



Beyond 2030

The Future of Life Sciences

Meet tomorrow prepared



Contents

Contents	2	<i>The price of connectivity</i>	13	<i>Cure now, bill later</i>	29
		<i>The next opportunity</i>	15	<i>When accountability outlives the product</i>	29
Foreword	3	2. The Innovation Stack:	16	<i>The next opportunity</i>	30
		Who turns discovery into scale?			
Key findings	4	<i>Discover, de-risk, acquire</i>	17	What changes in practice	31
What changes in practice:	5	<i>The race to proof</i>	18	Data and methodology	32
Innovation beyond the lab		<i>When healthcare meets platform economics</i>	20		
Where the next opportunity lies:	6	<i>The next opportunity</i>	20	Acknowledgments	33
Building advantage beyond the product		3. The Self-Directed Patient:	21		
		Who is responsible for care beyond care?			
Beyond 2030:	7	<i>Care beyond the appointment</i>	22		
The Future of Life Sciences		<i>The age of individual medicine</i>	24		
		<i>The accountability gap</i>	25		
Micro trends:	9	<i>The next opportunity</i>	26		
Where stresses become strategy		4. The Cost of Cure:	27		
1. The New Health Cold War:	10	Who can afford the breakthrough?			
Who controls the means of making medicine?		<i>The end of the recurring-revenue model</i>	28		
<i>The end of optimization</i>	11				
<i>The battle for choke points</i>	13				



Foreword



Breakthroughs are accelerating. Delivery is not.

For much of the modern era, progress in life sciences has been measured by scientific breakthroughs. Today, artificial intelligence is accelerating those discoveries. Precision medicine is tailoring treatments to ever smaller patient groups. Cell and gene therapies are challenging healthcare models by offering potentially curative outcomes from a single intervention. Innovations that would have seemed improbable only a few years ago are rapidly becoming plausible.

But the next decade will be defined by a different question: [What happens after the breakthrough?](#)

Whether a discovery ultimately improves outcomes for patients depends not only on science, but on the systems around it. New technologies are creating powerful opportunities while increasing dependence on data, digital infrastructure and specialized capabilities. Governments are treating those same assets as matters of economic resilience and national security, defining where innovation occurs, which organizations can access critical capabilities, and what it costs to bring therapies to patients. At the same time, healthcare systems are being asked to fund more personalized and potentially curative therapies while managing aging populations, rising demand, and mounting fiscal pressure.

As the second in our [Beyond 2030 sector foresight series](#), this report explores the forces reshaping life sciences. Drawing on the perspectives of over 80 industry experts, it examines the parameters that determine whether innovation succeeds: the infrastructure that supports it, the institutions that govern it, the financing models that sustain it and the relationships that allow it to reach patients.

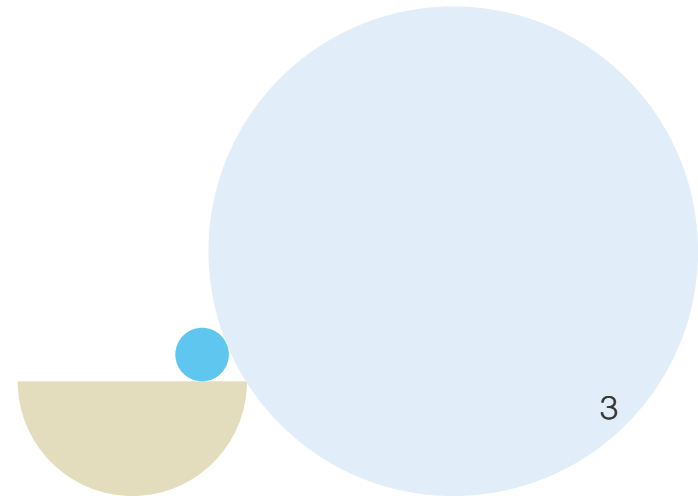
Our analysis does not seek to predict a single future, nor to provide a comprehensive view of every challenge facing the sector. Instead, it focuses on the most influential intersections of risks facing life sciences over the decade ahead, and on the decisions that will determine how the sector adapts in response.

Competitive advantage will increasingly depend on the capabilities that determine whether a breakthrough succeeds in the real world: clinical evidence, manufacturing, trusted data, the ability to anticipate regulatory and policy change, and long-term partnerships. In an industry defined by growing interdependence, resilience will depend on understanding how these systems connect, where vulnerabilities lie, and how emerging risks are anticipated, managed and shared.

The future of life sciences will undoubtedly be shaped by scientific progress. But as discovery accelerates, the organizations that succeed may be distinguished less by their breakthroughs than by what comes next.



Penny Seach
Chief Underwriting Officer International



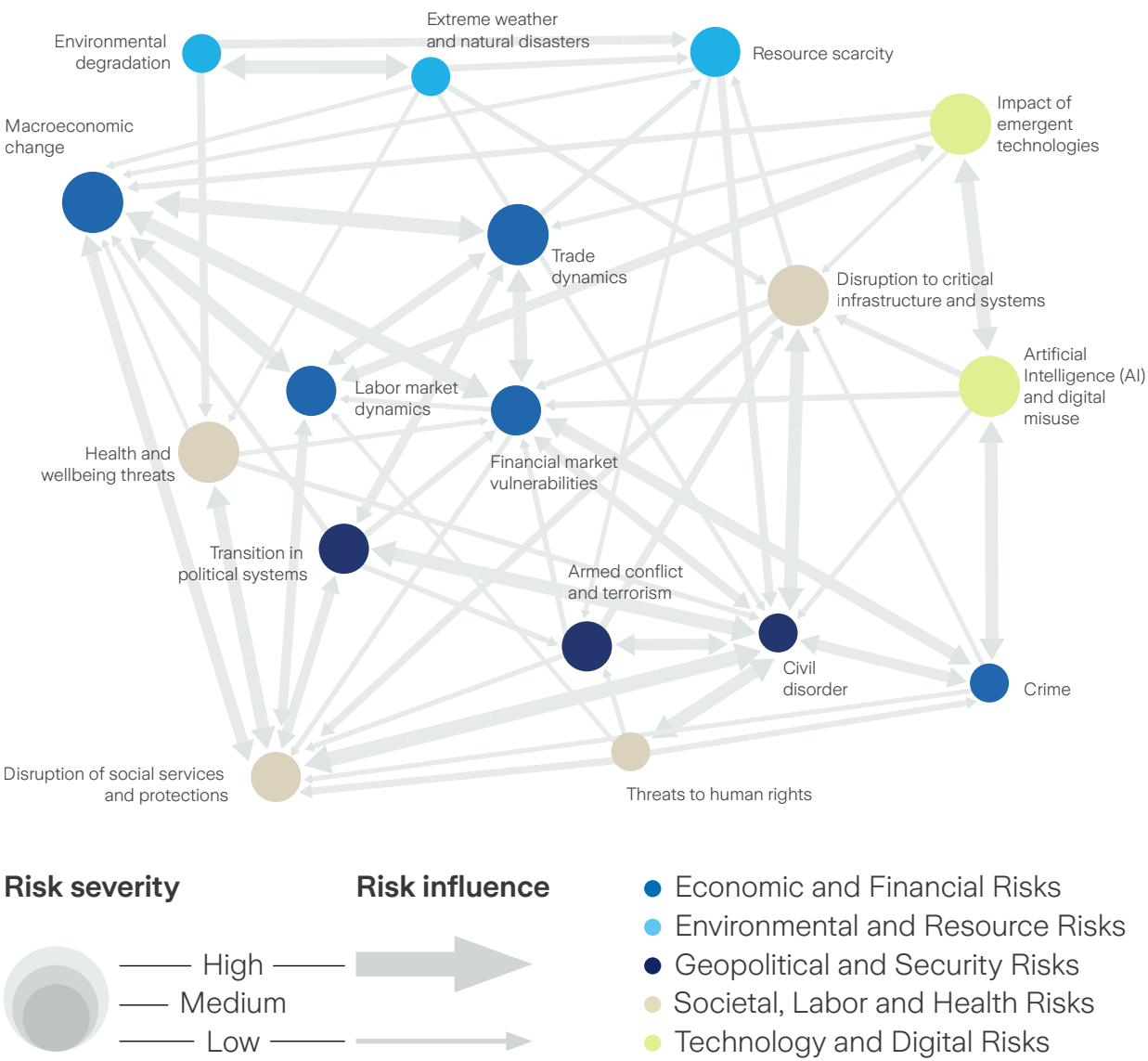
Key findings

Life sciences enter the 2030s with extraordinary scientific momentum. Yet many of the sector’s greatest challenges are emerging after discovery, in the evidence, infrastructure, institutions and economic models required to turn scientific advances into safe, scalable and insurable outcomes.

Artificial Intelligence (AI) and digital misuse (#1) and the Impact of emergent technologies (#2) are compressing timelines for research and development at the same time as creating new dependencies on data, compute, digital infrastructure and specialist capabilities. Trade dynamics (#4) and more active industrial policies are reshaping where innovation can occur, how it is financed and who can participate. The combination of Macroeconomic change (#3) and Health and wellbeing threats (#5) mean healthcare systems are facing growing pressures around access, affordability and outcomes.

Beyond 2030: The Future of Life Sciences

Risk network



What changes in practice: Innovation beyond the lab

The result is a sector where success depends on what happens after the breakthrough. Four distinct shifts are likely to shape life sciences over the next five years and beyond:

National security shapes innovation

Governments treat manufacturing capacity, clinical research, health data, compute and specialized technologies as matters of resilience and national security – controlling access to the infrastructure needed to develop, manufacture and deliver the next breakthrough.

See [↗ The New Health Cold War](#).

Proof is the bottleneck

Discovery accelerates faster than the path to patients. AI compresses target identification and early research, yet evidence generation, clinical development, manufacturing, reimbursement and adoption remain difficult, expensive and time-consuming.

See [↗ The Innovation Stack](#).

The cure breaks the business model

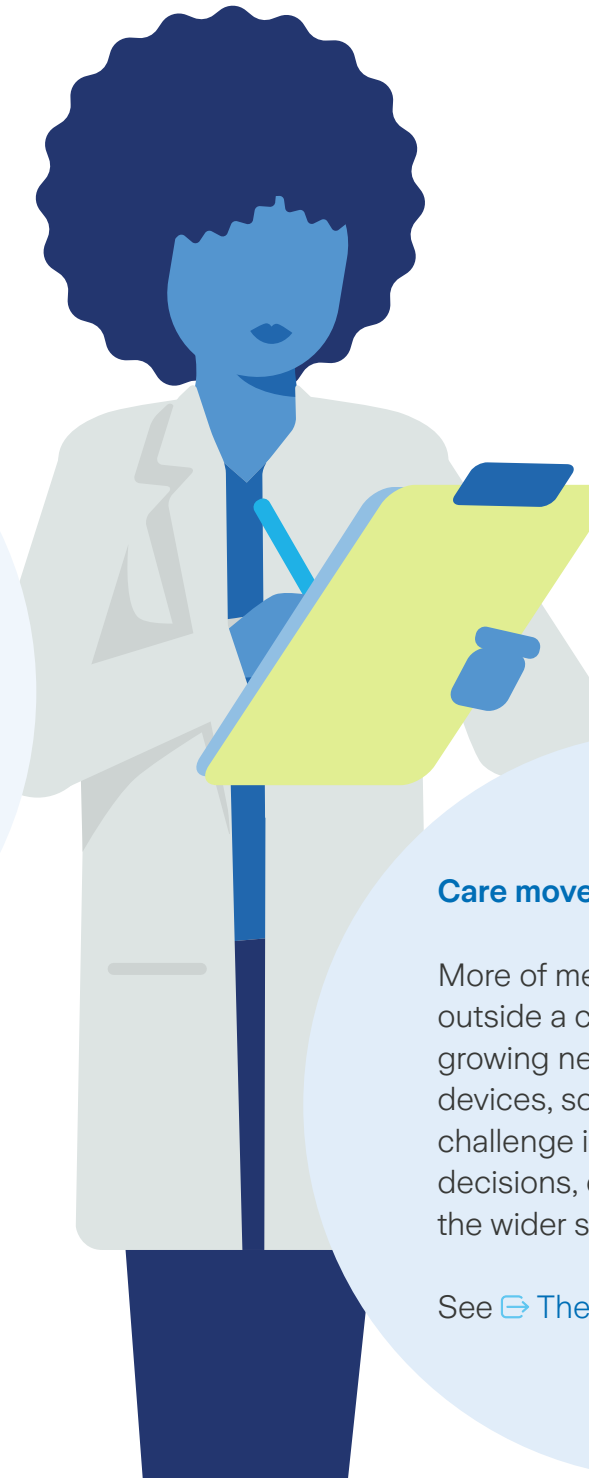
As more therapies reduce the need for ongoing treatment, they challenge business models built around repeated interventions and volume-based reimbursement. Healthcare systems are forced to rethink how innovation is funded and rewarded.

See [↗ The Cost of Cure](#).

Care moves beyond institutions

More of medicine's moments happen outside a clinician's sight, across a growing network of patients, platforms, devices, software and providers. The challenge is understanding who owns decisions, data and outcomes across the wider system.

See [↗ The Self-Directed Patient](#).



Where the next opportunity lies:

Building advantage beyond the product

While each shift is explored separately, they are deeply interconnected, pointing to three common strategic priorities:

1. Bring constraints forward

Many of the factors that determine success emerge long before launch. Trade policy, industrial policy, data governance, evidence requirements, pricing rules and reimbursement models can all reshape whether an innovation reaches patients and under what terms.

