LEK™

Japan Edition

The Biopharma Imperative (Japan Edition)

L.E.K. Insights on Innovation, Growth, and Competitive Advantage

Foreword

This collection brings together a focused selection of L.E.K. Consulting's perspectives on the forces reshaping life sciences and biopharma. Across research, development and commercialization, companies are operating in a more demanding environment defined by rising scientific complexity, tighter capital discipline, increasing competition and higher expectation from patients regulators and investors. The articles in this booklet examine those pressures from multiple angles and offer practical guidance for leaders seeking to make better strategic choices in a period of rapid change.

Our insights highlight several of the issues now most relevant to industry decision makers. They look at how companies can raise R&D productivity and sharpen portfolio choices, how they can capture the next wave of revenue growth from both existing and future assets, how they can translate strategy into commercial impact through more targeted go-to-market models. They also address the operational and strategic implications of emerging technologies, which has the potential to reshape how innovation is developed, launched and scaled. Across these topics, a consistent message emerges: competitive advantage will increasingly belong to organisations that combine scientific ambition with disciplined decision—making and operational focus.

At L.E.K., we help clients interpret change and convert it into decisive action. By distilling market signals, emerging opportunities and the pressure points that matter most, this collection offers leaders a clear view of what it takes to steer successfully through a period of structural shifts.

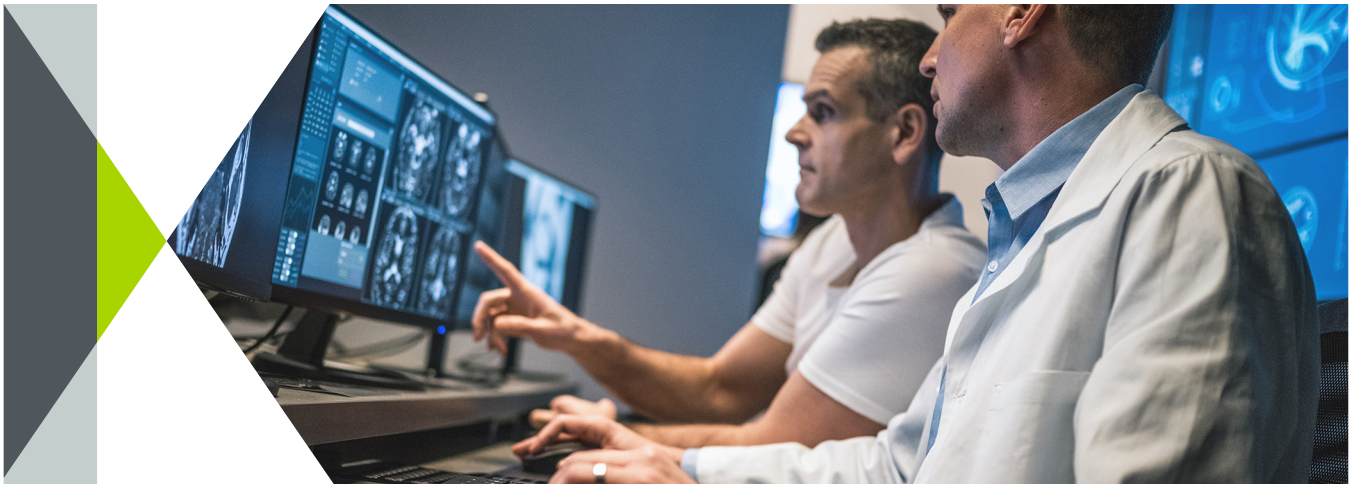
Helen Chen
Global Sector Co-Head for Healthcare
Head of Asia Healthcare

Patrick Branch
Partner and Head of Tokyo office

Contents

About L.E.K. Consulting

L.E.K. Consulting is a premier global strategy consulting firm that partners with clients to solve their most critical business challenges and deliver high-impact outcomes. We bring deep industry expertise and rigorous, evidence-based insight to global corporations, growth companies, and private equity investors, helping them turn strategy into action. Founded more than 40 years ago, L.E.K. now operates across 27 offices worldwide. Learn more at **lek.com**.



EXECUTIVE INSIGHTS

Quantum Computing in Biopharma: Future Prospects and Strategic Insights

Quantum computing — what can it do for biopharma?

Rising clinical thresholds, the growing need for complex drug modalities and extended development timelines are making novel molecular entities (NMEs) increasingly difficult to develop. The annual R&D spend per NME, from discovery to launch, is estimated at $1.5 billion-$3.5 billion,[1] with annual R&D spend across the top 15 pharmaceutical companies (PharmaCos) growing roughly one and a half times since 2010 and projected to reach up to $18 billion by 2030.[2] Compounding this challenge, biopharma faces mounting pressure to accelerate innovation due to compressed product life cycles under the Inflation Reduction Act, and more than $200 billion in biopharma revenue is potentially at risk from loss of exclusivity by 2030.[3]

Could technological advances in artificial intelligence (AI) or quantum computing (QC) help address biopharma's throughput and spending challenges? AI has seen explosive growth in the past five years, and QC is following suit, as evidenced by increasing publication trends (see Figure 1). QC leverages principles from quantum mechanics to process information exponentially faster than classical computing. The potential for QC and AI to revolutionize the biopharma industry together by offering unprecedented computational power and problem-solving capabilities is enormous.

Figure 1
PubMed mentions of QC and AI (October 2000-2024)

*Includes search terms "quantum computation," "quantum computational," "quantum computer," "quantum computers" or "quantum computing" anywhere in the article
Note: QC=quantum computing; AI=artificial intelligence
Source: PubMed; L.E.K. research and analysis

To date, AI has seen significantly more investment due to its relative maturity, accessibility and market readiness. However, AI's gain is not QC's loss. QC and AI are complementary. QC can enable faster training of and inference from AI systems and brings an ability to process data in ways classical computers cannot. Through this it can unlock computational possibilities that are currently unobtainable.

Investment in QC has grown globally. Cumulative investment in the QC market is fueled by both the public and private sectors, totaling around $8 billion in the U.S., approximately $15 billion in China and about $14.3 billion across the U.K., France and Germany through 2024.[4] While private investments in quantum technology have declined from COVID-19 highs due to tightening funding environments and higher interest rates ($2.3 billion worldwide private investment in 2022 versus around $1.3 billion in 2023),[5] quantum intellectual property (IP) development over the past 10 years has increased significantly.

Beyond growth in investment and IP development, the capacity of quantum computers via qubits — the fundamental units of quantum information — has expanded dramatically. IBM progressed from a 5-qubit processor in 2016 to a 433-qubit processor in 2022, with plans to achieve more than 1,000 qubits in 2025.[6] This advancement extends across the industry, with

companies such as Google, IonQ and QuEra also demonstrating remarkable improvements in qubit capacity.[7]

What is quantum computing?

Quantum computing (QC) harnesses the principles of quantum mechanics to solve complex calculations beyond the capabilities of classical computers, representing a branch within the broader field of quantum science.

QC compared to quantum science and quantum mechanics

QC applies principles from quantum mechanics to process information in fundamentally new ways, enabling exponentially faster problem-solving for certain tasks compared to classical computers. It is an interdisciplinary field within quantum science, which broadly studies quantum phenomena across physics, chemistry and engineering.

Quantum interference

A fundamental principle that enables QC to be successful is quantum interference, which emerges due to the wavelike nature of quantum particles. By combining the probability amplitudes of these waves to create patterns, quantum computers can process information uniquely.

Key aspects of quantum interference include:

- Computational parallelism: Enables simultaneous evaluation of multiple solutions, making certain problems tractable
- Precision enhancement: Amplifies correct solutions while suppressing errors, improving quantum sensing accuracy
- Coherent control: Facilitates precise manipulation of quantum states for advanced quantum logic and circuits

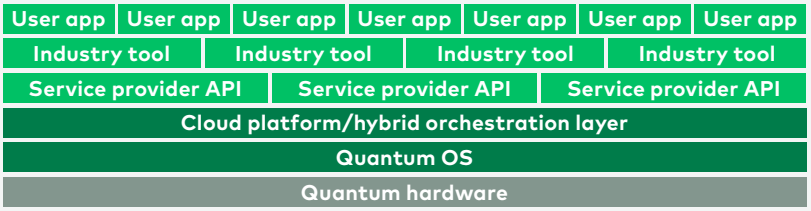
Quantum interference underpins quantum advantage across computing, communication and sensing, offering new insights into information processing.

Quantum stack

Integrating quantum interference into quantum networking requires a structured quantum stack, which defines the hardware and software layers essential for scalable QC.

(continued)

Quantum stack overview



- Production grade is **reliable**, **flexible** and **secure**
- Integrates **seamlessly** with customer's production workflow
- **Rapid** customer development and deployment

Note: API=application programming interface; OS=operating system
Source: L.E.K. research and analysis

Quantum networking

Quantum networking connects quantum computers using quantum mechanics to surpass classical communication. By transmitting quantum states instead of binary data, these networks enable secure, high-performance distributed computing.

