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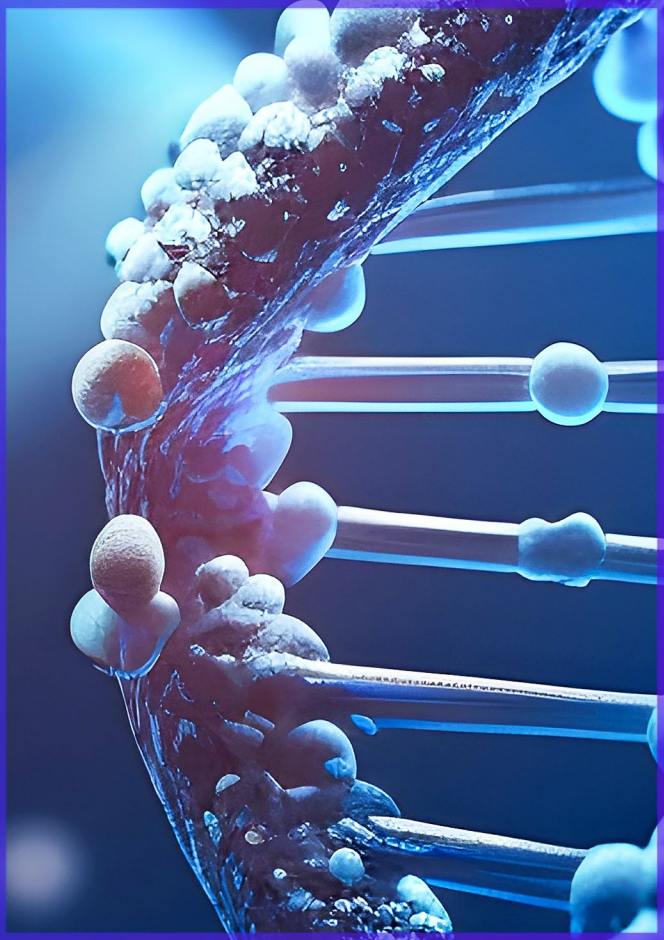
The future of life sciences



Pressing issues and critical imperatives that will shape the new model for the industry—the connected life sciences company.

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Foreword

In many ways, the response to the pandemic highlighted the life sciences industry at its best. The speed at which effective COVID-19 vaccines and treatments were identified, tested, developed, approved, and deployed on a global scale exemplifies the art of the possible when there is connectivity across all interests—public, industry, and government.

Today, however, public perception of life sciences organizations–and pharmaceutical companies in particular—has largely settled back to pre-pandemic levels. Patients, providers, and payers have come to expect organizations to innovate at a faster pace to meet emerging clinical needs, be transparent about drug pricing, and demonstrate a higher purpose than profits.

Achieving these goals is, of course, complicated by current economic and geopolitical volatility. Some companies are hunkering down to weather the storm. Others are rethinking their operating models to ensure they can meet stakeholder expectations, anticipate and withstand threats, and capitalize on data-driven insights to win in the marketplace.

In this paper, we examine the four primary signals of change impacting the industry now. We also identify four strategic imperatives to help organizations seize opportunities in the current environment. We believe those who make the most of these opportunities now will shape the future of life sciences.

What's inside

Signals of change

Pharmaceutical companies and medical device manufacturers are evolving to become integral parts of the healthcare value chain. This means that increased connectivity and communication are expected by all stakeholders from payers to providers to patients. Precision medicine, digital health products, and lifestyle tools that incorporate machine learning and artificial intelligence now represent a greater percentage of life sciences' companies' portfolios than they did even a few years ago. And while these connectivity trends promise to improve both the patient experience and clinical outcomes, they also increase the potential attack surface for cyber-criminals, requiring a much more robust approach to cybersecurity and privacy.

The following signals of change are the key drivers pushing the life sciences industry into the future and make up the most pressing issues for firms to address and understand.

Four signals of change

1 Precision medicine changes the game.

The life sciences industry has made major breakthroughs in precision medicine, which comprises treatments tailored to individuals' unique genetic profiles and, in some cases, engineers a therapy from a patient's own cells. Clinicians gain insight into molecular changes and personal characteristics that can underlie disease in an individual patient and, in some cases, offer cures for previously untreatable diseases.[1] In only the last two years, a number of new CAR-T drugs were approved by the U.S. FDA[2], and companies are racing to build out their manufacturing capacity to meet rapidly growing demand.

Key drivers of precision medicine are multiomic technologies, which, in the clinical setting, combine genomics, proteomics, and metabolomics-based diagnostics into one holistic picture of a patient, drawing on data from the whole body. While not all clinical diagnostics laboratories have the platforms to do this work, the industry is striving to overcome access challenges through meaningful connections between diagnostics and life science tool companies, testing centers, and reference labs.

Autologous therapies require a "made-to-order" supply chain, challenging pharma companies to implement new capabilities around scheduling, logistics, and patient data management. Going forward, the U.S. federal government, through an ambitious program led by the White House Office of Science and Technology Policy, has made a commitment to increasing the manufacturing scale of cell-based therapies 10-fold.[3]

Scaling precision medicine will require more than just increasing manufacturing capacity and furnishing clinical labs with new technologies. It requires connection and coordination across a variety of functions: The additional complexity of these therapies increases the onus on medical affairs resources to support Healthcare Providers (HCPs). And certain therapies require formal Risk Evaluation and Mitigation Strategies (REMS) programs.

No longer aspirational, precision medicine is real and is moving life sciences directly into the patient care continuum. As more therapies come to market, precision medicine manufacturers will be evaluated not only on the efficacy of their therapies, but also on their ability to seamlessly connect with HCPs and support them in care delivery. (See "Rethink the Supply Chain")

Global precision medicine market

2022: US$83.43 billion
2023: US$95 billion (CAGR of 13.9%)
2027: US$157.26 billion (projected)

Source: March 2023, Precision Medicine Global Market Report 2023, 6241913.