Bring regulatory intelligence, payer engagement and market access much earlier into the development process. As scientific timelines compress, value will come from anticipating constraints rather than from reacting to them.

2. Secure the bottlenecks that matter

Few organizations can control every source of uncertainty. The priority is to identify the dependency that would materially affect development, manufacturing or market access if lost.

That may be a manufacturing partner, specialist dataset, cloud platform, clinical-trial network, regulatory pathway or other capability that competitors cannot easily replicate. Map where operational, regulatory and geopolitical risks coincide, and understand how disruption would affect the ability to develop, manufacture or commercialize innovation.

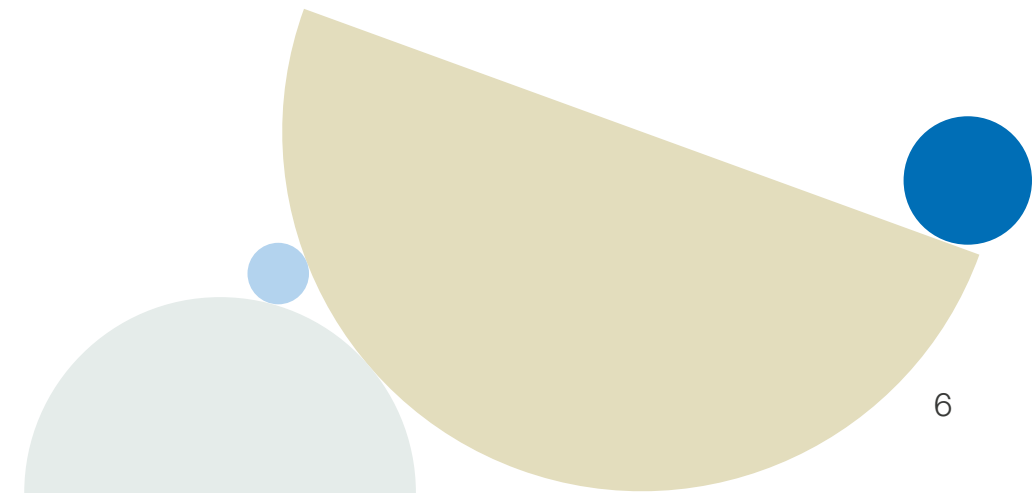
Some efficiency may need to be traded for flexibility, whether through alternative suppliers, additional manufacturing locations, backup technology providers or retained internal capability.

3. Build accountability into product design

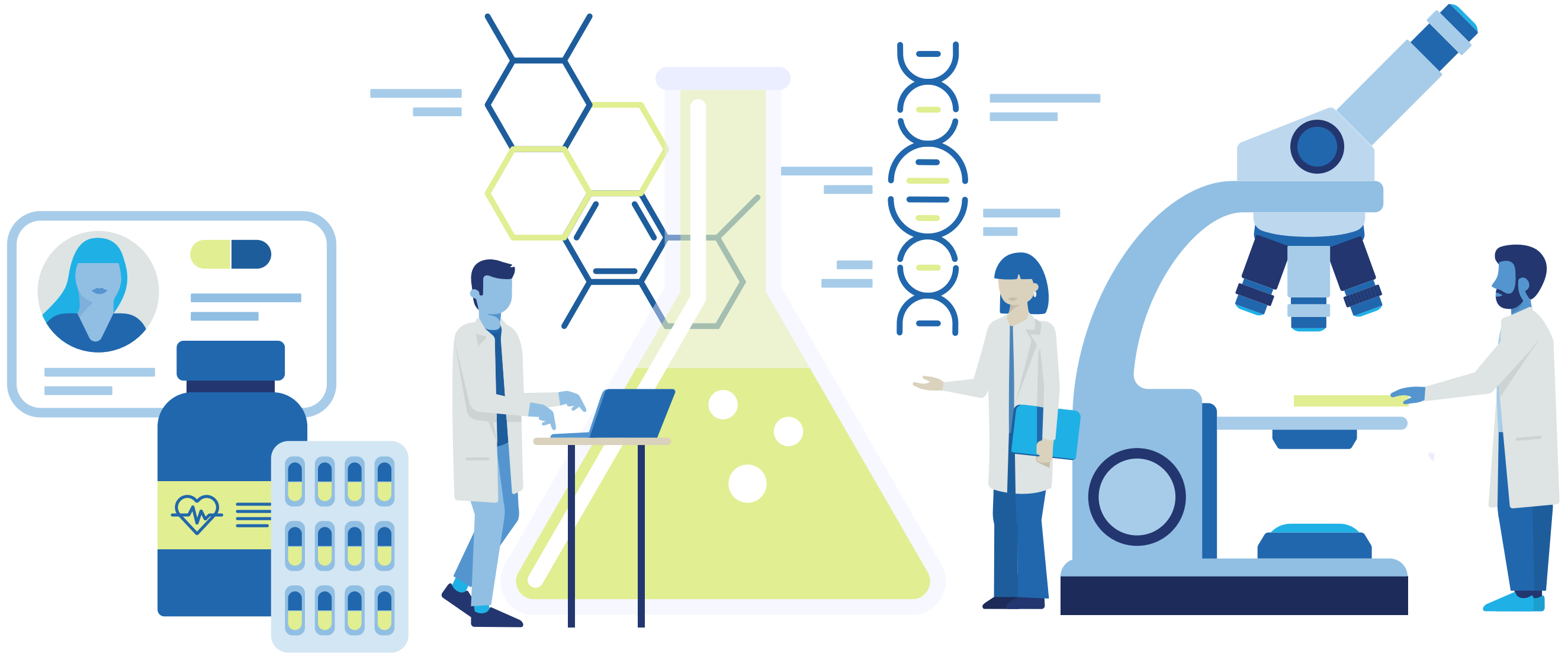
Outcome-based contracts, connected products, AI-enabled systems and personalized therapies can create obligations that extend years beyond the original transaction, requiring new approaches to governance, financing and risk sharing.

Treat governance, accountability and lifecycle management as integral parts of product design, with documented clarity about who owns decisions, data, outcomes and support obligations.

The organizations best positioned for the next decade will be those that can orchestrate the systems required to scale, finance and deliver innovation. Success will depend on understanding where new dependencies, liabilities and accumulations of risk are forming across increasingly interconnected systems.



Beyond 2030: The Future of Life Sciences



Beyond 2030: Bottleneck or breakthrough?



New therapies, AI-powered discovery tools, advanced diagnostics and personalized treatments are rapidly expanding what is medically possible.

But the greatest challenges facing life sciences sit beyond the science itself, emerging only after discovery. As scientific discovery accelerates, a growing share of the challenge lies in developing, manufacturing and financing innovation.

[Artificial intelligence and digital misuse \(#1\)](#) and the [Impact of emergent technologies \(#2\)](#) top the perceived risk profile for the sector over the next five years. These technologies are reshaping discovery, development, clinical decision-making and patient engagement, but they are also concentrating dependence on data, cloud infrastructure, specialist compute and a relatively small number of technology providers. Faster technological progress is creating new questions around governance, accountability and trust.

[Macroeconomic change \(#3\)](#), [Trade dynamics \(#4\)](#) and [Health and wellbeing threats \(#5\)](#) point to mounting concern about the affordability, accessibility and resilience of healthcare systems. Governments are taking a more active role in shaping supply chains, data flows and industrial capabilities, influencing where innovation occurs, who can participate and what it costs. Meanwhile, aging populations and rising healthcare costs are putting pressure on funding models that often reward treatment more readily than prevention or cure.

[The result is a sector where success depends on navigating bottlenecks as much as pursuing breakthroughs.](#) Political priorities shape supply chains. Technology platforms influence clinical decisions. Financing models determine access to treatment. Scientific discovery remains essential, but in the 2030s, competitive advantage will rest on the ability to coordinate the interconnected systems of technology, regulation, healthcare delivery and finance required to turn innovation into tangible outcomes.

Beyond 2030: Top risks facing life sciences

Perceived severity of risks in the life sciences sector over the next five years
Seven-point scale (1 = Extremely low, 7 = Extremely high)

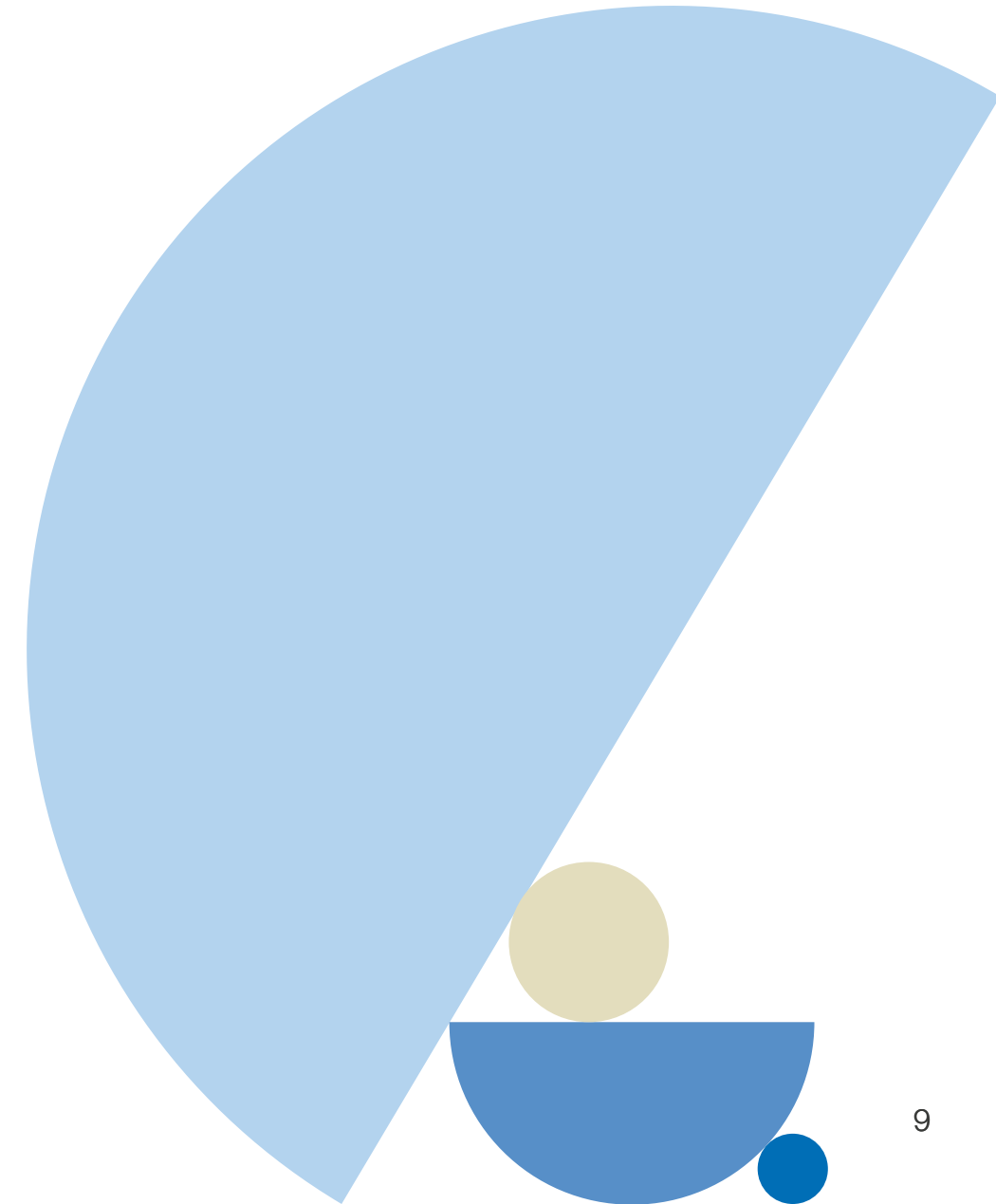
Rank	Risk	Severity
1	Artificial Intelligence (AI) and digital misuse	5.2
2	Impact of emergent technologies	5
3	Macroeconomic change	4.7
4	Trade dynamics	4.6
5	Health and wellbeing threats	4.6
6	Disruption to critical infrastructure and systems	4.3
7	Labor market dynamics	4.3
8	Resource scarcity	4.2
9	Financial market vulnerabilities	4.2
10	Transition in political systems	4.1
11	Armed conflict and terrorism	4
12	Disruption of social services and protections	4
13	Crime	3.6
14	Environmental degradation	3.6
15	Extreme weather and natural disasters	3.5
16	Civil disorder	3.1
17	Threats to human rights	2.9

Source: Zurich Insurance Group, The Future of Life Sciences survey (2026).