Potential benefits to biopharma from quantum networking include:

- Secure transmission of clinical trial data/real-world data
- Interoperability across pharma entities for collaboration

Pioneering QC applications in drug discovery and clinical trials

QC has the potential to revolutionize the biopharma value chain by overcoming classical computing's limitations in handling complex datasets and simulations (see Figure 2). The most impactful areas are expected to be in drug discovery and research. QC directly addresses the inherent limitations of classical computing in computer-aided drug design because molecules operate by quantum rules — their behavior fundamentally involves dealing with exponentially large-state spaces, which classical systems can only approximate at great computational cost. Quantum-enhanced generative models can also explore vast chemical spaces faster than classical techniques can, leading to the discovery of more novel drug candidates previously inaccessible for many years with classical computing, reducing R&D timelines, lowering costs and improving success rates.

In clinical design and operations, QC can enhance patient stratification and trial optimization by analyzing complex genomic, biomarker and real-world patient data. Quantum machine learning can identify optimal patient subgroups for personalized medicine, reducing trial failures and improving efficacy predictions. Quantum optimization can also refine trial site selection and adaptive trial designs, increasing efficiency and reducing costs.

Beyond R&D, QC can drive efficiencies across other areas of the value chain. QC can help optimize manufacturing and supply chain processes, improve predictive analytics for commercial functions, and increase efficiency of operations to improve sustainability.

While still evolving, QC's ability to tackle biopharma's most computationally challenging problems could lead to groundbreaking efficiencies and transformative advancements.

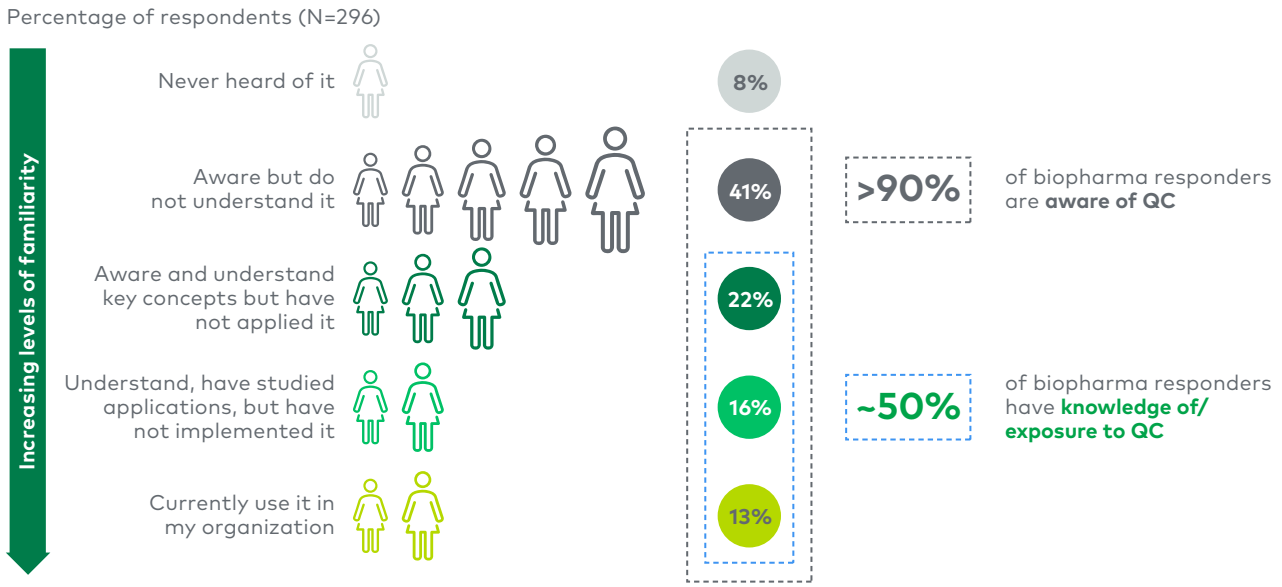
Figure 2
Six areas of biopharma capabilities for quantum technology use cases

Note: ADME=absorption, distribution, metabolism and excretion; DMPK=drug metabolism and pharmacokinetics; LCM=life cycle management
Source: L.E.K. research and analysis

Emerging interest is driving QC into a pre-utility phase in biopharma

With these high-value QC use cases, it is not a surprise that an L.E.K. Consulting survey of roughly 300 U.S. and EU biopharma stakeholders indicated that over 90% of them are aware of QC and its potential. Additionally, about 50% of respondents, representing 110 unique biopharma companies, stated they understand key concepts and have had exposure to QC or have experience studying its applications (see Figure 3).

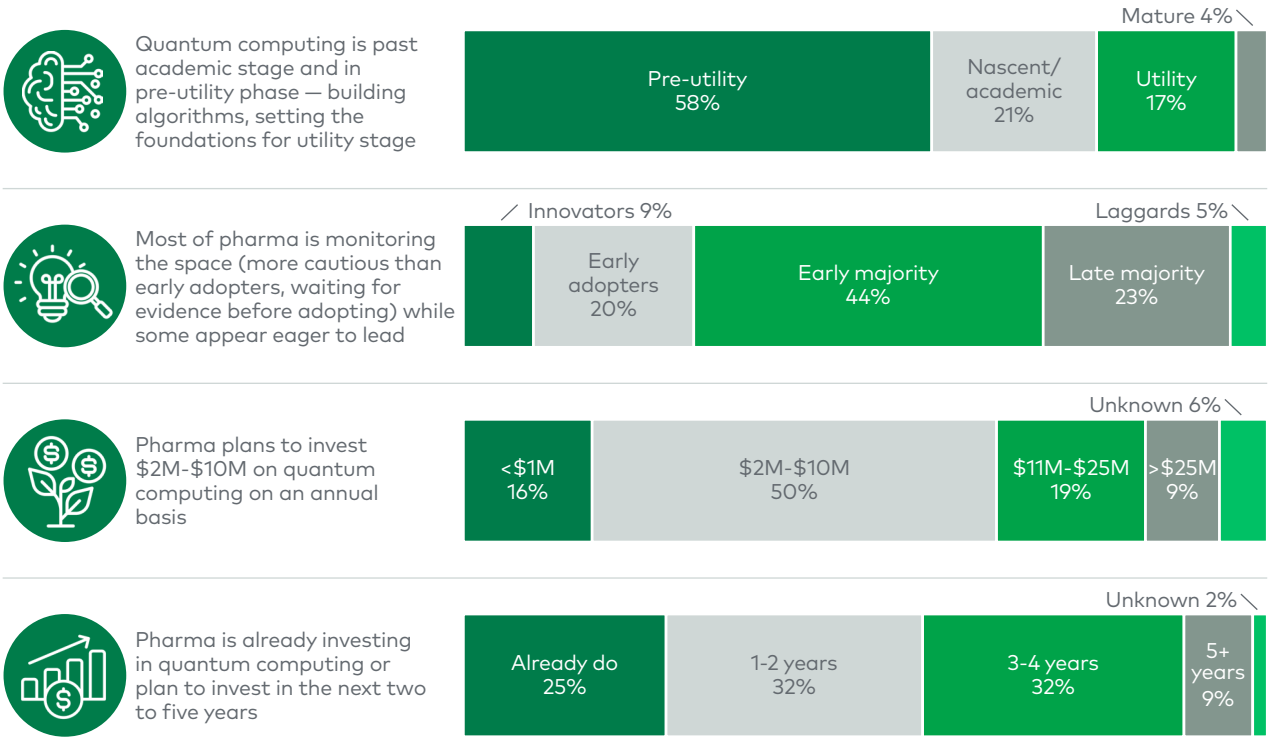
Figure 3
Biopharma familiarity with QC



Note: QC=quantum computing
Source: L.E.K. survey of U.S. and EU biopharma stakeholders across R&D, commercial, manufacturing, medical and business development functions (L.E.K. biopharma quantum survey)

Biopharma participants suggest that QC is making significant early strides, transitioning from academic research to a specialist, pre-utility phase.[8] In this phase, there is a focus on developing practical algorithms and applications to lay groundwork to drive commercial value. Approximately 44% of biopharma stakeholders are in the "early majority," awaiting evidence before integrating QC, while 30% are innovators or early adopters eager to drive innovation. Investment in QC is set to grow, with 50% of PharmaCos planning annual budgets of $2 million-$10 million and 20% expecting $11 million-$25 million over the next five years. This reflects a growing recognition of QC's benefits (see Figure 4).

Figure 4
Biopharma expects to develop quantum capabilities by leveraging partnerships



Source: L.E.K. biopharma quantum survey

PharmaCos are experimenting with QC applications across the pharmaceutical value chain, first focusing on drug discovery and clinical trials (see Figure 5).

