizon involves a full embrace of all the submission transformation elements, including scaling new technology, such as gen AI, and adopting a human-in-the-loop operating model.

— Examples of outcomes include achieving filing speeds in fewer than six weeks and positioning the organization for such radical changes as fully paperless filings and real-time data sharing with health authorities. A precursor to the latter innovation is the US Food and Drug Administration's real-time oncology review, which aims to accelerate access to safe, effective cancer treatments through streamlined reviews and early communication with applicants.

Exhibit 5C

## A staggered approach to submission transformation allows pharma companies to adjust and streamline underlying processes more efficiently.

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— The DBL-to-filing time is fewer than six weeks.

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Leading pharma R&D companies are prioritizing faster clinical development and shorter regulatory-filing timelines to capture massive value for their stakeholders. While such companies have made impressive progress, others could achieve ambitious timeline reductions by achieving submission excellence and upgrading their core technology. Leaders of regulatory-affairs teams should make informed decisions, develop winning technology plans, and equip teams with game-changing capabilities. Done correctly, an improved regulatory-filing process could play an outsize role in accelerating the delivery of life-saving medicines to the patients who need them most.

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# Gen AI: A game changer for biopharma operations

From the shop floor to the supply chain, gen AI can transform how biopharma companies operate. Four use cases show how it can enhance productivity, improve quality, and reduce costs.

*This article is a collaborative effort by Boyd Spencer, Parag Patel, and Vivek Arora, with Krithiknath Tirupapuliyur and Raj Rajendran, representing views from McKinsey's Life Sciences and Operations Practices.*

**Gen AI has become a hot topic** among leaders at most big companies, more than two-thirds of which intend to increase their investments in the technology over the next three years.[1] McKinsey has estimated the opportunity for gen AI in biopharmaceutical operations at $4 billion to $7 billion annually through workload and cost reductions, productivity gains, improvements to equipment effectiveness, and quality enhancements. Many biopharma organizations now have sophisticated operations and are moving to use gen AI to take advantage of their data repositories. However, only a few organizations have started to realize value from it. This raises a question: Are organizations deploying gen AI in the places with the highest potential benefits?

Over the past five years, biopharma has adopted various digital and analytics solutions, including in silico models, process optimizers, and lab and manufacturing automation.[2] This article explores how gen AI, which differs from traditional AI and other analytics, can help biopharma solve industry-specific challenges.

There are at least a dozen proven and potential gen AI use cases along the biopharma operations value chain. They fall into three main categories:

— entry-level use cases that biopharma organizations and vendors are already deploying using off-the-shelf products

— novel use cases that incorporate product, technology, organization, and domain-specific intelligence and require custom, in-house development

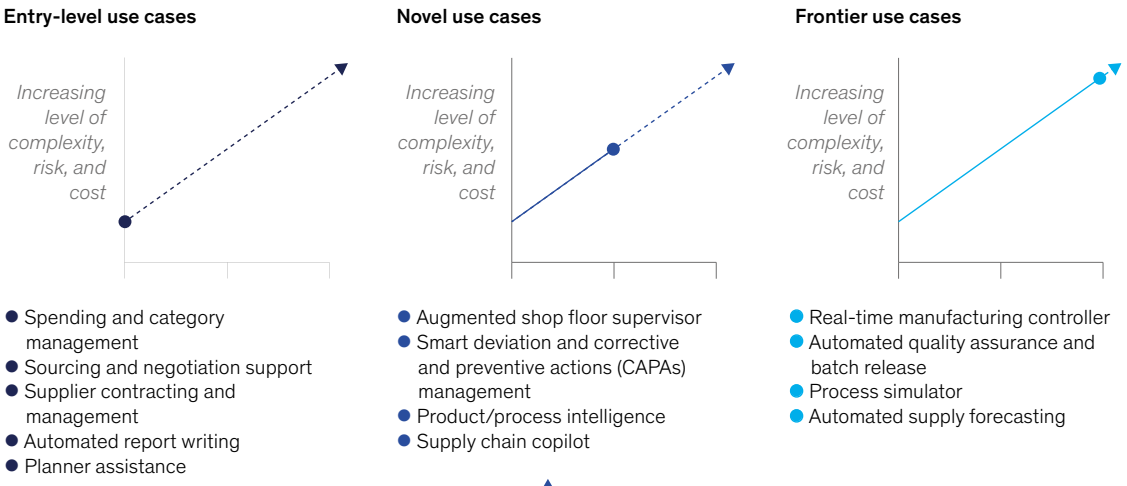
— frontier use cases that typically require fast processing of large amounts of real-time numerical data and affect elements of operations that require tight quality and regulatory oversight (Exhibit 1)

[1] "Generative AI in the pharmaceutical industry: Moving from hype to reality," McKinsey, January 9, 2024; "The state of AI in 2023: Generative AI's breakout year," QuantumBlack, AI by McKinsey, August 1, 2023.
[2] The McKinsey and World Economic Forum Global Lighthouse Network now includes 25 centers for life sciences.

Exhibit 1

## At least a dozen proven and potential gen AI use cases exist across the biopharma operations value chain.

**Spectrum of gen AI use cases in biopharma operations, by level of complexity, risk, and cost**

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Vendors continually implement and improve entry-level use cases in their products. For instance, enterprise-resource-planning vendors are employing gen AI to improve such functions as demand forecasting, inventory management, and transportation planning. Many smaller companies are also developing gen-AI-supported point solutions for those entry-level use cases.

At times, companies need to customize the solution to fit their needs and workflows better, but they generally do so in partnership with the relevant vendors. So to take advantage of the existing technology, biopharma companies need only buy or upgrade software as it becomes available.

At the other end of the spectrum are frontier use cases, which are too risky today for most companies to want to explore. In this article, we focus on four novel use cases that require bespoke development but are within the current capabilities of gen AI. Agentic AI use cases, which incorporate a layer of autonomous execution, build upon other AI applications and fall into this category as well.

## Novel use case examples

As the capabilities of gen AI evolve, the number of viable use cases is likely to increase. We discuss four ways that biopharma organizations can currently benefit from novel gen AI use cases.

### Use case one: Boosting shop floor efficiency with gen-AI-assisted supervision

In our experience, supervisors spend up to 40 percent of their time manually producing reports, collating information, triaging equipment failures, and supporting maintenance. To communicate with their teams, they also spend time preparing and retrieving production data, creating visualizations, preparing for meetings, and crafting update emails.

A gen AI supervisor can support a human supervisor in all these activities (Exhibit 2):

— *Provide technical assistance.* The use of gen AI supervisors can save teams considerable time and effort by giving access to and synthesizing information from various sources, such as

machine history, technical manuals, and production data. They can analyze machine data to diagnose equipment issues and identify potential solutions quickly.

— *Automate shift preparation.* Gen AI supervisors can provide immediate access to data such as batch records, equipment sensors, and in-process measurements. They can identify bottlenecks, aggregate performance data from previous shifts, and proactively communicate critical inputs for the upcoming shift. This safeguards continuity in production and improves overall efficiency.

— *Enhance team leadership.* By automating the creation of shift reports, presentations, and emails, gen AI supervisors can facilitate communication with team members and stakeholders. This allows supervisors more time for mentoring, coaching, developing skills, and fostering a more engaged and productive workforce.

After implementing a gen AI copilot tool for maintenance support, one biopharma manufacturing team achieved 5 percent reductions in breakdown time, speed losses, and minor stoppages and a 30 percent reduction in execution time. It also experienced a 40 to 50 percent workload reduction for corrective maintenance.

A gen AI technical assistant typically reduces the time spent identifying and synthesizing a technical solution by 20 to 40 percent.[3] Gen AI production and huddle assistants can reduce the time spent aggregating shift metrics and preparing communications by 40 percent.

Exhibit 2

## Pharma shop floor supervisors can spend less time producing reports, triaging equipment failures, and more with the help of gen AI.

**Gen-AI-assisted shop floor supervision** (illustrative example)

| Supervisor without gen AI help | Identify pain points | Aggregate data | Synthesize solutions |
|---|---|---|---|
| | Walk the line, gather notes on production, review prior shift reports | Pull relevant safety, quality, delivery, and cost metrics for current and prior shifts | Prepare start-of-shift script with focus areas, action items, and data visualizations |
| **Supervisor with gen AI help** | **Automatically identify status and performance** | **Aggregate prior performance** | **Create scripts and visualizations** |
| | Identify problem areas and performance status by querying data in natural language | Aggregate data on performance of prior shift and communicate action item inputs for upcoming shift | Synthesize full start-of-shift script and status emails to share with team and stakeholders |

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[3] McKinsey estimates from tracking a typical day for production supervisors.

**Use case two: Streamlining production maintenance with smart deviation management**

The end-to-end process for managing both deviation and corrective and preventive actions (CAPAs) requires 4 to 6 percent of a manufacturing site's resources and is fraught with challenges.[4] Common pain points include delayed detection, manual tasks, a low rate of right-first-time solutions, low effectiveness, inconsistent documentation, and a reactive process.

Our conversations with pharma companies highlight a unique value proposition for such a tool. We found that 65 percent of drug shortages are caused by issues related to deviation management and that 15 to 20 percent of deviations recur because of ineffective remediation. A gen AI tool can help an investigator manage deviations, providing proactive support and insights throughout the process (Exhibits 3 and 4):

— *Identify similar deviations.* Gen AI can analyze historical deviations with similar characteristics and provide context and potential solutions.

— *Accelerate root cause analysis.* By automatically summarizing potential root causes based on similar deviations, gen AI can allow investigators to focus their efforts and quickly identify the source of the problem.

— *Suggest effective CAPAs.* Gen AI can leverage historical records to recommend proven CAPAs tailored to the specific deviation. This can improve the effectiveness of remediation and preventive efforts.

— *Automate documentation.* By autopopulating reports with relevant information, gen AI can streamline documentation and provide consistency and compliance with quality standards.

A gen AI tool for one life sciences manufacturing company could synthesize 70 percent of deviations and connect them to similar events. This allowed for easy investigation and hypothesis generation. The same tool also generated a first draft of CAPAs for more than 80 percent of cases.

This approach typically results in 30 to 40 percent fewer deviations through improved prevention, with greater reductions in recurring and critical deviations. Case studies also show a 40 percent reduction in deviation closure time and 10 to 30 percent fewer quality- and expiry-related write-offs through reduced mechanical degradation.

**Use case three: Accelerating product development with product process intelligence**

The race to bring new therapies to market depends on the speed and efficiency of process design, process development, and technology transfers. The data required to take a product through these steps are often fragmented among various systems and functions within an organization. Gathering and distilling input can take time and delay decisions on unit-operation design, parameter optimization, and scale-up. Such delays can also lead to quality issues and high costs of goods and development.

A gen-AI-powered tool can act as a centralized hub for product and process knowledge. It can seamlessly integrate and analyze historical data from R&D labs, pilot plants, and commercial manufacturing sites, providing scientists and engineers with valuable insights to accelerate development:

— *Leverage prior designs*. By identifying successful unit operation designs and configurations for different molecules, gen AI can aid in raw material selection and early-stage parameter optimization.[5]

— *Optimize parameters.* Gen AI can refine critical process parameters such as temperature, pH, and raw material variability to safeguard robust quality and cost-effective performance at scale. It can accelerate trial design and execution by generating draft protocols from historical trial data and automating document creation.[6]

[4] Case studies; POBOS by McKinsey; *Tenth annual report on drug shortages for calendar year 2022*, US Food and Drug Administration, June 2023.
[5] Torsten Welte and Tam Harbert, "How manufacturers can best use generative AI," SAP, June 17, 2024.
[6] Wing Lon Ng, "Revolutionizing clinical trials with generative AI," Clinical Research News, July 19, 2024.

Exhibit 3

## Gen AI can provide proactive support and insights to pharma investigators.

**Gen-AI-assisted help for investigator managing deviations** (illustrative example)

| | | | |
|---|---|---|---|
| **Investigator without gen AI help** | **Research past events** | **Analyze root causes** | **Develop a corrective plan** |
| | Gather data from multiple systems and create extensive documentation of often repetitive information | Hold multiple meetings with technical experts to record root causes that may not be optimal | Draft an extensive corrective and preventive actions (CAPAs) plan and manage multiple, likely inconsistent action plans opened for the same events |
| **Investigator with gen AI help** | **Search for relevant past events** | **Make a hypothesis-driven prediction of root causes** | **Generate action plan in compliance with quality frameworks** |
| | Event description is automatically logged into the system based on past events | Root-cause summaries are generated for experts based on similar deviations | First draft is automatically generated using successful actions for similar deviations |

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Exhibit 4

## A gen AI tool can power a deviation and corrective and preventive actions workflow from beginning to end.

**Deviation and CAPAs[1] workflow powered by gen AI** (illustrative example)

**1 Identify similar deviations**

- Identify a quality event or deviation
- Log the deviation and start the investigation and data collection on personal device
- Use tool to search for similar deviations across multiple sites
- Identify recent deviations on-site and across the network and select the most relevant
- Continue to assess the impact of the deviation and structure problem-solving

**2 Accelerate root-cause analysis**

- Consult the tool for root causes of similar deviation types, including their recurrence
- Assess each root cause for relevance and explore possible new root causes
- Identify the root cause and close the investigation
- To quickly find relevant actions, tailor the deviation list in the tool based on the identified root cause

**3 Suggest effective corrective actions**

- Have the tool summarize previously implemented actions for the deviation
- Assess the degree to which the generated actions might prevent the deviation
- Expand on the actions with own assessment and finalize the list

**4 Automate documentation**

- Use the tool to write a first draft of report
- Have the tool check for gaps, highlight sections, and create auto-suggestions
- Review and submit the draft action plan, ensuring alignment with global quality standards
- Make an implementation plan and close the deviation

[1]Corrective and preventive actions.

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— *Streamline experiment design.* By capturing and organizing knowledge from experienced process engineers, gen AI can make it readily available to others. It can automatically generate process documentation, including flow diagrams, operating procedures, and batch records, to save time and reduce errors.

— *Guide technology transfer.* Gen AI can facilitate smooth and efficient technology transfers among facilities by identifying potential risks, generating training materials for new technology transfer staff, and answering questions from researchers and technology transfer professionals via chatbots.

Such a gen AI tool can reduce the integrated cost of development by reducing lab space, the number of experiments, and the quantity of materials needed to design and optimize processes. It can also improve the cost of goods and the robustness of commercial processes by optimizing parameters and enabling prompt troubleshooting. Last, it can permit quicker development and launch cycles.

We have seen similar but more traditional AI and machine learning use cases reduce the timeline to investigational new drugs by nearly one-third. Additionally, we have seen them increase development efficiency by 40 percent.

**Use case four: Optimizing supply chain performance with a copilot**

The data required to make accurate supply chain decisions are often fragmented among supplier databases and production systems. This can lead to limited visibility of stock levels, lead times, demand forecasts, and delivery performance. Such limitations can result in stockouts, production delays, overstocking, and operational disruptions, all of which affect the availability of products and the cost of goods.

An integrated gen AI tool can consolidate supply chain data, demand data, performance targets, and production data from multiple sources into a unified platform. This can provide a comprehensive view of inventory and performance, from raw materials to finished products. The tool can therefore facilitate informed decisions about stock levels, procurement, logistics, and production (Exhibit 5):

Improve decision-making. By providing planners with insights and what-if-scenario analyses, gen AI can empower them to make informed decisions that improve efficiency and responsiveness.[7]

Optimize inventory management. Gen AI can help reduce stockouts and excess inventory by accurately forecasting demand, predicting potential bottlenecks, creating data views, and analyzing scenarios to help optimize inventory levels.[8]

Increase productivity. Using gen AI to automate routine tasks and provide easy access to critical information can free planners to focus on strategic initiatives and higher-value activities.

Mitigate risk. Gen AI can analyze data from the supply chain and on markets, the weather, and geopolitical events to identify potential disruptions and allow for timely mitigation.[9]

By consolidating, analyzing, and providing insights on fragmented data, such a gen AI tool can help biopharma companies double the productivity of their supply chain organizations, improve product availability, and reduce the overall cost of goods. We have seen such use cases create a 2 to 3 percent decline in supply chain costs, a 15 percent increase in forecast accuracy, and a 20 to 30 percent workload reduction for planners.

[7] *HCL Technologies blog*, "GenAI: Revolutionizing supply chain demand prediction," blog entry by Lisa Clontz and Arindam Sen, April 13, 2024; *Logility Supply Chain Solutions blog*, "ChatGPT and the revolution of AI-first forecasting," blog entry, November 20, 2023.
[8] *HCL Technologies blog*, "GenAI: Revolutionizing supply chain demand prediction," blog entry by Lisa Clontz and Arindam Sen, April 13, 2024; Jorge Amar, Sohrab Rahimi, Zachary Surak, and Nicolai von Bismarck, "AI-driven operations forecasting in data-light environments," McKinsey, February 15, 2022.
[9] Glenn Steinberg, Matthew Burton, and Ayoub Abielmona, "How supply chains benefit from using generative AI," EY, January 9, 2024.