Micro trends: Where stresses become strategy



1. The New Health Cold War: Who controls the means of making medicine?	10
2. The Innovation Stack: Who turns discovery into scale?	16
3. The Self-Directed Patient: Who is responsible for care beyond care?	21
4. The Cost of Cure: Who can afford the breakthrough?	27



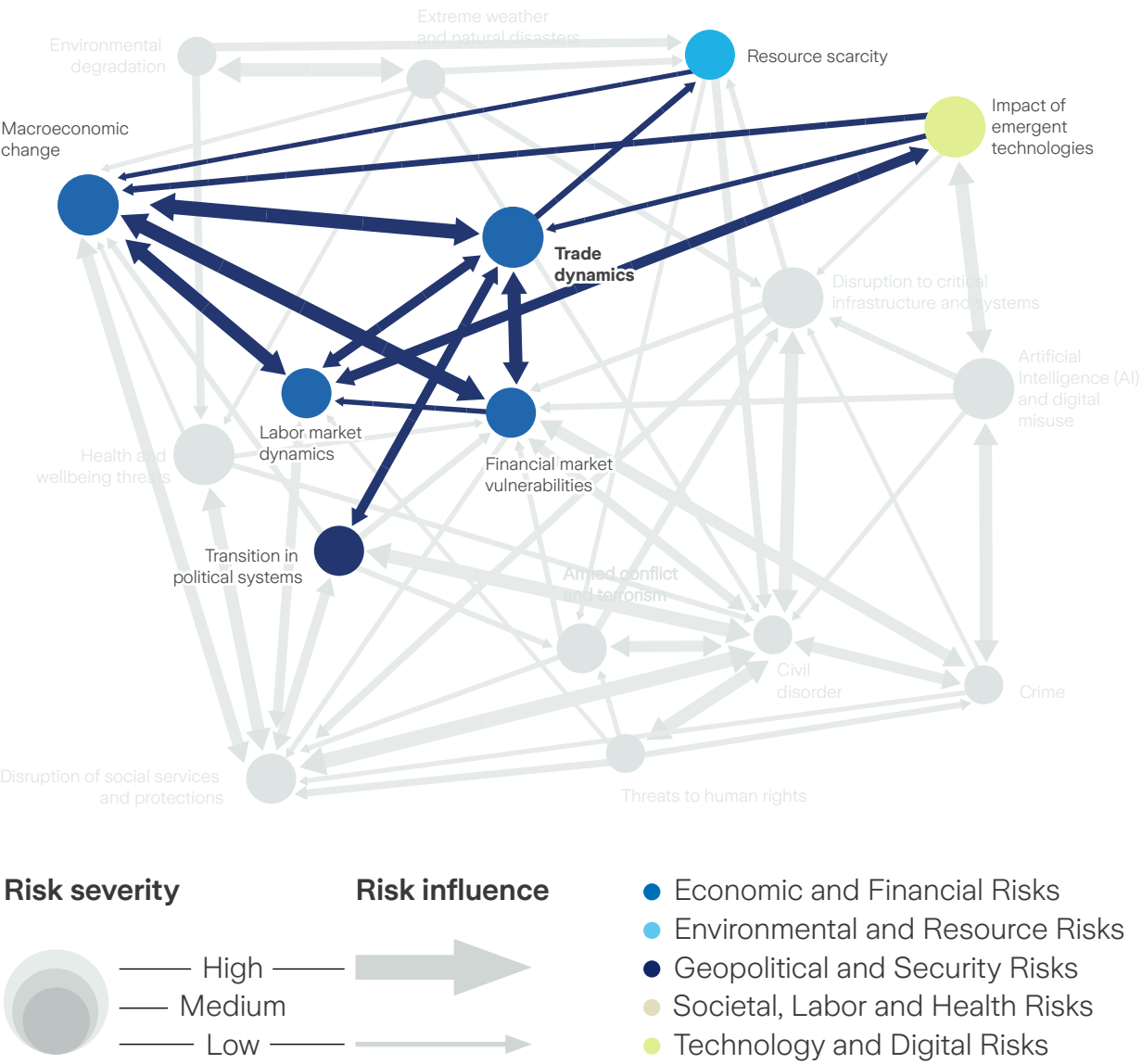
1. The New Health Cold War: Who controls the means of making medicine?

Healthcare has always mattered to states: No government wants to be caught without vaccines, antibiotics or blood products in a crisis.

But where policy once focused primarily on price, reimbursement and market access, competition in the next decade will extend beyond products to the infrastructure that makes innovation possible.

National security is directly intersecting with commercial decision-making. Manufacturing capacity, clinical trials, data, compute, and logistics are becoming strategic assets in their own right. An organization can have breakthrough science and still find itself blocked from reaching patients by an export control, a tariff schedule or a data-localization rule it never saw coming.

The New Health Cold War
Risk network of Trade dynamics



The end of optimization

For decades, life sciences ran on a simple logic: optimize globally, source wherever costs are lowest, and smooth out shocks with inventory and supplier diversification. That model is giving way to something more fragmented and more political.

In the coming decade, national security considerations may increasingly influence where medicines are developed, manufactured and supplied, affecting which products reach certain markets and how quickly they do so. The same forces that turned energy and semiconductors into arenas of strategic competition are reaching pharmaceuticals and medtech. These industries share similar characteristics: high strategic value, concentrated production and a limited number of critical choke points.

The goals are also familiar: to ensure critical capabilities are available within domestic or trusted regions, while reducing dependencies on a small number of suppliers or production hubs – or specific countries.

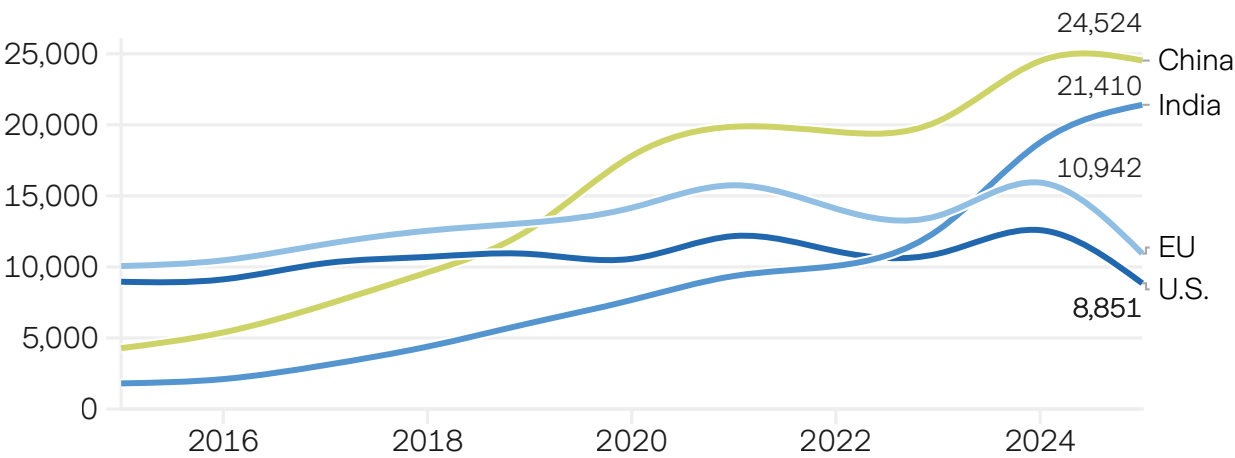
China's growing role in licensing, clinical development and drug discovery is challenging assumptions about where life sciences leadership resides. Cross-border licensing deals with Chinese biotechs reached a record USD 135.7 billion in 2025, and roughly one-third of externally sourced molecules entering large pharmaceutical companies' pipelines now originate there.¹ The same market represents both a strategic vulnerability and a growing source of future innovation.

In response, governments are enacting policies that determine where medicines are produced, where data can be stored, whom organizations can partner with, and which technologies they can access. Tariffs, procurement restrictions, export controls and biosecurity legislation are becoming structural features of the policy landscape. The European Union's new Critical

1. DIA Global Forum. [China's Out-Licensing Deals Bear Fruit in 2025 \(2026\)](#); SynBioBeta. [The Year China Surpassed the USA in Biotech Innovation, Deal Value, and Clinical Output \(2026\)](#).

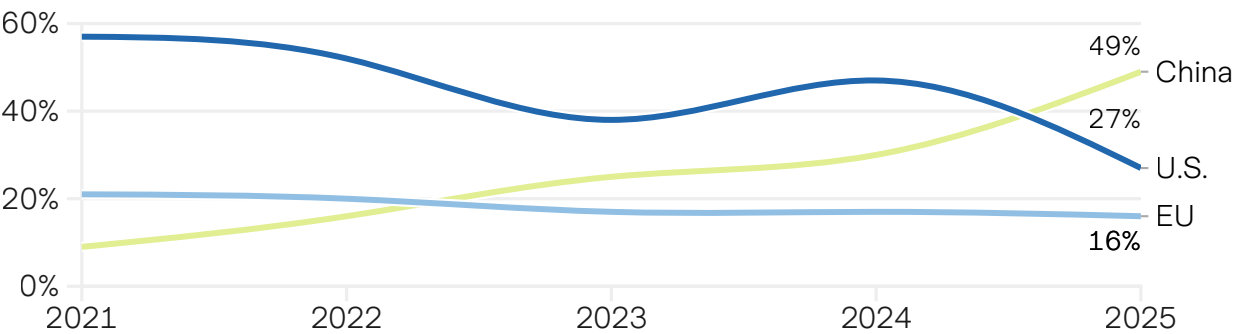
Who takes the lead?

Clinical trial activity (# of trials)
by region, 2015-2025



Source: [Global Observatory on Health R&D, World Health Organization \(2026\)](#).

License-out deal value
Share (%) by region, 2021-2025



Source: [SynBioBeta \(2026\)](#).

Medicines Act seeks to shore up supply resilience, regional manufacturing and procurement policies,² while the US pharmaceutical tariffs and the BIOSECURE Act³ are designed to influence where manufacturing, research and technology partnerships are located.⁴

Country of origin is also influencing how evidence is evaluated by regulators. China-developed therapies, particularly those supported primarily by single-country clinical data, are facing heightened scrutiny in some Western markets, driving cross-border partnerships and multi-regional development programs capable of generating evidence that can satisfy major regulatory authorities.⁵

These interventions are not without trade-offs. Efforts to localize production or reduce strategic dependencies can increase costs, exacerbate shortages and place additional pressure on already fragile markets. This is particularly the case for low-margin generic medicines, where manufacturers may struggle to absorb major tariff increases while remaining commercially viable.⁶

The overall effect is to bring trade, industrial and security policy onto the same strategic planning horizon as capital investment and product strategy. The question is whether efforts to improve resilience and reduce dependency can be achieved without making innovation slower, more expensive or less competitive.

2. The European Parliament and Council reached provisional political agreement on the European Union's Critical Medicines Act in May 2026. The Act aims to strengthen the security of supply of critical medicines by diversifying supply chains, supporting strategic manufacturing projects in Europe, and requiring public procurement processes to take supply resilience, not simply price, into account. It also provides mechanisms for collaborative procurement among Member States and supports strategic partnerships with trusted international partners. Council of the European Union. [Critical medicines act: Council and Parliament reach provisional deal](#) (2026).
3. Whilst the specific form and scope of trade measures may continue to evolve, the April 2026 proclamation introduced tariffs of up to 100 percent on certain patented pharmaceutical imports and associated ingredients, alongside country-, product- and company-specific exemptions and lower rates for approved onshoring or pricing agreements. The U.S. BIOSECURE Act restricts federal agencies and, on a phased basis, federal contractors and recipients of federal grants or loans from procuring or using biotechnology equipment or services from designated biotechnology companies of concern (BCCs). U.S. Government. [H.R. 8333 \(RFS\) - BIOSECURE Act](#) (Accessed 2026).
4. The White House. [Fact Sheet: President Donald J. Trump Bolsters National Security and Strengthens U.S. Supply Chains by Imposing Tariffs on Patented Pharmaceutical Products](#) (2026).
5. MedPath. [FDA Tightens Requirements for China-Developed Drugs, Mandates Multi-Regional Trials](#) (2025).
6. Newsweek. [How Trump's drug tariffs could hit millions of Americans' medicine bills](#) (2026); Troyer. [Experts Warn Tariffs Could Negatively Impact 'Pretty Fragile Supply' Of Generic Drugs](#) (2025); FDA. [FDA Drug Shortages](#) (Accessed 2026); ASHP. [Drug shortages](#) (Accessed 2026).
7. BioNTech. [BioNTech Achieves Milestone at mRNA-based Vaccine Manufacturing Site in Rwanda](#) (2023); CEPI. [BioNTech and CEPI expand partnership to strengthen Africa's mRNA vaccine ecosystem](#) (2024).

Spotlight

Modular biomanufacturing

A containerized manufacturing unit was installed in Kigali, Rwanda in 2023 as part of a broader effort to establish regional mRNA manufacturing capacity outside the handful of countries that have traditionally dominated production.

Modular biomanufacturing, using small, self-contained units for mRNA, cell therapies and other biologics, is often presented as a solution to supply-chain resilience. It can bring production closer to patients, reduce dependence on distant manufacturing hubs and create new options for surge capacity in crises.

But this model also introduces new complexities. Each module is effectively a manufacturing site in its own right, requiring validation, inspection, workforce capability and regulatory oversight. Instead of managing three large facilities, an organization may find itself managing 30 smaller ones, each with its own quality, cyber and operational risks.⁷

In that sense, modular biomanufacturing does not eliminate risk. Less dependence on a handful of mega-plants can create new exposures across a larger, more distributed network.

The battle for choke points

The prioritization of resilience is forcing organizations to look beyond where products are made to the bottlenecks on which modern healthcare depends.

Some of these choke points are physical. Life sciences companies, particularly medtech, remain exposed to critical shipping routes such as the Red Sea, the Strait of Hormuz and the Taiwan Strait. Delays can disrupt supplies of components, polymers and electronics used across healthcare, while temperature-sensitive biologics and clinical trial materials face additional risks around product integrity, compliance and development timelines.

Others extend beyond raw materials to the capabilities that determine whether innovation can be developed and delivered: specialized manufacturing capacity, semiconductor components, clinical-trial expertise, investment capital, and access to critical technologies. Consolidation among Contract Development and Manufacturing Organizations (CDMOs) is further narrowing the number of viable partners for specialist processes, leaving many biotechnology companies heavily dependent on a small number of providers.