2 Digital health alters the landscape.

While the healthcare media has been talking about digital health for almost a decade, life sciences companies are only now breathing new life into existing technologies, and introducing new innovations at a breathtaking pace. Consumers expect better-connected healthcare experiences, which these technologies enable.

Historically, healthcare and life sciences have lagged banking and retail in offering engaging digital experiences. Enormous bandwidth, extensive smartphone adoption, and a high level of digital fluency are converging to fuel explosive growth in digital health offerings.

Generation X, Y, and Z workers collectively make up 75 percent of the workforce as the Baby Boom and earlier generations retire.[4] As digital natives, Generations Y and Z are the most likely to prefer the convenience of tailored connected experiences. With the burden of cost shifting to the individual, patients are taking more active roles in their own care with fitness devices, wellness apps, and easily accessible information online. Healthcare providers increasingly expect to have easy and convenient access to information and analysis and tools to help them connect with patients and improve their clinical outcomes. With many healthcare provider systems struggling for talent at every level and the cost of care

[1] Source: Jill Collins, "5 Leading Healthcare Trends For 2023," Forbes, February 16, 2023.
[2] Source: Alex Smith, "The promise of CAR-T therapy in cancer treatment," News Medical, March 21, 2023.
[3] Source: The White House Office of Science and Technology Policy, "Bold Goals for U.S. Biotechnology and Biomanufacturing," March 2023.
[4] Source: Michael Timmes, "Millennials And Gen Z: Now Is The Time To Reshape Businesses To Harness Their Power," Forbes, June 27, 2022.

becoming unsustainable, the potential for digital health tools to drive workflow efficiency and geographical reach is compelling.

Many well-funded start-ups and tech giants are bringing their know-how in connected infrastructure, advanced analytics, and user experience to this opportunity. Over the past five years, many medical device companies have rebranded themselves as "MedTech" companies. Pharmaceutical companies are investing and forging digital health partnerships to supplement and differentiate their core therapies and help improve quality of care and patient experience. Whether focused on the care provider or the patient, the plethora of innovative solutions being developed all have the following criteria in common: engaging user experiences, seamless integration, secure data, and real-time connectivity.

As of November 2022, the FDA had already authorized more than 520 medical artificial intelligence (AI) tools.[5] Over the next five years, we expect to see a broad spectrum of new digitally enabled care paradigms that improve access, enhance quality of care, and lower total cost. (See "Design Tech-Enabled, Customer-Centric Experiences")

Digital Health Market

2022: US$742.7 billion
2029: US$4.5 trillion (CAGR 29%+)

Source: December 2022, Digital Health Market Size, Share & Trends Analysis, 2029, FBI100227.

3 Artificial intelligence and machine learning are everywhere.

Artificial intelligence (AI) and machine learning (ML) have gone from novel experiments to the top of the C-suite agenda across most industries. Life sciences has been ahead of the pack, using AI in research and development and decision support long before the current excitement about AI.

Medical technology companies are leveraging ML in the development of devices and diagnostics, which has helped them realize accelerated cycle times, reduced costs, and improved quality. The resulting devices are perhaps the area of connected digital health with the most future growth potential. Further, using AI in the drug research process is allowing pharmaceutical companies to enhance discovery and innovation, connect with potential clinical trial participants worldwide, bring therapies to market faster, and shorten the time to realize return on investment (ROI) on new drugs.

Although the power of AI to detect patterns, synthesize structured and unstructured data, and predict patient outcomes is clear, it is important to consider the broader context. Getting full value out of AI tools requires robust data curation and an evolution of the extended operating model. In other words, "becoming digital" requires transformation beyond algorithms to include the operational processes and skills that can change "how work gets done."

It is important to note that, although technology advances such as AI and ML, as well as smart devices and digitalization of the supply chain, are critical to the growth and resiliency of the industry, this level of connectivity also introduces new security risks. There are both government- and industry-led efforts advocating for increased governance and oversight to ensure AI algorithms are unbiased, sensitive patient data is secure, and solutions don't create cybersecurity vulnerabilities. Although truly catastrophic medical device breaches have yet to occur, a September 2022 FBI report concluded that more than 50 percent of connected medical devices in hospitals have critical vulnerabilities.[6]

Worldwide, regulators expect industry to shore up the cybersecurity of AI-based devices. In December 2022, the U.S. FDA passed a law requiring medical device manufacturers to include cybersecurity plans along with their pre-market submissions.[7] Although the FDA has said it won't start issuing "refuse to accept" notices right away, the law will be in full force by October of this year—putting pressure on life sciences companies to prepare more robust cybersecurity plans to accompany new innovations. For "high-risk" AI systems that perform a safety function within medical devices, there are new certification procedures out of the European Union that encompass data governance, record keeping, transparency, accuracy, and security to earn a CE mark.[8] (See "Develop AI partnerships for faster time to market" and "Manage Cyber Risks")

AI's expected impact on global economy: US$15 trillion by 2030

Source: Andrew R. Chow and Billy Perrigo, The AI Arms Race is Changing Everything, Time, February 17. 2023

[5] Source: Rebecca Pifer, "How technology will shape healthcare in 2023," Healthcare Dive, January 17, 2023.

[6] Source: September 12, 2022, Unpatched and Outdated Medical Devices Provide Cyber Attack Opportunities.

[7] Source: U.S. Department of Health and Human Services, March 30, 2023, Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act Guidance for Industry and Food and Drug Administration Staff.

[8] Source: Elizabeth Anne Wright, Jessica Koffel, and Edward Turtle, "Five potential EU regulatory changes impacting the life sciences industry in 2023," European Pharmaceutical Review, February 7, 2023.