Exhibit 5

## The data required to make accurate supply chain decisions are often fragmented among supplier databases and production systems.

**How gen AI helps a supply chain planner** (illustrative example)

| | | | |
|---|---|---|---|
| **Planner without gen AI help** | **Identify insights manually** | **Rely on APS[1] experts to build new scenarios** | **Discuss the risks of each scenario** |
| | Navigate through multiple dashboards to identify root causes and exceptions | Wait for APS experts and data analysts to build new data cuts and graphs for scenario analysis | Hold meetings with various stakeholders to discuss the pros and cons of each scenario |
| **Planner with gen AI help** | **Provide rapid insights via chat** | **Automatically generate new data cuts and graphs** | **Analyze multiple scenarios to determine the most optimal** |
| | Chat with gen AI to quickly identify key insights and take actions | Independently build new data views and scenario analysis | Gen AI drafts outcomes of each scenario to help drive decisions |

[1]Advanced planning and scheduling.

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### Implementing gen AI: Building the foundation for success

Biopharma companies, with their vast proprietary data sets for products, facilities, and technologies, are in an optimal position to capitalize on gen AI. As the technology becomes integral to the industry, those that adopt a value-focused approach will begin to drive transformational change. For a successful gen AI transformation, organizations must know the limits and risks of the technology before deploying use cases so they can prepare the right foundations.

The challenges to implementing gen AI in the biopharma industry include the risk of errors, commonly known as hallucinations, particularly when dealing with numerical data. Human oversight and verification are essential to address this. Companies should deploy gen AI only sparingly in complex tasks, such as batch release and forecasting, for which numerical accuracy is critical.

Additionally, gen AI isn't suitable for high-volume, time-sensitive tasks, such as real-time monitoring and control of the supply chain and production. Moreover, successful gen AI adoption requires extensive training for engineers, operators, and technicians to ensure that they can spot errors, prompt appropriate queries, and make informed decisions.

Gen AI initiatives are also vulnerable to risks, such as intellectual property (IP) theft and algorithmic bias. For instance, a gen-AI-created design might infringe on another company's IP, or the company's own IP might leak into the public domain. Also, a gen AI tool that is trained on biased historical data may exhibit demographic bias when assigning tasks.

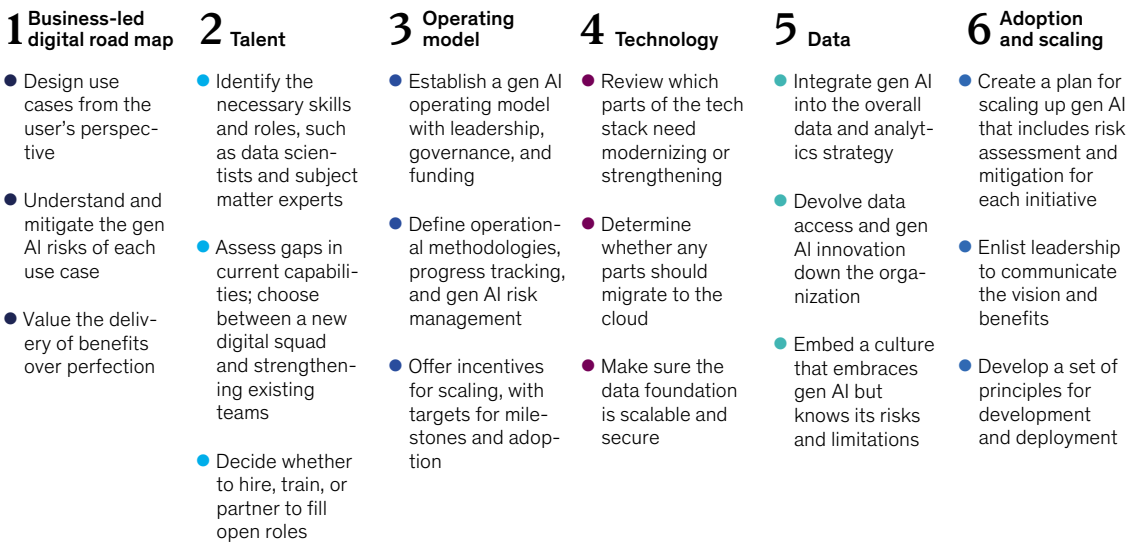
Finally, the biopharma industry's highly regulated environment demands rigorous risk assessment and robust guardrails to secure compliance when using gen AI for tasks such as batch record reviews, quality audits, and batch releases. Companies should enforce the appropriate guardrails and policies to ensure that they're using the tools for the intended and validated tasks.

To overcome these constraints and transform sustainably at scale requires foundational capabilities in six areas (Exhibit 6). *Rewired: The McKinsey Guide to Outcompeting in the Age of Digital and AI* (Wiley, 2023) describes these areas in more detail. With such capabilities in place, it

Exhibit 6

## Six foundational capabilities are essential for successful deployment of gen AI in pharma operations.

**Foundations for successful deployment of gen AI in pharma operations[1]**




[1]Eric Lamarre, Kate Smaje, and Rodney Zemmel, *Rewired: The McKinsey Guide to Outcompeting in the Age of Digital and AI* (Wiley, 2023).

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becomes easier to accelerate decision-making, transform an operating model, and migrate talent and resources to the highest-potential opportunity areas.

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The biopharma industry stands on the cusp of a gen AI revolution. By strategically selecting use cases, building foundational capabilities, and fostering a culture of innovation, companies can harness the power of gen AI to accelerate drug development, optimize operations, and ultimately improve patient outcomes. While navigating the complexities and risks associated with gen AI is crucial, the potential rewards for organizations that embrace this transformative technology are immense. The future of biopharma operations is intelligent, automated, and driven by the power of gen AI.

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# The speed-to-market imperative for life sciences capital delivery

Life sciences companies are spending big on new capital projects. Industry leaders who embrace capital excellence could secure a competitive edge.

*This article is a collaborative effort by Erikhans Kok, Parag Patel, Piotr Pikul, and Tacy Foster, with Adam Kuzmik, representing views from McKinsey's Life Sciences Practice.*

**Life sciences companies** are entering a new era of capital intensity. The life sciences industry's capital expenditures grew 13 percent per year from 2022 to 2024 as biopharma and medtech firms committed tens of billions of dollars to expand production capacity and improve supply chain resilience, particularly in the United States. This surge in investment was also spurred by breakthroughs in messenger RNA (mRNA), cell and gene therapies, new large-scale drugs such as GLP-1s, and efforts to localize supply chains in response to changing policies and an uncertain macroeconomic and geopolitical landscape. The industry's growth trend is expected to continue: Firms have announced more than $150 billion in new capital projects before 2030 (Exhibit 1).

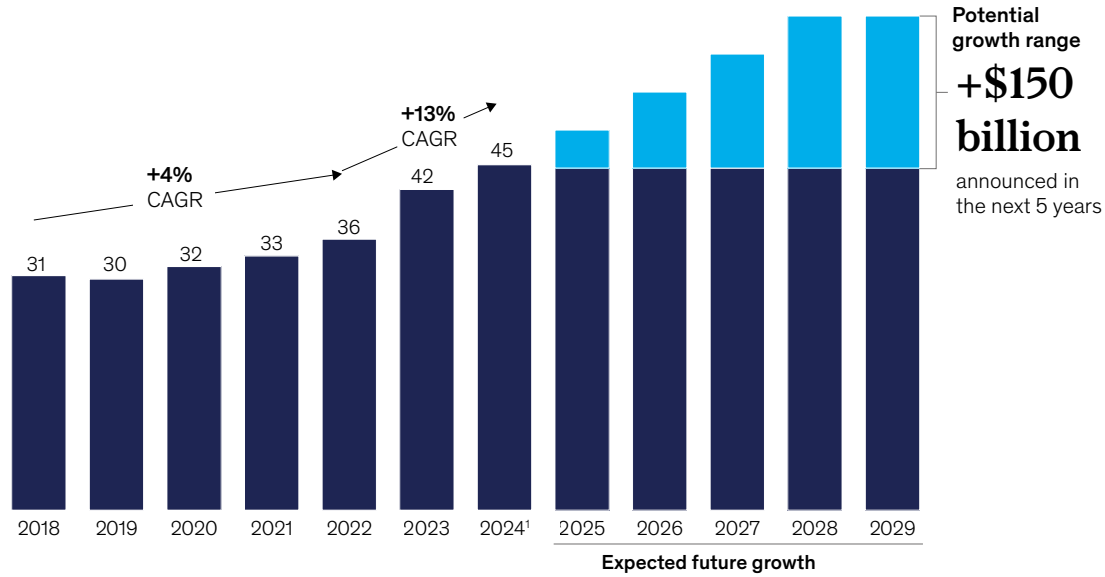
But capital alone doesn't drive outcomes, and many life sciences companies lack strong, integrated capabilities in project management, talent strategy, and capital project delivery to help them get the most out of their investments. Furthermore, many life sciences companies have focused only on one major capital project at a time. Today, they must execute multiple complex programs in parallel, juggling long lead times for items such as transformers and complex process equipment with skilled-labor shortages as they compete for talent both inside and out of life sciences. Indeed, as other industries continue to invest in capital projects, there will be increased competition for skilled labor, specialized equipment, materials, and other resources.

As a result, many life sciences companies may not be ready to leverage this influx of capital efficiently and effectively. This can have a significant financial impact: In a ten-year net-present-value (NPV) calculation of a company launching a $2 billion product, for instance, even a six-month delay could cause the company to miss out on more than $750 million in NPV.

Exhibit 1

## The life sciences industry's year-on-year growth trend is anticipated to continue thanks to newly announced capital projects.

**Growth in capital expenditures for top 20 pharma companies,[1]** $ billion




[1]Includes capital expenditure announcements through 2024.
Source: S&P Global Market Intelligence; McKinsey analysis

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Life sciences companies for which time to market is a critical capability can embrace a time-based capital strategy. In this article, we discuss four capabilities that could decrease risks and costs while enabling companies to deliver faster and more reliably on projects: schedule-first project management; strong strategic procurement and contracting models; improved commissioning, qualification, and validation (CQV) readiness; and a fully integrated delivery capability and talent strategy.

Life sciences leaders who prioritize capital excellence could generate stronger financial outcomes and increase their ownership over the product life cycle, all while bringing life-saving medicines and therapies to market—and patients—sooner.

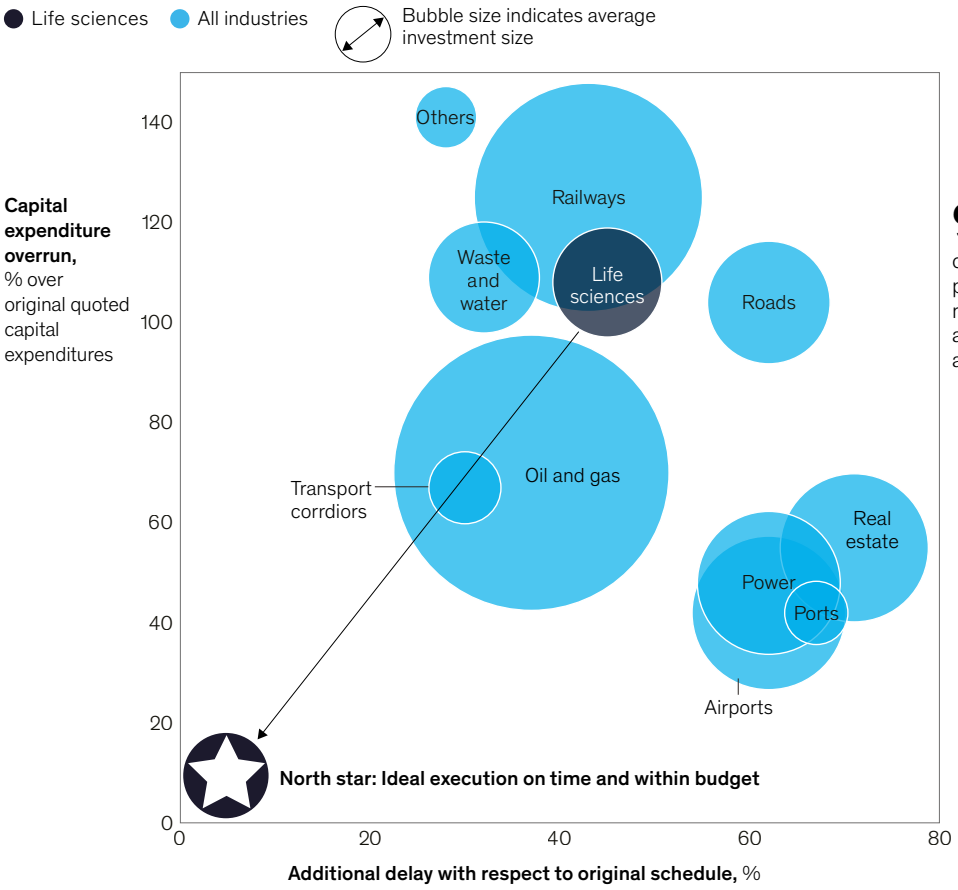
## Barriers to effective and efficient delivery for life sciences capital

As the flow of capital to the life sciences industry accelerates and companies undertake multiple capital-intensive projects, many industry leaders face barriers to capturing value at speed. Life sciences companies face three unique capital delivery challenges that can lead to delays and budget overruns (Exhibit 2):

Exhibit 2

## The life sciences industry experiences higher percentages of delays or capital expenditure overrun than almost all other industries.

**Average delays and overruns for life science projects vs others[1]**




**95%**
of life sciences projects did not meet their authorized cost and schedule

[1]Based on a sample of 532 recent capital projects across industries.

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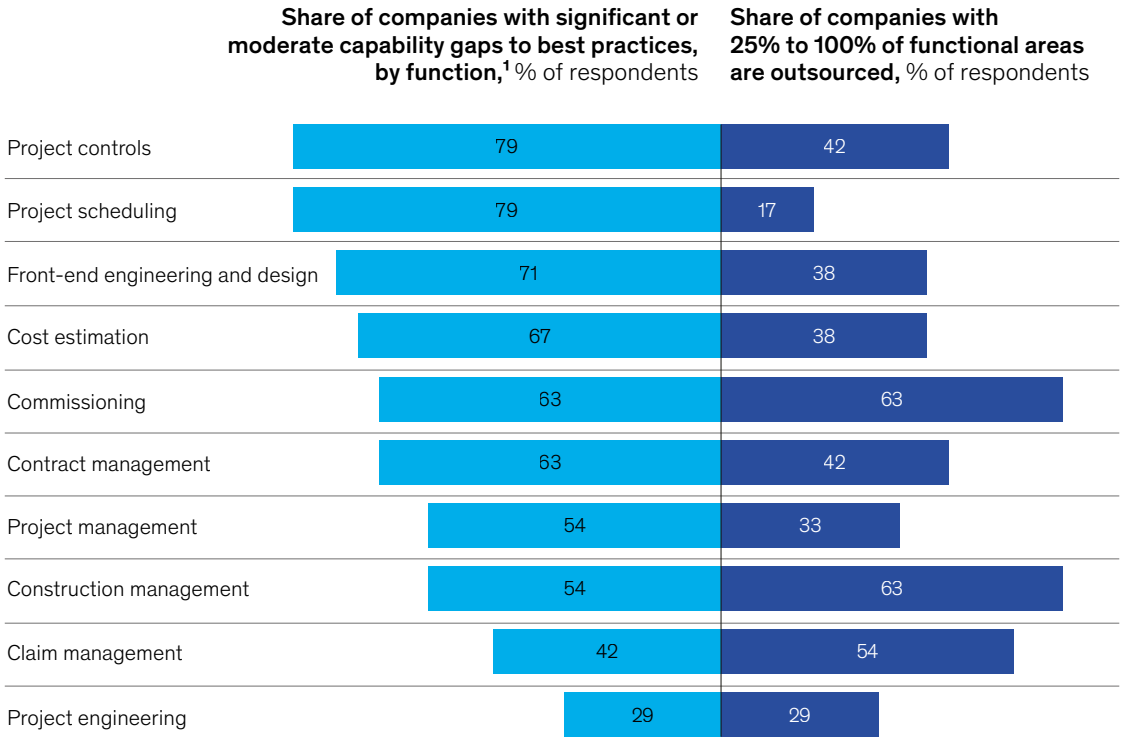
*Traditional approaches to capital project delivery.* Many companies still view capital delivery through a transactional lens. They may look to cut features, downsize the scope, pressure contractors to contain spending, or try to pass most of the risk onto contractors. Such companies need to shift their mindset to see that capital is a strategic investment tied to product life cycle impact, rather than one-time spending to accelerate delivery.