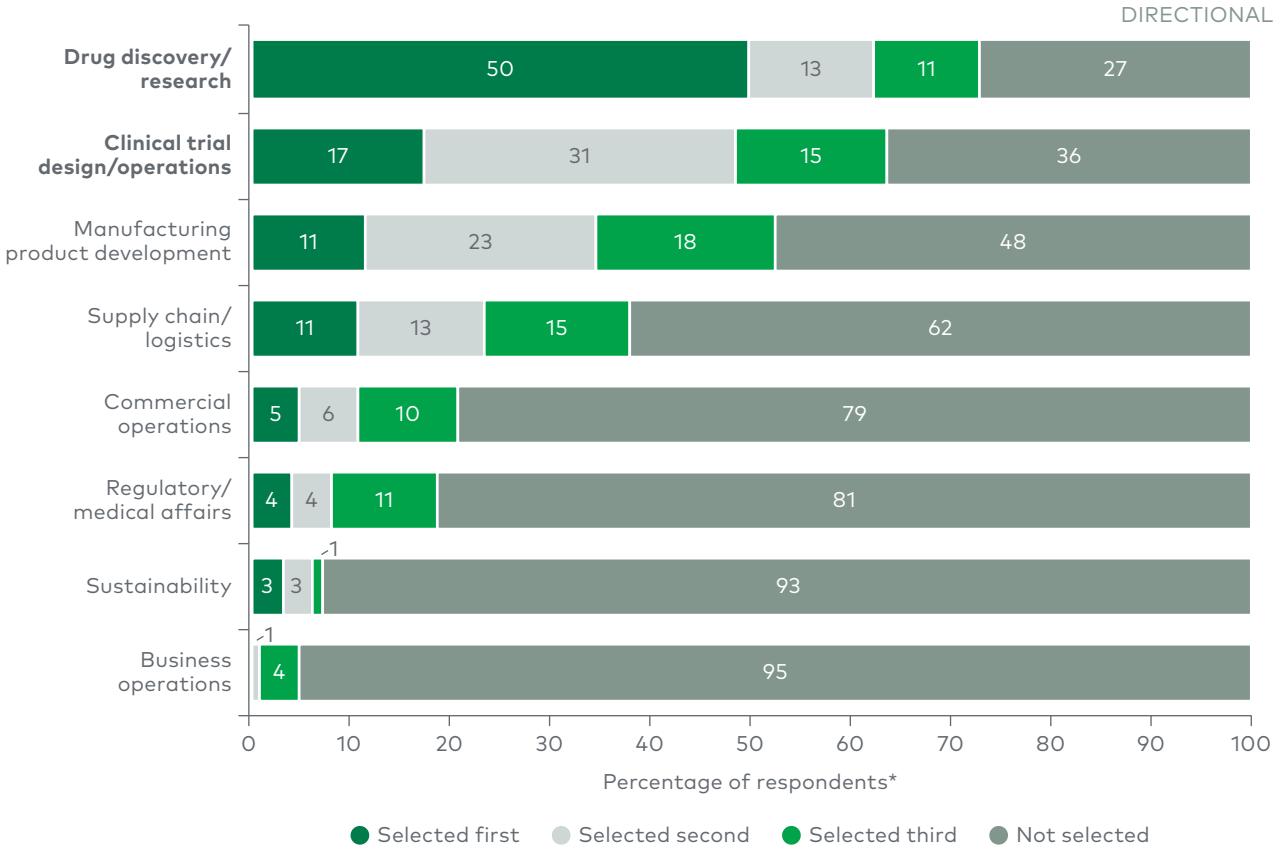
Expansion of capabilities within sustainability, commercial operations, manufacturing and product development may also be enabled by QC technology. However, the exact impact and best-suited QC modalities for each use case are still being defined.

Recent key advances in QC lead to the need for biopharmas to engage with quantum processing units and enablers

Given the excitement and investment in the space, the landscape of QC is quickly evolving, marked by significant technological advances across the ecosystem. Major milestones from large tech players in 2024 include:

- IBM's launch of Quantum Heron, its most advanced quantum computer with 156 logical qubits[9]
- Google Quantum AI's new Willow chip, which enables exponential error reduction and enhanced performance in superconducting quantum systems

Figure 5
QC benefits across the value chain



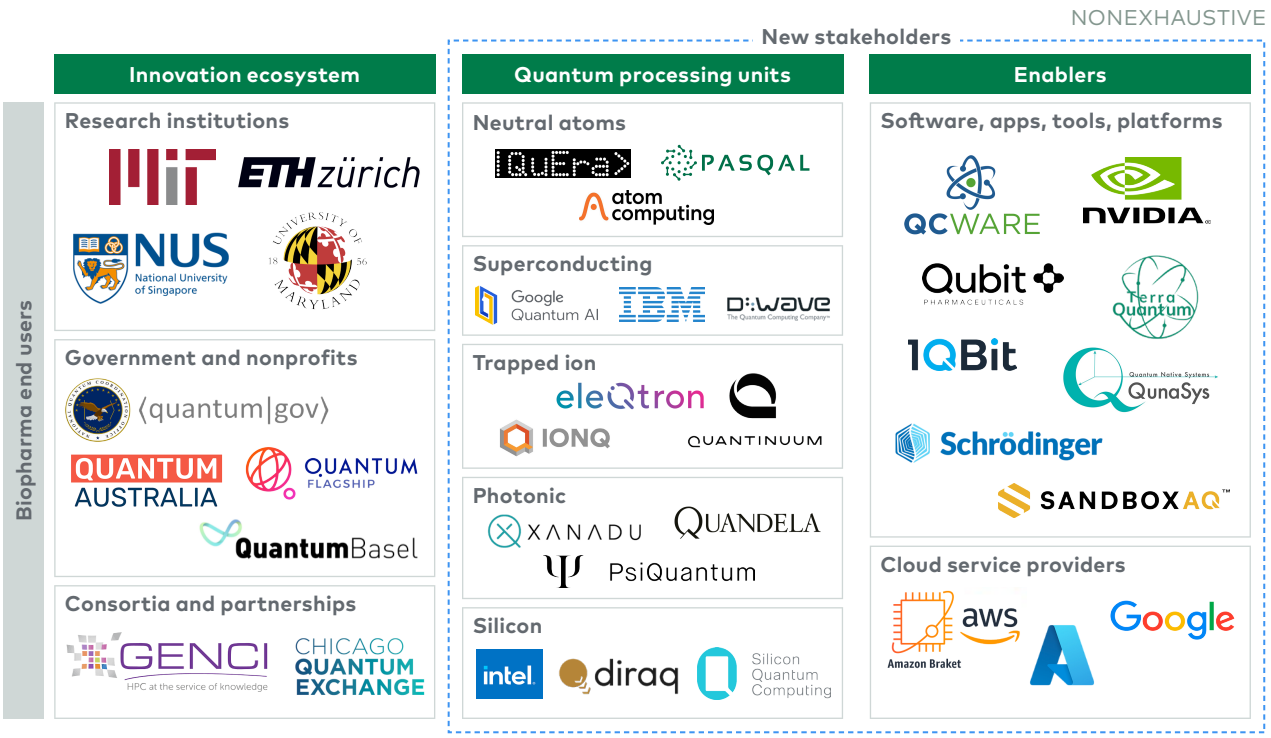
*Survey questions: Where along the value chain do you see the greatest benefit of leveraging quantum computing in your organization? (select up to three in order of importance) Where along the value chain do you believe lie the biggest hurdles or challenges to adopting quantum computing in your organization? (select up to three in order of importance)
Note: Other challenges include insufficient quantum processing units/software stack, information technology and financial investment; QC=quantum computing
Source: L.E.K. biopharma quantum survey

Pure-play QC players have also made substantial strides, including:

- IonQ's Tempo quantum computer achieving 99.9% 2-qubit gate fidelity, positioning the company as a leader in trapped-ion technology
- Quantinuum's achievement of 12 logical qubits with its system model H2, a threefold advance over previous models

With these advancements in QC, two key stakeholder groups are emerging: the quantum processing unit providers and the enablers that facilitate access to QC. These stakeholders drive momentum and funding for QC. Like engaging with AI players, biopharma stakeholders should proactively collaborate with these diverse QC ecosystem players to fully harness these technologies and stay competitive in this evolving field (see Figure 6).

Figure 6
Growing number of new stakeholders in the evolving QC ecosystem



Note: QC=quantum computing
Source: L.E.K. research and analysis

Strategic partnerships needed to compete within a specialized market

Due to the growing complexity of the QC ecosystem, successful integration of workflows depends on building capabilities through strategic partnerships. Notable collaborations include:

- **IBM Quantum with GSK, Moderna and AstraZeneca:** Optimizing messenger RNA research and clinical data imputation using IBM's Quantum Heron and Condor processors
- **Google Quantum with Boehringer Ingelheim:** Exploring molecular simulation algorithms to aid in drug discovery with Google's Sycamore processor

Partnerships underscore the industry's commitment to integrating QC into pharmaceutical workflows, highlighting the collaborative efforts needed to overcome technical challenges and achieve utility (see Figure 7). Building in-house expertise and fostering external partnerships will be crucial to leverage necessary talent quickly. Companies that act swiftly will gain a competitive advantage, positioning themselves as leaders in this emerging field.