4 Critical risks persist: Supply chain disruption, cyber breaches, and counterfeiting.

The pandemic shed light on the vulnerability of the life sciences supply chain to disruption, which caused shortages of critical medications including cancer drugs, sterile injectable products, pain killers, and even over-the-counter cold and flu medicines. The number of drugs impacted by shortages reached a peak of 295 in late 2022.[9] Currently, nearly 80 percent of active pharmaceutical ingredients (API) manufacturers are located outside of the U.S.,[10] highlighting the U.S.'s reliance on foreign sources, which could pose a national security risk in the event of another crisis like the COVID-19 pandemic.

Drug shortages did not start with COVID-19. A 2019 study U.S. Senate study identified concerning gaps in supply chain insight and the pervasive inability to trace sources of supply. The ability to forecast and avoid or mitigate shortages depends on accurate data. Even long-term, loyal API suppliers can provide a false sense of security if many pharmaceutical manufacturers are using the same sources. If, for example, one of them is compromised, it may be challenging to find an alternative supplier. Therefore, greater transparency is needed into supplier operations, which will require substantial investments in data integration and data protection.

Life sciences supply chains are also vulnerable to both criminal cyber threats and counterfeit products, as highlighted by the Organisation for Economic Cooperation and Development (OECD) in a recent study.[11]

On the cyber front, patient data held by life sciences companies—as well as healthcare organizations—is particularly susceptible to cyber-theft, as this data purportedly sells on the black market for more than financial data. Compounding the problem is the increased dependence on foreign and domestic third-party suppliers with varying degrees of cyber maturity. If third parties are breached, their close connectivity to pharmaceutical companies could cause myriad impacts, such as:

1. Allowing threat actors to use the third-party as a gateway to the pharma company's systems to introduce a virus or access IP or sensitive patient data
2. Driving life sciences companies to divert business from a breached supplier, potentially impacting the flow of drug supply and demand
3. Causing long-term shortages of life-saving drugs if sole suppliers are compromised.

When it comes to counterfeiting, the OECD is encouraging the industry and regulators to improve control over product distribution.[12] In the early days of the pandemic, bad actors seized the opportunity of the huge spike in demand for drugs and medical equipment to market counterfeit and substandard products from medical devices to ineffective hand sanitizer. Looking forward, the issue of counterfeit products is likely to be most acute in emerging markets,[13] although it is a major concern in the U.S. as well. The final phase of the Drug Supply Chain Security Act (DSCSA), initially passed in the U.S. in 2013, goes into effect in November 2023[14] and seeks to ensure electronic records and traceability at the smallest saleable unit level. The data and insights generated by these efforts will provide valuable business insight well beyond regulatory compliance. (See "Manage Cyber Risks")

Prime cyber targets: Life Sciences & Healthcare

Price on the black market for a medical record

~$250 USD

Average financial impact of a security breach on a life sciences organization

$7.13 million USD

Source: Paul Nadrag, "Industry Voices—Forget credit card numbers. Medical records are the hottest items on the dark web," Fierce Healthcare, January 26, 2021.

[9] Source: Marina Kopf and Catie Beck, As cancer drug shortages grow, some doctors are forced to ration doses or delay care, NBC News, May 26, 2023.

[10] Source: Phillipe Drechsle, "Halting Europe's essential medicines manufacturing exodus," European Pharmaceutical Review, February 2, 2023.

[11,12] Source: OECD, April 21, 2020, Covid-19 crisis underscores need to address trade in fake pharmaceuticals, say OECD & EUIPO.

[13] Source: Hannah Balfour, "The latest on pharmaceutical counterfeiting," European Pharmaceutical Review, May 3, 2022.

[14] Source: U.S. Food and Drug Administration, "The DSCSA Implementation and Readiness Efforts for 2023 Virtual Public Meeting," December 7-8, 2022.

Four strategic imperatives to take now

Life sciences companies seeking to differentiate themselves from the competition would be wise to accelerate their journey toward increased connectivity. "Customers"–comprising payers, providers, patients, and, increasingly, employees–expect the same convenient, accessible, engaging experiences from interactions with life sciences companies that they have come to enjoy in other aspects of their lives. When it comes to artificial intelligence, the life sciences industry is ahead of most others, using the technology to enhance critical functions that help bring innovative, new drugs to market faster. The need to modernize and digitalize the supply chain became crystal clear during the pandemic, and life sciences companies are taking heed by fostering more digitalized processes, segmenting their supply chains to support new innovations like precision medicine, and endeavoring to stay ahead of potential disruptions. Finally, as mentioned above, upgrading and bolstering cybersecurity and privacy protection programs have taken on new weight in this age of connectivity, requiring life sciences companies to bring security teams to the table as early as possible in the development of these new connected capabilities.

To win in this new, highly connected healthcare marketplace, life sciences firms should act on the following four crucial strategic imperatives.

1 Design tech-enabled, customer-centric experiences

For many industries, "customer centricity" has been the driving force of business transformation. Retail, consumer goods, and banking have reimagined their businesses with "the customer at the center," digitalizing their operations and designing next-level connected experiences. Ironically, life sciences—the industry that adopted customer relationship management (CRM) technologies the earliest—is among the furthest behind in putting the customer at the center of its decision-making.

For most of the industry, the typical concept of "customer" doesn't fit. Still, there is a critical need to deliver intentional, connected interactions to meet the needs of the industry's three key stakeholders—payers, providers, and patients (and, to an extent, regulators). Delivering a great user experience requires listening to the unique needs of each stakeholder and delivering the appropriate products, services, and information in an accessible and sustainable way.