*Gaps in internal capabilities and talent.* Even when capital is available, execution delays and scope creep can dilute returns. Without stronger internal capabilities in project management, scheduling, and field execution, increasing capital spending won't translate to faster, better outcomes. Many life sciences companies have chosen not to build capital expenditure capabilities because of the lumpy nature of capital expenditure spending—and they're unsure of what to do with those capabilities once projects are complete. But a survey of leaders in the life sciences industry found that the top drivers of delivery gaps are sourcing internal talent through limited pipelines and outsourcing core expertise such as construction management and oversight to external partners (Exhibit 3). For example, companies often end up relying on engineering, procurement, and construction management partners to help deliver projects. Additionally, the labor shortage for skilled trades is a growing risk that will affect timelines and costs.[1]

Exhibit 3

## Life sciences companies may have capability gaps across capital excellence functions and rely heavily on outsourcing.




Source: McKinsey survey of representatives of top life sciences companies, 2025 (n = 24)

McKinsey & Company

[1] Ezra Greenberg, Erik Schaefer, and Brooke Weddle, "Tradespeople wanted: The need for critical trade skills in the US," McKinsey, April 9, 2024.

*ROI compression*. While cost remains important, speed is now the critical driver of value. Organizations need to manage time, cost, and risk as an integrated system, and they need to develop capabilities that enable them to deliver on all three.

Life sciences firms need to move beyond simply spending more; they need to develop the integrated capabilities to improve delivery speed and assurance without increasing risk or cost variability.

## Embracing a time-based capital strategy

For many high-margin life sciences companies, speed to market often matters more than cost; each month of delay can mean lost revenue, reduced patient access, and a weaker competitive position. To compete in this environment, companies need to rethink how they deliver capital projects—focusing not only on spending less but also on increasing speed and dependability. Some other industries with heavy capital experience have already moved in this direction (see sidebar "Capital excellence in the specialty chemical industry: A case example").

The upside is substantial. Best-in-class capital delivery can increase ROIC by four to eight percentage points. Consider a $500 million facility delivering a product with $1 billion in annual cash flow at an 80 percent gross margin: Launching just one year earlier can unlock $600 million in additional EBIT and materially uplift enterprise value.

Achieving this requires more than isolated project wins. It demands institutionalizing capital excellence and embedding capabilities that scale. The most effective organizations are integrating four capabilities that consistently drive speed, control, and sustainable value creation across their capital portfolios (see sidebar "One step further: Additional actions to support capital delivery").

## Capital excellence in the specialty chemical industry: A case example

**Life sciences companies** and specialty chemicals companies may produce different products, but their capital projects face similar realities: billion-dollar facilities, strict environmental controls, and enormous execution risk. One specialty chemicals manufacturer achieved consistent and reliable delivery thanks to several approaches.

*Modular and copy-exact design*. This manufacturer replicated fab layouts with precision, reduced design cycles, and derisked commissioning. Life sciences companies can emulate this by standardizing cleanroom modules, reusing validation packages, and preintegrating skids to shorten commissioning, qualification, and validation (CQV). Companies that implement these approaches could reduce total design and commissioning time by 15 to 25 percent.

*Owner-led delivery*. This company staffed their capital team with in-house engineers, schedulers, and cost controllers, with engineering, procurement, and construction management supporting the process. Life sciences players could follow suit by building capital centers of excellence, embedding critical roles, and directly owning project control. Owner-led models have been shown to reduce change order volumes by 30 to 40 percent and improve decision-making speed.

*Early supplier lock-in*. For this project, the manufacturer secured long-lead tools early and linked the delivery to takt time schedules. Similarly, life sciences firms should lock in equipment details by the end of the design phase and align factory and site acceptance testing milestones to project timelines. Organizations that practice early lock-in can compress lead times by up to 20 percent.

*Digital simulation*. The manufacturer simulated throughput, material flow, and process bottlenecks before construction began. Life sciences can apply the same logic by using process digital twins to validate layouts, zoning, and cycle times well ahead of CQV. Digital simulation can save up to 10 percent in start-up time by decreasing rework during commissioning and optimizing layout.

*Takt-based scheduling*. This project used takt-based scheduling to break up chip projects into fixed work beats that were tracked every day to quickly catch and fix any delays. Life sciences teams can apply this to streamline utility start-up and validation.

Even with capital complexity, this case example illustrates that capital projects can deliver products with greater speed, control, and precision. By adopting the same discipline, life sciences firms could gain a step change in capital effectiveness.

**1. Adopting a schedule-first project management mindset**

A schedule-first approach both tracks and drives progress. When fully embedded, this approach becomes a powerful lever to compress timelines, accelerate value capture, and increase ROI. Life sciences companies can take several actions to implement this approach.

*Treat the schedule as the operational backbone*. In most capital projects, the schedule is treated as a passive reporting tool (provided by contractors) that is updated periodically but rarely drives critical decisions. High-performing life sciences organizations flip this mindset. They treat the integrated master schedule (IMS) as the operational backbone, which aligns all functions—including design, procurement, construction, and CQV—on a single, authoritative plan.

*Embed schedulers early to influence upstream decisions*. Execution starts by embedding experienced schedulers by the conceptual design phase so teams can influence sequencing, resource planning, and lead-time assumptions early in the process, before they become permanent.

*Use generative tools to simulate and optimize*. Players that are more advanced go a step further by using generative scheduling platforms to simulate execution paths, identify acceleration levers, and model trade-offs dynamically. For example, a biologics expansion team used generative scheduling to resequence the installation of a clean room and quality control lab, shortening the schedule by six weeks.

*Align culture and governance around the IMS*. Effective implementation requires alignment in culture and governance. Functions need to accept the IMS as the shared plan of record instead of maintaining fragmented subschedules. Governance teams need to link decisions about releasing capital to schedule maturity, treating speed-to-impact risk with the same scrutiny as the budget and scope.

Organizations that have embedded schedule-first project management report timeline reductions of 10 to 15 percent, with improved transparency and better coordination across workstreams.

**2. Implementing strategic procurement and contracting models**

When done right, strategic procurement reduces costs and secures reliable delivery. It requires looking at the full cost across the whole contract as opposed to just "buying cheapest." It protects the schedule, improves capital efficiency, and enables execution at the pace required for modern life science portfolios. Adopting progressive contract models means organizations can reliably execute

## One step further: Additional actions to support capital delivery

**Beyond the four** core capabilities, leading life sciences firms are also exploring a broader set of enablers to further compress timelines and increase predictability:

- *Design simplification or standardization and value engineering* help reduce cycle times and design complexity. Companies that adopt simplified and standardized facility platforms and modular components can cut design and construction time by 10 to 20 percent and lower rework during commissioning.
- *Cost intelligence functions* enable more-strategic capital deployment. Internal benchmarking teams that perform line-by-line cost analysis and design-to-value modeling often achieve 5 to 15 percent cost optimization while redirecting spending toward schedule-critical activities.
- *Agile capital governance* such as weekly "war rooms" and real-time dashboards allows for faster decision-making. Companies that institutionalize this approach are typically able to resolve issues faster and see fewer schedule delays, particularly during critical execution windows.
- *Construction excellence*—including modularization, takt planning, and digital field management tools—can reduce on-site labor congestion, minimize delays, and accelerate mechanical completion by several weeks.

# Leaders can prioritize capital excellence by shifting their mindset from product-driven approaches to time-based capital strategy.

processes even when complexities arise. Several actions help implement this approach:

*Reframe procurement as a frontline driver.* Procurement is often treated as a downstream function that is activated only once the scope is locked and schedules are set. But in accelerated capital delivery, procurement must move upstream. Strategic sourcing becomes a pacing item, and delays in procurement can stall an entire project. Conducting should-cost or cleansheet analysis up front can help drive value for procurement from the beginning.

*Engage suppliers early to shape execution.* Leading life sciences organizations bring contractors and key suppliers into the process early—usually during concept design—to shape scope, clarify specifications, and lock in lead times before the schedule is determined. Rather than sourcing monolithically, teams break scope into early bid packages, allowing parallel progress on design and procurement, and giving long-lead equipment a head start.

*Shift to outcome-based contracting models.* Companies can leverage new, more-collaborative contracting models, such as progressive design-build or integrated project-delivery contracts, to link incentives via gainshare and painshare arrangements to outcomes for everything from schedule milestones to installation readiness. These models share risk, align incentives, and give owners greater control over the project life cycle.

*Structure contracts to reflect real-world complexity.* To ensure contracts account for real-world complexity, life sciences companies can prenegotiate escalation terms, lead-time buffers, and productivity assumptions. Teams can also engage commercially capable owner reps—that is, people who can negotiate performance structures, manage claims risk, and keep suppliers aligned to the most efficient scheduling.

Companies adopting strategic procurement approaches have seen procurement cycle time improved by up to 20 percent, as well as greater cost certainty through reduced claims and change orders.

**3. Strengthening CQV readiness**

To deliver products that are safe, high-quality, and compliant, organizations need to integrate robust CQV into the workstream. If implemented correctly, CQV can accelerate products' time to market, increasing ROI. There are several ways organizations can deliver timely, high-quality CQV:

*Integrate a front-loaded CQV strategy in the construction process.* CQV is often handled separately from the rest of the project, which creates avoidable delays. A front-loaded CQV strategy avoids these bottlenecks and can accelerate the construction process without compromising compliance or product release timelines.

*Make CQV a critical-path workstream from day one.* To accelerate project delivery, life sciences companies can assign a CQV lead at project to ensure validation logic is built into the IMS alongside design and procurement. Teams align user requirements specifications early, coordinate closely with process engineering, and structure deliverables to support qualification readiness from the start.

*Use modular, prevalidated systems to gain speed.* To compress timelines further, advanced teams deploy skid-mounted, prevalidated systems that

arrive on site with major portions of commissioning and testing already completed. Where possible, factory and site acceptance testing are executed off-site in controlled environments, where teams can test equipment separately from the construction progress and reduce start-up risk.

*Leverage digital tools and risk-based validation*. Digital validation platforms—digital tools that manage and automate protocol execution, deviation tracking, and the integration of quality management systems and laboratory information management systems—add another layer of speed and control. Combined with risk-based validation approaches, these tools help focus resources on critical systems, reduce protocol bloat, and speed up batch release.

Firms that integrate CQV from the start could accelerate start-up by three to six months, while also improving compliance and documentation quality.

**4. Building institutional delivery capabilities and talent strategies**

The right talent and internal capabilities can lead to smarter, faster, and more-resilient manufacturing outcomes. Organizations can take several actions to build expert internal teams and capabilities to control the delivery process.

*Institutionalize control and repeatability*. We have observed leading organizations taking a different approach by using engineering, procurement, and construction management to provide short-term execution capacity while companies increase their institutional capabilities to achieve repeatable, high-value delivery.

*Stand up a capital projects center of excellence (capital COE).* To enable this shift, organizations are creating capital COEs, dedicated functions that codify best practices, provide expert support to projects, and enforce governance standards across the portfolio. The capital COE houses critical roles such as engineers, schedulers, contract strategists, and controls experts and deploys them flexibly across projects.

*Standardize execution through playbooks*. To enable consistency and speed, capital COEs develop standardized capital playbooks that cover stage gates, contracting models, scheduling protocols, and CQV workflows.

*Hardwire execution via digital tools*. Digital tools are critical to institutionalizing delivery. Project controls platforms centralize cost, schedule, and risk data; capital dashboards provide real-time visibility; validation systems ensure compliance at speed; and structured training programs help build internal teams with the skills to plan, negotiate, and manage capital effectively.

Companies that have built strong internal delivery teams report fewer delays, faster ramp-up of new sites, and a 15 to 30 percent increase in capital project throughput across the portfolio.

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With substantial capital pouring into the life sciences industry, leaders can prioritize capital excellence by shifting their mindset from traditional, product-driven approaches to time-based capital strategy. Leaders who shorten project life cycles could rise above the competition while quickly and efficiently delivering life-saving medicines and therapies to the patients who need them.

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The authors wish to thank Frederic Redmond and Ranjana Chandramouli for their contributions to this article.

# Simplification for success: Rewiring the biopharma operating model

To compete in an increasingly complex market, companies will need to unleash distinctive capabilities, reduce low-value work, speed up decision-making, and harness AI and digital.

*This article is a collaborative effort by Alix Burke, Greg Graves, Jan van Overbeeke, Michael Balz, and Shail Thaker, with Michael Rumbaugh, representing views from McKinsey's Life Sciences Practice.*

**Mounting headwinds** in recent years have prompted biopharmaceutical companies to redefine how they create and sustain value. Over the past decade, the industry has produced major scientific breakthroughs, leading to improved outcomes for patients and strong shareholder returns of roughly 9 percent annually.[1] However, companies are increasingly competing within crowded therapeutic spaces, asset life cycles are compressing, and major patents are expiring—all of which are compounded by stagnant R&D productivity, shifting geopolitical and regulatory landscapes, and increasing expectations to rewire the organization with digital and AI.

In response, pharma leaders have begun exploring fundamental changes to their capabilities, talent, and processes. Our analysis of more than 100 industry announcements reveals widespread simplification efforts that could yield more than $7 billion in cost savings. Top pharma executives have publicly committed to organizational transformations—from "streamlining our ways of working" and "reducing management layers" to what one leader describes as a "complete redesign" of the company's operating model.

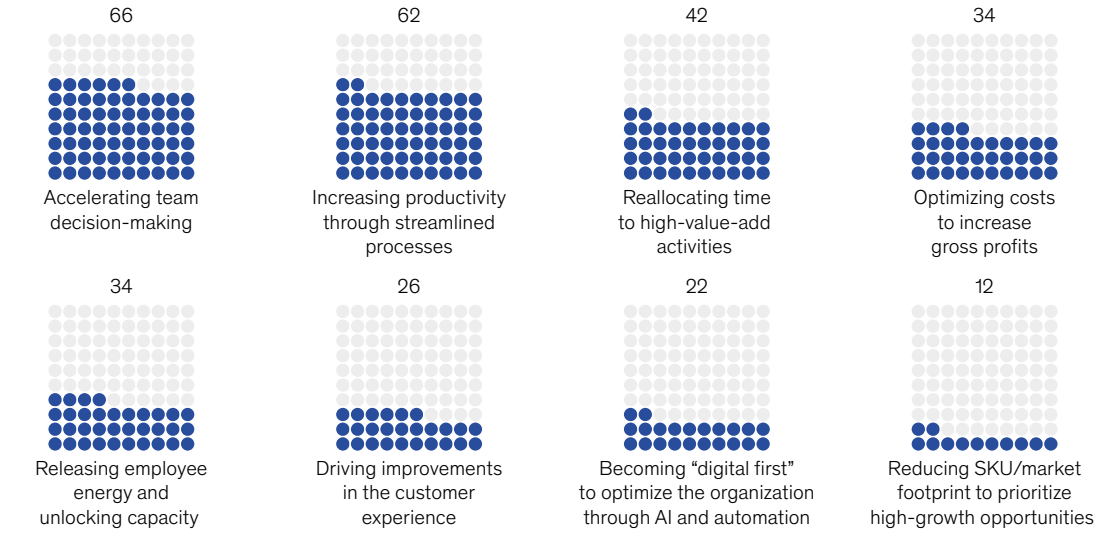
These signals are also reflected in the results of our recent survey of 50 global life sciences leaders.[2] Thirty-seven of them expect their organization to pursue a simplification effort over the next 12 months. Thirty-two respondents say they believe they need a significantly different operating model, and nearly half indicate that they must completely abandon their traditional business model to enable innovation, accelerate decision-making, and remain competitive. Thirty-three of them rank accelerating decision-making as one of their top three priorities for simplification (Exhibit 1). Only three respondents believe they have already solved a critical value-diminishing bottleneck: reducing manual workloads that prevent teams from focusing on high-value tasks. The message is clear: Simplification is no longer just a theoretical aspiration; it is now a strategic imperative.

[1] Brandon Parry, Rachel Moss, Katarzyna Smietana, and Michelle Suhendra, "Making more medicines that matter," McKinsey, July 31, 2024.
[2] McKinsey Global Life Science Leaders Simplification Survey, November 2024; n = 50.

Exhibit 1

## Pharma companies are seeking to accelerate decision-making and boost productivity through simplification.

**Highest-priority goals for simplification,** % of respondents (top three choices ranked)




Source: McKinsey Global Life Science Leaders Simplification Survey, Nov 2024; n = 50

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In this article, we explore challenges that are reshaping pharma and propose simplification strategies to move companies toward their next horizon.

## Trends reshaping pharma

Among the varying forces that are compelling pharma organizations to rethink their operating models, three trends stand out.

### Portfolio diversification, crowding, and life cycle compression

To capture growth opportunities, companies are expanding into new therapeutic areas, but this has led to increasingly crowded markets. In 2020, two-thirds of the portfolios of the top ten global pharma companies targeted areas with significant "herding"—a sharp rise from just 16 percent in 2000.[3] Over the same period, the time for three or more competing products to enter the same disease area has shrunk dramatically, from 15 years to just two. Meanwhile, the window to achieve 50 percent of lifetime sales has been reduced by 18 months since 2000, intensifying the urgency for companies to maximize return on investment before competition erodes margins.

