Deloitte.

The digital enterprise at scale: A CEO imperative for 2022

Digital becomes our reality

Continued accelerated growth and record investment

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

> " Digital innovation has been accelerated 10 years by what has happened over the course of the last 18 months. "
>
> *Manoj Raghunandan, President, Global self-care and consumer experience for Johnson & Johnson.[3]*

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

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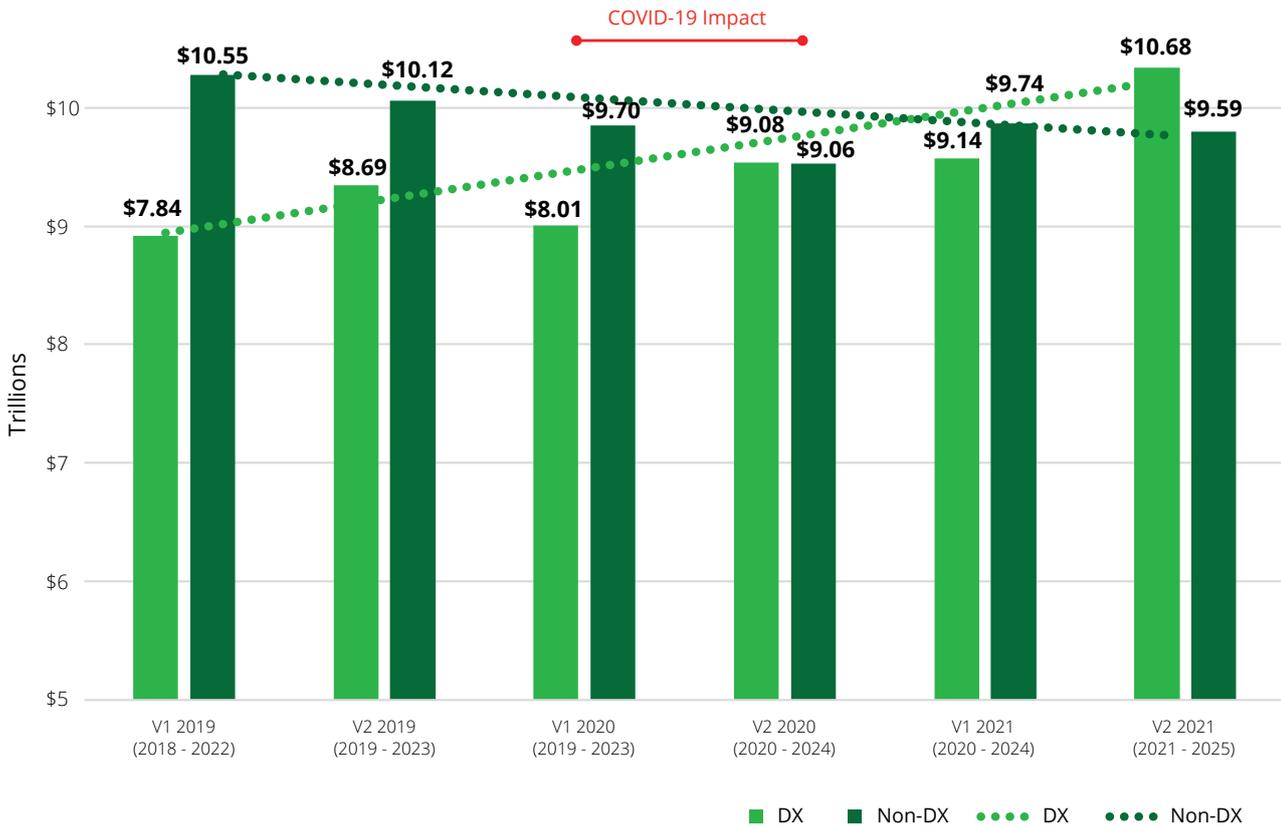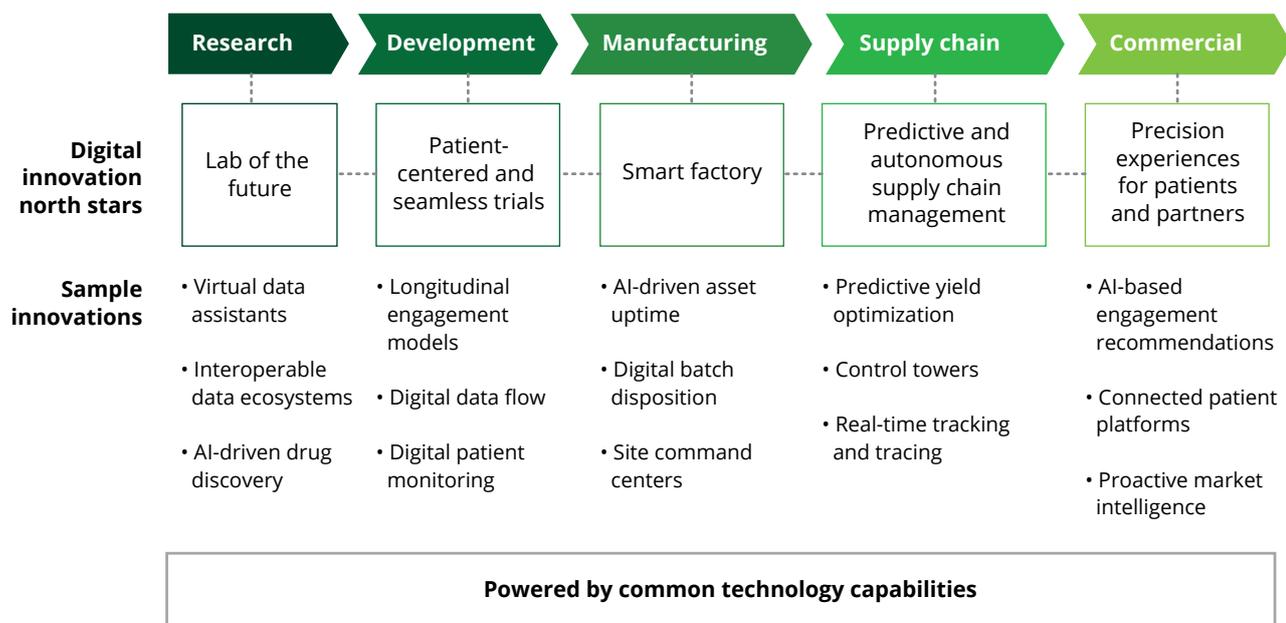