These dependencies are digital as well as physical. [Discovery, development, and even delivery now depend on data, cloud infrastructure and computing power as much as on laboratories and manufacturing plants](#). Health data – biobanks, real-world evidence, clinical trial data and longitudinal patient records – is a strategic national asset and is protected accordingly. Data localization requirements are expanding, requiring organizations to keep certain patient, trial or genomic data in-country, limiting how multinational datasets can be assembled.⁸ At the same time, questions of provenance are arising, with regulators placing greater scrutiny on where data originates, how it was obtained and how it has been curated.

AI adds another layer of dependency. Access to frontier models, specialist chips, and cloud infrastructure is concentrated among a limited number of providers and jurisdictions, while export controls and commercial policies determine who can access them.

Boards that would never accept a single-source supplier for a critical raw material are often willing to rely on a single cloud platform, AI provider or specialist technology partner for critical

discovery, data-management or diagnostic functions. Whether those dependencies will prove as resilient as organizations expect remains largely untested, particularly under simultaneous geopolitical, regulatory and cyber stress.

The price of connectivity

Digital choke points may prove the most fragile of all. Hospital networks, pharmaceutical manufacturers, logistics providers and cloud platforms form part of the critical infrastructure on which modern healthcare depends – making their disruption an attractive means of coercion for criminals and hostile states alike.

Historically, healthcare has benefited from special protections under international humanitarian law. In practice, digital infrastructure enjoys no such immunity. Healthcare was the most targeted critical infrastructure sector in the U.S. in 2025, experiencing 460 ransomware attacks and 182 data breaches.⁹ State-linked actors have been associated with attacks against healthcare providers and medical technology organizations.¹⁰ Others have obtained persistent access to parts of critical infrastructure that could be used to enable disruptive or destructive effects during future conflicts.¹¹

Few industries experience such a direct connection between cyber exposure and human wellbeing. Disruption of access to clinical systems, diagnostic imaging, pharmacy operations or connected medical devices directly affects the delivery of care. When ransomware took a clearinghouse of U.S. healthcare transactions offline in 2024, almost three-quarters of hospitals reported disrupted patient care, including delays to medically necessary treatment authorizations.¹²

8. European Commission. [European Health Data Space Regulation \(EHDS\)](#) (Accessed 2026).

9. American Hospital Association. [FBI: Health care was top target for ransomware, other cyberthreats in 2025](#) (2026). FBI. [Internet Crime Report 2025](#) (Accessed 2026).

10. Halycon Ransomware Research Center. [Pay2Key Iranian-Linked Ransomware is Back, Back Again](#) (2026).

11. CISA, FBI, NSA et al. [PRC State-Sponsored Actors Compromise and Maintain Persistent Access to U.S. Critical Infrastructure](#) (2024).

12. American Hospital Association. [AHA Survey: Change Healthcare Cyberattack Significantly Disrupts Patient Care, Hospitals' Finances](#) (2024); American Hospital Association. [Change Healthcare Cyberattack Underscores Urgent Need to Strengthen Cyber Preparedness for Individual Health Care Organizations and as a Field](#) (2025).

The efficiencies of digitalization will continue to be accompanied by new vulnerabilities, including:

1. **Concentration risk:** A single cyber incident can halt trials, disrupt supply chains, delay treatment or expose intellectual property across multiple organizations simultaneously.
2. **Expanding exposure:** Every connected monitor, wearable, smart inhaler or home diagnostic device that extends healthcare beyond the clinic ([➡ The Self-Directed Patient](#)) also increases the number of systems through which patient data, clinical insights and treatment decisions can be compromised.
3. **Legacy systems:** MRI and CT scanners, infusion pumps, radiotherapy systems and laboratory analyzers often remain in service for many years and can be difficult to patch without operational disruption. More than half of network-connected medical devices are estimated to contain at least one known critical vulnerability.¹³
4. **Data as a target:** Clinical-trial data, genomic repositories, AI models and drug-discovery platforms are becoming strategic assets whose value rivals that of the medicines they help create. A 2026 cyber-extortion attack on a major pharmaceutical company reportedly involved attempts to obtain proprietary research data and internal AI assets, illustrating how the economics of cyber risk are evolving.¹⁴

13. Censinet: [🔗 FBI Warnings on Unpatched Medical Devices](#) | Censinet 2026; RunSafe Security. [🔗 2025 Medical Device Cybersecurity Index](#) (2025).

14. Reuters. [🔗 Hacking group claims major hack of Novo Nordisk and attempted \\$25 million extortion](#) (2026); ShieldWorkz. [🔗 Deep dive into the Novo Nordisk cyber extortion and data breach](#) (2026); Cyber Security News [🔗 Novo Nordisk Confirms Cyber Attack — Hackers Accessed Patient Medical Data and Internal AI Assets](#) (2026).

15. Boehringer Ingelheim. [🔗 Quantum Computing: Boehringer Ingelheim and Google Partner for Pharma R&D](#) (2021); IBM. [🔗 Cleveland Clinic, RIKEN, and IBM Model a 12,635-Atom Protein – the Largest Known to Be Simulated with Quantum Computers](#) (2026); IBM. [🔗 Quantum Roadmap Strategic Milestones](#) (Accessed 2026); Google. [🔗 Quantum frontiers may be closer than they appear](#) (2026); IBM [🔗 How IBM will build the world's first large-scale, fault-tolerant quantum computer](#) (2025); Google. [🔗 Our quantum error correction milestone](#) (Accessed 2026).

16. Frontiers in Health Services. [🔗 Post-quantum cryptography for healthcare: securing medical data, connected devices, and digital health infrastructure](#) (2026).

Spotlight

The post-2030 threat to health data

Quantum computing has the potential to accelerate drug discovery by modeling molecular interactions and chemical processes that are difficult for conventional computers to simulate. While transformative applications are likely to emerge gradually during the 2030s,¹⁵ the more immediate concern is security.

Much of the encryption protecting today's clinical-trial data, genomic records, patient information and drug-discovery databases relies on mathematical problems that a sufficiently powerful quantum computer could solve, an event often referred to as 'Q-Day'. The computer may not yet exist, but the risk already does: 'harvest now, decrypt later' strategies mean encrypted data stolen today could be decrypted in the future.¹⁶

Life sciences is particularly exposed because many of its most valuable assets must remain secure for decades. Clinical-trial archives, genomic repositories, longitudinal patient records and proprietary discovery datasets all have unusually long lifespans. Beginning the migration to quantum-resistant encryption will need to start years before the threat becomes immediate.

The next opportunity

Sovereignty and resilience are related, but not identical. Regional manufacturing may reduce exposure to distant shocks while creating new domestic concentrations. Local data storage may improve regulatory certainty while limiting access to global datasets. Dedicated infrastructure may improve control while reducing flexibility.

This creates openings for firms that can navigate these trade-offs.

1. Build Plan B before you need it

Few organizations can diversify every dependency, so the priority is to identify the one that would be existential if lost: a single active pharmaceutical ingredient (API) source, CDMO, cloud platform, trial network, regulatory pathway or reimbursement route. Once identified, that dependency should influence investment decisions, insurance purchasing and board-level risk appetite.

Map the network of plants, CDMOs, Contract Research Organizations (CROs), data centers and logistics partners, and identify where operational, regulatory and political risks converge. For those critical nodes, establish alternatives, backup facilities, data-access rights and escalation plans. Consider dual sourcing, mirrored data environments and flexible capacity; where full duplication is unaffordable, secure transfer rights and validated fallback arrangements.

Accept that some efficiency will be traded for flexibility, whether through secondary suppliers, multiple trial geographies or multi-region infrastructure.

2. Embed policy and regulatory intelligence into strategic decision-making

Trade policy, data governance, export controls, pricing rules and clinical-data scrutiny increasingly shape market access. The speed of developments such as the Critical Medicines Act, the BIOSECURE Act and recent U.S. tariff measures show how quickly the operating environment can change.

For many organizations, particularly those without dedicated government affairs or market access capabilities, regulatory intelligence should extend beyond compliance and function as a strategic planning capability. The goal is to identify the policy shifts most likely to affect manufacturing, partnerships, data strategy, market access or investment decisions.



2. The Innovation Stack: Who turns discovery into scale?

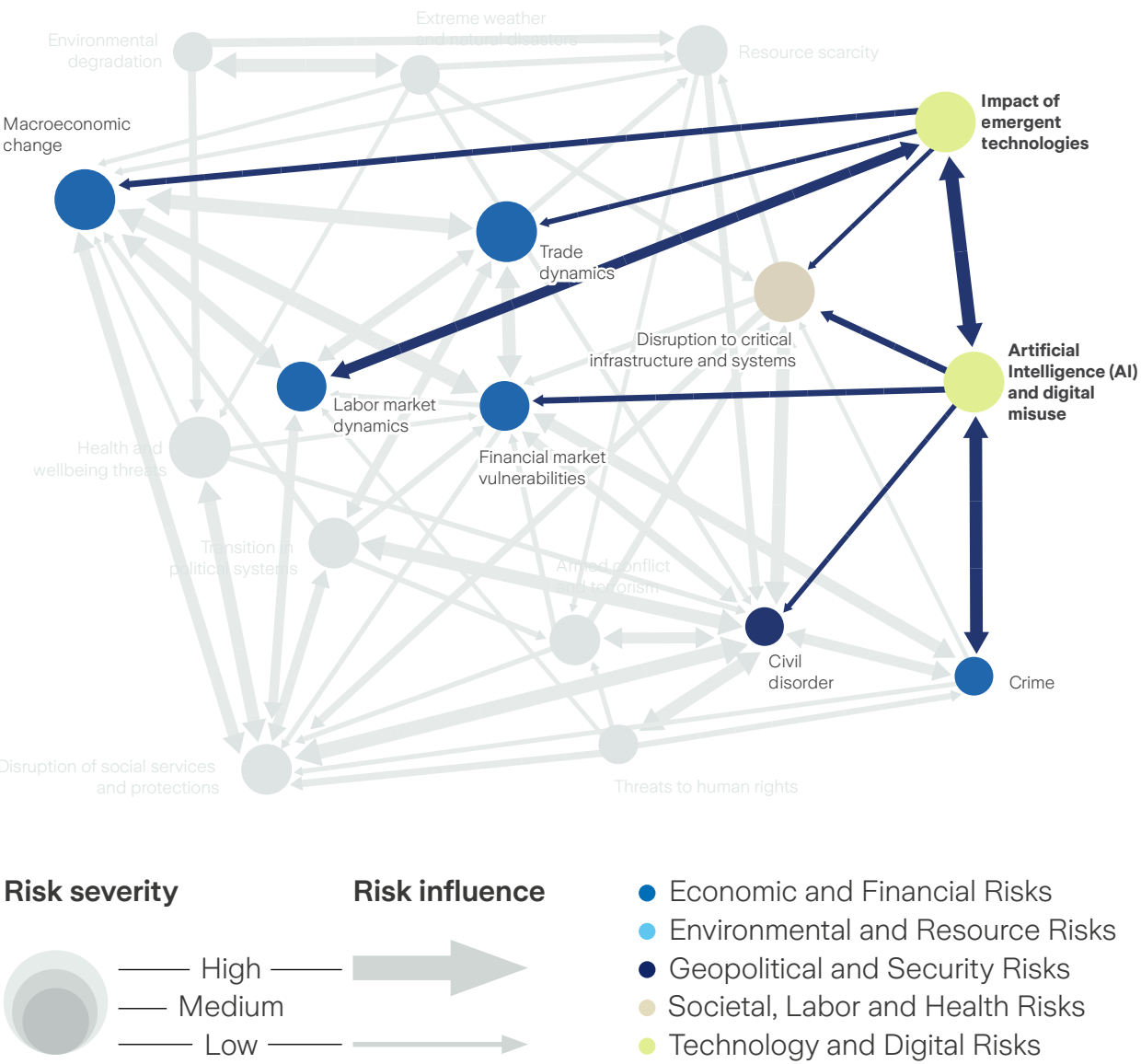
An AI system designs a promising drug candidate in days. Ten years later, there is still no guarantee that a patient will receive it.

In the next decade, **discovery will accelerate faster than the path to patients**. AI and computational biology are compressing the earliest stages of innovation. The rest of the journey, through evidence generation, approval, manufacturing, reimbursement and adoption, remains slow, expensive and uncertain.

For medicines, devices and diagnostics alike, scientific discovery is only the start. Turning an idea into a viable product requires data, capital, access to patients, regulatory expertise, manufacturing capacity and payer confidence. While AI is lowering barriers to discovery for some, many capabilities remain concentrated in a small number of datasets, platforms, manufacturing networks and specialist providers.

The innovation landscape will be shaped by a series of choices about what to build, buy, license or share: which discovery platforms to license rather than develop internally, which trial or validation functions to retain, and which data to protect as a competitive asset rather than treat as a shared utility.

The Innovation Stack
Risk network of AI and digital misuse and Impact of emergent technologies



Discover, de-risk, acquire

Historically, small firms often focused on discovery, generating novel therapeutic candidates or device concepts. Mid-sized firms frequently specialized in de-risking, advancing assets through early clinical development and establishing initial safety and efficacy signals. Larger organizations were often best positioned to scale, providing the capital, clinical development infrastructure, regulatory expertise and commercial reach needed for late-stage development and launch.

The route looks different for diagnostics and medical devices, but the underlying division is similar: generating an idea, proving it can work safely and reliably, and building the system required to scale it. Each stage rewards a distinct set of capabilities, and relatively few organizations excel across the entire value chain.

But these expectations no longer map neatly onto company types. A discovery firm with an unusually clean, well-documented dataset could secure partnership terms and valuations once reserved for de-risked clinical-stage assets. A developer with a strong regulatory and clinical track record in a specific disease area may behave like an acquirer within that niche, in-licensing assets from smaller peers.