### Policy pressures and pricing dynamics

Regulatory and policy changes, coupled with payer and health system consolidation, are reshaping industry economics. In the United States, the Inflation Reduction Act has given the Centers for Medicare and Medicaid Services the authority to negotiate drug prices after seven years for small-molecule drugs and 11 years for large-molecule drugs, with an estimated $50 billion to $70 billion EBITDA reduction for pharma companies through 2028.[4] Similar pressures exist globally: Germany

[3] Christian Fougner et al., "Herding in the drug development pipeline," *Nature Reviews Drug Discovery*, August 2023, Volume 22, Issue 8.
[4] "The Helix report: Is biopharma wired for future success?" McKinsey, October 27, 2022.

has halved its free pricing period to six months, while Japan has moved from off-year to annual price revisions. These shifts are forcing companies to propel operational efficiency to offset growing pricing pressures.

**Integrating AI and digital**

AI is set to transform life sciences, with gen AI alone expected to generate $60 billion to $110 billion in value across the industry. The most significant impact areas include clinical development ($13 billion to $25 billion), research ($15 billion to $28 billion), and commercial operations ($18 billion to $30 billion).[5] AI and digital capabilities are no longer confined to data science teams—they are becoming essential capabilities across general and administrative functions, R&D, operations, commercial, and medical affairs. However, as companies race to harness these technologies, they face a critical challenge: acquiring the right talent and integrating AI capabilities at a pace faster than previous industry transformations.

Across these trends, we see challenges and opportunities. Pharma companies are under pressure to adapt as competition intensifies, regulatory policies evolve, and uncertainty lingers. To stay resilient in this environment, companies should be able to make decisions and allocate resources quickly. At the same time, gen AI and other digital tools offer new opportunities for efficiency and innovation, but unlocking their full value will require targeted investment in capabilities, organizational rewiring, and meaningful change management.

## Four strategic actions for simplification in pharma

To navigate these challenges and seize the new opportunities, we have outlined four key strategies that pharma companies can take to streamline their operations, enhance productivity, and maintain competitiveness.

**1. Identify and build distinctive capabilities**

As the industry innovates, companies will need to upgrade their enterprise capabilities to remain competitive (Exhibit 2). Pharma companies should identify the capabilities that are essential for their future portfolios and differentiate between areas where they must excel and those where industry standards suffice. Less than a third of the 50 leaders we surveyed believe their organization currently possesses the talent and capabilities required to support future product portfolios, including those involving new modalities and technologies.

For example, a leading rare-disease pharma company that was expanding into new therapeutic areas performed an analysis to assess the gap between current and anticipated future capabilities. The analysis identified three kinds of capabilities needed to deliver the pipeline: expanding current expertise, new but nondifferentiating capabilities, and critical new areas requiring distinctiveness. This segmentation enabled the executive team to collectively focus on building essential organizational capabilities while allowing individual functions to address their specific business needs in a resource-efficient manner.

To close capability gaps, companies should decide whether to hire, acquire, build, or partner. For example, companies can upgrade their talent base by reshaping teams around current priorities or embed relevant expertise through partnerships. Across functions, from R&D to commercial, teams should weigh whether to build their own custom technology solutions, partner with vendors, or buy solutions and tailor them to their purposes.

More than half of pharma companies now outsource commercial capabilities, a trend expected to continue. A recent McKinsey survey supports this: more than 80 percent of pharma R&D leaders anticipate supplier spending to rise by 10 to 30 percent over the next two to five years. While outsourcing can accelerate the adoption of external technologies, it also introduces complexity. Leading firms balance these trade-offs by investing in internal capability building alongside strategic partnerships.

**2. Simplify organizational structures**

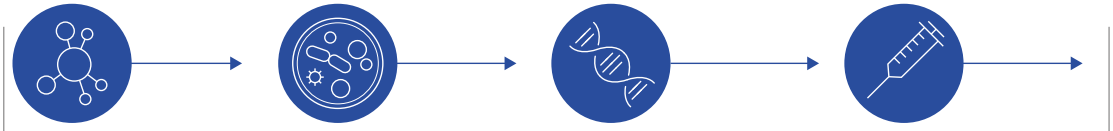
Overly complex, matrixed organizations present a major barrier to agility. In our survey of life science

[5] *Generative AI in the pharmaceutical industry: Moving from hype to reality*, McKinsey, January 9, 2024.

Exhibit 2

## The next evolution of pharma innovation will require capability upgrades across the enterprise.

**Pharma industry evolutions**



| Phase 1 | Phase 2 | Phase 3 | The next evolution |
|---|---|---|---|
| Small-molecule drugs with high competition | Increasing number of monoclonal antibodies and biologics | Treatments for rare diseases across new modalities (eg, gene therapies) | Highly competitive broad-population specialty drugs (eg, GLP-1[1]-based and immunology-based drugs) |
| **Key capabilities** (nonexhaustive) | **Key capabilities** (nonexhaustive) | **Key capabilities** (nonexhaustive) | **Key capabilities** (nonexhaustive) |
| ◆ Primary care field force<br>◆ Direct-to-consumer (DTC) marketing<br>◆ Small-molecule manufacturing | ◆ Medical engagement<br>◆ Reimbursement support<br>◆ Formulation<br>◆ Biologics manufacturing | ◆ Patient finding and engagement<br>◆ Access and patient support<br>◆ Clinical trial management<br>◆ Real-world evidence generation | ◆ Digitally integrated primary care field force<br>◆ DTC engagement<br>◆ Access and reimbursement<br>◆ Manufacturing capacity and flexibility |

[1]Glucagon-like peptide-1.

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leaders on simplification, roughly one in five respondents say they believe their current operating model enables timely decision-making at the appropriate organizational levels.

Some organizations have successfully simplified their structures by eliminating duplication between global, regional, and local layers. One biopharma company consolidated its markets into just two regions—international and the United States—transitioning to an above-market versus in-market structure. This shift brought decisions closer to customers, reduced bureaucracy, and provided employees with clearer roles and responsibilities.

Others have focused on flattening hierarchies by expanding the spans of control and reducing management layers. The benefits of these efforts include faster responses to market changes, improved decision-making, and standardized role responsibilities.

### 3. Streamline burdensome processes

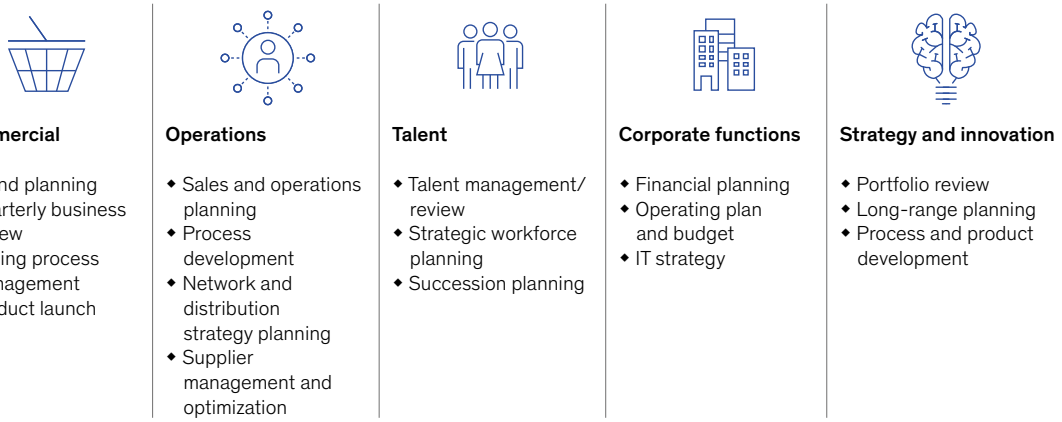
Pharmaceutical organizations often struggle with time-consuming processes that demand excessive involvement across multiple levels of the company, including financial planning, performance management, and business reviews (Exhibit 3). We have observed organizations that have streamlined cumbersome processes across multiple functions, reducing time requirements by 3 to 15 percent and freeing up resources for higher-value activities.

One company described a financial-planning exercise that took more than six months and required input from nearly everyone, from brand teams to the CEO. A better approach that some companies are undertaking is to empower small

Exhibit 3

## Redesigning routine processes can reduce time requirements by 3 to 15 percent, allowing resources to be allocated to higher-value activities.

**Examples of processes (by function) that could be redesigned**

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cross-functional teams to encourage process simplification. A midcap pharma company did just that: it reduced the timeline of its brand planning cycle by eliminating inefficiencies and standardizing outputs, cutting a traditionally eight-month process by two months.

Similarly, a large pharma company struggling with a six-month forecasting process lacked a singular source of truth, leading to inefficiencies and inaccuracies. By convening a cross-functional team to assess best practices, prioritize key metrics, and simplify inputs and communications, the company reduced its planning horizon by 50 percent while improving forecasting accuracy.

**4. Rewire with digital-first strategies**

Although digital transformations can initially add complexity, the long-term benefits are substantial. Companies that effectively integrate automation and gen AI can drastically simplify access to information, reduce manual workloads, and free up time for high-value tasks.

High-impact digital strategies require new ways of working. For instance, one pharma company deployed a digital-first approach across its 6,000 employees in key corporate functions, generating hundreds of millions of dollars in savings. A major use case involved developing a self-service portal that provided the local presidents of the company's different country offices, as well as the brand teams, with instant access to more than 50 common finance queries.

Moreover, some digital solutions can deliver immediate value without requiring major organizational rewiring. One pharma company applied AI-driven procurement analytics and uncovered $10 million in value within four weeks, just from analyzing 10 percent of its spending. Similarly, streamlined collaboration among marketing, sales, and tech teams has led to a 10 to 15 percent sales uplift in organizations that embrace digital strategies.

To maximize the benefits of digital-first strategies, companies must establish robust processes for scaling AI and automation. Without a structured approach, digital initiatives often stall at the proof-of-concept stage or introduce new inefficiencies that prevent cost-effective scaling. Leading companies are now adopting machine learning operations to create scalable AI solutions and more reliable deployment of digital tools.

Pharma leaders who act decisively amid mounting industry challenges can build the adaptability they need to thrive. By identifying distinctive capabilities, streamlining processes, and embracing digital-first strategies, they can create more nimble organizations. Success demands a bold commitment to simplification—one that empowers teams to focus on their core mission: accelerating the delivery of life-changing therapies to patients.

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This article was edited by Jermey Matthews, an editor in the Boston office.

# 3

# Navigating Market Dynamics and Driving Strategic Growth



# Clear, credible, compelling: Mastering investor engagement in life sciences

Life sciences' long R&D cycles and high stakes can test market confidence. Companies that excel at six engagement essentials can sustain investor trust in their value creation story.

*This article is a collaborative effort by Andy West, Bart Van de Vyver, Greg Graves, Jennifer Heller, Laura Furstenthal, and Ryan Davies, with Karl Mahler and Matty Cheng, representing views from McKinsey's Life Sciences and Strategy & Corporate Finance Practices.*

**Value creation** in life sciences tends to come in waves. The life sciences sector—including pharma, biotech, and medtech—has historically delivered solid long-term returns and has recently corrected from its COVID-19-era spike (Exhibit 1).

Life sciences companies face challenging structural realities such as long, high-cost innovation cycles; rigorous regulatory standards; and complex supply chains. In pharma, developing a new molecule now costs more than $4 billion (including the cost of failures), and only 13 percent of candidates entering Phase I trials reach approval.[1] Those numbers feed into market uncertainty and the wide forecast spread—the widest of any industry—between upside and downside performance scenarios (Exhibit 2). What distinguishes pharma is that its R&D pipelines consist of consequential products with clinical outcomes that are highly uncertain and often binary.

Although analysts view medtech as less risky than pharma, they are not as bullish about its upside. This dynamic puts pressure on medtech companies to innovate and operate more efficiently. With slowing growth as well as rising labor and raw material costs, investor expectations have only heightened for these companies to deliver sustainable performance and improved margins.[2]

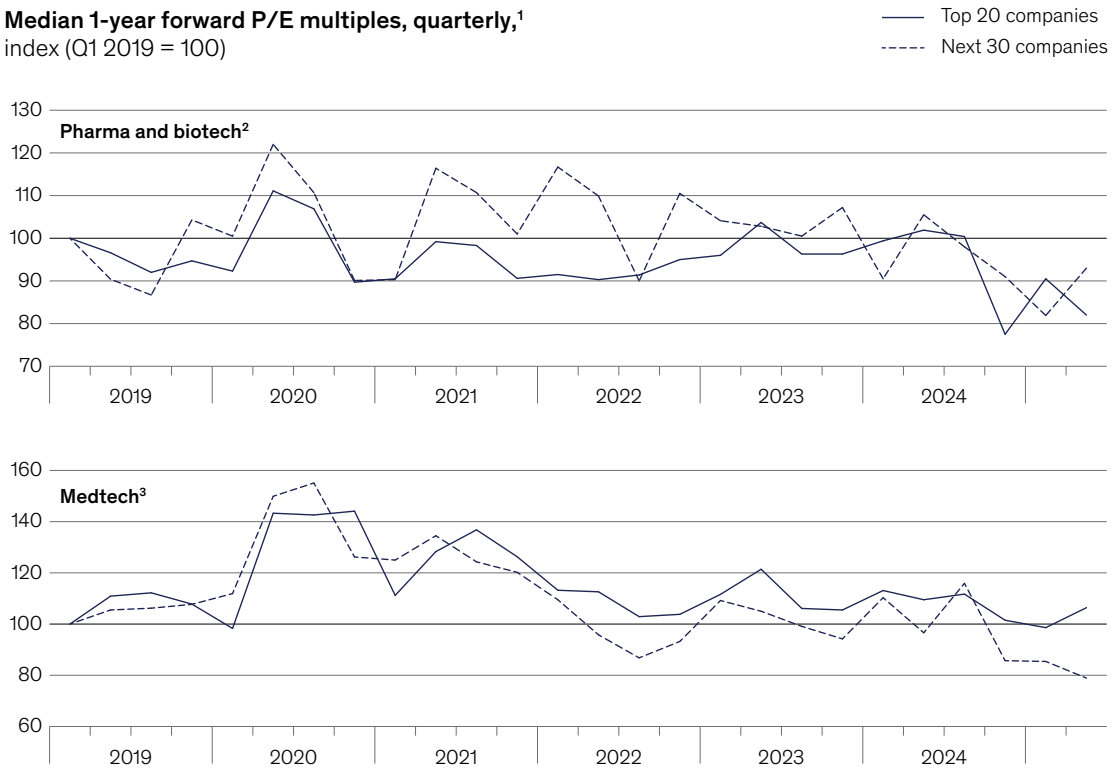
At the same time, new pressures are complicating the funding environment for both sectors. In pharma, competition is increasing across crowded therapeutic areas, and in some segments of medtech, such as cardiovascular, innovation and funding are concentrated toward select disease segments, narrowing the path for emerging technologies to scale. Across both sectors, inflation, geopolitical uncertainty, and evolving regulatory and reimbursement landscapes are adding further strain.

[1] "Charting the path to patients," McKinsey, January 9, 2025; "Accelerating clinical trials to improve biopharma R&D productivity," McKinsey, January 22, 2024.
[2] "The transformation imperative: Igniting value creation in medtech," McKinsey, February 18, 2025.

Exhibit 1

## Life sciences valuation multiples have fallen since the COVID-19 pandemic highs.

**Median 1-year forward P/E multiples, quarterly,[1]**
index (Q1 2019 = 100)




[1]Calculated quarterly, using share price and enterprise value as of each quarter and using forward one-year earnings per share and EBITDA estimates for calculation.
[2]Top 20 pharma and biotech represents the median of the top 20 companies by market cap as of Q2 2025, classified under MIC for "Pharma & Biotech." Next 30 pharma and biotech represents the median of the next 30 companies by market cap.
[3]Top 20 medtech represents the median of the top 20 companies by market cap as of Q2 2025, classified under MIC for "Medical & Technology" (inclusive of tools and diagnostics companies and contract development and manufacturing organizations or contract research organizations). Next 30 medtech represents the median of the next 30 companies by market cap.
Source: McKinsey Value Intelligence

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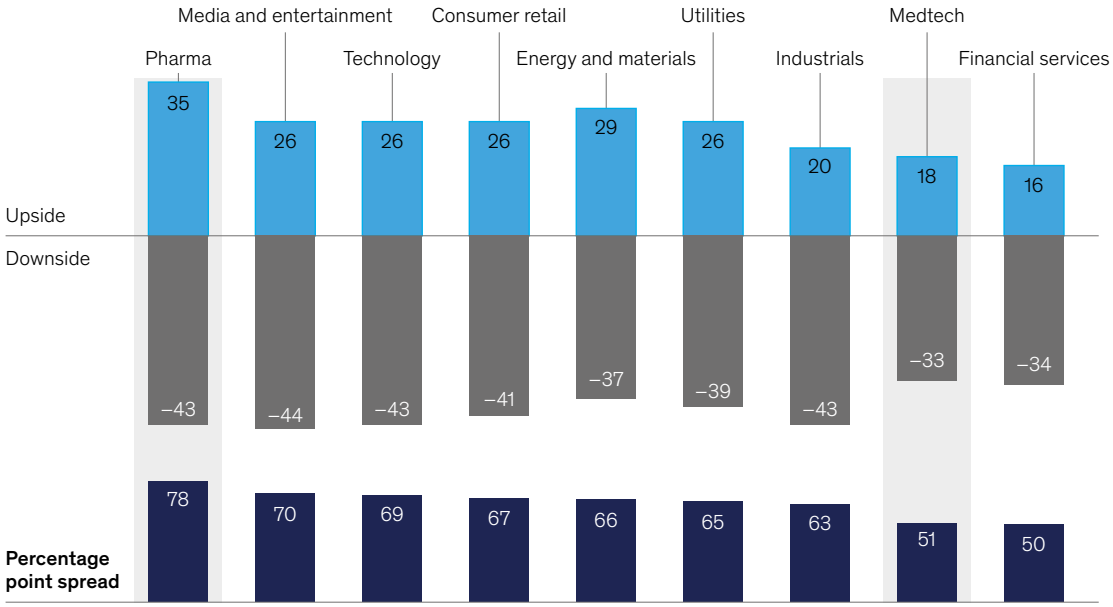
Amid these challenges, effective investor engagement has never been more critical to ensuring that market valuations reflect the sector's intrinsic value. A strong investor relations strategy can close the valuation gap—and reduce exposure to activist pressure—by grounding communications in data-backed proof points, explaining how the business is addressing external pressures, and framing short-term challenges within a credible long-term growth narrative.