Note: DX represents digital transformation

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

Scaling digital for end-to-end transformation

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

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

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

	Research	Development	Manufacturing	Supply chain	Commercial
Digital innovation north stars	Lab of the future	Patient-centered and seamless trials	Smart factory	Predictive and autonomous supply chain management	Precision experiences for patients and partners
Sample innovations	• Virtual data assistants • Interoperable data ecosystems • AI-driven drug discovery	• Longitudinal engagement models • Digital data flow • Digital patient monitoring	• AI-driven asset uptime • Digital batch disposition • Site command centers	• Predictive yield optimization • Control towers • Real-time tracking and tracing	• AI-based engagement recommendations • Connected patient platforms • Proactive market intelligence

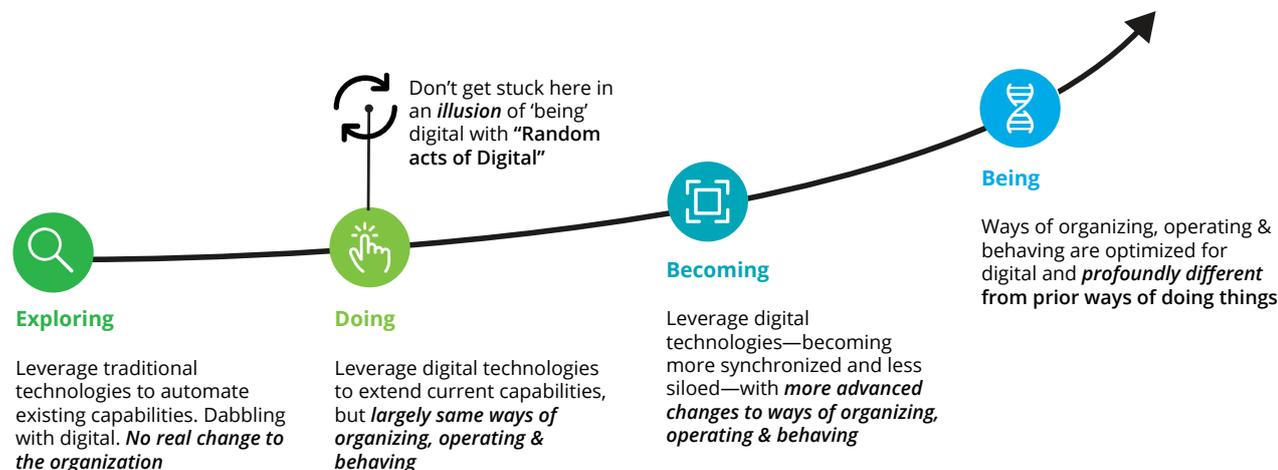**Powered by common technology capabilities**

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

Shifting from 'doing digital' to 'being digital'

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

Figure 3: Progression of 'doing digital' to 'being digital'

Don't get stuck here in an *illusion* of 'being' digital with **"Random acts of Digital"**

Exploring

Leverage traditional technologies to automate existing capabilities. Dabbling with digital. *No real change to the organization*

Doing

Leverage digital technologies to extend current capabilities, but *largely same ways of organizing, operating & behaving*

Becoming

Leverage digital technologies—becoming more synchronized and less siloed—with *more advanced changes to ways of organizing, operating & behaving*

Being

Ways of organizing, operating & behaving are optimized for digital and *profoundly different from prior ways of doing things*

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

## *What does "being digital" at scale really mean?*

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

At the core, being digital involves:

- Moving beyond transactions creating a meaningful, differentiated, and personalized experience for customers and patients
- Enabling more evidence-based decision-making for health care and payment
- Modernizing processes/systems across the entire value chain and in core functions
- Leveraging data/analytics to create actionable insights that drive growth and operational efficiency
- Breaking down functional silos to create empowered and accountable multi-disciplinary teams that drive and track investment decisions and performance[13]
- Enhancing business agility to keep pace with the constant sea of changes[14]

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

Figure 4: Going digital in life sciences and health care
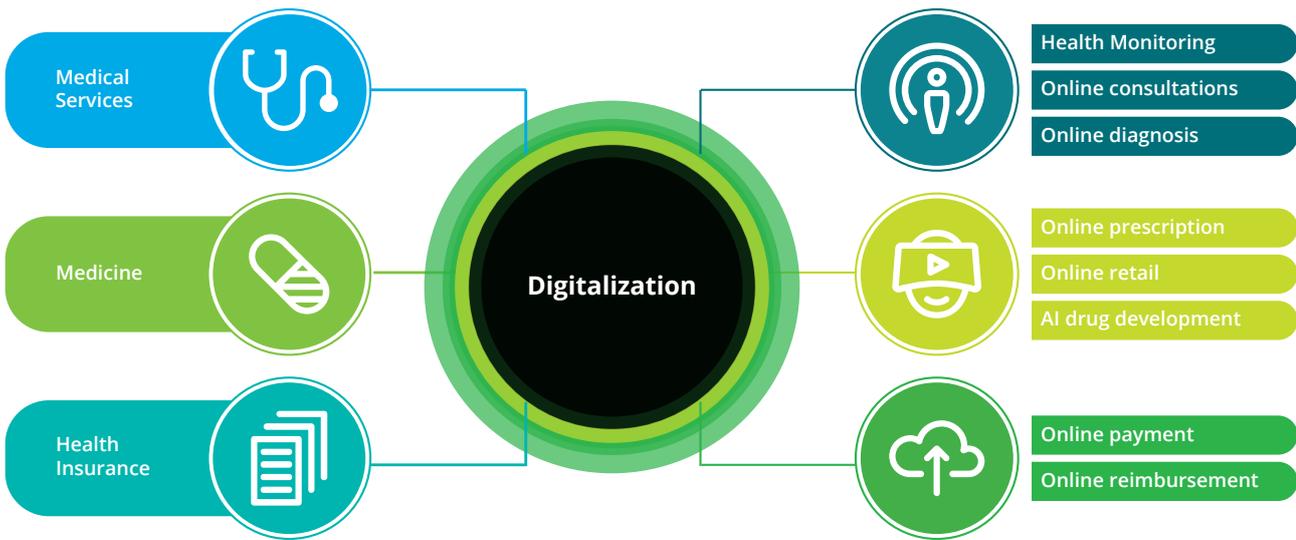