This is because [the source of value is changing](#). For decades, it accrued primarily to whoever moved a molecule or device to the next stage. Today, a proprietary dataset, a platform technology, an AI-enabled discovery engine, a specialized manufacturing capability or privileged access to a patient population will carry material value before a single stage gate is cleared.

Buyers are already pricing the datasets, platforms and manufacturing capabilities behind an asset alongside the asset itself. For example, one recent acquisition valued at approximately USD 12 billion combined three advanced clinical programs with a muscle-directed RNA-delivery platform capable of supporting future products, illustrating how scalable capabilities can be valued alongside the assets they produce.¹⁷

Spotlight

Foundation models for biology

Foundation models for biology are emerging as a new layer of scientific infrastructure. Trained on vast collections of genomic, molecular, structural and clinical data, these models seek to identify patterns across biological systems, allowing researchers to explore more possibilities, test hypotheses faster and identify promising candidates earlier.

Like large language models in software, biological models have the potential to become a shared layer of scientific infrastructure used across research, development and experimental design.

But if biological foundation models become a core input to innovation, ownership and control of those models begin to matter. A shared model, accessible to many organizations, lowers barriers to entry and spreads development costs. Yet it also creates common dependencies. If a widely used model contains hidden biases, flawed assumptions or security vulnerabilities, those weaknesses can propagate across many users simultaneously. A proprietary model avoids that shared exposure but creates a different risk: dependence on a single provider's technology, pricing, governance and long-term viability.

The race to proof

AI-assisted tools for target discovery, protein design and in-silico modelling are compressing stages that once defined the pace of innovation.

Yet access to those capabilities is not evenly distributed. Frontier AI depends on scarce inputs: compute, advanced chips, proprietary datasets, specialist expertise and foundation models. These resources are expensive to build, concentrated among a small number of providers and, in some cases, further constrained by political priorities (⇒ [The New Health Cold War](#)).

As access becomes more strategically contested and potentially more costly, many organizations will be forced to rely on external platforms whose terms, pricing and development roadmaps they do not control. Yet even for those able to access the latest discovery tools, promising technologies may stall because the funding required to generate evidence, navigate regulation or reach scale becomes harder to secure.

It still takes around a decade and can cost well over USD 1 billion to develop a new medicine and bring it to market.¹⁸ Of every 100 drugs that enter human trials, fewer than 10 are ultimately approved.¹⁹ Devices and diagnostics follow different routes, but evidence, validation, quality systems, manufacturing and reimbursement still determine whether an innovation reaches routine use.

Much of that time is spent in clinical development and regulatory review, stages that remain difficult to accelerate even as discovery tools improve. Recruitment may stall, manufacturing may not scale, regulatory expectations may change, or funding may run out before the evidence is complete.

Companies are beginning to apply AI to some of the most time-consuming aspects of clinical development, from trial design and site selection to patient recruitment and data analysis. Decentralized clinical trials, using combinations of remote monitoring, digital consent, connected devices, telemedicine and home-based assessments, are also helping to accelerate recruitment and improve retention. However, they introduce new challenges around data quality, protocol consistency, cybersecurity and regulatory oversight.

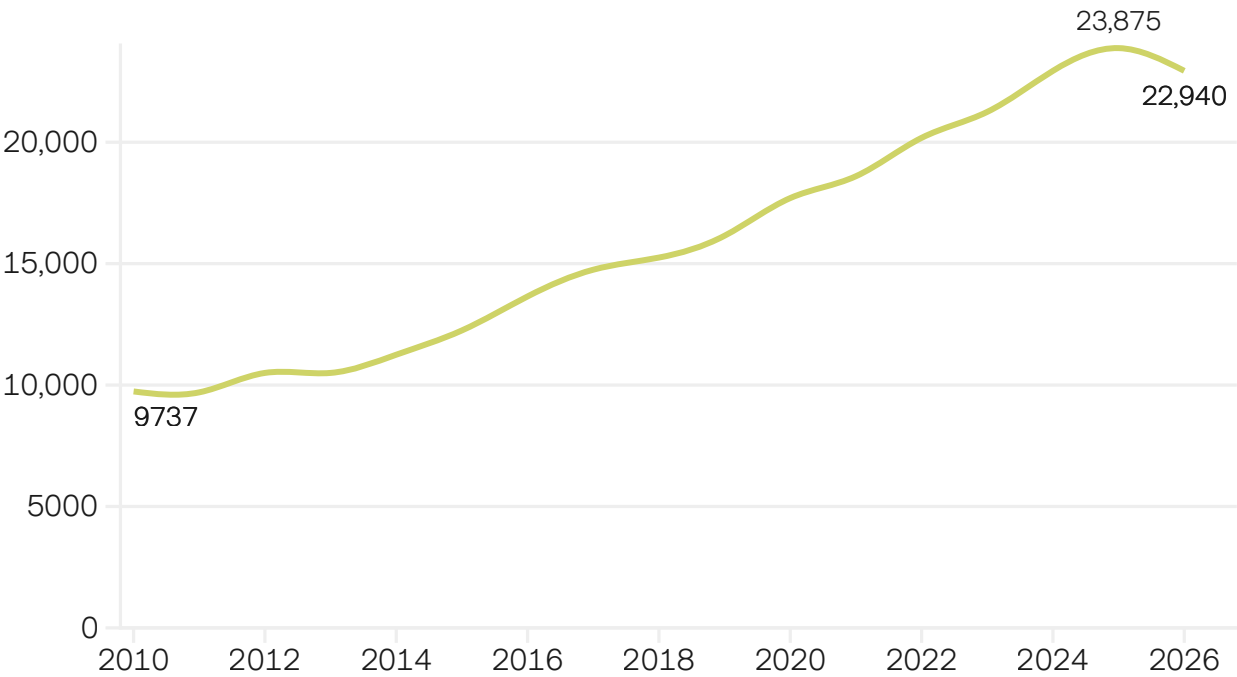
Regulators are responding. The FDA has announced a pilot program to explore how AI-enabled technologies could improve the speed, quality and efficiency of decision-making in early-phase clinical trials.²⁰ The European Medicines Agency has qualified Unlearn's AI-based digital twin methodology for use in certain trials; studies suggest it can reduce the number of patients needed in control groups without compromising the reliability of trial results.²¹ China has also become a major force in early-stage clinical development (⇒ [The New Health Cold War](#)), supported by regulatory reforms, large patient populations, dense CRO networks and trial execution speeds that often exceed those seen in Western markets.²²

Yet despite these attempts to smooth the approval path, organizations face the challenge of generating evidence that satisfies multiple regulators operating under different priorities, timelines and political pressures.

Money is also becoming more selective. The global drug-development pipeline is experiencing its first decline in roughly 15 years, even as R&D funding rose 45 percent year on year.²³ Preclinical programs have fallen 14 percent, while Phase II and III programs grew by approximately 9 percent.²⁴ Changes in pipeline tracking may explain this in part, but it also suggests capital has changed direction: fewer early programs, more investment in assets that have already cleared important scientific and clinical hurdles.

17. Novartis. [Novartis successfully completes acquisition of Avidity Biosciences, strengthening late-stage neuroscience pipeline and advancing xRNA strategy](#) (2026).
18. Congressional Budget Office. [Research and Development in the Pharmaceutical Industry](#) (2021); PhRMA. [Research and Development Policy Framework](#) (Accessed 2026).
19. pfuda.bio. [Clinical Trial Success Rates by Phase](#) (2026); PMC PubMed Central, [Why 90% of clinical drug development fails and how to improve it?](#) (2022).
20. FDA. [AI-Enabled Optimization of Early- Phase Clinical Trials Pilot Program; Request for Information](#) (2026); RAPS: [FDA asked to clarify AI pilot objectives for early-phase clinical trials](#) (2026).
21. Clinical Trials Arena. [EMA qualifies Unlearn's AI-driven approach for smaller trials](#) (2022); Drug Discovery & Development. [How digital twins could support more affordable Alzheimer's research](#) (2024).
22. McKinsey & Company. [The emerging epicenter: Asia's role in biopharma's future](#) (2026).
23. BIO.News. [BIO 2026: As capital returns, focus on quality over quantity](#) (2026).
24. BIO.News (2026).

Global biopharma R&D pipeline
Number of drugs under development, 2010-2026



Source: BIONews (2026).

The result may be a growing divide between scientific promise and financial viability. New and emerging companies remain an important source of innovation. However, capital could concentrate around later-stage assets, proven platforms and organizations with a clearer route to commercialization.

25. Mirror Biology Dialogues Working Group. [Technical Report on Mirror Bacteria: Feasibility and Risks](#) (2024); Smithsonian Magazine. [Scientists Weigh the Risks of 'Mirror Life,' Synthetic Molecules With a Reverse Version of Life's Building Blocks](#) 2025; Wyss Institute. [Researchers call for global discussion about possible risks from "mirror bacteria"](#) (2024).

Spotlight

When innovation outruns governance

Beyond issues of ownership and access lies a more fundamental boundary: which capabilities should be developed at all.

Few technologies illustrate the widening gap between scientific capability and governance as clearly as mirror life. Mirror-life organisms create a form of biology fundamentally different from anything found in nature. Although researchers remain years, if not decades, from building a fully functional mirror bacterium, advances in synthetic biology have made the concept scientifically plausible enough to trigger serious debate. Potential applications in medicine, industrial biotechnology and advanced manufacturing are being countered by concerns that the characteristics that make mirror organisms attractive could also make them difficult to control.

Mirror life is an early sign that governance may itself become a constraint on innovation, and that scientific capability without public confidence may carry limited commercial value.²⁵

When healthcare meets platform economics

Therapies, diagnostics, devices, software and services are entering the market as connected systems that evolve after launch. For example, diabetes-management ecosystems combine continuous glucose monitors, mobile applications, analytics tools and connected insulin-delivery devices into integrated systems whose value increases with every new data point. A modern robotic surgical system is likewise part of a broader platform, combining imaging software, procedural analytics and ongoing software support.

As these platforms mature, an increasing share of value may sit not in the scanner, sequencer or diagnostic device itself, but in the data, algorithms and collective intelligence that connect them. Traditional pharmaceutical and medical technology models concentrated value in the product itself. [Connected systems create additional value through data and the network of patients, providers and partners around them.](#)

In such systems, control of discovery platforms, data environments and clinical interfaces can influence which assets are developed, validated and adopted. Organizations do not need to be conventional pharmaceutical or medical-device manufacturers to gain leverage; the orchestrator of these interactions may be a technology company, a payer, a hospital network, manufacturer or diagnostic company.

Technology companies are already moving into this terrain, investing across diagnostics, continuous monitoring, preventive health, AI-assisted decision-making, and even directly in drug discovery.²⁶

Access terms, interoperability and the ability to move data or programs elsewhere are therefore becoming strategic choices.

The next opportunity

The innovation stack is becoming more interconnected. Organizations that understand where they add the most value and align their investments accordingly will be better placed than those that treat each stage as separate:

1. Build redundancy into critical development pathways

Avoid tying critical programs to a single external partner, platform or model without a fallback. This could mean ensuring that trial data, protocols and site relationships can transfer to another CRO if the original partner fails, testing more than one discovery platform for key targets, or retaining sufficient internal expertise to verify external outputs. Redundancy helps protect against technical failure, partner disruption and shifts in market or regulatory conditions.

This does not mean duplicating every function. It means identifying the dependency that could stop a program in its tracks and ensuring there is another route forward if it disappears.

2. Own the bottleneck

Identify which part of your contribution others cannot easily replace: a unique dataset, a specialized trial network, a patented process, a manufacturing capability or trusted access to a patient population. Focus investment there. Leverage may come from owning the channel, the evidence or the capability that others need. In practice, strategic advantage may depend less on developing the best algorithm than on controlling trusted access to longitudinal patient data, real-world evidence or critical decision points within the care journey.

The technologies will change. The harder task is retaining enough control, evidence and flexibility to carry the next breakthrough through the stack.

26. Google Cloud Blog. [How Isomorphic Labs uses machine learning models to explore new frontiers in drug discovery](#) (2024).