Life sciences stakeholders require differentiated experiences

01 Payers

- Does a new product significantly improve the economics with comparable outcomes?
- Does it offer significantly improved outcomes at a higher cost?
- Does the therapy lower the total cost of care?

02 Providers

- Do I believe my patient will have a better outcome and/or fewer side effects with this therapy?
- Is this treatment easier to deliver, sustain, and manage?

03 Patients

- Do I trust my doctor's advice?
- Will my insurance cover this therapy?
- What have I heard about this therapy from other sources?

Payer communications should be centered around value—not just for the payer, but for the patient and broader society. Value propositions for new products, including digital health solutions, should be supported by compelling data and insights. Payers are interested in understanding whether products represent improvements over existing offerings, how they will impact the length and severity of the disease burden, how closely costs are aligned with value, and whether there are new payment model options, such as outcomes-based agreements.

The Centers for Medicare and Medicaid (CMS) in the U.S. have announced three new potential drug payment models that will be tested by the CMS Innovation Center. All three models will impact the price of drugs for U.S. patients covered under Medicare Part D, Medicare Part B, and Medicaid. The three models include the "Medicare High-Value Drug List," which comprises a standardized list of high-value, low-cost generic drugs; "Cell & Gene Therapy Access," designed to provide Medicaid beneficiaries with access to high-cost cell and gene therapies to treat rare and severe diseases; and "Accelerating Clinical Evidence," which provides manufacturers with incentives to complete confirmatory studies for accelerated-approval drugs in a timelier fashion.[15]

[15] Source: S. Lawrence Kocot, Tracey McKutcheon, and Ross White, "CMS announces model concepts to reduce prescription drug costs," KPMG Center for Healthcare Regulatory Insights, February 17, 2023.

Healthcare providers (HCPs) are under significant stress due to: a hangover effect from the pandemic; significant staff shortages, particularly among nurses; inflation and supply chain disruptions; and increased demands from patients and healthcare systems. Life sciences companies should be mindful of these stressors and ensure that the products and services they offer lessen HCPs' burden instead of adding to it. Further, since 70 percent of today's HCPs are digital natives,[16] traditional sales representative and medical science liaison (MSL) support models are being used less often in favor of connected, ongoing digital interactions that can be delivered on providers' preferred timelines.

Therapeutic breakthroughs are of little value if the healthcare system does not have the capacity to deliver them, so life sciences companies should consider whether the solutions they bring to market ease or add to the strain on healthcare systems. For example, with HCPs considering practicing precision medicine, life sciences companies would be well advised to provide support for the complex companion diagnostics and risk evaluation/mitigation strategies involved, lest delivery requirements become so great a burden that treatments never reach the patients. Similarly, digital health solutions should streamline HCP care coordination and connectivity with patients, as opposed to functioning as bottlenecks.

Patients need to be at the center of all life sciences decisions—whether individuals are highly knowledgeable about their disease, thirsty for knowledge, or only focused on access to medication. Developing a patient journey map is an effective way to understand the patient experience. While much of that experience lies in the healthcare delivery domain, life sciences companies should position themselves as a conduit between healthcare providers and patients to help patients manage their health and ensure they have exceptional care experiences. For example, pharmaceutical companies can offer companion apps designed to improve patient health habits through services like gamification and real-time health indicator monitoring.

Further, increasingly sophisticated smart devices are empowering patients and caregivers to connect to each other to better manage chronic conditions and improve overall wellness. Smart watches have been prompting users to increase their physical activity for years. However, more recent improvements in sensor technology allow these devices to assess sleep quality, detect heartbeat irregularities, and monitor high blood pressure, with promising future features that include blood glucose testing.[17]

Connecting all these stakeholders, we see a trend toward platform-based ecosystems (PBE) that offer omni-channel experiences allowing real-time troubleshooting between manufacturers and clinicians, tailored content delivery, personalized products and services, tele-health services, and patient support through patient-advocacy groups. Specifically, omni-channel has expanded as customers expect touchpoints across social media, email, video, portals, chatbots, forums, phone, forms, and face-to-face encounters. Examples of transforming channels include AI-enabled chatbots that support patient screening prior to physician assessment, basic chat FAQ handling, and addressing procedure backlogs by separating care pathways—such as those related to COVID-19—from business as usual.

Don't forget the fourth stakeholder: Employees

The explosive growth in precision medicine, cell and gene therapy, biomanufacturing, AI, and data science is leading to a huge demand for skilled workers in these areas. However, there are currently an insufficient number of potential hires to meet this demand. In AI alone, there are currently 1,500–2,000 job openings across big pharma. Attracting and retaining these workers will require a laser focus on the employee value proposition, comprising a connected, digitally enabled enterprise; meaningful opportunities for training, reskilling, and advancement; commitment to environment, social, and governance (ESG); commitments to diversity, equity, and inclusion (DEI) and a strong corporate culture; and work/life balance, including the appropriate mix of virtual, hybrid, and in-office work models. Life sciences companies that lose the war for talent will likely find that both innovation and growth will be hindered in the long term.

Source: Brian Buntz, "What to expect from AI-enabled drug discovery in 2023," Drug Discovery & Development, December 13, 2022.

[16] Source: Jan van den Burg, "Addressing the Need for Digital Engagement with Healthcare Providers," The Journal of mHealth, January 22, 2020.

[17] Source: Mark Gurman, "Apple Makes Major Progress on No-Prick Blood Glucose Tracking for Its Watch," Bloomberg, February 22, 2023.

Case study: Pharma firm's physician-focused CX strategy drives ROI and organizational value

01 **Situation:** A global pharmaceutical leader in pain management wanted to transition its approach to meeting the needs of its healthcare provider (HCP) clients from product-centric to customer-centric. This required a holistic understanding of the existing experience for HCPs. The KPMG team helped the client gather and translate voice of customer (VoC) and voice of business (VoB) insights into the design and delivery of intentional HCP experiences.