Exhibit 2

## Investors view pharma as a high-risk but high-reward sector.

**Average Wall Street forecast spread between "upside" and "downside" stock price scenarios,[1] %**




[1]Calculated as the weighted average of the top 10 companies by market cap in each sector (for companies with available "high" and "low" scenarios modeled by Wall Street banks in last year); sectors grouped by typical Wall Street analyst groupings.
Source: S&P Capital IQ

McKinsey & Company

During recent tariff-driven volatility, for example, pharma companies that demonstrated strong investor relations were better able to sustain investor confidence and stock performance, even as broader market sentiment fluctuated (Exhibit 3). The same dynamic holds across sectors: According to the 2024 McKinsey Investor Survey, 82 percent of investors say a company's equity story strongly influences their decisions,[3] and most expect that story to be consistent across all communications. While investors still rely on financial performance and the strength of the balance sheet, they also assess management quality, strategic clarity, and responsiveness to industry trends. Investor relations at its best effectively weaves these elements into a cohesive equity narrative.

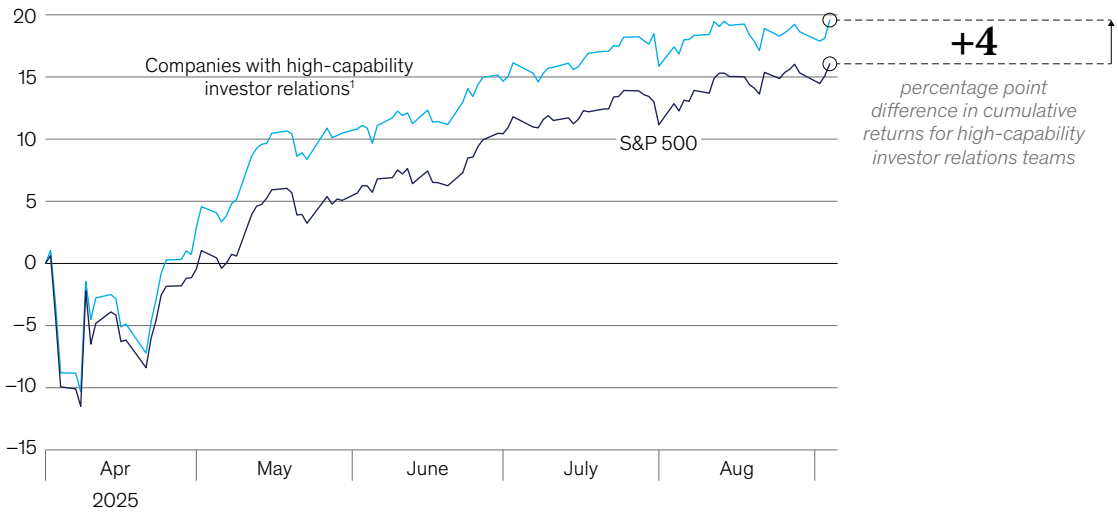
This article outlines six essentials of effective investor engagement that can help companies sharpen their equity story, reinforce credibility through proof points, and sustain investor optimism over the near and long term.

[3] Joseph Cyriac, Filip Abrahamsson Kwetczer, and John Evers, "McKinsey survey shows investors seek fundamentals and long-term vision," McKinsey, August 25, 2025.

Exhibit 3

## Companies with strong investor relations outperformed the broader market during volatile periods.

**Average stock returns,** index (Apr 1, 2025 = 0)




[1]Companies with high-capability investor relations determined by Investor Relations (IR) Impact Survey (pre–April 2025) that ranks firms based on IR capabilities as voted by investors and investment analysts, with ~100 companies ranked as "winner" or "nominee."
Source: IR Impact Survey, Apr 2025 (n = 100); S&P Capital IQ

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## A flywheel of strategy, execution, and investor engagement

The challenge for an investor relations team is to align a company's market value with its intrinsic value. Leading life sciences companies treat investor engagement as part of a "flywheel" that connects it to a company's strategy and execution (Exhibit 4).

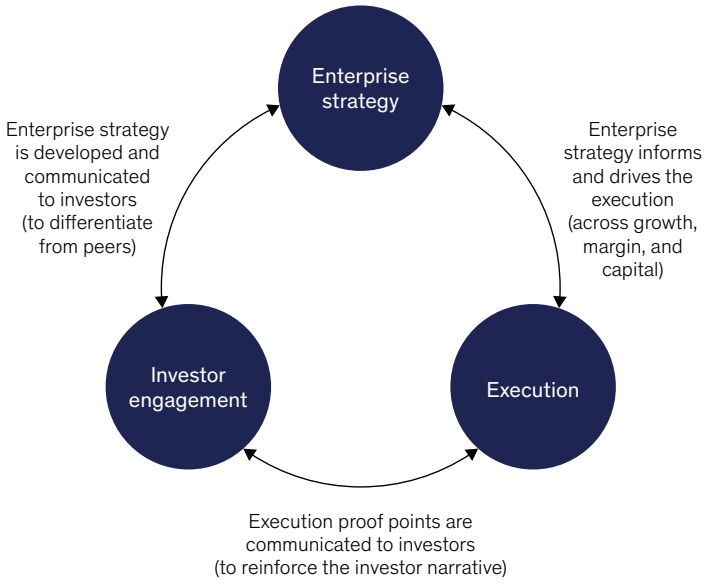
The flywheel turns through three interconnected components:

1. *Shaping enterprise strategy and sharing with investors.* Clearly articulate to investors how strategic choices create long-term value and position the company favorably within its competitive context.
2. *Driving execution of the strategy (and updating strategy as informed by execution progress).* Deliver outcomes across growth, margin, and capital that demonstrate progress and reinforce management's credibility.
3. *Providing investors with execution proof points.* Use each milestone to strengthen the equity story, close the gap between intrinsic and market value, and ensure that investor communications reflect both learned experiences and results.

Exhibit 4

## Investor engagement is critical to amplifying the strategy and execution message.

**Flywheel of strategy, execution, and investor engagement**

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## The six essentials of effective investor engagement

The flywheel illustrates the core factors that drive effective investor relations and explains why those factors matter. Six essentials of effective investor engagement can help companies build and sustain investor confidence (Exhibit 5).

**A. Compelling overall investor narrative**

More than 80 percent of investors say that an unclear or unattractive equity story reduces a company's appeal.[4] A strong narrative defines milestones, sets expectations, and provides a foundation for consistent messaging across all investor communications. The narrative should communicate the enterprise strategy, both in the near term and longer term, and what makes it distinctive. For pharma companies, this means explaining how their therapies address unmet needs, how their mechanisms differentiate them from the standard of care, and how regulatory and access paths support commercial success, including addressing patent cliffs.

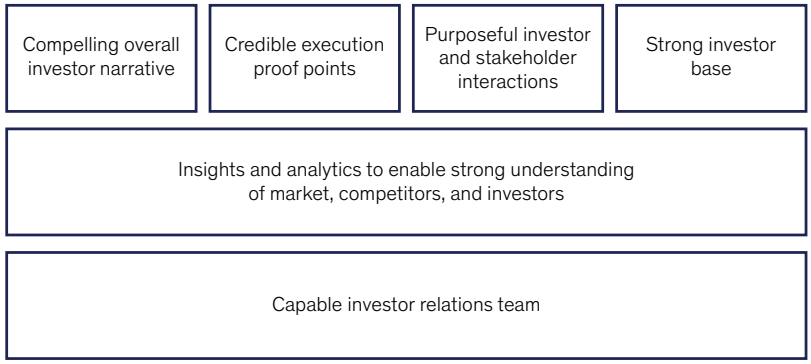
AbbVie, for example, sustained investor confidence after losing exclusivity for its

[4] Joseph Cyriac, Filip Abrahamsson Kwetczer, and John Evers, "McKinsey survey shows investors seek fundamentals and long-term vision," McKinsey, August 25, 2025.

Exhibit 5

## An effective value-creation narrative is built on clear communication and credible proof points and strengthened by data-driven insights.

**Six essential components for effective investor engagement**

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blockbuster drug Humira by charting a clear path for long-term value creation through newer immunology therapies such as Skyrizi and Rinvoq, and by demonstrating visible pipeline progress and consistent delivery against guidance.[5] AstraZeneca has strengthened investor confidence in its long-term strategy by emphasizing launch momentum and patient impact across its oncology and respiratory portfolios, most notably through the rapid global uptake of Tagrisso and Farxiga.[6] These therapies now serve patients worldwide and have driven double-digit revenue growth.

In medtech, where the focus is on connecting innovation to strong fundamentals, companies can describe how disciplined capital allocation, recurring revenue, and efficiency programs support growth. Stryker, for example, has built confidence through its robotics and trauma-device platform strategy—driving recurring consumables and service revenue tied to its installed base and delivering double-digit organic growth and margin expansion.[7] A compelling narrative has a full package that clearly articulates the long-term enterprise strategy, execution progress, and link to value.

### B. Credible execution proof points

Investors seek clear evidence that the strategy is translating into results. Not surprisingly, survey respondents rank financial performance and health as the strongest gauge of a company's attractiveness,[8] but a company can also demonstrate credibility by providing context and clarity for both financial and nonfinancial milestones. In pharma, value creation is often event-driven and tied to trial readouts, regulatory

[5] "AbbVie long-term guidance and pipeline update," AbbVie, February 2, 2024.
[6] "Full year and Q4 2024 results," AstraZeneca, February 6, 2025.
[7] *2024 comprehensive report: Financial, environmental, social and governance*, Stryker, 2025.
[8] Joseph Cyriac, Filip Abrahamsson Kwetczer, and John Evers, "McKinsey survey shows investors seek fundamentals and long-term vision," McKinsey, August 25, 2025.

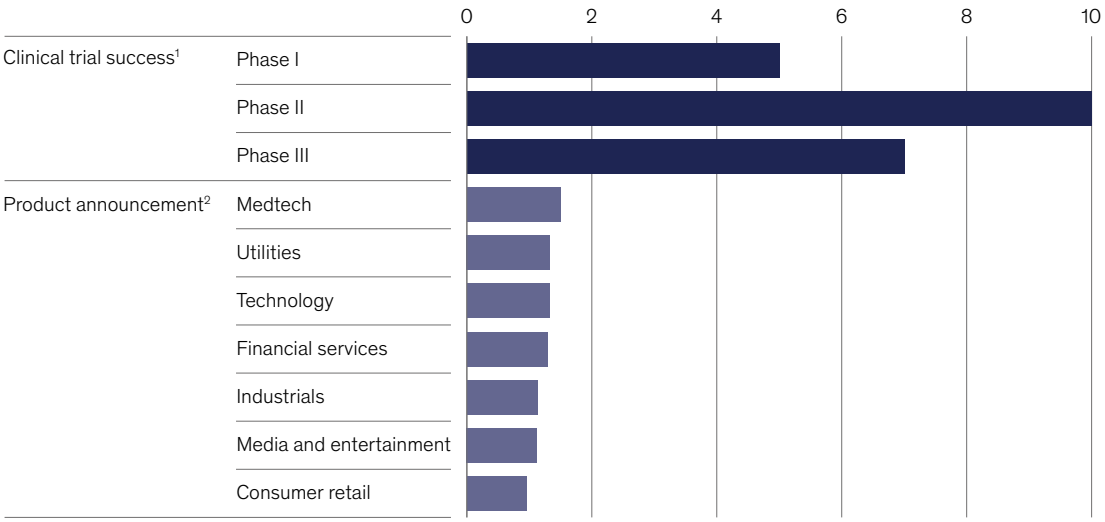
approvals, and scientific progress that signal future revenue potential. For example, successful late-stage clinical announcements trigger a 7 percent stock price reaction, on average, far exceeding the market response to product announcements in other sectors, including medtech (Exhibit 6). Clinical trial outcomes—particularly those that alter a company's valuation or strategic outlook—should be communicated as soon as possible after validation, with earnings calls and investor presentations then used to provide additional context and integrate trial developments into the broader R&D and financial narrative.

Pharma companies should also articulate other factors beyond traditional financial measures that they view as value drivers. For instance, Roche considers ability to address unmet needs, development feasibility and scalability, therapeutic differentiation, and path to value when evaluating assets for investments.[9] In medtech, financial proof points in adoption, recurring revenue, and margin expansion connect disciplined execution to long-term value creation. For example, the strong organic growth of Abbott's medical devices business, notably through products such as Structural Heart, demonstrates how disciplined execution in scaling innovation and sustaining product momentum supports recurring revenue and long-term value creation.[10] Consistency across guidance, delivery, and follow-up builds trust. When results deviate from expectations, clear explanations can sustain confidence.

Exhibit 6

## Pharma markets react more strongly to nonfinancial milestones than other industries do.

**Change in stock price after milestone announcement,** %




[1]Based on stock price change after clinical trial readouts (calculated as difference in closing stock price for day before announcement and day after announcement) for all available announcements (~1,500 events) for public companies since 2015.
[2]Based on stock price change after major new (not subsequent generations of existing) product announcements (calculated as difference in closing stock price for day before announcement and day after announcement) for top companies for each sector; energy and materials excluded due to industry structure that does not have traditional product launches.
Source: Evaluate; S&P Capital IQ

McKinsey & Company

[9] *HY 2025 results*, Roche, July 24, 2025.
[10] "Strong performance by Abbott's base business drives Q3 earnings," Abbott, October 16, 2024.

### C. Purposeful investor and stakeholder interactions

Every investor interaction should have a defined purpose. Leading companies plan the rhythm of their communications such that each event reinforces the overarching equity story. Capital markets days, conferences, and site visits help investors see progress firsthand and build conviction over time.

Investors consistently value clarity and access; according to the 2025 survey, they rank the quality of materials and executive participation as the most important aspects of quarterly calls.[11] Proactive investor engagement, organized around themes that matter most—such as pivotal trial progress, launch performance, and pipeline prioritization—can transform communications from one-way reporting into genuine two-way dialogue, strengthening both relevance and credibility.

To provide the clarity and access investors value, pharma and medtech companies often use R&D days and lab tours to explain complex science and highlight progress toward key milestones. Sanofi, for example, used a recent R&D day to highlight portfolio priorities and research advances in areas such as immunology and discovery-model transformation.[12] Roche took a similar approach with its pharma day, emphasizing innovation excellence across core pipeline areas such as oncology and neurology.[13] These sessions featured company leaders with scientific backgrounds, providing a high level of credibility and technical transparency that benefited investors and other participants. Lab tours also play a significant role in investor interactions. For instance, Agilent Technologies arranged a lab and factory tour to emphasize innovation across its portfolio following its latest investor day.[14]

### D. Strong investor base

Leading investor relations teams map their investors by style[15]—for example, intrinsic, trading-focused, or quantitative—and tailor communications to engage current holders while attracting potential new ones. In life sciences, they also assess the scientific literacy of their investors to calibrate messaging, providing the appropriate level of detail when highlighting scientific differentiation. Companies such as Merck, Novartis, and Sanofi adapt their investor communications to meet audience needs, varying the level of technical detail and data format. Scientific forums (where investors are also present) feature in-depth, research-driven presentations, while investor events focus on concise, results-oriented messaging. Messages are timed to highlight near-term progress or long-term opportunity, depending on investor priorities.

### E. Insights and analytics to enable strong understanding of market, competitors, and investors

Investor relations teams increasingly use analytics and gen AI to monitor sentiment, benchmark peers, and clarify messages. Thirty-one percent of investors now view technology use as a defining feature of well-managed companies.[16] Investor relations teams are increasingly leveraging gen AI with example applications, including anticipating analyst questions, analyzing the language and tone of investors and peer statements, and drafting materials such as earnings scripts and presentations.[17] In life sciences, analytics and AI can help teams turn complex R&D data into clear insights that link scientific progress to shareholder value. Teams can also use these tools to craft faster responses to investor questions and align internal and external messages more closely.