3. The Self-Directed Patient: Who is responsible for care beyond care?

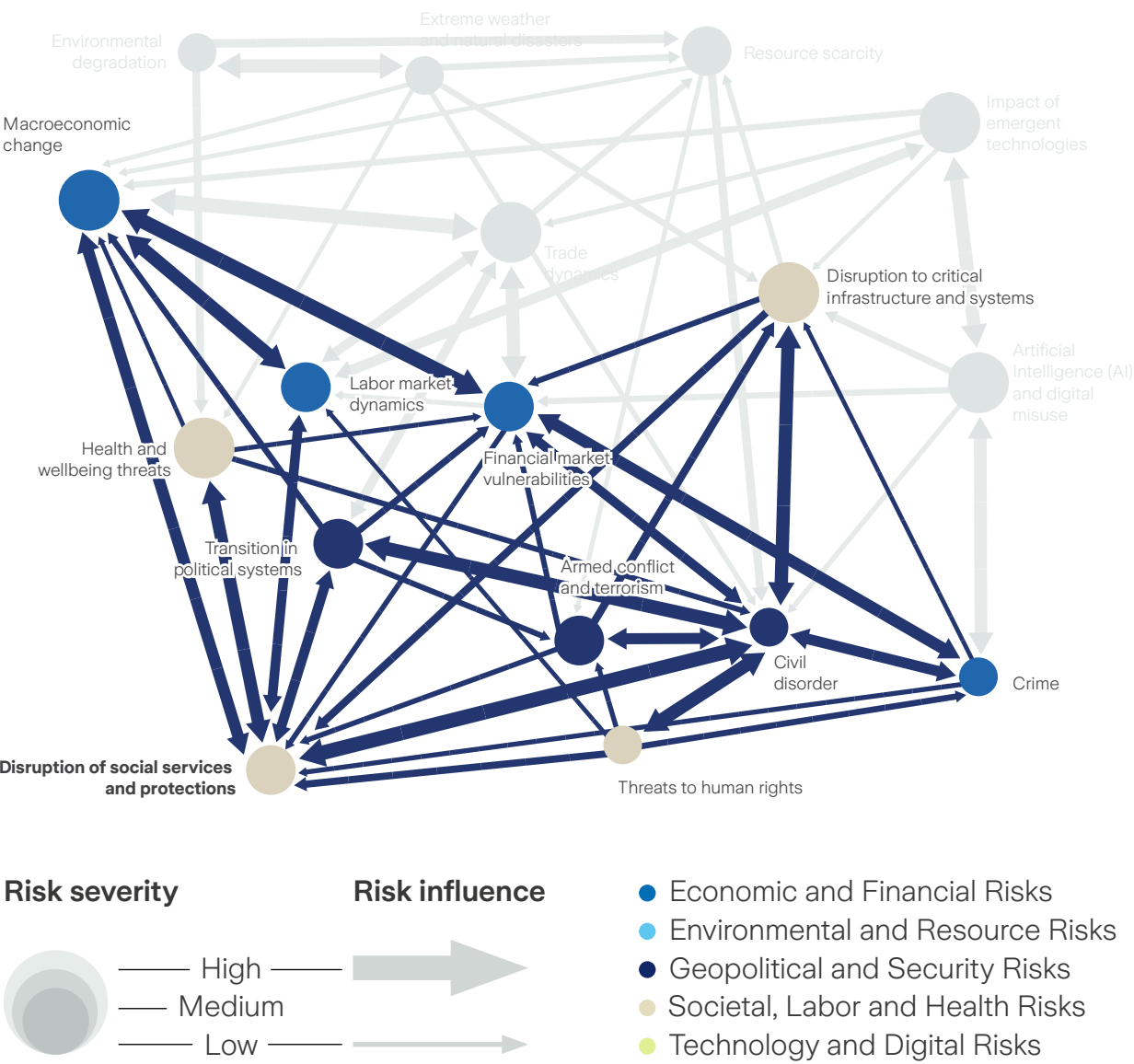
A smartwatch flags an irregular heart rhythm at two in the morning. The wearer opens an app, which asks a series of questions and suggests the pattern is consistent with a common, usually benign, arrhythmia – but recommends seeing a doctor if it recurs.

No healthcare professional has yet been involved, and none may be for weeks. If the advice is wrong, or the follow-up never happens, the device manufacturer, the software developer, the health system that recommended the wearable as part of a prevention program, and the patient who decided not to act, may all have played a part.

In the 2030s, **more of medicine's moments will happen outside a clinician's sight**. Technology is extending its influence across the entire health journey: helping people identify risks before they enter the system, shaping decisions inside it, and tailoring care once they do.

But as decisions migrate from institutions to platforms, devices and algorithms, accountability becomes harder to trace. Who sets the standards for advice generated by software? Who decides when a signal requires intervention? And who carries responsibility when patients, clinicians, devices and algorithms all contribute to an outcome?

The Self-Directed Patient
Risk network of Disruption of social services and protections



Care beyond the appointment

The starting point of healthcare is shifting. Care starts at home, continues through digital platforms and only sometimes reaches a healthcare provider.

Health systems are encouraging this shift to relieve pressure on clinics and hospitals confronting one of medicine's oldest constraints: not enough people to deliver it, with a projected global shortfall of 11 million workers by 2030.²⁷

Every symptom checker, wearable and triage tool that enables care to begin before an in-person appointment is, in part, a response to that arithmetic. Spending on connected monitoring devices and platforms is projected to keep growing at a double-digit annual rate through the early 2030s, as health systems use remote monitoring to support chronic disease management at home and in the community.²⁸

Search and self-diagnosis may not be new, but it is now far more convincing. A conversational AI assistant can generate a plausible differential diagnosis in seconds, tailored to a user's symptoms. Some of these tools do what they promised: earlier detection, healthier behavior, and self-management. Others generate noise – false positives, unnecessary consultations, anxiety, and burden on systems.

Care before care only works if it connects back into the clinic in ways that professionals trust and systems can handle. [An AI assistant may sound like a clinician, but it does not carry the licensing, liability, or audit trail of a clinical consultation.](#)

The use of these systems within the healthcare environment raises a similar set of questions around validation, safety, oversight and liability, including for the organizations choosing to implement them.

27. World Health Organization. [Health workforce](#) (Accessed 2026).

28. Fortune Business Insights. [Remote Patient Monitoring Devices Market Size, Share & Industry Analysis](#) (2026); MarketsandMarkets: [Remote Patient Monitoring Market Report](#) (2026).



From screening to prediction

The same tools that move care beyond the appointment are also changing how we decide who enters the system in the first place.

Preventive healthcare largely relies on broad population rules: age thresholds, family history and standardized screening schedules. Increasingly, those rules are being supplemented by predictive models that combine genetic, clinical, behavioral and demographic information to estimate individual risk and guide how, when and for whom monitoring takes place.

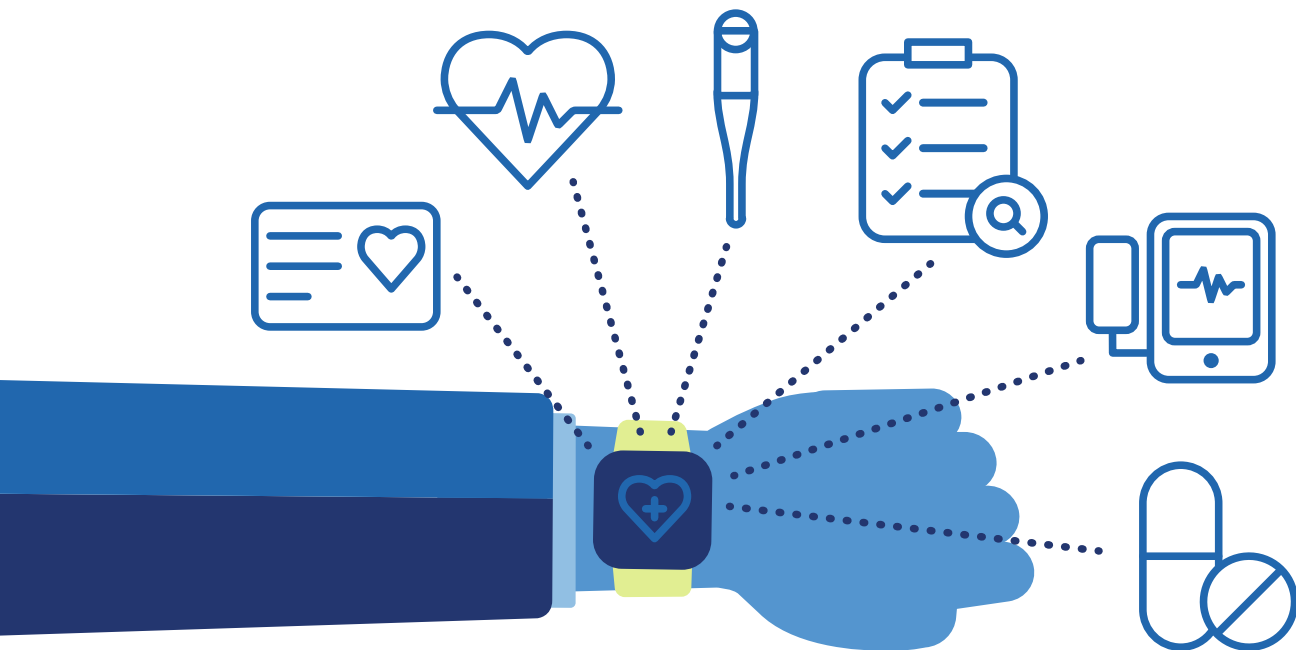
The shift is already becoming visible in breast cancer. The referral criteria currently used by the UK's National Health Service was shown to identify only a small proportion of women who would develop breast cancer within the following decade in comparison to a newer model that combines family history, genetics, reproductive history and lifestyle factors.²⁹ Comparable approaches are emerging across cardiovascular disease, diabetes, neurodegeneration and mental health.

The benefits of a shift towards continuous, individualized risk prediction are obvious: earlier detection, more targeted prevention and better use of healthcare resources. But the model also tests explainability, bias, consent, liability and access. As healthcare becomes more predictive, organizations will be judged on how accurately, fairly and responsibly they identify risk before disease becomes visible.

One of the most useful near-term roles for AI is not replacing clinicians but multiplying what each one can do. For example, physicians and nurses spend a disproportionate share of their working day documenting care in electronic health records rather than delivering it, a burden widely associated with burnout and workforce attrition.³⁰ By 2025, roughly two-thirds of U.S. hospitals using the Epic electronic health record had adopted at least one ambient AI scribe tool to automatically draft clinical notes,³¹ with early evidence suggesting that these tools can significantly reduce the burden of documentation.³²

These systems may save time, but they do not remove responsibility. If an AI-generated note omits a symptom, invents a detail or contributes to a later error, questions quickly emerge around who remains accountable for the outcome.³³

- 29. British Journal of Cancer. [Comparison of NICE criteria with the BOADICEA multifactorial risk model to guide breast cancer risk assessment and referral amongst women under age 50 within primary care](#) (2026); University of Cambridge. [NICE referral criteria miss up to 95% of women under 50 who go on to develop breast cancer within 10 years](#) (2026).
- 30. PubMed Central. [Burnout Related to Electronic Health Record Use in Primary Care](#) (2023); JAMA Network. [Electronic Health Record Usability, Satisfaction, and Burnout for Family Physicians](#) (2024).
- 31. American Journal of Managed Care. [Ambient AI Tool Adoption in US Hospitals and Associated Factors](#) (2026).
- 32. Annals of Emergency Medicine. [Ambient Artificial Intelligence Scribe Adoption and Documentation Time in the Emergency Department](#) (2026); Journal of the American Medical Informatics Association. [Ambient artificial intelligence scribes: physician burnout and perspectives on usability and documentation burden](#) (2025).
- 33. JCO Oncology Practice. [Liability Risks of Ambient Clinical Workflows With Artificial Intelligence for Clinicians, Hospitals, and Manufacturers](#) (2025).



The age of individual medicine

The first wave of digital health moved care closer to patients. The next wave aims to make care more specific to each patient, using data, genetics and continuous monitoring to tailor decisions to the individual rather than the population.

Individualized medicine spans:

- **Personalized diagnostics and risk scores** – tools that stratify patients into precise groups based on genetic, molecular, clinical and behavioral data.
- **Tailored therapies** – interventions adjusted to an individual's genetic, molecular or behavioral profile.

Most medicines are developed and approved based on average effects observed across patient populations. Individual responses often vary substantially, meaning patients may need to try multiple therapies before finding one that is effective and well tolerated. Some of that variability is attributable to genetic, biological and environmental factors that can increasingly be measured in advance.

This is the promise that has powered two decades of investment in precision medicine. Cell therapies, gene therapies, companion diagnostics and sophisticated genomic tools are accelerating the shift towards treatments designed for smaller and more precisely defined patient groups.

It promises better outcomes in principle. But it often requires smaller, more complex trials, raises questions around equity of access, and carries higher up-front costs whose benefits may take years to verify.

In the coming decade, **a growing number of therapies will prove clinically effective, but sit uneasily within evidence and approval systems designed for broader populations and more conventional treatment models.** As treatments become more personalized, healthcare systems may need to decide whether traditional approaches to proving safety, efficacy and value remain fit for purpose.

There is also a structural risk inside precision medicine's promise. Diagnostics and risk scores are only as fair as the data used to build them, and much of the genomic and clinical data available today skews heavily towards a narrow set of countries and populations. A risk score trained overwhelmingly on one ancestry group can underperform, or produce less reliable predictions, when applied to another – which means that technology that promises more personalized care can, without careful design, entrench rather than close existing gaps in outcomes. That is a data-governance problem as much as a scientific one, and it belongs alongside consent, access and pricing as a core design consideration rather than an issue to address later.

1 in 3

of new FDA approvals relate to personalized medicines

PMC. [New PMC Report Shows FDA Advancing a New Era of Personalized, Patient-Centered Care \(2026\).](#)

Access before approval

Systems built for population medicine are coming under pressure from therapies designed for individuals.

One manifestation of this tension is the growing debate over access. In 2025, a U.S. state expanded its Right to Try law to allow certain experimental therapies to be made available outside traditional approval pathways. Supporters argue that patients facing serious or life-threatening conditions should have greater freedom to access promising treatments before regulators have completed years of review. Critics warn that earlier access can shift risk onto patients while reducing many of the safeguards that normally accompany evidence-based medicine.

The debate reflects a broader tension running through healthcare: the more treatments are tailored to individual patients, genetic profiles or small populations, the harder it becomes to rely on the conventional evidence pathways that shaped modern drug approval.

And as therapies become more personalized, and as patients gain greater access to data, information and alternative treatment pathways, healthcare systems will need to decide where the balance sits between protection and autonomy – and just how much responsibility a patient is willing, and expected, to assume for their own care.³⁴

34. MIT Technology Review. [Montana's plan to become an experimental medical hub just pushed forward](#) (2026); FDA. [Right to Try](#) (Accessed 2026).
35. FDA. [Artificial Intelligence-Enabled Medical Devices](#) (2026); IntuitionLabs [FDA's AI Medical Device List: Stats, Trends & Regulation](#) (2025); MedTech Dive. [The number of AI medical devices has spiked in the past decade](#) (2024).