02 **Approach:** Developed a holistic view of the current HCP experience by assessing what factors constitute a great customer experience, identifying existing pain points, and prioritizing areas of opportunity.

- Aligned on a CX vision, defined CX guiding principles, and leveraged current-state insights to identify strategic enablers of the future-state CX.
- Defined the processes to capture and operationalize customer feedback, quantify the impact of CX, embed CX excellence into the organization's operating model, and leverage the CX Playbook to pilot initiatives.

03 **Outcomes:** Clearly defined CX reporting and escalation processes with initial ROI modelling to determine the impact of the CX transition.

- An enhanced CX governance hybrid model that embeds CX across the organization
- A detailed content strategy that allows for personalization based on advanced customer profiling and tagging
- CX Measurement Program
- Go-to-customer process evaluation for optimized data collection
- Replicable best practices for optimizing CX to drive ROI

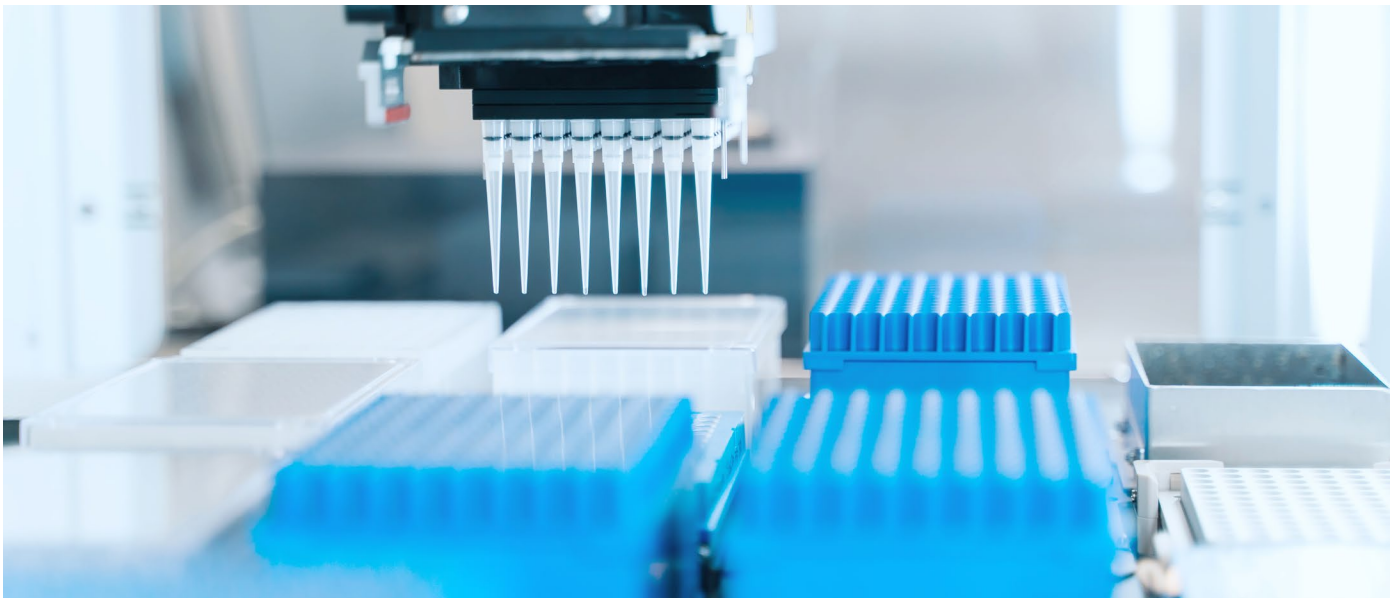
2 Develop AI partnerships for faster time to market

The timeline for maximizing the return on investment for new innovative products has shrunk dramatically. Consider the following comparison: when Roche received FDA approval for the first personalized oncology treatment, Herceptin, in 1998,[18] the company had nearly 10 years to maximize its returns on the product. It wasn't until 2010 that the second entrant in the class–GSK's Tykerb–was FDA approved.[19] In contrast, the March 2015 approval of BMS's checkpoint inhibitor Opdivo for non-small-cell lung cancer[20] was followed just six months later by a drug for the same indication, Merck's Keytruda.[21]

Clearly, in today's faster moving drug development environment, life sciences companies seeking competitive advantage need to be more decisive and nimbler than their competitors from drug development through to market entry. This is especially important in areas such as oncology, as treatments target increasingly stratified patient populations based on biomarker status. This means that companies are competing for the same small patient populations, not only from a commercial perspective, but also for recruitment into clinical trials, the latter of which requires connected technologies to make it possible to enroll participants from across the globe.

To this end, pharmaceutical companies are looking to a future in which drugs will be brought to market in a fraction of the current timeline, i.e., under a year as opposed to the 10 or more years to which the industry is accustomed.[22] Although the first AI-developed drug is still years away from approval, life sciences companies are forging partnerships with a range of AI companies, from focused startups to Big Tech. These firms can already help pharmaceutical companies predict which existing drugs will work best in a particular patient, identify the most appropriate candidates and optimized dosing for clinical trials,[23] unmask virus genomics, identify virus candidates prior to human testing, and rapidly analyze clinical trial data to support speed to market.[24]

This is not to say that other advanced technologies will be completely eclipsed by AI. Robotic automation and ML models will continue to be used for applications like identifying small cellular changes so that multiple drugs can be tested simultaneously on patients with treatment-resistant diseases, like rare cancers.[25] And we still do not see a future where laboratory-based science is completely eliminated.



[18] Source: Gina Kolata and Lawrence M. Fisher, "Drugs to Fight Breast Cancer Near Approval," The New York Times, September 3, 1998.