Source: Deloitte analysis

Bringing enterprise agility to scale

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

Adopting a team-based approach to meet changing needs

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

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

How we think an organization works...

How it actually works...

Functional Formal Structure

Cross-Functional Informal Network
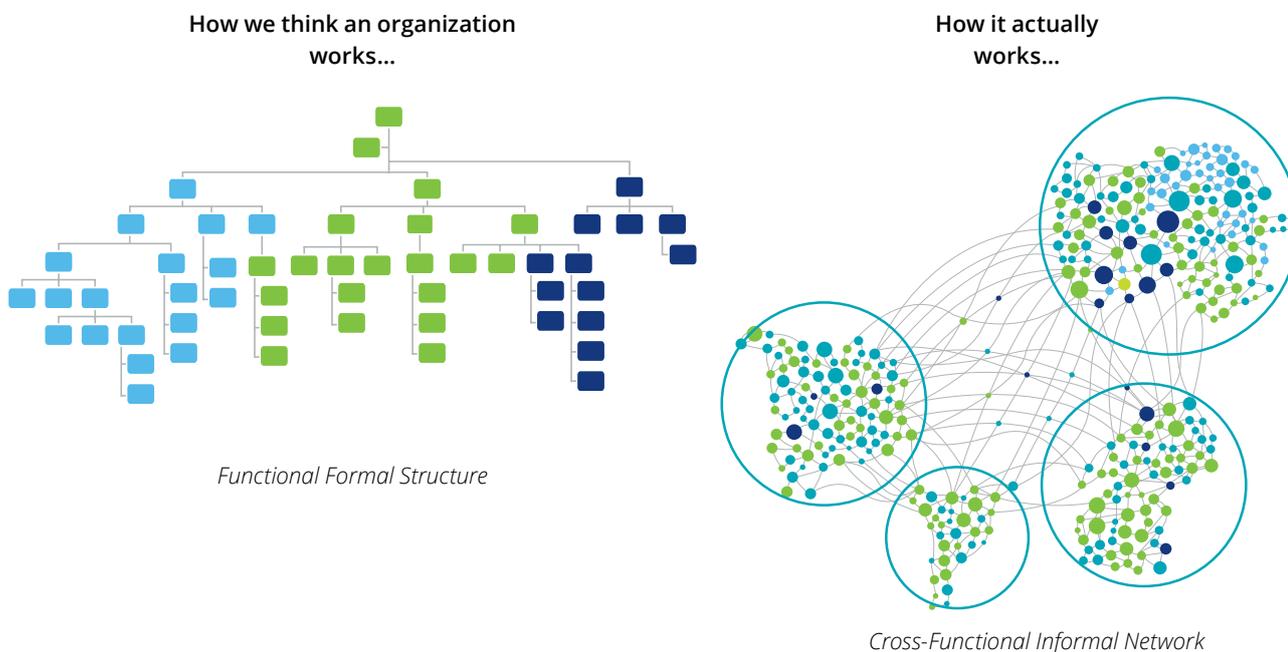
Source: "The Adaptable Organization, Harnessing a networked enterprise of human resilience," Deloitte, 2018.