The accountability gap

A health outcome is no longer linear; it is distributed across patients, clinicians, devices and algorithms. The hand-offs that once seemed clear become blurred:

- Who made the diagnosis?
- Who interpreted the data?
- Who recommended the treatment?
- Who owns the outcome?

These rarely have a single answer, and the absence of one is where liability, disputes and regulatory scrutiny tend to concentrate.

In practice, product, clinical and cyber risks are converging around the same incidents: a missed diagnosis that begins with a miscalibrated algorithm, compounded by a fragmented hand-off between platforms, which results in patient harm. Mapping which contract, workflow and software system influenced a decision, before a dispute forces that mapping to happen under pressure, is rapidly becoming as important as the clinical protocol itself.

Regulators are adjusting to this reality, and the pace of that adjustment signals just how central software has become to care. By the end of 2025, the U.S. FDA's public list contained more than 1,450 AI-enabled medical devices, up from fewer than 1,000 little more than a year earlier.³⁵ Regulators are already developing frameworks that treat software and AI as products that carry their own regulatory and liability obligations.³⁶

The expectation is that manufacturers design foreseeable misuse and failure modes out of consumer-facing tools at the product-development stage rather than manage them through warnings and labelling after the fact. That shifts responsibility further upstream, into design decisions made months or years before the first user opens the app.

36. FDA. [Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions](#) (2025); MedDeviceGuide. [FDA PCCP Guide for AI/ML Medical Devices](#) (2026); European Union. [Artificial Intelligence Act \(Regulation \(EU\) 2024/1689\)](#) (2024); European Union. [Directive \(EU\) 2024/2853 on liability for defective products \(recast\)](#) (2024).

Psychedelics

Psychedelic-assisted therapies are one of the clearest examples of healthcare convergence, combining a molecule, a therapeutic protocol, clinical supervision and digital support within a regulatory framework that remains unsettled.

Two large regulators have taken markedly different approaches. Australia allows specifically-authorized psychiatrists to prescribe MDMA for post-traumatic stress disorder and psilocybin for treatment-resistant depression.³⁷ The pathway is deliberately narrow: psychiatrists must obtain approval from a human research ethics committee and then further authorization. Yet it is a live, functioning regulatory route, making Australia the first country to establish a national pathway for the prescribed therapeutic use of either substance outside a clinical trial.

The U.S. FDA has taken a markedly different approach. In 2024, it declined to approve Lykos Therapeutics' application for MDMA-assisted therapy for PTSD, citing concerns about the adequacy and reliability of the clinical evidence and requesting an additional Phase 3 trial before resubmission.³⁸

The divergence highlights how regulatory trust depends on more than clinical data: It is whether an entire treatment system, comprising the therapy, protocol, clinical supervision and supporting infrastructure, can be delivered safely and consistently outside the controlled environment of a clinical trial.

The next opportunity

Technology-assisted care can make healthcare more accessible, responsive and efficient. It can also fragment accountability and widen gaps in outcomes, particularly under very different regulatory expectation, if not managed carefully.

1. Design out foreseeable misuse

Digital health tools, connected devices and patient-facing applications are judged by the mistakes they permit as much as by the benefits they deliver. Identify the most likely points of misuse, misunderstanding or failure across drug–app–device ecosystems and address them through design, workflow and escalation pathways rather than relying solely on warnings and training.

Where a tool's output, whether a clinical note, triage recommendation or risk score, is generated by AI, it should be validated with the rigor applied to any other clinically relevant process, and organizations should be explicit about who reviews, approves and remains accountable for its use in patient records or treatment decisions. That chain of accountability is exactly what regulators, insurers and courts will look for first.

2. Design for trust before the point of care

Treat first contact, whether through an app, a device, a clinical-trial enrolment platform, a patient-support portal or a device onboarding process, as a critical trust moment. Ensure that explanations are clear, permissions are understandable and expectations are realistic. Involve patients and clinicians in the design process so materials and interfaces reflect how they actually use and understand the technology, rather than internal assumptions. For tools built on models that continue to evolve after launch, document which changes are pre-approved and which require a fresh review. Regulators are asking organizations to demonstrate exactly that distinction.

37. Therapeutic Goods Administration (TGA). [Re-scheduling of psilocybin and MDMA in the Poisons Standard: questions and answers](#) (2023); Psychedelic Health. [Australian patients can now access psilocybin and MDMA](#) (2023).

38. FDA. [Complete Response Letter to Lykos Therapeutics for Midomafetamine \(MDMA\)-Assisted Therapy for PTSD](#) (2024).

4. The Cost of Cure: Who can afford the breakthrough?

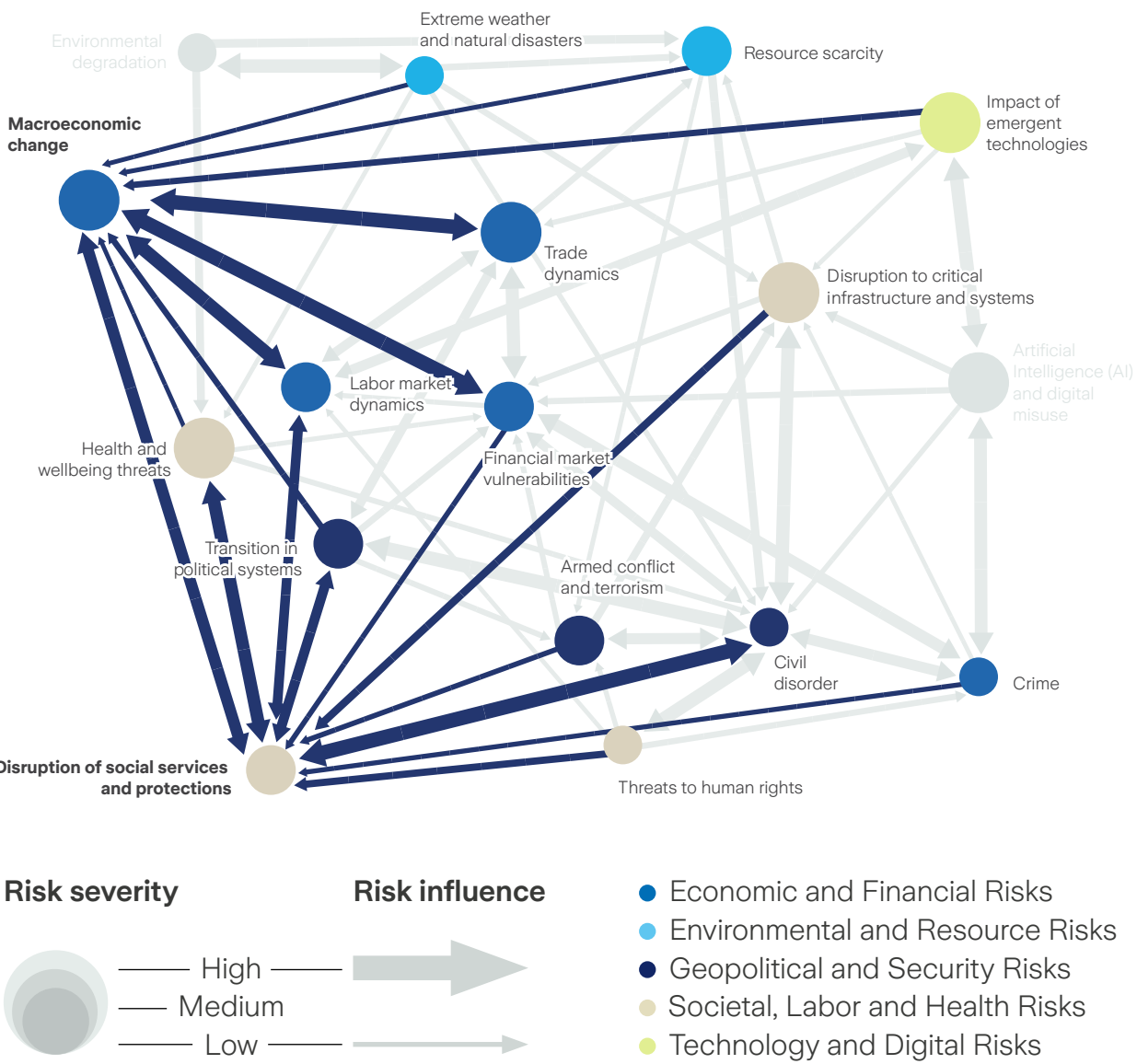
A child receives a one-time gene therapy for a rare inherited disease. The treatment takes hours to administer. The clinical benefits may last decades.

For much of modern healthcare, funding and reimbursement have been built around repeated transactions: a prescription refilled, a procedure repeated, a device replaced or a service delivered.

The next decade in life sciences could see [more therapies providing lasting benefits from a single intervention](#) rather than ongoing treatment.

This creates a different economic tension. A treatment delivered once may need to demonstrate value for decades. The clinical effect may be immediate, but the financial, contractual and evidentiary obligations can persist long afterwards. These new forms of value will need to be designed, financed and insured without creating exposures that neither the organization nor its partners can carry.

The Cost of Cure
Risk network of Macroeconomic change and Disruption of social services and protections



Antimicrobial Resistance

Antimicrobial resistance (AMR) is often framed as a scientific problem. But it is also an economic one.

Society needs new antibiotics, but the traditional business model for developing them is weak. A successful new cancer medicine is often used widely. A successful new antibiotic is frequently held in reserve and used sparingly to preserve its effectiveness.

The result is one of the clearest market failures in healthcare. Medicines that are essential to modern healthcare frequently generate insufficient returns to sustain investment. Resistant infections are becoming more difficult and more costly to treat, yet several antibiotic developers have entered financial distress or bankruptcy despite bringing clinically valuable products to market.

What makes AMR particularly significant is that it challenges a longstanding assumption: that value is created when more products are sold. In the case of antibiotics, the economic value comes from using it less, preserving treatment options that healthcare systems may one day depend upon in a crisis.

This is driving experimentation with new payment models. Rather than paying for each prescription, some health systems are exploring subscription-style approaches that reward manufacturers for ensuring access and maintaining innovation regardless of utilization. In effect, they are paying for resilience rather than volume.

The implications extend well beyond antibiotics. Gene therapies, preventive interventions and outcome-based healthcare models all challenge traditional relationships between product use, revenue and value creation. As healthcare moves from selling treatments toward delivering outcomes, organizations will need business models that reward long-term health impact rather than short-term consumption.

The end of the recurring-revenue model

Traditional healthcare payment models were built around repeated transactions: prescriptions refilled, procedures repeated and services delivered.

Innovation is moving in the opposite direction. One-time or short-course therapies may generate benefits that last for years or decades, while payment is increasingly linked to outcomes, availability or long-term performance rather than volume.

Healthcare systems are beginning to experiment with new approaches, from subscription models for antibiotics to outcome-based agreements for gene therapies. NHS England now pays fixed annual fees for selected antibiotics regardless of usage.³⁹ The approach aims to reward availability and innovation rather than consumption, though debate continues over how effectively it stimulates new antibiotic development.⁴⁰ Similar experimentation is underway in gene therapy: outcomes-based agreements for sickle-cell therapies, with rebates linked to clinical performance over time.⁴¹

At the same time, many life sciences organizations face their own funding constraints. A wave of major patent expirations expected between the late 2020s and early 2030s will expose some of the industry's largest products to generic and biosimilar competition, putting pressure on revenues at a time when development costs remain high. Competition for promising assets, partnerships and acquisitions is intensifying as organizations seek to replenish their pipelines and sustain future growth. [Healthcare systems must find new ways to pay for innovation, while life sciences organizations must find new ways to fund it.](#)

39. NHS England. [NHS lands breakthrough in global battle against superbugs](#) (2022); The Pharmaceutical Journal. [Expanded 'subscription model' for new antibiotics to be funded with £100m per year](#) (2024).

40. The Lancet Microbe. [Why is the UK subscription model for antibiotics considered successful?](#) (2023).

41. CMS. [CMS Expands Access to Lifesaving Gene Therapies Through Innovative State Agreements](#) (2025).

Cure now, bill later

Healthcare systems must decide how finite resources are allocated when a single gene therapy requires a level of upfront investment rarely seen in conventional care. That trade-off will become more visible, more political, and more consequential over the next five years.

Some of the arithmetic is favorable. One gene therapy for a rare neuromuscular condition launched with a price of just over USD 2 million, with its manufacturer arguing that this remained well below the projected cost of USD 4 million for a decade of chronic treatment.⁴² Another gene therapy for a rare bleeding disorder was priced at roughly USD 3.5 million, against estimated lifetime treatment costs that could exceed USD 20 million per patient.⁴³ However, such comparisons do not fully resolve the debate, as uncertainty often remains around durability, real-world outcomes and whether projected long-term savings ultimately materialize.

The disagreement is about timing. A payer writes the full check in year one; the offsetting savings, if they materialize as promised, show up over the following 10, 20 or 30 years, spread across a system that may not be the same payer by the time they arrive. Financing structures built around annual budgets and political cycles may struggle to capture benefits that emerge over decades, particularly when many governments are already managing high debt burdens, ageing populations and rising healthcare expenditure. Public systems will need to make more explicit decisions about how finite resources are allocated when treatments are designed for ever-smaller patient groups.