Figure 7
Major pharma companies have established relationships with QC organizations

NONEXHAUSTIVE

Note: QC=quantum computing
Source: Company press releases

The near-term impact: Intersection of QC, AI and classical computing

The most promising near-term advancement is combining QC with AI and classical computing in hybrid workflows. This combination leverages the strengths of all technologies, enabling more accurate simulations of complex systems, enhanced machine learning models and improved process optimization for larger datasets at significantly faster speeds. More than 70% of biopharma stakeholders anticipate that QC will augment classical computing and AI, offering more precise and efficient solutions, especially in navigating breakthroughs in drug discovery and development.

For example, Qubit Pharmaceuticals leverages QC for advanced target characterization and molecular dynamics within small-molecule drug discovery while simultaneously utilizing AI-driven generative modeling, virtual screening and predictive analytics. Additionally, Qubit has partnered with Pasqal to leverage both classical computing and QC to model proteins, NMEs and water molecules at high levels of accuracy.

Further, IonQ's collaboration with AstraZeneca includes the creation of an applications development center within AstraZeneca's BioVentureHub to advance QC for drug discovery and development. In addition, IonQ has collaborated with NVIDIA, AstraZeneca and AWS to advance drug development using computational tools — achieving 20x speedups in molecular simulations versus AWS' previous implementation — and paving the way for quantum-accelerated biopharma and materials science.

Further advancements, including running AI on quantum computers, are exciting but not expected to be seen for longer periods of time.

The path forward for QC in biopharma

The integration of QC into the pharmaceutical industry holds immense potential to revolutionize drug discovery and clinical trials. While QC represents a longer-term (five-to-10-year) strategic investment requiring scalable hardware, advanced error mitigation and correction, and specialized algorithms, the opportunities it presents are significant. QC can enhance predictive analytics, optimize clinical trial designs and expedite the discovery of novel therapies, ultimately accelerating drug development and reducing time to market for new treatments.

Despite current challenges such as talent acquisition and a steep learning curve, strategic investments, partnerships and AI integration can enable the industry to harness QC's transformative power. Continued collaboration and innovation will be crucial.

Biopharma stakeholders should address the following key questions to effectively utilize QC's benefits and remain competitive:

- Does my organization have a clear plan on how to experiment with and deploy QC within key functions, especially R&D?
- Within R&D, are there specific use cases that would be most appropriate for QC? On what basis should these be identified?
- How do I balance external partnerships and collaborations alongside internal capabilities to accelerate realization of the potential from QC in R&D?
- To implement QC effectively, what key internal operating model requirements must be met, specifically regarding talent, hardware, data infrastructure and software?
- To what extent should QC be leveraged alongside AI? Is there a benefit from integrating early (e.g., hybrid workflows) or operating independently prior to integration? What is the optimum roadmap for my organization?

By considering these questions and investing strategically in QC, the pharmaceutical industry can harness new opportunities and achieve remarkable progress across drug discovery, clinical development and operation, the supply chain, and manufacturing.

Note: L.E.K. conducted a number of interviews with both AI and pharma experts including Google, IONQ, Qubit and others to help triangulate and inform the findings.

For more information, please **contact us**.

Endnotes

[1]Taylor & Francis Online, "A novel perspective on pharmaceutical R&D costs: opportunities for reductions." https://www.tandfonline.com/doi/full/10.1080/14737167.2022.1987219#abstract

[2]L.E.K. analysis of Evaluate Pharma.

[3]PharmaVoice.com, "How steep is pharma's patent cliff?" https://www.pharmavoice.com/news/pharma-patent-cliff-Merck-Keytruda-Pfizer-Seagen-Humira/652914/

[4]Statista.com, "Quantum technology historic public funding as of 2022, by country." https://www.statista.com/statistics/1319273/planned-public-funding-quantum-computing-country/

[5]CSIS, "Innovation Lightbulb: Private Investment in Quantum Technology." https://www.csis.org/analysis/innovation-lightbulb-private-investment-quantum-technology

[6]IBM.com, "Expanding the IBM Quantum roadmap to anticipate the future of quantum-centric supercomputing." https://www.ibm.com/quantum/blog/ibm-quantum-roadmap-2025

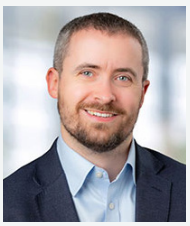
[7]PatentPC.com, "How Fast Are Quantum Computers Getting? Performance Growth Stats Over the Years." https://patentpc.com/blog/how-fast-are-quantum-computers-getting-performance-growth-stats-over-the-years

[8]LEK.com, "Quantum Computing — New Paradigm or False Dawn?" https://www.lek.com/insights/ei/quantum-computing-new-paradigm-or-false-dawn

[9]Livescience.com, "IBM's newest 156-qubit quantum chip can run 50 times faster than its predecessor — equipping it for scientific research." https://www.livescience.com/technology/computing/ibms-newest-156-qubit-quantum-processor-runs-50-times-faster-than-its-predecessor-equipping-it-for-scientific-research

About the Authors

Delia Silva
Delia Silva is a Managing Director and Partner in L.E.K. Consulting's Boston office. Delia specializes in the Life Sciences and Pharma practice, with a focus on growth strategy and O&P. Her expertise spans many therapeutic areas and product modalities, including neuroscience, rare disease and infectious disease. Delia has supported clients through organizational scale-ups and design, launch planning, portfolio growth strategy, market entry assessments, due diligence, commercial strategy and GTM modeling.



Stuart Robertson
Stuart Robertson is a Partner in L.E.K. Consulting's London office and is the firm's Disruptive Analytics Lead. Stuart focuses primarily on the transport industry, covering operators and equipment and infrastructure suppliers. With particular expertise in the interaction between the public and private sectors, he has deep experience in transport infrastructure, pricing and revenue management, transport technologies, consumer engagement, and litigation and dispute resolution.

Sej Brar
Sej Brar is a Partner in L.E.K. Consulting's London office and a member of the Life Sciences and Pharma practice. Sej focuses on enabling biopharma and medical devices companies to deliver projects in corporate strategy, investment advisory and O&P, with expertise in franchise/product strategy, growth strategy, business development/transaction support, commercial excellence and organizational effectiveness.

Ethan Hellberg
Ethan Hellberg is a Consultant in L.E.K. Consulting's Boston office dedicated to the Life Sciences practice. Ethan has extensive experience across infectious disease, ophthalmology, neuroscience and oncology. He advises clients on a broad range of issues, including growth strategy, forecasting and valuation, portfolio prioritization, M&A, and due diligence.

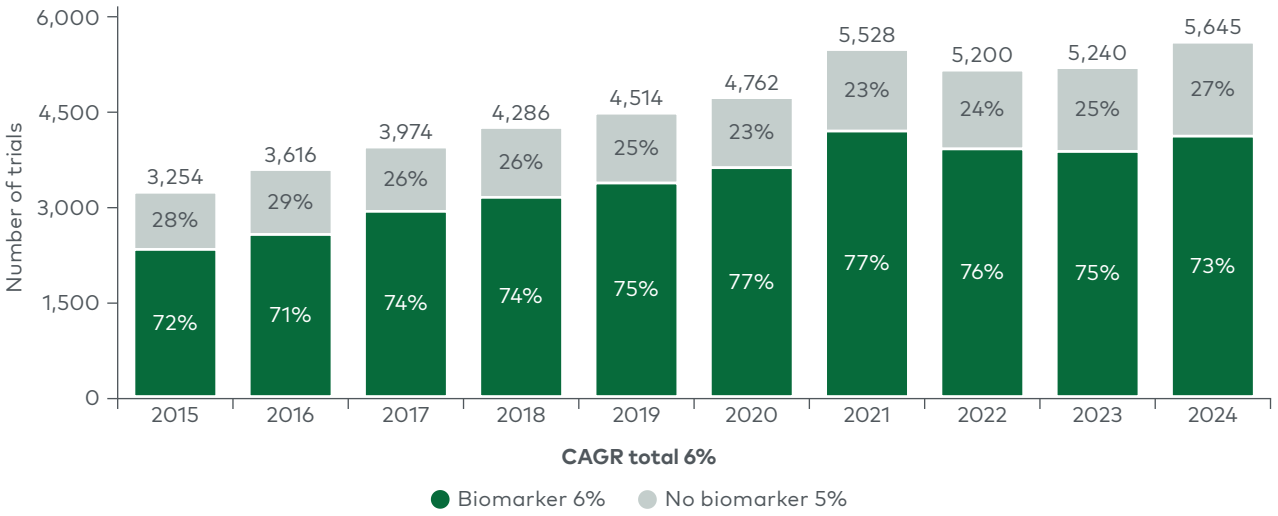
EXECUTIVE INSIGHTS

Launching Novel CDx for Oncology: 7 Strategies for Biopharma Companies

Early genetic screening, targeted therapies and other precision medicine (PM) offerings in recent years have transformed care and significantly improved outcomes for oncology patients while delivering substantial value creation that drives increased pharma investment. PM leverages biomarker (BM) strategies to successfully develop, commercialize and differentiate therapeutics by improving R&D efficiency and optionality, supporting regulatory filings, and enabling smaller and more productive clinical trials. To achieve commercial success for an oncology PM therapeutic, however, biopharma companies must also accomplish the effective launch of a companion diagnostic (CDx) that identifies eligible patients and informs ongoing treatment decisions.