Leading transformational change with continuous improvement

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

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

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

Cris Wilbur, Chief People Officer, Roche.

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

Leaders of multi-functional agile teams

- Provide a clear vision
- Orchestrate vs command and control (pull, not push)
- Lead with empathy and optimism
- Communicate openly and transparently
- Comfortable in showing vulnerability
- Provide psychological safety

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

How do you want to change the world?

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

Figure 6: V2MOM framework to guide enterprise agility

VISION
What do you want?

METHODS
How do you get it?

MEASURES
How will you know you have it?

VALUES
What's important about it?

OBSTACLES
What might stand in the way?

Source: Deloitte analysis

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

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

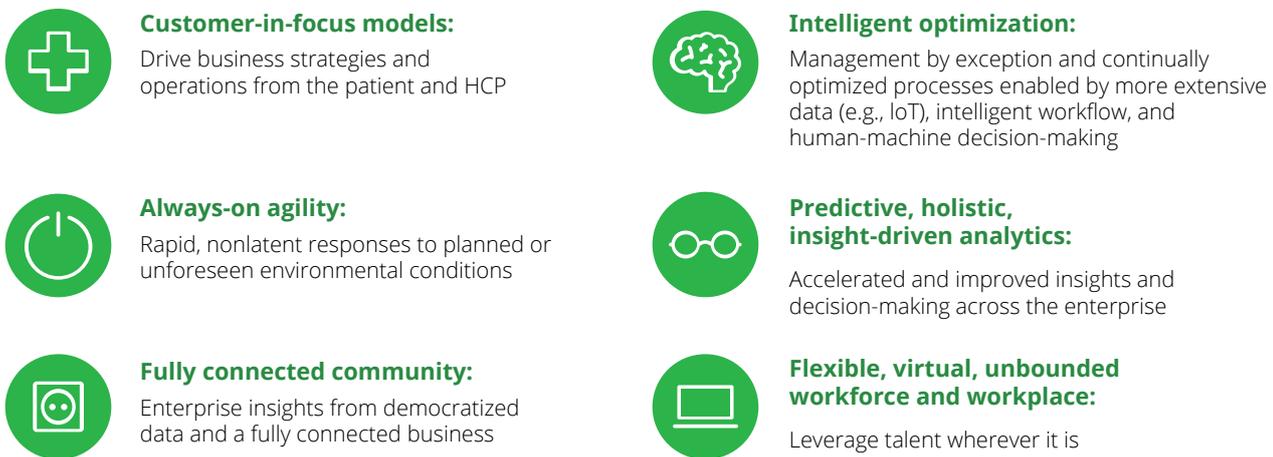## Large, legacy organizations vs. nimble, digitally-native organizations

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

Adopting more digitally-strategic objectives

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

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

Figure 7: Digital strategic objectives

Customer-in-focus models:
Drive business strategies and operations from the patient and HCP

Intelligent optimization:
Management by exception and continually optimized processes enabled by more extensive data (e.g., IoT), intelligent workflow, and human-machine decision-making

Always-on agility:
Rapid, nonlatent responses to planned or unforeseen environmental conditions

Predictive, holistic, insight-driven analytics:
Accelerated and improved insights and decision-making across the enterprise

Fully connected community:
Enterprise insights from democratized data and a fully connected business

Flexible, virtual, unbounded workforce and workplace:
Leverage talent wherever it is

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

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

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

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

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

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

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

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

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

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

Establishing new ventures to gain agility

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

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

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

- Capitalize on rapid shifts
- Enter new markets
- Monetize growing data assets
- Execute on bold new ideas
- Navigate nontraditional competitors
- Leverage changing customer needs, demographics, and behaviors
- Extend boundaries of the business, while building a legacy of leadership[34]