[11] Joseph Cyriac, Filip Abrahamsson Kwetczer, and John Evers, "McKinsey survey shows investors seek fundamentals and long-term vision," McKinsey, August 25, 2025.
[12] "Press release: Sanofi enters next chapter of Play to Win strategy," Sanofi, October 27, 2023.
[13] *Roche Pharma Day 2025*, Roche, September 22, 2025.
[14] "Agilent Technologies: Expanding leadership in LC & LC/MS," Agilent, September 30, 2025.
[15] Jay Gelb, David Honigmann, and Werner Rehm, "What your most important investors need to know," McKinsey, November 28, 2023.
[16] Joseph Cyriac, Filip Abrahamsson Kwetczer, and John Evers, "McKinsey survey shows investors seek fundamentals and long-term vision," McKinsey, August 25, 2025.
[17] Mark Maurer, Kristin Broughton, and Jennifer Williams, "When IR met AI: How the technology is shaping earnings-day prep," *Wall Street Journal*, November 19, 2024.

For example, companies have begun integrating gen AI–based analytics into their investor relations and communications workflows to monitor investor sentiment across earnings calls and benchmark peer disclosures. These tools complement, rather than replace, human judgment by increasing speed, consistency, and data-driven insight in investor communication.

**F. Capable investor relations team**

Strong investor relations organizations have a team of leaders with both strong financial expertise and industry expertise. In life sciences, it is critical that leaders have a strong background and understanding of scientific concepts, their translation to financial outcomes, the patience required to realize outcomes, and how to clearly communicate to investors. For example, the heads of investor relations at Roche and AstraZeneca have strong science backgrounds, enabling them to translate clinical data into value narratives that resonate with investors.[18] Leading teams are also closely connected to their company's science, development, and medical affairs functions, enabling them to exercise sound judgment and communicate milestones with balance, context, and credibility.

## Turning investor trust into a strategic asset

Investor relations is more than a communication channel. When investors can trust the company's ability to deliver, short-term volatility becomes easier for leaders to manage. That confidence gives them room to allocate capital boldly and stay focused on innovation. For example, AstraZeneca's decision to remain independent rather than merge with Pfizer was rewarded by investors because the company demonstrated credible progress and a clear long-term vision.[19] Ultimately, effective investor relations creates the conviction and stability that enable companies to stay the course and invest for sustained growth.

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Few industries have the same combination of deep scientific complexity, long R&D cycles, and rigorous regulation as life sciences. Yet these dynamics also create a powerful opportunity for differentiation through investor engagement. Companies that master the six essentials of investor engagement can shape a narrative that strengthens investor trust and position themselves to lead the next wave of sustainable value creation in the industry.

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This article was edited by Jermey Matthews, an editor in the Boston office.



[18] Garnet Roach, "Roche's new head of IR discusses his latest role," IR Impact, October 20, 2022; "AstraZeneca: Investor day biographies," Market Screener, May 21, 2024.
[19] Ian Johnston, "AstraZeneca hits £200bn valuation," *Financial Times*, August 13, 2024.

# GLP-1s are boosting demand for medical aesthetics

Industry stakeholders can take steps to better understand the needs and preferences of GLP-1 patients who seek to address one—and often multiple—aesthetic concerns.

*by Leigh Jansen, Nils Peters, and Olivier Leclerc with Lauren Davis*

**The rapid adoption** of glucagon-like peptide-1 (GLP-1) agonists is changing the life sciences landscape, with ripple effects extending well beyond cardiometabolic and obesity care. Global prescriptions of GLP-1 agonist therapies grew at a remarkable rate of roughly 38 percent annually between 2022 and 2024[1]—sales are forecast to reach $100 billion by 2030.[2] This growth has prompted interest in the downstream effects across healthcare and life sciences. In the medical aesthetics sector, the impact is already being felt. These medications are not only changing patients' cardiometabolic health; they are also altering their appearance and, in turn, fueling demand for aesthetic products and services.

To better understand the impact of GLP-1-induced weight loss on the aesthetics industry and on facial aesthetics specifically, we surveyed 174 medical spas, dermatology and plastic surgery clinics, and other aesthetics providers at the end of 2024.[3] Our findings suggest that GLP-1 therapies are expanding and reshaping the aesthetics customer base. For example, 63 percent of patients seeking facial aesthetic products or procedures were not active users of medical aesthetics services (Exhibit 1). Roughly half of these patients had never considered aesthetics prior to their weight loss. The rest of them were converted fence-sitters—people who had indicated their intention to receive an aesthetics treatment within the next five years.

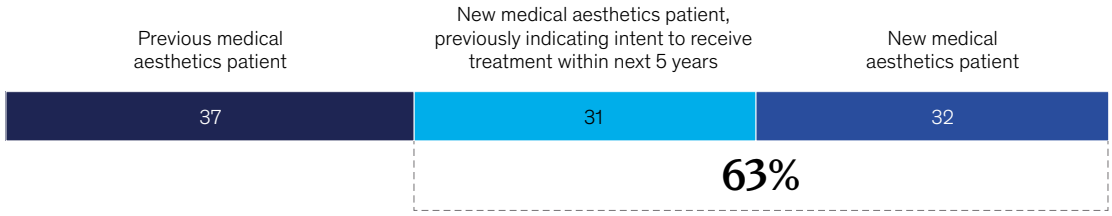
This influx of new patients presents both opportunities and challenges for aesthetics providers, manufacturers, and investors. In this article, we provide insights into the expectations and needs of this emerging cohort, and we suggest actions that stakeholders can take to serve these patients effectively and become market leaders.

[1] McKinsey analysis of Komodo Health and Evaluate Pharma data, accessed August 2024.
[2] "The increase in appetite for obesity drugs," JPMorgan Chase, November 29, 2023.
[3] McKinsey US medical aesthetics providers survey, December 2024; n = 174.

Exhibit 1

## Most GLP-1 patients seeking aesthetic services are new to the market.

**Patients receiving medical aesthetics treatment after losing weight using glucagon-like peptide-1 (GLP-1) agonists, by medical aesthetics use, US,**[1] % of respondents




[1]Question: For patients coming in for facial medical aesthetics after losing weight using GLP-1 agonists, to what extent is this a new group of patients/consumers? Please estimate the distribution of patients/consumers across the following categories.
Source: McKinsey US Medical Aesthetics Providers Survey, Dec 2024 (n = 174)

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### What GLP-1 patients want

Recent demand for medical aesthetics has been propelled by new patient segments, growing societal acceptance of aesthetic treatments, and an expanding array of treatment options.[4] GLP-1 therapies are contributing to this momentum not only by expanding the patient pool but also by increasing engagement among fence-sitters, a key demographic that signals future market growth.

To capture and sustain this growth, the medical aesthetics industry should understand and address the specific needs of GLP-1 patients. Four defining traits of this cohort stand out:

— *Many GLP-1 patients have multiple aesthetic concerns.* Weight loss, whether through lifestyle changes, surgery, or medication, can lead to common aesthetic concerns such as loose skin and facial volume loss, including the sagging and perceived aging of facial skin. GLP-1 agonists have multiple effects on fat and collagen production,[5] and as such, GLP-1 users may experience multiple changes in their facial appearance.

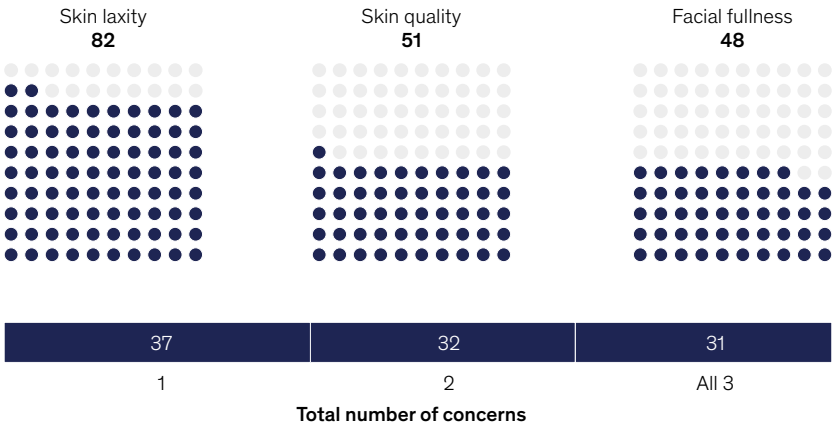
Patients who have undergone significant weight loss often choose less-invasive medical aesthetics treatments in addition to traditional surgical options such as facelifts.[6] Aesthetic providers reported that 61 percent of GLP-1 patients seeking treatment had lost 11 to 30 percent of their body weight. Many of them sought to improve skin laxity—particularly on the face and neck—skin quality, and facial fullness (Exhibit 2). Notably, 63 percent of these patients requested treatments for multiple concerns due to the interconnected changes between those aesthetic factors and weight-loss-driven changes to adipose and surrounding soft tissue.

[4] Leigh Jansen, Olivier Leclerc, and Nils Peters, "Here to stay: An attractive future for medical aesthetics," McKinsey, February 1, 2024.
[5] Alejandra Sataray-Rodriguez et al., "Investigating the impact of GLP-1 receptor agonist-induced fat loss on collagen synthesis and skin elasticity," *Journal of Biomedical Science and Engineering*, March 2025, Volume 18, Number 3.
[6] "AAFPRS reveals new statistics and trends in facial plastic surgery," American Academy of Facial Plastic and Reconstructive Surgery, February 4, 2025.

Exhibit 2

## Skin laxity is the primary aesthetic concern for many GLP-1 patients.

**Primary concerns of patients seeking medical aesthetics treatment after losing weight using glucagon-like peptide-1 (GLP-1) agonists, US,**[1] % of respondents




[1]Question: For patients/consumers who are coming in for medical aesthetics for the face after having lost weight using GLP-1 agonists, what are the main areas to be addressed? Please select all that apply.
Source: McKinsey US Medical Aesthetics Providers Survey, Dec 2024 (n = 174)

McKinsey & Company

— *GLP-1 patients have diverging aesthetic objectives.* One striking characteristic of this new cohort is that they are almost evenly split on the type of aesthetic they want to achieve. Roughly 56 percent of them say they are seeking a more "natural look"—a look that is closer to their pre-weight-loss baseline and that conceals any indications of aesthetic treatments—while 44 percent of them are exploring new looks and techniques.

— *Combination therapies and novel technologies may be required to fully address the range of needs of GLP-1 patients.* Treating GLP-1 users presents unique opportunities and challenges for aesthetics providers. Almost a third of those surveyed said they believe that more advances are needed to enhance clinical efficacy and outcomes for GLP-1 patients.

Emerging evidence is guiding the use of existing solutions—either alone or in combination—such as the use of Sculptra (a biostimulatory injectable) with Restylane Lyft or Contour (hyaluronic acid fillers)[7] or the use of single treatments such as platelet-rich plasma or radiofrequency (RF) microneedling.[8] Protocols that strategically and safely combine surgical and nonsurgical approaches may also hold promise for addressing the complex and interconnected aesthetic concerns of GLP-1 patients. For example, facelifts (rhytidectomies) and laser surfacing could be delivered as a combination or staged procedure, or autologous fat grafting could be combined with fillers and skin resurfacing. These procedures could be offered to patients through new collaborations, such as between med spas and plastic surgery clinics.

[7] "Galderma premieres positive interim results demonstrating the efficacy of its injectable aesthetics portfolio in addressing facial volume loss as a result of medication-driven weight loss," Galderma press release, January 14, 2025.
[8] Karen Montecinos et al., "Semaglutide 'Ozempic' face and implications in cosmetic dermatology," *Dermatological Reviews*, October 2024, Volume 5, Issue 5.

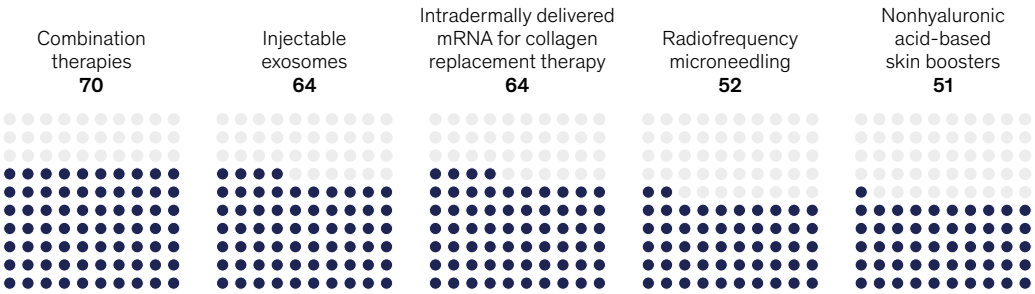
Respondents to our survey indicated strong interest in generating the clinical evidence base of these therapies and developing tailored therapies for GLP-1 patients. Nearly half of respondents are excited about combination treatments and innovations such as RF microneedling and mRNA-based collagen replacement (Exhibit 3).

— *The financial outlook for GLP-1 patients seeking aesthetic treatments is mixed.* For many GLP-1 patients who are highly motivated to improve their appearance through aesthetic services, the cost of ongoing GLP-1 therapy[9]—which can exceed $500 for a copay, even for those with insurance coverage—has created budget constraints. About 60 percent of patients report a reduction in overall aesthetics spending, while 40 percent say they have increased their investment in aesthetic treatments, driven by a heightened focus on their post-weight-loss facial appearance.

Exhibit 3

## Medical aesthetic providers are bullish about novel technologies and techniques.

**Share of respondents excited about select novel medical aesthetic technologies, US,**[1]
% of respondents




[1]Question: On a scale of 1 to 5, how excited are you about the following technologies for medical aesthetics for the face? Respondents selecting "1" and "2" shown.
Source: McKinsey US Medical Aesthetics Providers Survey, Dec 2024 (n = 174)

McKinsey & Company

[9] Nicholas Saraceno, "The financial barrier to GLP-1s," *Pharma Commerce*, April 1, 2025.

## How the industry can provide value

To respond to the growing demand from GLP-1 patients—and lead the next chapter of medical aesthetics—stakeholders can act decisively across multiple fronts. GLP-1 patients represent a new kind of aesthetics consumer, one who is often new to the industry and presents with multiple concerns. We propose five actions that stakeholders can take to meet the needs of these patients and capture value for their organizations.

### 1. Review marketing, messaging, and patient engagement

The GLP-1 patient cohort includes aesthetics customers who appear to have been previously unreached by traditional aesthetic marketing. This population could be targeted with precision marketing that considers the patient's demographic and psychographic profiles and their treatment goals. Educational campaigns could build on existing efforts to explain both the science of skin changes[10] and the potential solutions. These explanations could be delivered across a wide range of channels, such as digital health platforms, wellness influencers, and nutrition forums.

### 2. Consider the potential of tiered pricing or subscription models

To serve this financially diverse cohort, aesthetics providers can evolve their approach—blending traditional, high-touch strategies with digitally enabled, consumer-centric models that appeal to newer segments and foster long-term loyalty. Tiered pricing structures could offer accessible entry points, such as basic maintenance plans focused on skin quality, while still catering to premium consumers with comprehensive packages that can address additional concerns through a broader set of approaches, such as injectables, resurfacing, or combination therapies. Subscription models may further enhance affordability and engagement by spreading costs over time, encouraging routine care, and supporting better outcomes through consistent treatment.

### 3. Design treatment protocols tailored to post-weight-loss needs

A one-size-fits-all approach does not address the complex medical and aesthetic needs of GLP-1 patients.[11] Aesthetic providers could partner with manufacturers to develop evidence-based algorithms optimized for this population. They should consider treatment timing, sequencing of injectables, energy-based devices, and skincare regimens that most effectively address their goals while considering the patient's broader medical and psychosocial factors. Providers should also consider developing and implementing clinical guidelines to establish standard clinical pathways for different patient profiles and treatment approaches.

### 4. Expand access to combination therapies and novel technologies

Synergistic interventions may be more appropriate for GLP-1 patients seeking to address multiple aesthetic issues. In response to emerging research on weight-management patients, manufacturers should consider reviewing their R&D efforts and expanding their innovations, including injectable biostimulators, collagen-enhancing topicals, and RF microneedling devices. These solutions could be integrated into comprehensive treatment packages that are scalable across a range of provider settings—from medical spas to dermatology clinics.

[10] Zainab Ridha et al., "Decoding the implications of glucagon-like peptide-1 receptor agonists on accelerated facial and skin aging," *Aesthetic Surgery Journal*, November 2024, Volume 44, Issue 11; Kara Nesvig, "Ozempic is changing people's skin, say plastic surgeons," *Allure*, August 12, 2024.

[11] Yan Xie et al., "Mapping the effectiveness and risks of GLP-1 receptor agonists," *Nature Medicine*, March 2025, Volume 31, Number 3.