Over the past decade, the proportion of oncology trials using BMs has steadily tracked overall trial growth except for a slight post-pandemic decline amid tough U.S. and Chinese macroeconomic conditions. In 2024, three-fourths of all oncology clinical trials included the use of a BM (see Figure 1).

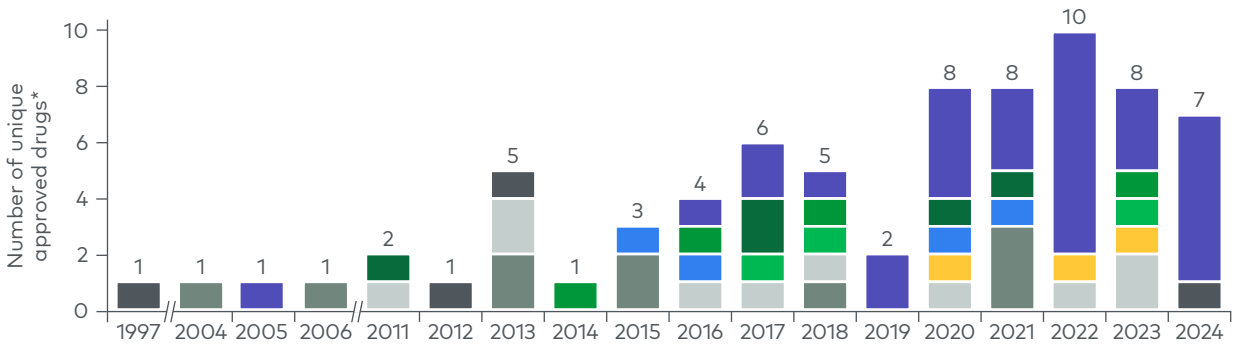
Figure 1
Biomarker use in oncology trials, by year (2015-24)



Note: CAGR=compound annual growth rate
Source: TrialTrove; L.E.K. research and analysis

Rising BM use in trials has predictably had an impact on product launches, with the U.S. Food and Drug Administration (FDA) approving seven to 10 oncology therapeutics with CDx annually since 2020 — and with an increasing focus on novel biomarkers rather than traditional ones (see Figure 2).

Figure 2
FDA-approved therapeutics with CDx, including novel oncological therapies (1997-2024)



	1997	2004	2005	2006	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Cumulative therapies	1	2	3	4	6	7	12	13	16	20	26	31	33	41	49	59	67	74
Cumulative indications**	1	2	3	4	7	8	14	15	20	26	32	42	49	69	82	100	116	132

ALK BRAF BRCA EGFR FLT3 HER2 PD-L1 RET Other***

*Count of unique companion diagnostic-therapy combination approvals
**Indication refers to broad cancer type and sample type (e.g., breast cancer or non-small cell lung cancer) rather than particular label indication, which may include factors such as age, line of therapy, other mutations or other patient/cancer characteristics
***Includes the following types of mutations or mutations in the following genes/gene classes: BCR-ABL, C-kit, dMMR, ESR1, EZH2, FGFR2, FGFR3, FOLR1, HLA, IDH1, IDH2, Ki-67, KRAS, MET, NTRK, PDGFRA, PI3KCA, ROS1, TP53
Note: FDA=Food & Drug Administration
Source: FDA list of approved companion diagnostic devices (accessed February 2025); L.E.K. research and analysis

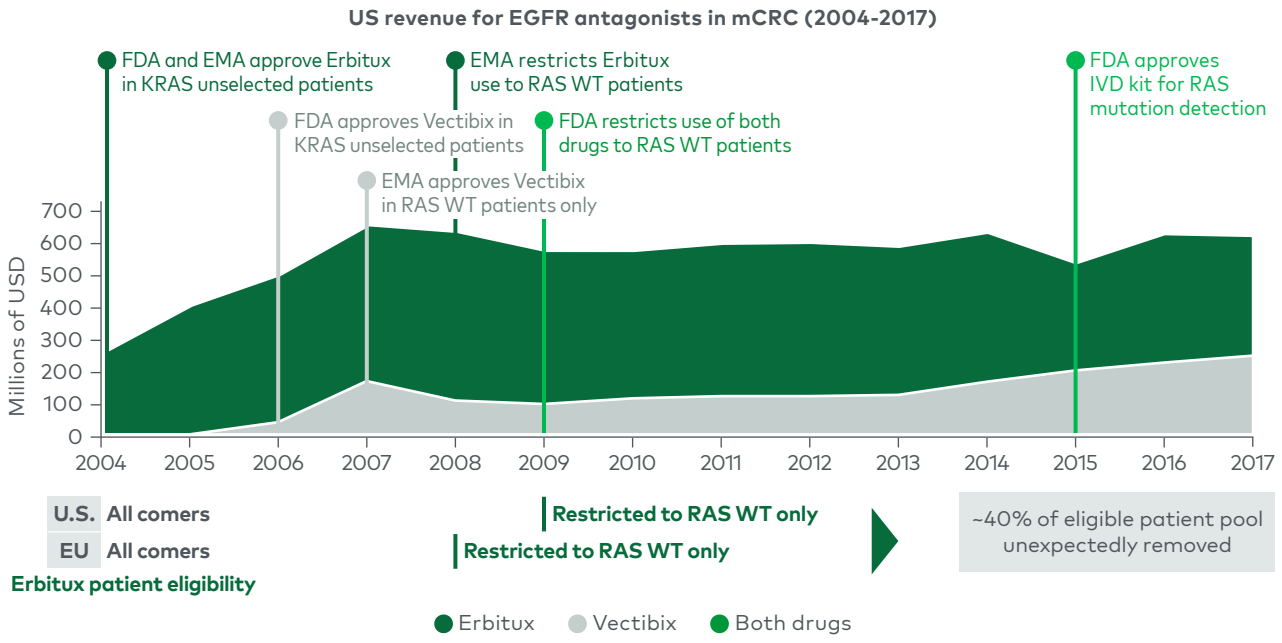
Given the advantages of launching a diagnostic (Dx) — and the many complexities involved — preparing to launch novel CDx in concert with the therapy itself is imperative. In working with biopharma companies to launch novel CDx for oncology therapeutics, L.E.K. Consulting has uncovered seven critical strategies to share.

1. Adopt an 'opt out' mentality.

Leaders in PM follow an opt-out approach: All new oncology programs start with a Dx component, consistently assessing needs and planning for them across the development life cycle. This mindset leads PM leaders to integrate Dx and therapeutic development through established Dx resources and capabilities. All-comers therapeutics can still be pursued, but this requires an active decision by leadership supported by clinical evidence.

The alternative "opt in" mindset — the assumption that an all-comers approach will work and BM development will follow — limits a company's ability to build Dx capabilities and processes, and disadvantages PM programs that require early and frequent collaboration between Dx and therapeutic teams. For example, in 2009 (after five years on the market), the FDA restricted Lilly's EGFR inhibitor Erbitux to KRAS wild-type patients (who comprise approximately 60% of colorectal cancers) based on data from a competitor's product. U.S. market adoption stagnated after the decision, and the cumulative revenue impact over the next decade reached hundreds of millions of dollars (see Figure 3).

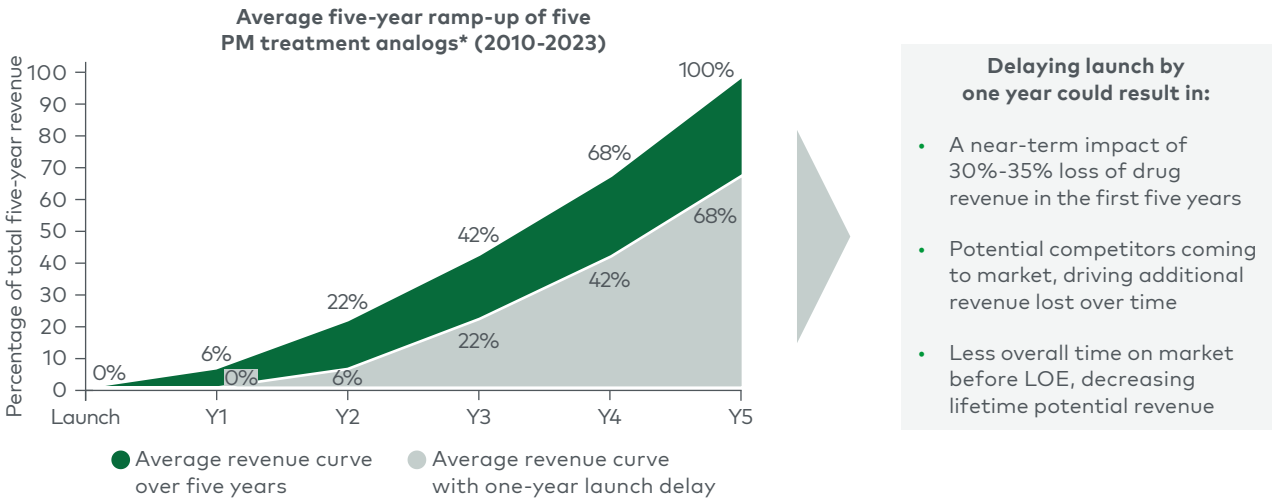
Figure 3
Case study: Erbitux in mCRC



Note: mCRC=metastatic colorectal cancer; FDA=Food & Drug Administration; EMA=European Medicines Agency; IVD=in vitro diagnostic
Source: Evaluate Pharma; FDA list of approved companion diagnostic devices; L.E.K. research and analysis

Indeed, historical averages suggest a one-year delay in launching a BM-directed drug could reduce the initial five-year cumulative revenues by 30%-35%, owing to the typical adoption ramp curve (Figure 4).