[19] Source: Press release: GSK's Tykerb® receives accelerated approval for first-line combination treatment of hormone receptor positive, HER2+/ErbB2+ metastatic breast cancer, GSK, January 29, 2010.

[20] Source: Press release: March 2015 approval of BMS's checkpoint inhibitor Opdivo for non-small cell lung cancer, BMS, October 9, 2015.

[21] Source: Press release: FDA Approves KEYTRUDA® (pembrolizumab) for the Treatment of Patients with Metastatic Non-Small Cell Lung Cancer Whose Tumors Express PD-L1 with Disease Progression On or After Platinum-Containing Chemotherapy, Merck, October 2, 2015.

[22] Source: Kevin Dunleavy, "2023 forecast: An 'inflection point' for biopharma, fueled by a flood of AI and machine learning products," FiercePharma, December 21, 2022.

[23] Source: Brian Buntz, "What to expect from AI-enabled drug discovery in 2023," Drug Discovery & Development, December 13, 2022.

[24] Source: "Life Sciences: Thriving in an AI World" (kpmg.us)

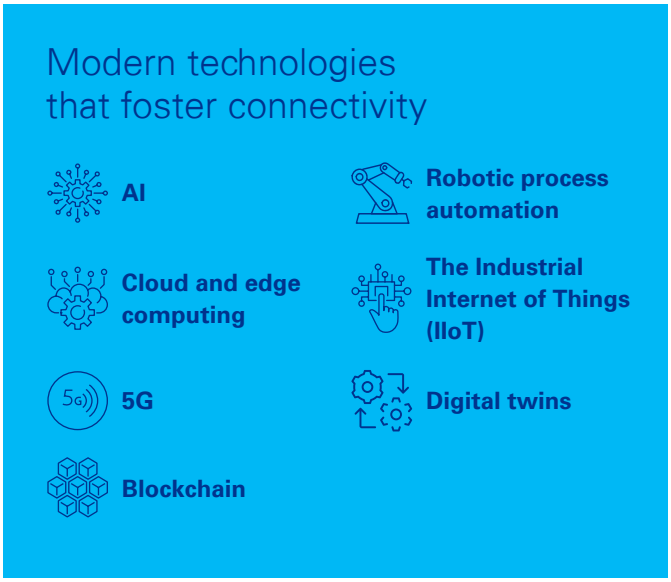
[25] Source: Will Douglas Heaven, "AI is dreaming up drugs that no one has ever seen. Now we've got to see if they work," MIT Technology Review, February 15, 2023.

3 Rethink the supply chain

From enabling a more connected, personalized customer experience, to supporting novel therapeutics and precision medicine, to finding ways to mitigate the risk of disruption, there are many reasons that transforming the supply chain has moved to the top of the life sciences agenda.

The connected supply chain: Life sciences companies that invest in transforming their supply chains should do so with the goal of creating a dynamic, interconnected healthcare ecosystem to enable a more personalized patient experience. In the future, we envision an autonomous supply chain that self-learns, adapts, and focuses on continuously meeting the needs of value-chain customers, patients, and caregivers, while driving cost efficiencies and top-line growth. Benefits may include autonomous and cognitive planning, predictive plant maintenance, automated re-stocking, and sensor-based replenishment and fulfillment to name a few examples.

Data will be central to future supply chains, giving leaders a 360-degree view of their customers and other value chain participants. Advanced data analytics should enable life sciences organizations to proactively forecast demand, access insights into usage patterns, ensure business continuity by anticipating supply chain risks, address supply chain fragmentation to ensure consistency and connectivity across sites, better collaborate with internal and external partners, track product movement, and monitor end-to-end supply chain quality.



Delivering on the promise of precision medicine: Pharmaceutical supply chain networks traditionally optimized for consistent, mass-market demand are increasingly being tasked with delivering precision medicine. This requires a shift to manufacturing low-volume, highly personalized, high-value products in a "make-to-order" versus "make-to-stock" model. To accommodate both traditional and precision models, supply chain strategies must evolve, and new capabilities must be developed and executed at speed. Precision medicine supply chains need to create a digitally enabled operating model to manage the complexities that come with connecting to the right patients to deliver the right drug therapy at the right time and place.

From planning to quality assurance to logistics, precision medicine therapeutics require not just a new set of processes, but also a new way of thinking. The very nature of precision medicine integrates the manufacturer into the care pathway and requires cross-functional connectivity and collaboration between the supply chain, commercial, and R&D organizations to align supply chain strategies around a deep understanding of patients and their health conditions.

Supply chain disruption: With today's increased cyber-threats from foreign actors and complicated geopolitical landscape, data sharing—between regulators and private industry—will be critical to creating a singular map of the entire pharmaceutical supply chain from API sources to distribution.[26] These collaborative efforts should allow for more effective predictive analyses and proactive identification and mitigation of vulnerabilities. Transparency is a critical first step, as exemplified by New Zealand's supply chain transparency model.[27] The country has a publicly available database that houses information on the API sources and manufacturing locations of all drugs on the market.

Life sciences organizations should rethink existing operating models to improve supply chain resilience and continuity. Is there sufficient diversification to withstand disruption? Is demand data informing network planning? In general, organizations need to be more agile so they can make rapid adjustments to production levels, shift to alternate suppliers, and reroute shipments, when necessary. More specifically, it is becoming increasingly critical to re-think supplier strategies and collaboration, diversify and segment the supplier base,

[26] Source: Chairman Gary Peters, "Short Supply: The Health and National Security Risks of Drug Shortages," United States Senate Committee on Homeland Security & Governmental Affairs, March 2023.