**5. Explore investment and dealmaking opportunities across the value chain**

The growing need for integrated treatment solutions, scalable care models, and differentiated, evidence-based technologies has created investment opportunities. Investors could engage in strategic M&A to acquire early-stage companies that are developing novel aesthetic tools and combination therapies, which could help bigger players accelerate their access to next-generation injectables, biotech innovations, and AI-enabled technologies. Alongside business development teams, investors could also build portfolios around the needs of GLP-1 patients and engage with other aesthetic providers within the weight loss and cardiometabolic ecosystem, including specialists and pharmacies

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In this pivotal moment, as demand for GLP-1 agonists continues to rise, providers, manufacturers, and investors should seize the opportunity to innovate, adapt, and shape the future of aesthetics. Those that act now—by developing novel and cost-effective treatment plans, investing in next-generation technologies, and creating tailored go-to-market and pricing strategies—can meet current demand and establish leadership in this evolving market.

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This article was edited by Jermey Matthews, an editor in the Boston office.

# The transformation imperative: Igniting value creation in medtech

Leading medtech companies are embarking on bold transformations and evolving their operating models to unlock sustainable growth and create efficiencies.

*This article is a collaborative effort by Ari Perl, Chris Eakins, and Richard Bartlett, with Adrian Lo and Shayne Skov, representing views from McKinsey's Life Sciences Practice.*

**The medtech sector** continues to face challenges in achieving profitable growth, causing some companies to embark on bold transformations to unlock value. Value creation and potential efficiencies are difficult to capture because they are often deeply interconnected across functions, requiring an evolved operating model and cross-functional collaboration to unlock. Executing a successful transformation in medtech can catalyze change by helping companies refocus on sustainable growth, reigniting a cycle of efficiency improvement and driving stronger performance overall.

## Continuing challenges with growth and margin expansion in medtech

As discussed in *Medtech Pulse: Thriving in the next decade*, the medtech sector has struggled to deliver value creation and has lagged behind the S&P 500 since 2021.[1] Our recent research further highlights a divergence in growth and value creation between leaders and laggards, with most of the sector's growth in TSR driven by top-decile performers.[2]

The approach to value creation is also evolving. While revenue growth remains crucial, investors are also placing increasing emphasis on margins. Before the COVID-19 pandemic, industry margins were on an upward trajectory, but that trend has reversed in recent years. Industry margins have dipped below 2019 levels, and only one in four medtech companies grew profitably above the industry average (Exhibit 1).[3] Industry leaders face persistent pressure on margins because of rising input costs from labor and raw materials, and slowing growth puts further pressure on profitability. In particular, bottom performers in margin have deviated further from the median since 2023.

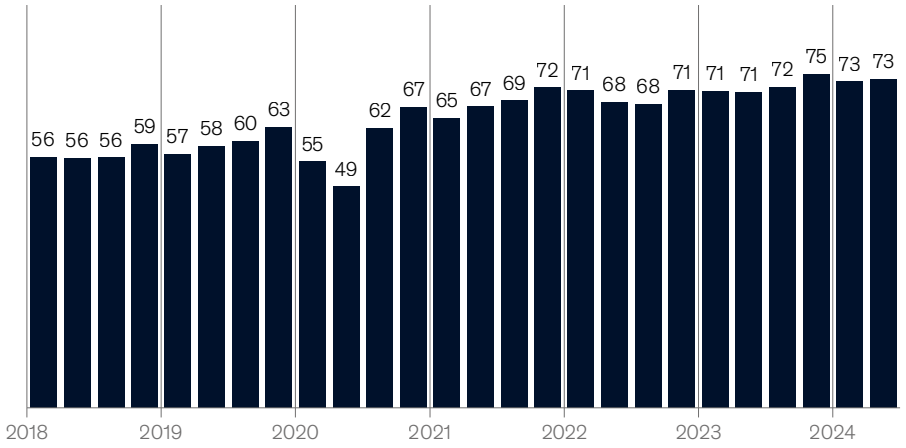
Specifically, we find that top-quartile performers in medtech have above-average revenue growth, while bottom-quartile performers lag behind peers in margin (Exhibit 2). Looking forward, only 25 percent of companies are expected to improve both revenue growth and EBITA margin in the next two years.

[1] *Medtech Pulse: Thriving in the next decade*, McKinsey, September 15, 2023.
[2] Delphine Nain Zurkiya, Gerti Pellumbi, Peter Pfeiffer, and Tommy Reid, "Value creation priorities shaping medtech," McKinsey, October 16, 2024.
[3] Based on McKinsey analysis of company filings by the top 20 medtech companies by market capitalization. Data from S&P Capital IQ, accessed August 31, 2024.

Exhibit 1

## Medtech growth has slowed, and margins remain suppressed.

**Reported sales and EBITA margin of top ~30 global medtechs,**[1] 2018–24 (Q2)




[1]Top ~30 medtechs by 2023 sales with 2018–23 data available, as of Aug 22, 2024.
[2]Calculated as Q2 2024 sales vs Q2 2023 sales.
Source: S&P Capital IQ, accessed on Nov 13, 2024

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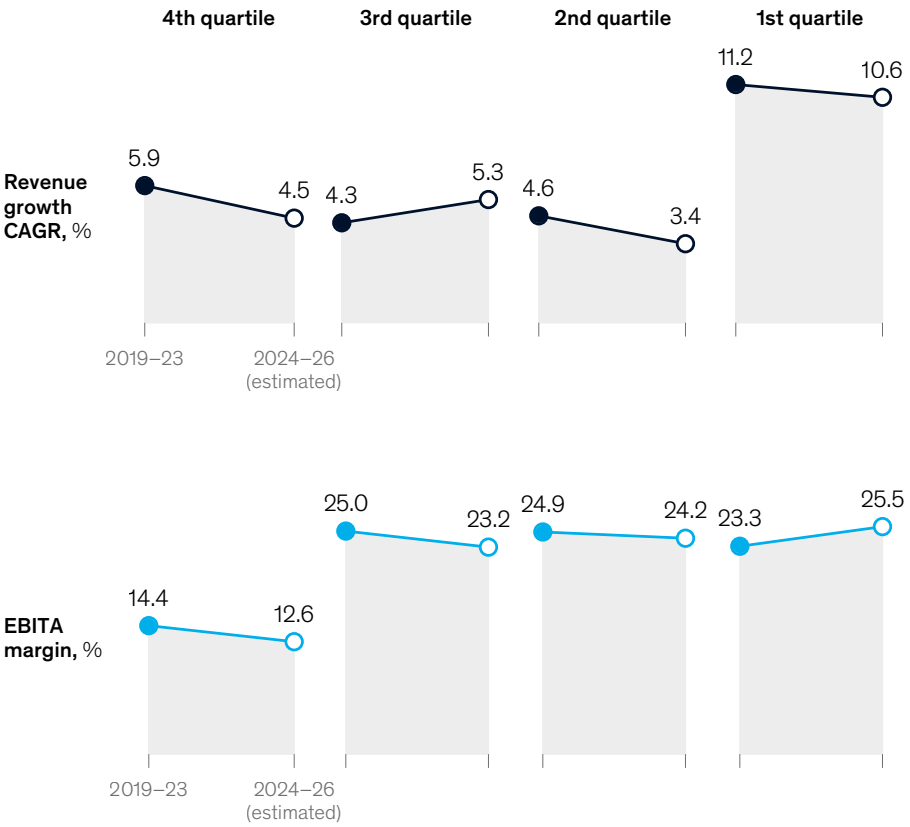
Exhibit 2

## Top-quartile performers in medtech have above-average revenue growth, while bottom-quartile performers lag behind peers in margin.

**Reported and forecasted revenue and EBITA margin,**[1] based on quartiles in TSR since 2019




**<25%** of medtech companies **expected to improve** revenue growth and EBITA margin in the 2024–26 period compared with the 2019–23 period

[1]Top ~60 medtechs with 2018–23 data available.
Source: S&P Capital IQ, accessed on Nov 13, 2024

McKinsey & Company

In addition, the industry is simultaneously confronting other challenges:

*Slowed pace of innovation.* Among incumbents, the pace of innovation has been slowing with R&D becoming more expensive, partly driven by a rising standard for clinical evidence and increasing difficulty identifying breakthrough opportunities. This has created opportunities for new competition, especially from China and India, to emerge.

*Continued impact from supply chain challenges.* Supply chain leaders are still grappling with the labor shortages and raw material cost inflation that came about during the COVID-19 pandemic, together with production delays and volatile demand. Many companies are still in the process of resetting their manufacturing and supply chain cost base and returning to the discipline of continuous cost optimization.

*Complex global markets.* Challenges in demand propelled by evolving regulatory and reimbursement landscapes, along with infrastructure investment considerations in nearshoring and localization, need to be managed with a new global playbook.

## Why medtech requires a bold transformation approach to unlock value

While most companies have initiated strategic initiatives to improve productivity and ambitiously manage cost, medtech companies face a particularly challenging set of hurdles when embarking on the transformation journey for several reasons:

*Value levers are deeply interconnected across functions.* Efforts to improve gross profit and reduce manufacturing costs, for example, require close collaboration among platforms (portfolio optimization, product mix, and life cycle management); commercial (contracting and tenders); R&D (product innovation and design to value); and supply chain (network strategy and procurement), to name a few. It often takes months or even years for medtech companies to align these diverse functions—each with its own priorities and timelines—to execute a single meaningful change. Without cross-functional collaboration, medtech companies will continue struggling to achieve transformative results within and across functions.

*Potential efficiencies are difficult to capture.* While many medtech companies have already undertaken cost transformations, their efforts have often been limited to easy-to-do, one-off actions that do not deliver recurring value. Potential efficiencies in core operations such as network design and simplification are often difficult to extract, in part because of the number of decisions involved and the complexity of the operating model. Individual efforts to simplify a specific portfolio or streamline the network for one business unit may not be able to deliver the full value, given overhead and stranded costs in functional areas, without other actions. A holistic approach would consider where these capacities and costs can be redeployed to support additional value-creating activities and higher-growth opportunities.

*Operating models hamper speed and clear end-to-end accountability.* The operating models at many large medtech companies have evolved over decades into siloed, functional organizations with complex matrices and diffused decision making. With few exceptions, organizations' business units are primarily responsible for portfolio management and R&D, regions manage commercialization, and operations oversees all manufacturing and supply chain functions. In the spirit of centralizing across units to identify operational synergies and consolidating expertise, companies traded in speed, agility, and proximity to customer feedback. This has hampered major decision making by increasing communication cost and reducing direct accountability of performance across profit and loss (P&L).

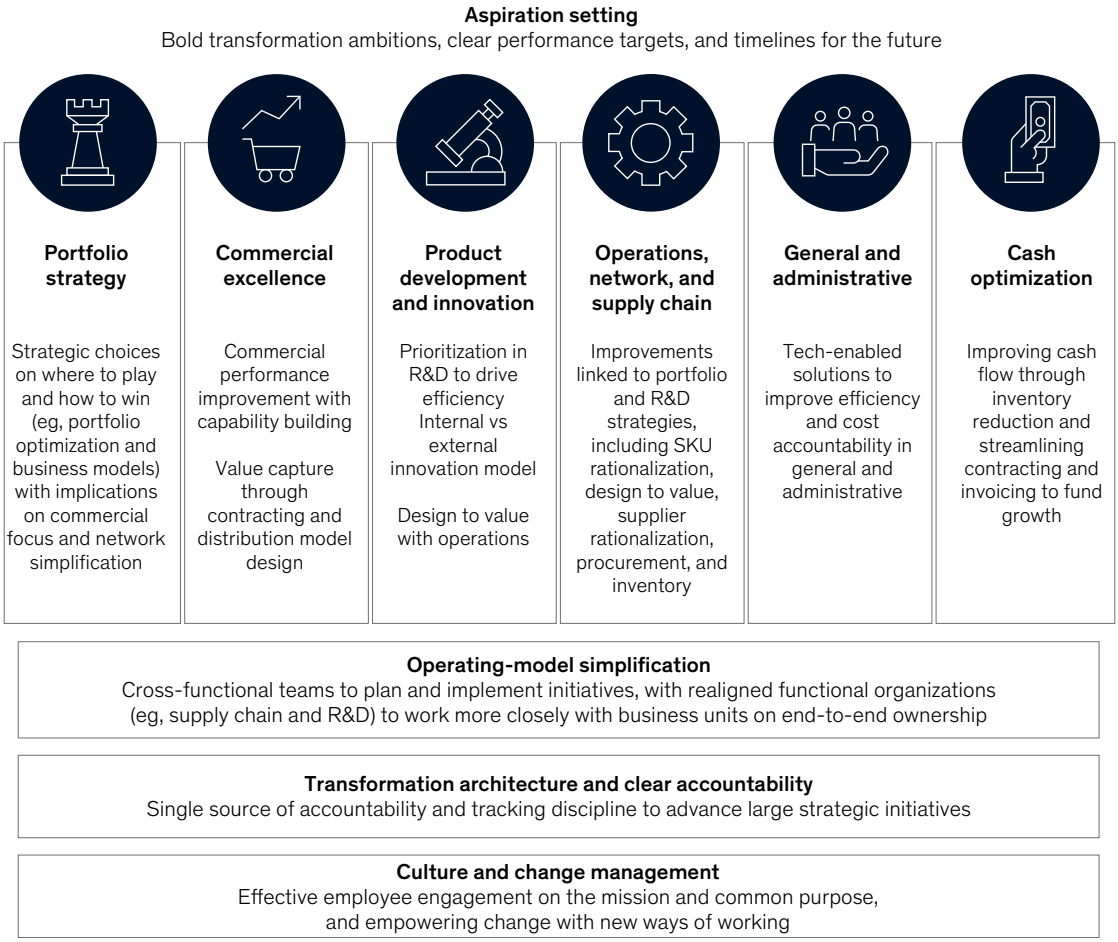
Successful companies break existing silos to reset the operating model, often streamlining decision making and appointing clear business and initiative owners to steer end-to-end activities and address cross-functional interdependencies. This reflects a prevalent industry trend characterized by a return to a divisional organizational model (for example, reintegrating supply chain and R&D functions into business units) to reinforce end-to-end accountability. We observe many companies rebuilding the organizational muscle needed to achieve end-to-end P&L. And business leaders, having come through commercial or marketing functions in many cases, are adapting to a culture of end-to-end decision making, especially in cost and operations.

## How medtech transformations work: Managing interconnected levers

Successful transformations start from the top with a clear vision of the company's growth and margin aspirations and the biggest hurdles to overcome. There is no single medtech transformation playbook, given the different business models and innovation cycles across verticals, even within the same medtech company. Typically, successful transformations are anchored on one or two primary objectives that address a unique challenge for end-market customers and achieve the greatest shareholder value. The transformation framework then comprises initiatives and activities that address these objectives, and the framework ensures a cross-functional approach to resolve dependencies (Exhibit 3).

Exhibit 3

## Successful medtech transformations comprise six interconnected levers and cross-functional support.

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### The six interconnected levers of medtech transformation

Six common, interconnected levers unlock value for medtech organizations.

*Portfolio strategy.* Portfolio strategy is a critical starting point in transformations because it provides focus and guides resource allocation based on market attractiveness and a company's right to win. A strategic assessment of the growth and margin profile of each segment helps prioritize incremental innovation and commercial investments that drive further differentiation.

In addition to achieving excellence in portfolio planning (with R&D investments, acquisitions, and divestitures), effective strategies also closely coordinate with the commercial and supply chain organizations to manage regional differences and unlock value through simplification and efficiency.

Working closely with global commercial teams, portfolio strategists need to manage increasing regional differences in user preferences, contract and tendering needs, and competitive dynamics. Portfolio teams can create value by enforcing best practices in life cycle management, such as accelerated product upgrades, SKU rationalization, and timely product discontinuation.

Portfolio teams can also engage with supply chain organizations to unlock potential for operating margin improvement beyond annual targets through efforts such as supplier optimization and network simplification. To capture maximum value, choices (such as product mix and prioritization) often need to be coordinated across the portfolio, commercial, and supply chain functions.

*Commercial excellence.* Elevating commercial capabilities and performance to drive growth through better execution is a no-regrets move. A full assessment of potential opportunities will span pricing execution, commercial model innovation, spending optimization, and launch excellence. Enhancing commercial performance requires medtech companies to upskill their sales forces with digital and AI-enabled capabilities and develop customer segmentation and tailored engagement strategies.

In addition to driving growth, commercial functions can also meaningfully contribute to efficiency and identify hidden value across the value chain. Exploring the gross-to-net waterfall may reveal additional levers in contract compliance and invoicing, the distribution model, and commercial inventory that can also add to transformation success.

*Product development and innovation.* Improving R&D efficiency and output is a top item on the industry's agenda, but more-complex products and regulatory requirements make it more challenging to do so. Enhancing the performance of R&D organizations often entails reviewing processes, structure, and governance to ensure they effectively, and above all, propel strategic prioritization of resources to create the biggest impact in the near and long terms. Conversations about the role and effectiveness of internal versus external innovation models (including acquisitions and build-to-buy investments) are also crucial as companies reassess how to best meet customer needs and maintain agility.

*Operations, network, and supply chain.* Operations still has substantial potential for optimization. True transformation in medtech entails elevating the role of supply chain across the organization—instead of treating it as an afterthought—and pursuing systematic approaches to reduce complexity.