Figure 4
Revenue loss from launch delays in PM technology



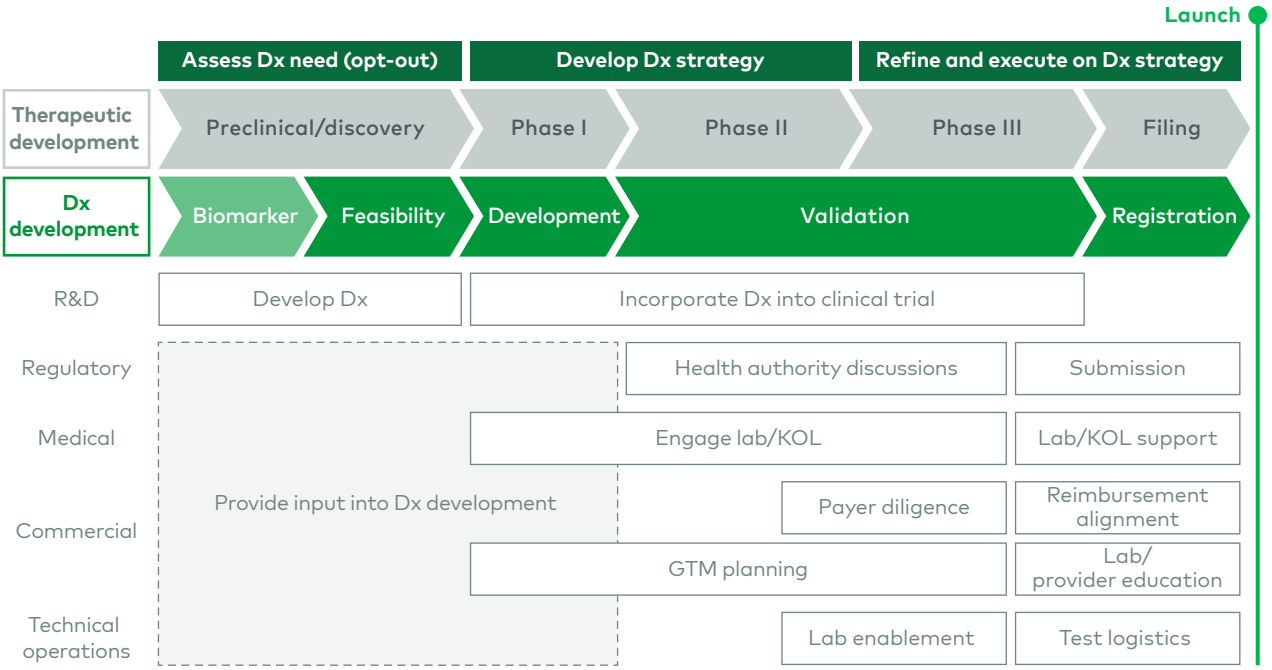
*Includes Lynparza (2015-20), Rydapt (2017-22), Vitrakvi (2020-25F), Xalkori (2011-16), Zelboraf (2011-16)
Note: PM=precision medicine; LOE=loss of exclusivity
Source: L.E.K. interviews, research and analysis; Evaluate Pharma

Dx leaders codify the opt-out mentality in their processes, requiring teams to consider Dx needs early and to continually reassess those needs throughout development — whether by adopting a proactive approach to BM discovery through comprehensive patient profiling, banking multiple bio samples and so forth; focusing on post hoc analysis to identify predictors of response; or continually optimizing by, for example, tracking molecular origins of resistance. Furthermore, they tend to organize personnel in ways that encourage dedicated focus on individual programs while maintaining centralized leadership and integrating functions and programs at the therapeutic area and enterprise levels. Embedding strategic Dx planning throughout the program drives preemptive discussion and collaboration and ensures organizationwide sharing of lessons and resources, thus increasing efficiency and institutional knowledge.

2. Start planning for CDx launch in preclinical development.

A successful Dx launch requires multifunctional support across the value chain, and companies should start planning as early as the preclinical stage. Dx development occurs parallel to therapeutic development, with key Dx launch readiness activities stage-gated by both therapeutic and Dx milestones (see Figure 5).

Figure 5
Key Dx activities by function throughout the value chain



Note: Dx=diagnostic; KOL=key opinion leader; GTM=go-to-market
Source: L.E.K. research and analysis

To drive efficiencies, R&D must incorporate cross-functional input from commercial and medical functions during preclinical development. This approach ensures that Dx addresses patient needs and that clinical endpoints support its commercialization. Commercial and medical readiness activities should focus on understanding and educating the market, developing a Dx-specific strategy and preparing the organization for Dx launch.

3. Address the unique operational challenges of adding CDx.

Companies must consider how the specific complexities of a Dx test should inform the commercial and go-to-market strategy. During development, an individual Dx faces specific commercial obstacles that differ from challenges with therapeutics — surrounding the analyte, such as protein or DNA; the testing technology, e.g., PCR or NGS; validated instrumentation such as 510(k) clearance; and the testing format, whether an in vitro diagnostic (IVD) or a laboratory-developed test (LDT) (see Figure 6). Pharma companies looking to develop a therapeutic with CDx should first understand the BM requirements for their indication. Next steps include determining whether they can support a decentralized testing model and building a robust payer strategy.

Figure 6
Considerations for Dx approach

Dx technology		
Immunohistochemistry	**PCR**	**NGS**
• Test for single protein marker/receptor • Lowest cost and fastest turnaround • Less-straightforward interpretation	• Targeted test for one to four or more genes • Medium cost and moderate turnaround • Binary result with minimal interpretation	• Broad test for 10+ genes • High cost and lengthy turnaround • Binary result with minimal interpretation

Test modality		
	In vitro diagnostic kit	**Laboratory-developed test**
Test content	**Lower complexity** Typically single analyte	**Higher complexity** Typically complex, multi-analyte
Flexibility	**Locked in** Assay is designed, developed and regulated "as is"	**Evolutionary** Can evolve as needed
Location	**Decentralized** Can be run on IVD-cleared instruments in any CLIA lab	**Centralized, single site** Site-specific assays that require extensive validation to set up
Regulatory	**FDA-regulated/CE marked (EU)** Highly regulated content/devices	**FDA (+ CE mark, until recently) not required** May operate without regulatory clearance in U.S.
Access	**Higher rate of successful reimbursement** Often inherently better trusted to provide reliable results	**Lower rates of successful reimbursement** Reimbursement may depend on the reputation of the lab

Note: Dx=diagnostic; PCR=polymerase chain reaction; NGS=next-generation sequencing; IVD=in vitro diagnostic; CLIA=Clinical Laboratory Improvement Amendments; FDA=Food & Drug Administration; EU=European Union
Source: L.E.K. research and analysis

For example, LDTs may face reimbursement issues and require extensive lab validation, yet in the U.S. they often are faster to market and support more numerous and complex BMs because regulatory clearance is not required. Alternatively, IVD kits are FDA regulated, do not support all analytes and face greater competition from other diagnostics, but any CLIA laboratory with the correct instrumentation can run them — and typically enjoy a higher rate of reimbursement. For some companies, launching and supporting, for example, both LDT and IVD versions of the same Dx adds further complexity and requires additional readiness planning and resources.

4. Build a separate Dx launch strategy.

PM leaders treat Dx launch and therapeutic launch as interconnected yet distinct processes, with different stakeholders and challenges. Because key CDx stakeholders are a diverse group that shares little overlap with therapeutics stakeholders — think pathologists versus prescribing oncologists — targeted outreach is the best way to build awareness and willingness to prescribe. Given the intricacy involved in effective testing (particularly with novel CDx), a launch strategy needs to address the necessary instrumentation or other technology; consider laboratory needs, such as LDT support and sample prep guidance; and take market access into account.

Ideally, companies should consider the interplay between Dx and therapeutic launch strategies when planning for launch. For instance, typical sales incentive structures based on the number of patients on a therapy may be unsuitable in a PM setting, where the number of patients screened for a therapy is potentially a more meaningful measure. Developing a Dx-specific launch strategy can enable widespread adoption and enhance the overall PM opportunity.