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

Scaling AI across the value chain

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

Startups leading medtech

Deloitte teamed up with MedTech Innovator (MTI) to look through the lens of 1,000 medtech innovators participating in MTI's global accelerator program in 2021.[36] These startups are developing a new class of digitally-enabled technologies—including Software as a Medical Device (SaMD), bespoke algorithms, wearables, and other connected devices. About 70% of their technologies include a digital-health component, and nearly 30% that identify as digital say they employ artificial intelligence (AI) and machine learning.[37]

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

Integrating AI into the organization, top outcomes and challenges

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

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

Need for high quality data

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

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

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

Advanced data collection and analysis is essential to:

- Shortening the R&D cycle
- Meeting the needs of patients
- Transforming surgery from an isolated event to a connected, data-driven endeavor[51]
- Deepening the understanding of access issues across the globe
- Creating tailored experiences for health care providers
- Anticipating key challenges across the ecosystem, including those of suppliers and manufacturers[52]

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

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

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

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

Gaining an edge requires ongoing transformation

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

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

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

Transforming digital surgery and colonoscopy with artificial intelligence

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

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

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

In 2022, as life sciences executives address the urgency for more investments and take more risks, digital technology and AI are expected to come together to change the status quo and transform functional areas and value streams.[61] It's time to take advantage of this technological momentum and lessons learned from the pandemic—operating by being digital and competing by being agile.