Payer engagement has already become an early-stage strategic issue at the individual therapy level. The next question is structural: whether the financing and risk-sharing models themselves need rebuilding. The key is to ensure that new revenue models are backed by appropriate capital, reserves and coverage – and that success does not produce an unmanageable tail of commitments.

42. Novartis. [AveXis Announces Innovative Zolgensma® Gene Therapy Access Programs for US Payers and Families](#) (2019).

43. FIERCE Pharma. [Costing \\$3.5M, first hemophilia B gene therapy wins FDA approval](#) (2022).

44. Latham & Watkins. [New EU Product Liability Directive Comes Into Force](#) (2024); Pinsent Masons. [Revised EU product liability regime expands to AI software providers](#) (2024).

45. NAMSA. [FDA Premarket and Postmarket Medical Device Cybersecurity](#) (2025); FDA. [Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions](#) (2026).

When accountability outlives the product

For all their differences, these models share a common problem: proving that the promised outcomes have actually been delivered.

A subscription contract for an antibiotic still needs someone to verify that the drug remains available and effective years into the agreement. An outcomes-based rebate for a gene therapy still requires an agreed definition of treatment failure, one that survives changes in clinical practice, diagnosis and patient monitoring – and relies on the ability to collect, retain and interpret data for years after treatment. Software updates may be required for safety years after hardware is discontinued.

Many of these models have little historical precedent. Organizations are being asked to price, finance and govern long-term outcome commitments before decades of evidence exist to guide them. And as therapies, diagnostics, software and services become more interconnected, accountability no longer maps neatly to a single product or organization. A connected infusion pump failure may involve a device manufacturer, software provider, cloud platform, healthcare provider and clinical team, all of whom contributed to the final outcome – [but where does responsibility begin and end?](#)

The regulatory definition of products is expanding accordingly, to include software and digital elements, clarifying that liability can extend across complex supply chains, and expecting lifecycle management that continues after launch. The clearest example is the European Union's revised Product Liability Directive; for the first time, EU law explicitly treats software and AI systems as products, subjects them to strict product-liability rules and gives claimants enhanced rights to obtain technical evidence needed to support a claim.⁴⁴ Other jurisdictions are explicitly targeting cybersecurity vulnerabilities; U.S. law requires manufacturers of internet-connected medical devices to maintain cybersecurity plans across a device's total product lifecycle, with guidance including ongoing vulnerability monitoring and the timely deployment of security updates.⁴⁵

For therapies delivered through combinations of drugs, software and monitoring services, the practical effect is that responsibility spans multiple organizations long before a claim is filed.

The next opportunity

Delivering value through outcomes rather than transactions has the potential to create more sustainable, patient-centered healthcare. Organizations that deliberately align product design, operating models, insurance and governance with these realities will be better placed to grow without over-extending themselves.

1. Price the promise, not the product

Consider early how success could reshape your risk profile. What happens if a therapy or platform reaches ten times the expected population? How do outcome guarantees and subscriptions behave at scale? Which policies – product liability, professional indemnity, cyber, tech, errors and omissions (E&O) – respond to different failure modes?

Test the operating model against plausible failure scenarios before launch, including whether contractual indemnities, reserves and existing product, cyber and professional-liability cover respond as intended. External risk and insurance specialists can help identify gaps while products and agreements can still be redesigned.

2. Design for outcomes, not products

Begin with the outcomes that patients and healthcare systems care about, and design the combination of therapies, diagnostics, digital services and data flows needed to deliver them. This helps clarify which partners are essential, what evidence is required, and how responsibilities should be shared.

It also makes conversations with payers and regulators more concrete. Critically, it forces organizations to confront access early: who will use the intervention, who will pay for it, and whether the economics can support adoption beyond a narrow population segment.

Organizations that leave this conversation until after launch may find themselves negotiating access and price while responding to early real-world safety signals, increasing uncertainty and execution risk at a critical stage of market uptake.



What changes in practice



Advantage will not rest with those that discover the most innovations, adopt the most technology or move the quickest. It will belong to those that can combine scientific progress with resilience, evidence, trust and long-term stewardship.

In the 2030s, growth in life sciences will be shaped by three distinct principles:

1. Competitive advantage moves beyond the product

Success depends on access to infrastructure, data, manufacturing capacity, regulatory pathways, clinical evidence and trusted relationships. For many organizations, the most important strategic asset may be a capability that allows innovations to reach patients at scale.

2. Dependencies become a defining source of risk and value

The most significant constraints sit outside organizational boundaries: geopolitical tensions, critical suppliers, digital platforms, cloud infrastructure, datasets, trial networks and reimbursement systems. Decisions about what to own, share, outsource or localize are becoming as important as decisions about what to invent.

3. Responsibility does not end at launch

As healthcare becomes more connected, personalized and outcome-focused, organizations will be expected to support products, software, data, outcomes and patient relationships for years after initial deployment, creating longer tails of accountability, governance and risk.

In that environment, insurability becomes an important signal of readiness, helping organizations distinguish what can be developed from what can be scaled sustainably.



Data and methodology



Beyond 2030: The Future of Life Sciences brings together expert insight on the risks shaping the life sciences sector over the next five years and beyond.

The report relies on structured expert elicitation to map risk interconnections and develop foresight. Similar approaches are designed to work with a small and diverse set of internal and external experts, with insights emerging from the quality of expertise, rather than the volume of input.

Contributions from 34 experts, including external industry specialists and Zurich colleagues, were collected through interviews conducted from June to August 2026 (see [Acknowlegements](#)).

The report also integrates findings from a short survey ('The Future of Life Sciences survey') undertaken by internal and external experts (n = 62). It included three sections:

1. [Risk severity](#) invited respondents to assess the likely impact (severity) of 17 risks on the life sciences sector over the next five years. Results reflect a simple average of responses on a seven-point scale (1 = Extremely low, 7 = Extremely high).
2. [Risk interconnectivity](#) asked respondents to consider potential relationships between risks. For each selected risk, respondents could select up to five risks most likely to arise as consequences. To limit survey burden, each respondent was shown a random subset of risks from the full list of 17, resulting in a limited number of observations for any given risk. The map is intended to illustrate relative patterns of interconnection rather than a complete risk system. Identified relationships are based on a simple tally of responses, with infrequently observed relationships (<40%) excluded. Circle size reflects perceived severity, grouped into three tiers based on the distribution of observed scores (tertiles) to ensure clear visual separation between risks.
3. [Qualitative input](#) allowed respondents to share, in free text, which risk they were most concerned about and why.

Risks were presented in alphabetical order in the survey, and included:

Economic and Financial Risks

1. [Crime](#) (e.g., cyber crime, fraud, money laundering).
2. [Financial market vulnerabilities](#) (e.g., asset bubbles, debt, liquidity, digital currencies).
3. [Labor market dynamics](#) (e.g., automation, green transition, aging workforce, talent / labor shortages).
4. [Macroeconomic change](#) (e.g., inflation, recession).
5. [Trade dynamics](#) (e.g., monopolies / oligopolies in strategic resources, tariffs etc.).

Environmental and Resource Risks

6. [Environmental degradation](#) (e.g., biodiversity loss, soil decline, pollution, habitat loss).
7. [Extreme weather and natural disasters](#) (e.g., heatwaves, floods, wildfires, earthquakes).
8. [Resource scarcity](#) (e.g., price hikes or shortages of water, energy, food, arable land).

Geopolitical and Security Risks

9. [Armed conflict and terrorism](#) (e.g., war, terrorism, proxy conflicts by state and non-state actors).
10. [Civil disorder](#) (e.g., violent or disruptive protests, strikes, social unrest).
11. [Transition in political systems](#) (e.g., regime change, elections, coups).

Societal, Labor and Health Risks

12. [Health and wellbeing threats](#) (e.g., pandemics, new diseases, anti-microbial resistance, mental health).
13. [Disruption to critical infrastructure and systems](#) (e.g., transport, IT, energy, finance).
14. [Disruption of social services and protections](#) (e.g., education, healthcare, pensions).
15. [Threats to human rights](#) (e.g., erosion of civic freedoms, censorship, child labor).

Technology and Digital Risks

16. [Artificial Intelligence \(AI\) and digital misuse](#) (e.g., privacy breaches, misinformation, online harms).
17. [Impact of emergent technologies](#) (e.g., biotech, quantum, geoengineering).

Acknowledgments



This report was developed under the efforts and guidance of Rosanna Cubelli, Sophie Heading, and Vincent Landon, with design by Joël Giroud.

This report has greatly benefited from the insight and expertise of: [Ina Burgstaller](#), Founder & CEO, Bionabu; [Prasun Chakraborty](#), CEO & Founder, Genevation; [Gianluca Corbinelli](#), CEO, Molteni Farmaceutici; [Eric Fumière](#), Head of Corporate Insurance, UCB; [Ilan Hayman](#), General Manager, Mind Clinics Australia; [Tom Heck](#), Commercial & Marketing Head, Alembic Therapeutics; [Henry Hollamby](#), Co-Founder & CEO, Viscera Technologies; [Nikki Jessop](#), Director of Hospitals Business Unit, Kent Pharma; [Inderpreet Kambo](#), CEO, Improzo; [Moritz Kloss](#), SVP - Registry & Local Markets, Clariness; [Cyril Lelarge](#), Global Head of Insurance – Vice President, Financing, Treasury & Insurance Division, Sanofi; [Tim McCormick](#), Head of Global Commercialization, Dyne Therapeutics; [Pierre A. Morgon](#), CEO, MRGN Advisors, Venture Partner RocketBio Capital; [Tim Oldham](#), CEO & Managing Director, AdAlta; [Frank Pokrop](#), Director Regulatory Affairs, Werfen North America; [Negar Shahmoradi](#), CEO, ExoSphere; [Chris Whelan](#), Vice President of Product Development, ITL BioMedical.

It also reflects valuable input from Zurich colleagues, including: [Marta Alises de la Peña](#), Underwriter P&C Services, Automation & Pharma, Spain; [Max Bell](#), Manager Underwriting Liability, Sweden; [Vivien Bilquez](#), Global Head Cyber Resilience, ZRS; [Jelena Buha](#), Head of Life Sciences Product Development; [Yannick De Ryck](#), Manager Underwriting, Liability, Belux; [Rahel Dür](#), Head Underwriting, Liability Domestic & Multinational, Switzerland; [Louisa Frank](#), Senior Underwriter, Life Sciences, London; [Celine Garnier](#), Head of Underwriting Casualty, France; [James Hoang](#), AVP, Life Sciences Underwriter, West Region, U.S.; [Gian Iannella](#), Senior Risk Engineer, Life Sciences, ZRS; [Asha Patel](#), International Head of Life Sciences; [Leah Rastiello](#), Head of Life Sciences U.S. Middle Market.

About us

Zurich Insurance Group (Zurich) is a leading global multi-line insurer founded more than 150 years ago, which has grown into a business serving more than 82 million customers in more than 200 countries and territories, while delivering industry-leading total shareholder returns. Reflecting its purpose to ‘create a brighter future together,’ Zurich offers protection services that go beyond traditional insurance, to support its customers in building resilience. Since 2020, the Zurich Forest project has supported reforestation and biodiversity restoration in Brazil’s Atlantic Forest. The Group has more than 65,000 employees and is headquartered in Zurich, Switzerland. Zurich Insurance Group Ltd (ZURN), is listed on the SIX Swiss Exchange and has a level I American Depositary Receipt (ZURVY) program, which is traded over-the-counter on OTCQX. Further information is available at www.zurich.com.



Disclaimer:

This publication has been produced solely for informational purposes. The analysis contained and opinions expressed herein are based on numerous assumptions concerning anticipated results that are inherently subject to significant economic, competitive, and other uncertainties and contingencies. Different assumptions could result in materially different conclusions. All information contained in this publication has been compiled and obtained from sources believed to be reliable and credible but no representation or warranty, express or implied, is made by Zurich Insurance Group Ltd or any of its subsidiaries (the 'Group') as to their accuracy or completeness. Opinions expressed and analyses contained herein might differ from or be contrary to those expressed by other Group functions or contained in other documents of the Group, as a result of using different assumptions and/or criteria.

The Group may buy, sell, cover or otherwise change the nature, form or amount of its investments, including any investments identified in this publication, without further notice for any reason.

This publication is not intended to be legal, underwriting, financial investment or any other type of professional advice. No content in this publication constitutes a recommendation that any particular investment, security, transaction or investment strategy is suitable for any specific person. The content in this publication is not designed to meet any one's personal situation. The Group hereby disclaims any duty to update any information in this publication. Persons requiring advice should consult an independent adviser (the Group does not provide investment or personalized advice).

The Group disclaims any and all liability whatsoever resulting from the use of or reliance upon this publication. Certain statements in this publication are forward-looking statements, including, but not limited to, statements that are predictions of or indicate future events, trends, plans, developments or objectives. Undue reliance should not be placed on such statements because, by their nature, they are subject to known and unknown risks and uncertainties and can be affected by other factors that could cause actual results, developments and plans and objectives to differ materially from those expressed or implied in the forward-looking statements.

The subject matter of this publication is also not tied to any specific insurance product nor will it ensure coverage under any insurance policy.

This publication may not be reproduced either in whole, or in part on other communication channels, without prior written permission of Zurich Insurance Group Ltd, Mythenquai 2, 8002 Zurich, Switzerland. Neither Zurich Insurance Group Ltd nor any of its subsidiaries accept liability for any loss arising from the use or distribution of this publication. This publication is for distribution only under such circumstances as may be permitted by applicable law and regulations. This publication does not constitute an offer or an invitation for the sale or purchase of securities in any jurisdiction.