5. Leverage partner capabilities purposefully while developing internal expertise.

When empowering critical partners (internal and external) for their expertise in developing, filing and manufacturing Dx tests, biopharma companies should be intentional about expanding specific activities and achieving sufficient oversight. Depending on the organization's size and capabilities, tasks such as BM selection, test development, study result interpretation or Dx sales may be beyond internal capacity. On the other hand, activities that require close interaction with the therapeutic team (e.g., sample collection and banking) or that are strategic in nature (e.g., market access) may be better managed in-house.

Even when leveraging a partner, launching a Dx requires dedicated internal resources with Dx-specific expertise across the value chain. Specialists who understand both Dx and PM therapeutics are rare and in high demand, requiring early planning and strong retention efforts. Finding the right balance between external expertise and internal foundational knowledge will be crucial to overseeing Dx partners, who may lack the broader in-house context or may not be incentivized to optimize tests or fully invest in launch activities (see Figure 7).

Figure 7
Key development activities ownership: Dx partner vs. pharmacy team

Dx launch

Dx development	Biomarker discovery	Biomarker feasibility	Biomarker development	Clinical validation	Filing	Commercial-ization
Activities owned or co-owned by Dx partner or pharma	Dx partner vetting and selection	Determination of detection method	Test development	Stakeholder training/education and test marketing	Filing for regulatory approval	
Expected role of Dx partner	• Engage with pharma and provide relevant information	• Determine detection method for use in Dx test	• Develop pilot assay and validate assay in clinical studies	• Support IVD kit field sales and stakeholder training/education	• File for Dx regulatory approval according to strategy set by pharma	
Expected role of pharma Dx team	• Engage Dx partner and gather relevant input from functions	• Determine detection method for use in Dx test/coordinate supply chain	• Define strategy and manage sample collection, banking and analysis	• Drive stakeholder awareness and manage marketing for LDT	• Drive global regulatory filing strategy and ensure alignment with Dx partner	
Expected role of pharma Tx team	• Provide input on Dx partner selection process	• No role	• Run clinical trials	• Tx sales representatives to share basic Dx test information during detailing of oncologists • Tx MSLs to address basic Dx questions if pathologists/oncologists contact pharma	• In market, Tx FTEs to support local filing as needed	

Note: Dx=diagnostic; IVD=in vitro diagnostic; LDT=laboratory-developed test; Tx=treatment; MSL=medical science liaison; FTE=full-time equivalent
Source: L.E.K. research and analysis

Scaling a Dx ecosystem appropriately can prevent delays in Dx launch planning and execution. Overall, costs incurred when empowering an external partner or developing in-house talent should be viewed as imperative for product success — a strategic investment into that asset franchise rather than just a necessary evil to be minimized.

6. Infuse dedicated Dx expertise throughout the organization.

Successful Dx launch planning requires an environment where Dx needs are supported, integrated across functions, scaled appropriately and prioritized across the value chain. Essential strategies such as adopting an opt-out Dx mindset and investing in early Dx development and launch planning (as discussed earlier) can be up against an inertial mindset around an all-comers approach. Overcoming pushback from various levels of the company and other headwinds — such as the high costs associated with Dx development and the relatively low direct revenue from Dx versus therapeutic investment — will require unequivocal and sustained support from leadership. In prioritizing Dx investment, savvy PM leaders must also

expedite alignment of activities and incentives across Dx and therapeutic teams to generate the cross-functional collaboration needed for a successful launch.

7. Incorporate a thoughtful LCM strategy.

To become leaders in the PM space, companies must adopt a dedicated life cycle management (LCM) strategy that supports continuous evolution and improvement. Early and proactive planning is crucial for a biopharma company's ability to create sustained impact of BM oncology therapies, but Dx strategy does not end at launch. A meaningful LCM strategy will empower the organization to anticipate next-generation technologies, expanding indications, real-world evidence planning and continuous engagement with key stakeholders — all of which advances the ultimate goal of maximizing therapeutic potential.

L.E.K. continuously monitors pressing issues throughout the biopharma industry landscape in order to deliver innovative lessons, cutting-edge insights and actionable support and strategies that enhance our clients' ability to achieve their goals.

For more information, or to explore strategies that can unlock new possibilities for your biopharma business, please contact us.

About the Authors

Aditya Natarajan
Aditya Natarajan is a Managing Director and Partner in L.E.K. Consulting's Boston office and a member of the Life Sciences practice. Aditya has led engagements across most therapeutic areas in the pharma, diagnostics and research tools space. With a focus on oncology, he advises both large and emerging biopharma clients on critical strategic and operational issues, including product and franchise strategy, portfolio optimization, M&A, and commercial planning.

Peter Rosenorn
Peter Rosenorn is a Managing Director and Partner in L.E.K. Consulting's Boston office. Peter specializes in the Life Sciences & Pharma sector with a focus on growth strategy and O&P. He advises clients on a range of critical business issues including organizational scale-up and development, launch planning and commercialization, transaction support, forecasting and valuation, and postmerger integration.

Alex Vadas
Alex Vadas, Ph.D. is a Managing Director and Partner in L.E.K. Consulting's Healthcare practice and co-leads the Life Sciences Enablers practice. Alex has worked with many financial and strategic clients from venture-backed to global multi-nationals in corporate strategy, product strategy and planning, as well as transaction support. He also specializes in life sciences tools and technologies, diagnostics and precision medicine, and advanced therapy bioprocessing and manufacturing.

EXECUTIVE INSIGHTS

Redefining Biopharma R&D Productivity: New Insights and Strategies

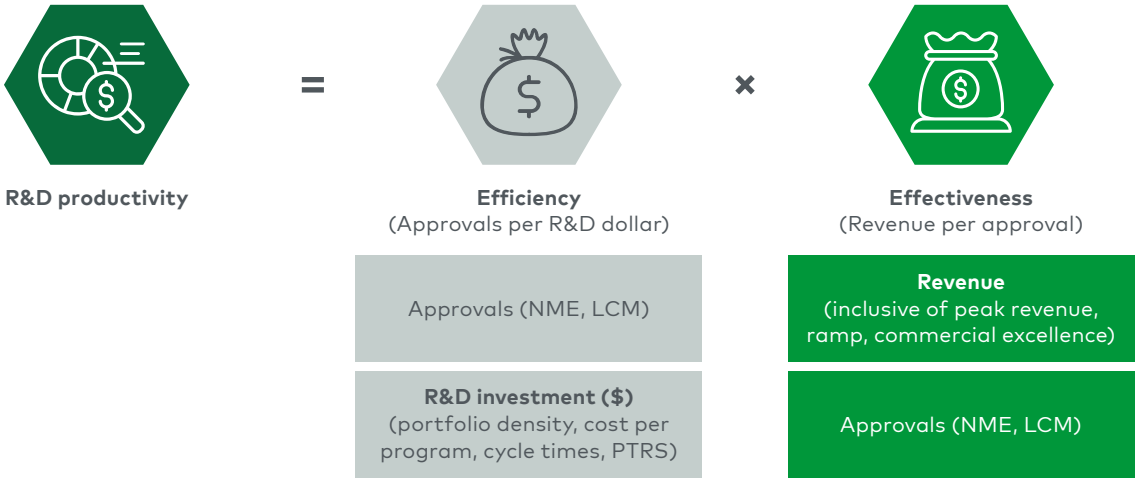
Introduction

R&D productivity stands as one of the most critical issues for biopharma executives, as it directly addresses the ability to transform pipeline investments into tangible revenue streams. Despite its importance, assessing R&D productivity is notoriously challenging due to the long innovation cycles and inherent uncertainties of drug development.

At its core, R&D productivity can be defined as the revenue generated per dollar of investment (see Figure 1). This broad concept can be further broken down into two essential components:

1. **Efficiency of the R&D engine:** This measures the number of drug approvals achieved per dollar invested in R&D. It reflects how well a company can generate successful outcomes from its research efforts within a given budget.
2. **Effectiveness of launches:** This assesses the revenue generated per approved drug. It indicates the ability of a company to maximize the commercial potential of its products through successful market entry, commercialization strategies and life cycle management.

Figure 1
R&D productivity framework



Note: NME=new molecular entity; LCM=life cycle management; PTRS=probability of technical and regulatory success
Source: L.E.K. research and analysis

Previous attempts to assess R&D productivity often suffered from outdated data, opaque methodologies or limited scope, focusing on a small subset of companies. However, with the biopharma industry undergoing significant shifts, it is more critical than ever to adopt a current and transparent approach to understanding how R&D productivity is evolving.

In this edition of L.E.K. Consulting's *Executive Insights*, we explore the two key components of R&D productivity and compares R&D efficiency and R&D effectiveness between Top 15 Biopharmas by revenue and the remainder of the industry (smaller companies).[1]

Such insights are essential to inform and optimize R&D strategies in this dynamic landscape. By understanding the nuances of R&D productivity across different segments of the industry, leaders can leverage mutual strengths to enhance productivity and navigate the evolving challenges and opportunities in drug development and commercialization.