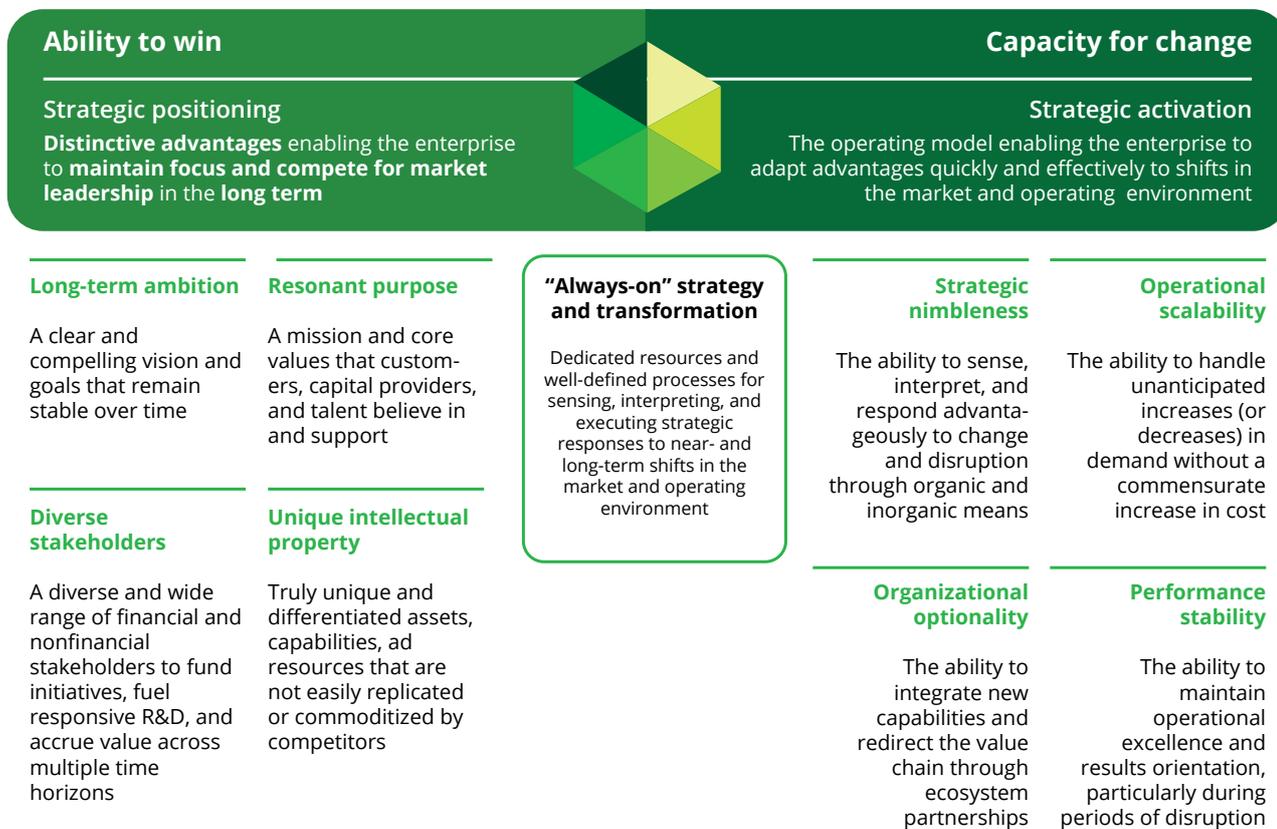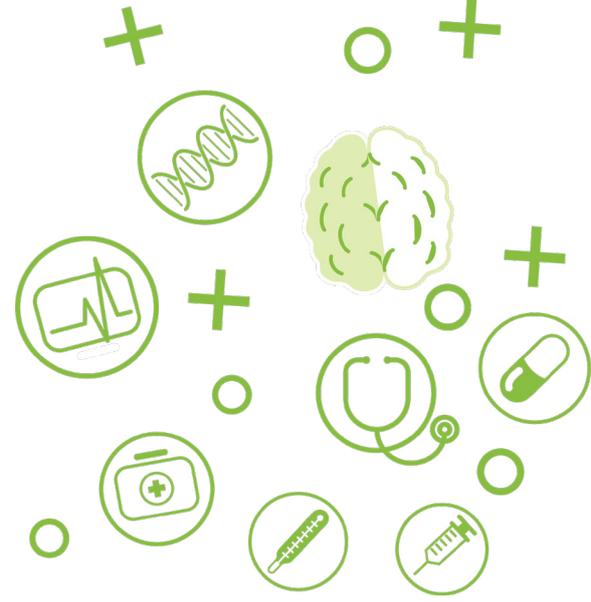
While some life sciences companies may remain ill-equipped to win in an environment teeming with disruptive forces,[62] others will be positioning themselves to win with a capacity for change (see figure 8).[63] The ability to sense, interpret, and execute strategic responses to major swings in the market and operating environment is enabled by bold strategic investments aligned to clear and compelling long-term ambitions.[64]

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

Ability to win | Capacity for change

Strategic positioning
Distinctive advantages enabling the enterprise to **maintain focus and compete for market leadership** in the **long term**

Strategic activation
The operating model enabling the enterprise to adapt advantages quickly and effectively to shifts in the market and operating environment

Long-term ambition A clear and compelling vision and goals that remain stable over time	**Resonant purpose** A mission and core values that customers, capital providers, and talent believe in and support	**"Always-on" strategy and transformation** Dedicated resources and well-defined processes for sensing, interpreting, and executing strategic responses to near- and long-term shifts in the market and operating environment	**Strategic nimbleness** The ability to sense, interpret, and respond advantageously to change and disruption through organic and inorganic means	**Operational scalability** The ability to handle unanticipated increases (or decreases) in demand without a commensurate increase in cost
Diverse stakeholders A diverse and wide range of financial and nonfinancial stakeholders to fund initiatives, fuel responsive R&D, and accrue value across multiple time horizons	**Unique intellectual property** Truly unique and differentiated assets, capabilities, ad resources that are not easily replicated or commoditized by competitors		**Organizational optionality** The ability to integrate new capabilities and redirect the value chain through ecosystem partnerships	**Performance stability** The ability to maintain operational excellence and results orientation, particularly during periods of disruption

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