As noted above, improvements in operations are closely linked to portfolio and product development strategies. Optimizing the portfolio and rationalizing SKUs reduce complexity within the network, which often enables an organization to optimize investments as well. Working with product development teams earlier in R&D cycles with a continuous design-to-value approach while exploring supplier optimization and resilience ensures a cycle of gross margin improvement.

Furthermore, systematically reviewing procurement capabilities and inventory management practices often generates sizable cash optimization. Capturing value from all of these drivers requires close coordination among operations, supply chain, and other functions.

*General and administrative (G&A).* New technology-enabled solutions—including those using generative AI—have shown potential to greatly improve efficiency in G&A functions. Establishing clear cost accountability and mature tracking mechanisms ensures transparency and control over expenses. This approach helps companies streamline operations and reduce overhead costs.

*Cash optimization.* Extracting near-term value from working capital is vital for funding business investments. In both commercial and operational levers, medtech companies have an opportunity to streamline contracting and invoicing processes and improve cash flow by pursuing inventory reduction strategies. These measures enable reinvestment in growth and innovation priorities.

### Cross-functional support for medtech transformations

These levers are enabled by three additional critical elements that distinguish a transformation effort from routine functional business improvement and that increase the chances of success.

*Operating-model simplification.* Transformation offers an optimal opportunity for organizations to simplify complex matrices with unclear decision points across platforms, regions, and functions. As cross-functional teams come together to plan and implement initiatives, successful transformations often take the opportunity to role model new ways of working that foster streamlined and data-driven decision making. This takes different forms depending on the organizational starting point. In some, it involves realigning functional organizations such as supply chain and R&D into the business unit with a stronger focus on resource prioritization; in others, it involves sharpening the role of business leadership and involvement in critical global markets to synchronize commercial execution strategies across regions.

*Transformation architecture and clear accountability.* Medtech organizations often struggle with advancing large, strategic cross-functional initiatives due to the lack of a clear, accountable owner and an inability to track initiatives. Transformation programs present an ideal opportunity to bring siloed functions together and unlock the full potential of integrated processes. Cornerstones of a successful transformation office include a single source of accountability enabled by integrated data sources to create visibility and transparency, as well as cross-functional initiative-tracking discipline with clear individual ownership. In our experience, many companies that go through transformational programs embed and incorporate these new ways of working into their business processes beyond the defined initiatives.

*Culture and change management.* Increasing employee engagement across the global organization is crucial to transformation success. Transformations come with change and disruption, and they can alter long-standing organizational habits and ways of working. To galvanize the organization's "will to transform," it is important to reignite a patient-centric mission and ground changes in a common purpose. A three-step approach centered on elevating a strong core of employees across levels to lead, empowering a broader group of change leaders to embody new ways of working, and energizing all employees to transform will help create the inertia to act.[4] Reinforcing common goals, in which winning together is valued over winning as individual functions, fosters a collaborative environment.

## How to embark on a successful transformation

While the impetus for transformation varies for each organization, major strategic events such as M&A and divestitures, preparation for major portfolio launches, quality and supply challenges, or investor activism often serve as catalysts to ignite the cause for change. While bringing together the entire organization to respond to internal and external challenges, leading medtech companies use those moments to reposition themselves for long-term success by adopting a transformative approach.

Successful transformations embed strategy in the core at the start.[5] Rather than striving for incremental improvement, organizations can apply optimistic and imaginative thinking to set ambitious goals and align transformation objectives with those of the broader business. Setting high aspirations, clearly articulating program objectives, and identifying early-impact levers are at the core of creating enterprise momentum. By translating a top-down assessment of the full potential opportunity, companies can build transformations upon an objective fact base to validate opportunities and build consensus on what is achievable among business and functional leaders.

Initiating a transformation starts with commitment from the C-suite and the board on a shared vision for the organization and clear goals. Leaders must embrace the aspiration and collective accountability for results, taking a holistic view beyond functional silos or business lines for the company's greater objectives.

[4] "Going all in: Why employee 'will' can make or break transformations," McKinsey, September 6, 2024.
[5] Kevin Carmody, Louisa Greco, and Rob Montgomery, "Defining your 'true north': A road map to successful transformation," McKinsey, May 22, 2024.

Delivering on a transformation requires a strong core team with the right accountability, authority, and infrastructure to engage the organization broadly. To drive effective change, it is important to allocate enough high-performing and high-potential talent to work on the transformation and ensure sufficient dedication and focus from other priorities. Long-term success requires that companies realize initiatives and targeted impact but also cultivate enthusiastic employees equipped with the right skills and mindset to translate the program into action. To achieve this, companies can consider incorporating collective metrics on transformation and celebrating contributions and leadership.

By embedding into the organization's DNA a culture of continuous improvement in growth and efficiency, as well as new ways of working emphasizing collaboration and accountability, medtech companies can sustain the impact of a successful transformation for the long term.

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# The hidden traps of business building: A guide for life science CEOs

CEOs in pharma, biotech, and medtech are increasingly building patient-centric businesses but are struggling to do so. Avoiding five common roadblocks can help leaders build successful businesses.

*This article is a collaborative effort by Akash Kumar, Arun Arora, Jake Henry, and Pepe Campello Gomis, with Franca Ziervogel, representing views from McKinsey's Life Sciences Practice and Leap by McKinsey.*

**Life science companies** have traditionally kept patients and consumers at arm's length. Pharmaceutical, biotech, and medtech companies have viewed providers and payers, not patients, as their key customers and have rarely interacted with them as end customers. This approach has had to evolve in recent years. Consumers are now accustomed to apps and smartwatches that provide a 360-degree view of their well-being, and they engage with direct-to-consumer brands such as Apple Health, Hims & Hers, and Noom to manage their own health.

In response, life science companies have rapidly launched new ventures and spinouts offering consumer wellness products and services that are not beholden to the same level of regulatory approvals as their main drugs and devices. Whether it's a medical-device company building a diet-and-recipe app or a pharmaceutical company launching an online destination for information on menopause, the trend is clear: patient engagement is now critical for life science companies' long-term success. Companies that do not build successful consumer businesses risk losing significant market share to nimbler competitors and digital disruptors.

Business building is a popular way for companies across industries to attract new customer segments and generate additional revenue from existing strengths (for example, existing partnerships or customer relationships). More than half of the 1,100 CEOs surveyed in a 2024 McKinsey Global Survey identified business building as one of their top priorities.[1] Life science companies are especially eager to launch consumer-centric businesses, especially those propelled by AI. Our survey shows that 45 percent of pharma and medtech companies plan to launch AI or analytics-driven businesses in the next five years, a 28 percent increase over 2023. Some of the consumer-focused ideas that life science companies are considering include virtual health platforms and benefit management apps that allow patients to track their healthcare spending.

[1] "How CEOs are turning corporate venture building into outsize growth," McKinsey, October 22, 2024.

But launching a new business is never easy; it takes a huge amount of strategic planning and execution. And the process is doubly hard in life sciences, where new ventures can fail due to regulatory complexities, talent acquisition issues, and lackluster go-to-market strategies. As a result, many life science leaders who are enthusiastic about building new businesses struggle with implementation.

This article provides life science CEOs with a practical guide to building consumer-centric businesses by highlighting five main pitfalls to avoid. CEOs who succeed with business building empower their teams to experiment, providing them access to the company's core competencies, technical infrastructure, and operational resources but shielding them from top-heavy corporate practices. By watching for these five red flags, CEOs can steer a new business from start to finish.

## 1. Relying too much on in-house regulatory and compliance expertise

Life science CEOs typically trust that their in-house teams have the expertise needed to navigate the complex regulations governing the creation of new customer-centric businesses. After all, the life science industry is one of the most highly regulated. Companies have extensive legal and data teams focused on ensuring compliance, navigating regulations, and protecting patient information. With so many experts at their disposal, life science CEOs often assume their companies have an advantage when it comes to launching new businesses in highly regulated environments.

But that's not always the case. When attempting to launch new consumer-centric businesses, many life science companies get bogged down in process, which can stifle innovation. In-house teams in compliance and legal—and HR, technology, and marketing—are familiar with taking measured steps to ensure strict compliance. That kind of diligence works well to support mature companies but can stall new-business creation. To succeed with business building, life science companies must often create independent business units or spinouts, distancing them from the parent organization.

A global medtech company is a case in point. The company launched a new consumer health business that was integrated into the larger company. It had to meet the same regulations as the parent company and abide by all corporate procedures. The team spent up to 30 percent of its time complying with these requirements. Meanwhile, the company's competitors offering stand-alone consumer health products were not encumbered by so many processes and could thus grow more quickly. To keep up, the medtech company changed course and created a new independent process for releases. The team unit was given more leeway to experiment and had to meet company-wide regulations for only a few select releases that touched on the core medical aspects of the product. After implementing this change, the new venture shortened the time it took to release software updates by 60 percent.

## 2. Perfecting products before launch

In life sciences, the development of new products often requires extensive research and testing in the form of clinical trials and studies. To make it to the commercial market, a drug or medical device must clear numerous regulatory hurdles and risk assessments. Thus, life science companies are more apt to develop each potential product sequentially, waiting for trial results before advancing to wider consumer testing.

In the consumer arena, the product development process is quite the opposite. Companies create new concepts rapidly and take them to market as early as possible to test hypotheses in real-life settings. Consumer products often launch even if they are not yet perfect and improve over time as customers interact with them. Consumer companies know that reaching product-market fit may take several attempts, and they test different iterations in parallel to see which ones resonate best with customers. In a similar vein, life science companies seeking to build consumer-focused businesses can speed up the development process by testing hypotheses more frequently before an official launch. Of course, even when life science companies build consumer health and wellness businesses that aren't beholden to the same strict regulatory approval processes that drugs

and medical devices are, they still need to meet consumer protection rules during this iterative product development phase.

The Apple Heart Study is an example of relying on rapid user testing to quickly launch a new consumer-facing service, all without compromising data privacy.[2] Collaborating with Stanford Medicine, Apple extended the value of an existing product, the Apple Watch, into a health diagnostic service. Using the watch to monitor heart rhythms in more than 400,000 participants, Apple studied the device's ability to detect atrial fibrillation in real time. To collect this data, Apple recruited participants by emailing customers who had bought Apple Watches and promoting the Apple Heart application in its app store, emphasizing the ease and accessibility of signing up for the program.[3] This opt-in approach allowed Apple to quickly test a hypothesis for a new potential service in parallel with an already-commercialized product without needing to go through the official clinical trial process.

In another example of how life science companies can roll out consumer-facing businesses through an iterative process, a global company used several types of user testing to build a business-to-business-to-consumer (B2B2C) marketplace. The company designed an initial minimal viable product (MVP) in two months and then tested it extensively with users. The company was able to release a closed beta within six months of starting development. Through this launch-fast, test-often model, the product team could rapidly assess and improve the marketplace to gain product-market fit.

## 3. Expecting consumer tech talent will be easy to attract

Most corporations, including those in life sciences, have large recruiting functions and established practices for onboarding new talent. Many life science CEOs assume it will be business as usual when hiring teams to build and launch new businesses. In our experience, this is not the case. Corporate hiring practices can often be slow, and HR teams can struggle to attract the caliber of talent needed to build new consumer businesses.

Instead of relying on current recruiting practices, life science companies can employ new processes to hire digital talent, including setting up separate people functions for this effort. The type of employees who succeed in the fast-paced, nonlinear process of business building are often different from those who prefer traditional hierarchies. They have a start-up mentality, can pivot quickly, and thrive wearing multiple hats. The separate people function will need recruiters who "speak the language" of candidates looking to join innovative teams. These recruiters must be surgical in their approach to finding external talent with the right mindset for the new business unit. Of course, every company also has at least some employees with the skills to build a new business, so identifying those people and asking them to take part in the project can also help build the team.

One global medtech company built a new consumer health venture in part by creating a separate people function. The new HR team crafted a unique value proposition to attract the type of consumer tech talent needed to make the venture a long-term success. The team modeled recruitment processes on those used by successful start-ups, partnering with external tech recruiters. With a streamlined interview process that went from application to offer in ten days or fewer, plus weekly check-ins with the CEO to ensure hires aligned with the company's long-term vision, the separate HR team successfully hired top data science and consumer tech talent, onboarding more than 200 new hires within a year.

[2] "Apple Heart Study: Assessment of wristwatch-based photoplethysmography to identify cardiac arrhythmias," Stanford University, March 30, 2020.
[3] Natasha Singer, "Apple's reach reshapes medical research," *New York Times*, November 14, 2019.

## 4. Relying on healthcare providers to propel sales

For typical product launches, life science brands look to evoke reliability and scientific pedigree by selling their products through trusted channels such as doctors and pharmacies. Even for an over-the-counter product, the route to market is often through doctors' offices or pharmacy-led wholesalers. When launching a consumer health product or service, life science companies may need to rethink their go-to-market approach to tap into current trends and desires. They can start by taking a page out of the consumer marketing playbook, adopting viral and product-led growth tactics.

The makers of popular consumer health products such as weight loss platform Noom, optometry and eyeglass provider Warby Parker, and online pharmacy Capsule have used these strategies from day one. These companies are experts at using digital marketing to evoke a value proposition that is both trustworthy and desirable. They use common consumer marketing strategies such as savvy branding and social media promotions to attract customers, and then deploy proven consumer user experience (UX) designs such as gamification and social networks to provide a sticky user experience.

One global life science company successfully scaled a B2B2C marketplace by leveraging a traditional sales force approach to onboard healthcare service professionals, combined with digital-marketing campaigns to reach patients. The company's agile, omnichannel marketing model included running rapid sprints and quickly diagnosing challenges, which led to fast adoption of its new marketplace.

## 5. Not using the full power of AI

AI is likely a part of nearly any business-building journey. The newest forms of AI tools and agents can help companies brainstorm, iterate, prototype, and test new product ideas far faster than before. Using AI to build new businesses can accelerate time to market and generate consumer insights at scale, all without compromising consumer privacy.

Unfortunately, many life science companies fail to use AI in the business-building process because they often lack the internal resources to create AI agents capable of performing this level of iterative work. Whether life science companies build AI capabilities in-house or partner with a third party, the investment can be well worth it. AI tools can allow companies to validate potential venture ideas rapidly, which can help them get from idea to the first launch in days or weeks instead of months or years.

AI can continue to offer value even after launch by helping product teams improve offerings based on predictive analytics, marketing teams improve campaigns to boost customer acquisition, and customer success teams increase retention. Of course, using AI in a business-building capacity means navigating today's quickly evolving regulatory environment regarding AI. This means employing either in-house or external data scientists, project managers, and compliance professionals who have expertise in implementing AI solutions that meet all legal requirements.

When starting any new business, CEOs who stay actively involved with the venture from ideation through execution can help transform their companies from the edge to deliver real ROI. Engaged CEOs set clear expectations about what success looks like, determine the right pace for growth, and champion the innovators who help take the company in a new direction. They also know how to avoid common pitfalls that can stymie business-building efforts. Once life science CEOs get a taste of building successful consumer-focused businesses, they almost always come back for more.

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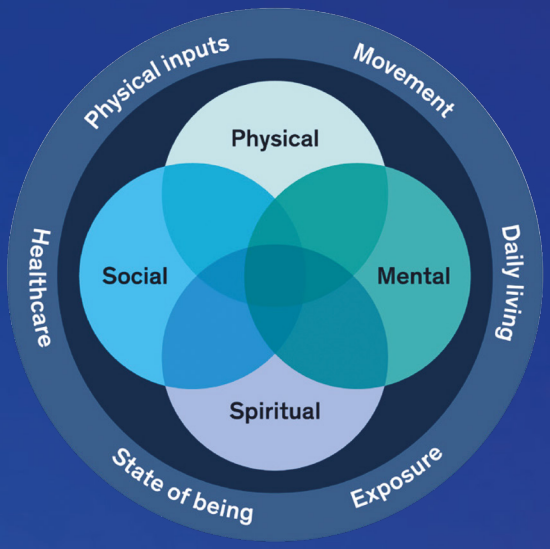
McKinsey Health Institute

# Adding years to life, and life to years

The McKinsey Health Institute (MHI) is an enduring, non-profit-generating institute within McKinsey & Company. It was founded on the conviction that, over the next decade, humanity could add as much as 45 billion extra years of higher-quality life. Our mission is to catalyze the actions and investment needed across continents, sectors, and communities to realize this possibility. In collaboration with a robust ecosystem oforganizations, we work to catalyze impact across historically underinvested areas of health. We do this by convening and activating leaders; advancing research; creating and promoting data and tools; and stimulating investment and innovation.

**Our modern understanding of health:**




**What we do:**

- Convene and activate leaders
- Advance research
- Stimulate investment and innovation
- Create and promote open-access data and tools

## Ecosystem

MHI collaborates with a robust network of organizations dedicated to advancing human health worldwide. We aspire to share resources, innovations, data, and findings in the public domain so others can replicate what proves effective, and look to our ecosystem partners to commit to the same.

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