[27] Source: Westpac NZ Government Innovation Fund, "Supply Chain Transparency," February 2021.

strengthen connections with top suppliers, institute intelligent platforms to quickly onboard new partners, and explore reshoring and onshoring.

The security of the pharmaceutical supply chain is receiving major attention by governments worldwide. The U.S. government is putting programs in place to foster biomanufacturing pathways that center around cost-effective domestic API production, as detailed in the recent White House publication, "Bold Goals for U.S. Biotechnology and Biomanufacturing."[28] "Fit for purpose" use of data/insight and advanced technologies will be crucial for operations teams as they seek to optimize the efficiency and security of the supply chain from source to end consumer across a diverse portfolio of products and platforms

> By 2025, 45 percent of global organizations will be impacted by a supply chain attack.
>
> Source: Susan Moore, "7 Top Trends in Cybersecurity for 2022," Gartner, April 13, 2022

4 Manage Cyber Risks

Understand the risks associated with digital and emerging technologies. While digital and emerging technologies like cloud, the Industrial Internet of Things (IIoT), AI, and ML can create marked improvements in manufacturing productivity and visibility, they introduce a new spectrum of cybersecurity risks, particularly when it comes to intellectual property and trade secrets. Further, although connecting factories to other factories and to corporate information technology allow business analytics to drive actionable insights, these technological advances dramatically expose life sciences companies by exponentially increasing the attack surface. To get full value from advanced technologies, life sciences organizations should institute more robust access-management protocols when, for example, digital supply chain data is used in the operational technology (OT) environment; engage with procurement during initial vendor discussions to identify potential risks and collaborate on appropriate adjustments; and educate the business on the value of evaluating and pressure testing products early in the technology integration process so the cyber team can institute compensating controls.

Take responsibility for third-party risk. Since many life sciences suppliers are small businesses with a limited ability to invest in robust cybersecurity programs, pharmaceutical manufacturers should ensure they conduct a thorough due diligence process before partnering with new suppliers. Third party risk management (TPRM) programs should specify the controls, systems, platforms, and security protocols approved suppliers must have in place. As pharmaceutical companies seek to wrap their arms around the spectrum of potential third-party cybersecurity risks, they should home in on priority suppliers that sell critical components, raw materials, and substrates for their products. Further, if third parties are reluctant to commit to adopting robust cybersecurity protocols, then life sciences organizations should consider whether changing vendors is warranted.

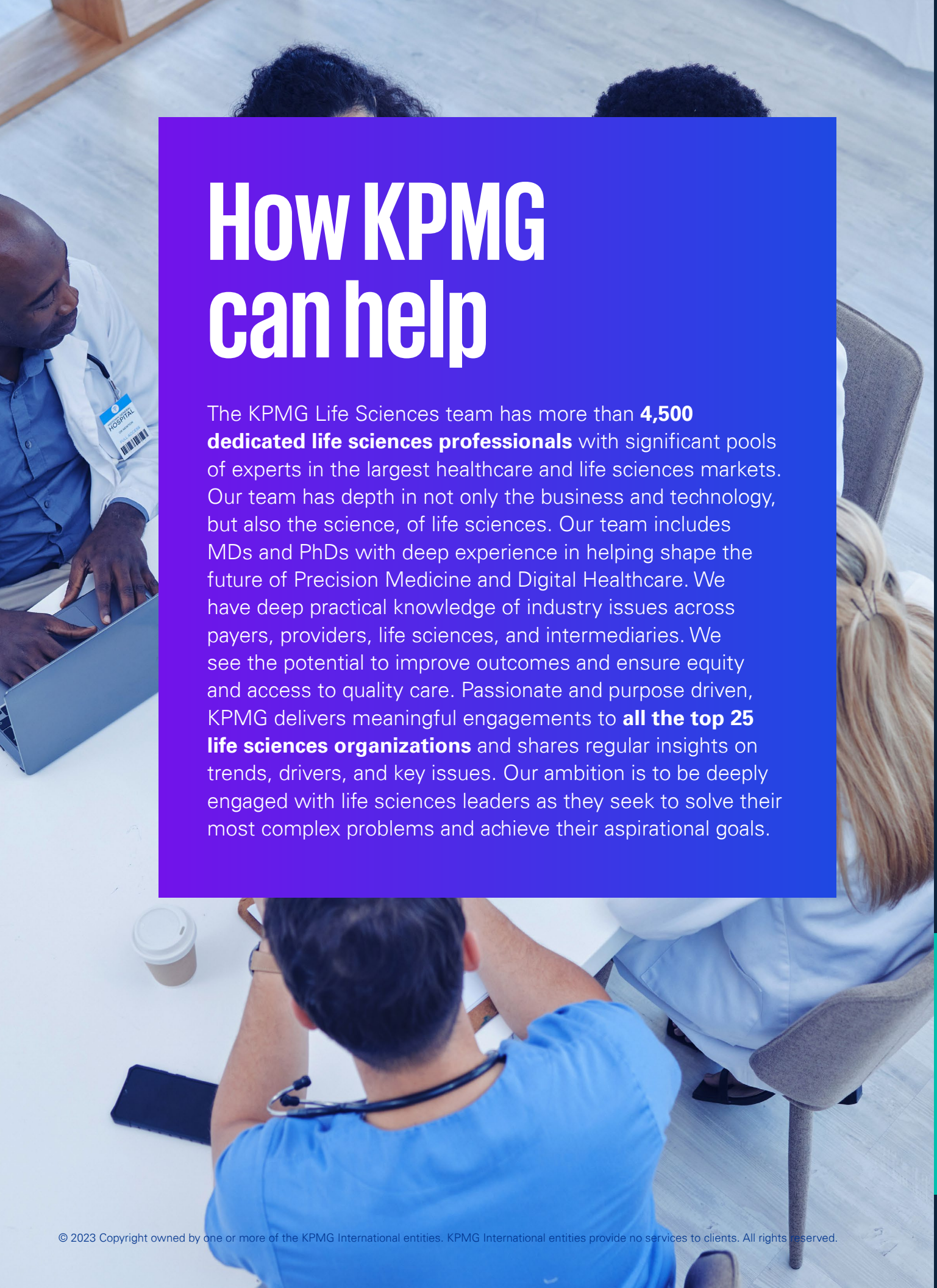
[28] Source: The White House Office of Science and Technology Policy, "Bold Goals for U.S. Biotechnology and Biomanufacturing," March 2023.

Conclusion

From precision medicine to digital health to AI, the prevailing trends in the life sciences industry signal a period of astonishing connectivity and innovation that are poised to change the way patients and their providers understand, manage, and even cure chronic illnesses. Organizations that analyze where they stand on the maturity curve in relation to these trends should be well prepared to act on the imperatives that will help them shape the future of life sciences.

That may mean developing tech-enabled connectivity between themselves and patients, providers, payers, and employees. Or it could entail accelerating time to market for breakthrough drugs through AI-enabled R&D, both in-person and virtual clinical trials, and new modes of commercialization. Connected to both the above endeavors will be the need to reimagine and, in some cases, segment the supply chain so that different types of drug manufacturing can proceed on parallel paths.

And, behind the scenes, life sciences cybersecurity and data privacy efforts must remain in lockstep with the pace of innovation. This should ensure that organizations can limit the funds spent on threat remediation that would be better spent on offering patients connected customer experiences, tighter control of their conditions, and, ultimately, a much better quality of life.



How KPMG can help

The KPMG Life Sciences team has more than **4,500 dedicated life sciences professionals** with significant pools of experts in the largest healthcare and life sciences markets. Our team has depth in not only the business and technology, but also the science, of life sciences. Our team includes MDs and PhDs with deep experience in helping shape the future of Precision Medicine and Digital Healthcare. We have deep practical knowledge of industry issues across payers, providers, life sciences, and intermediaries. We see the potential to improve outcomes and ensure equity and access to quality care. Passionate and purpose driven, KPMG delivers meaningful engagements to **all the top 25 life sciences organizations** and shares regular insights on trends, drivers, and key issues. Our ambition is to be deeply engaged with life sciences leaders as they seek to solve their most complex problems and achieve their aspirational goals.

KPMG member firms offer a wide spectrum of Connected Enterprise capabilities, detailed below, which can be applied across a life sciences enterprise. These connected capabilities can allow life sciences organizations to respond to the drivers outlined in this paper and take advantage of the opportunities represented by the recommended actions. KPMG professionals can help organizations evaluate their maturity across these connected capabilities, shape their transformation agenda and plans, and deploy improvements in the capabilities across the enterprise with the aim of providing the greatest value.

Our "Connected Enterprise" capabilities include:

Insight-driven strategies and actions:
We can help life sciences companies harness data and advanced analytics to gain real-time understanding of their customers and businesses to shape integrated business decisions.

Aligned and empowered workforce:
The Connected Enterprise's agile organizational structure allows life sciences companies to embrace change and recruit and attract the right talent at the right time. Once they are part of the organization, individuals understand and are committed to the mission and understand their roles and responsibilities.

Experience-centricity by design:
Successful life sciences companies design consistent, effortless experiences, supporting customer value propositions to deliver on key business objectives.

Digitally enabled technology architecture:
Intelligent and agile services, technologies, and platforms help life sciences companies meet patient needs with solutions that are secure, scalable, and cost-effective.

Responsive operations and supply chain:
Life sciences companies that operate their businesses and supply chains with efficiency and agility meet customers' rising expectations consistently and profitably. Companies can effectively integrate front-, middle-, and back-office operations to capture competitive advantage.

An integrated partner and alliance ecosystem:
The Connected Enterprise engages, integrates, and manages third parties to increase speed to market, reduce costs, mitigate risk, and close capability gaps.

Transformation never stops. Neither do we.

At KPMG we believe that business transformation is too good an opportunity to miss. Combining the right tech and the best processes with people whose insight is as broad as it is deep, are essential ingredients to successfully transform. KPMG has worked at the heart of global businesses for many decades, helping our clients realize the full potential of their people and technology and working together to achieve real-world outcomes. Because when people and technology are in harmony great things happen.

Making a world of difference:

KPMG people can make all the difference on your transformation journey. Together we can help you to orient your business around the customer, optimize functions for a new era, manage enterprise risk and regulation for a safer future, rise to a new level of value creation, and create an environment for managing ongoing change.

Authors

Alison Little
Global Leader, Connected Enterprise for Life Sciences, KPMG International and Principal, KPMG in the US
jalittle@kpmg.com

Mike Ricci
Managing Director and US Leader, Connected Enterprise for Life Sciences KPMG in the US
michaelricci@kpmg.com

Life Sciences Network contacts:

Adrian Griffiths
Partner and Life Sciences Leader in EMA, KPMG in the UK
Adrian.Griffiths@kpmg.co.uk

Peter Liddell
Partner and Life Sciences Leader in ASPAC, KPMG in Australia
pliddell@kpmg.com.au

Kristin Pothier
Global Lead, Healthcare and Life Sciences Deals Advisory, KPMG International and Principal, Global and US National Healthcare and Life Sciences Strategy Leader
kpothier@kpmg.com

Larry Raff
Global Head of Life Sciences, KPMG International and Senior Partner, KPMG in the US
lraff@kpmg.com

Steve Sapletal
Principal and Life Sciences Leader in US, KPMG in the US
ssapletal@kpmg.com

Colin Yu
Partner and Life Sciences Leader, KPMG China
cz.yu@kpmg.com

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