Smaller companies surpass large pharmas in R&D efficiency

Despite remarkable advances in science, technology and operational practices, the consensus within the biopharma industry is that R&D productivity has been steadily declining. This trend is evident in the widening gap between industry R&D expenditures and revenue growth over the past decade.[2] This situation stems from a steady decline in efficiency, a trend that has persisted over the past 50 years.[3]

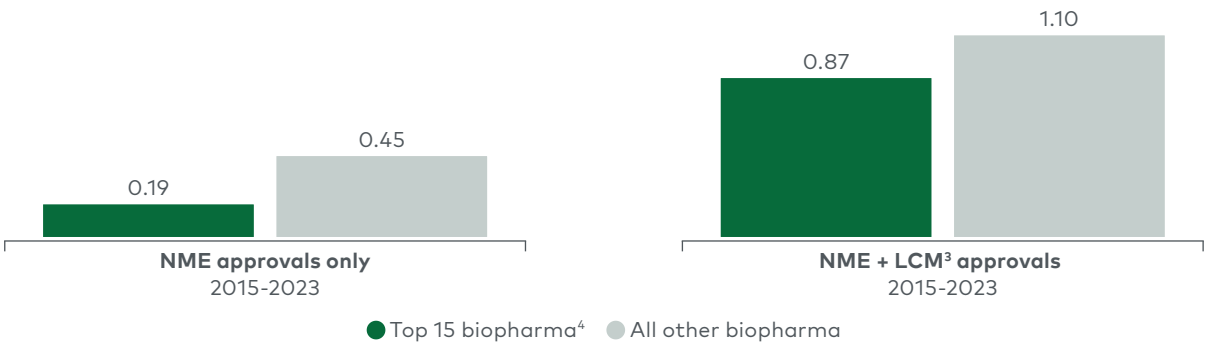
A major factor behind the decline in R&D efficiency is the escalating complexity of clinical trials. The scale and scope of these programs have expanded significantly, driven by evolving regulatory demands and a rapidly changing global clinical trial landscape. This has led to longer trial durations, greater enrollment challenges and higher investment costs. Consequently, the number of new approvals per R&D dollar has decreased over the past few decades.

Interestingly, large pharmas have been less efficient at converting R&D investments into new drug approvals compared to the rest of the industry (see Figure 2). Even when factoring in life cycle indications, the efficiency disparity remains evident, although less pronounced.

This is partly driven by their reliance on outliers — mega-blockbuster drugs such as Keytruda, Humira and Dupixent, among others — to drive top-line growth. To meet stringent internal revenue and return-on-investment thresholds, large pharmas concentrate their efforts on programs with the highest market potential, which typically have more life cycle management opportunities. While such drugs deliver transformative value, they also significantly raise the bar for R&D investments, demanding substantial financial resources and time to achieve market success. This heavy focus on blockbuster outcomes often leads large pharmas to prioritize effectiveness — producing high-impact, high-revenue therapies — at the expense of efficiency, limiting the number and diversity of opportunities pursued within their R&D investments and reducing the potential efficiency of their R&D portfolios in addressing broader medical needs.

Figure 2

R&D efficiency: R&D investment per approval by company type, including number of NME and NME + LCM approvals per $1B in R&D

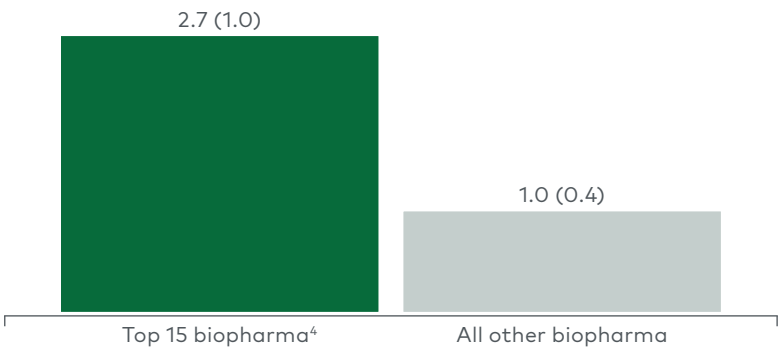


[1]Includes CDER and CBER approvals (vaccines and biologicals); [2]Approvals of acquired companies are included in NewCo company approval counts and revenues if approved after the acquisition date. [3]LCM includes new indication, new patient population, pediatric, and new route of administration; [4]Top 15 Biopharma companies were categorized based on biopharma revenues >$25B in 2024; 2024 trends show a continuing decrease in NME approvals per $1B of R&D spend with Top 15 Biopharma falling to 0.1 and All Other Biopharma pharma falling to 0.3
Source: FDA, company investor presentations and SEC filings

Large pharmas lead in effectiveness, generating more revenue per approval

Large pharmas consistently demonstrate greater R&D effectiveness than smaller companies, a difference largely attributable to their substantial commercial scale and capabilities. From 2015 to 2023, the average peak revenue for new molecular entities (NMEs) approved by large pharmas was approximately $2.7 billion, significantly exceeding the roughly $1 billion average for NMEs from smaller companies. This analysis, which includes historical and forecasted periods through 2030, highlights the revenue-generating advantage of larger organizations (see Figure 3).

Figure 3
R&D effectiveness: Average (Median) NME Peak Revenue[2] by Company[3] Type

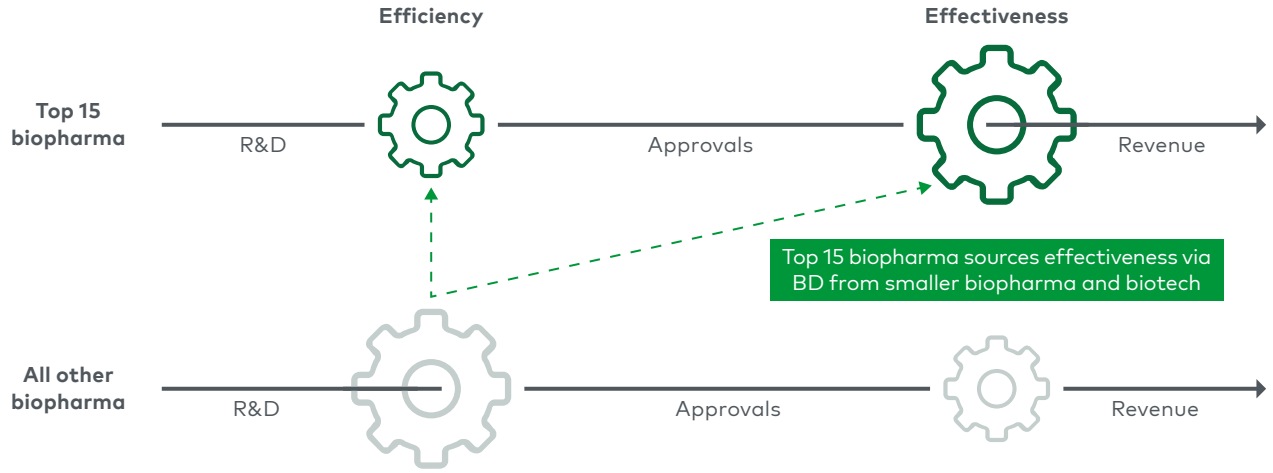


[1]Includes CDER and CBER approvals (vaccines and biologicals). [2]Revenue includes all LCM associated revenue. [3]Approvals of acquired companies are included in NewCo company approval counts and revenues if approved after the acquisition date; [4]Top 15 Biopharma companies were categorized based on biopharma revenues >$25B in 2024, All Other Biopharma is defined as all other innovative biopharma and biotech companies (excluding generics, devices, services, and platform/technology companies); When accounting for 2024 peak revenues for Top 15 Biopharma and All Other Biopharma NME approvals, Top 15 Biopharma remains constant while All Other Biopharma increases to $1.1B average peak revenue
Source: FDA, company investor presentations and SEC filings

Interestingly, large pharma drug candidates that are organically discovered or acquired at a preclinical stage, on average, generate higher revenue than those that were acquired or in-licensed during clinical development. This could be attributed to more stringent portfolio prioritization and the ability to invest earlier in lifecycle management opportunities for these assets.

Smaller companies often operate under significant financial constraints, driven by limited access to capital and a lack of scale in capabilities. As a result, they focus on advancing only those assets they can independently develop and commercialize, prioritizing R&D investments that are both cost-efficient and timely. For therapies targeting larger markets with higher barriers to entry, these companies typically lack the resources needed for full development and commercialization. This limitation often necessitates partnering with large pharmaceutical companies that can leverage their established clinical expertise and commercial infrastructure to bring these therapies to market (see Figure 4).

Figure 4
Conceptual model of R&D efficiency and effectiveness



Note: BD=business development
Source: L.E.K. research and analysis

Strategic actions for biopharma leaders

Large pharmas and smaller companies play distinct yet synergistic roles in driving innovation. Smaller companies act as incubators for novel ideas, while larger pharmas provide the scale and resources to transform these ideas into market-leading therapies. This interplay between small and large players needs to evolve to unlock new opportunities and drive greater value across the biopharma ecosystem.

Specifically, large-pharma executives should shift their R&D productivity to:

- Structuring their portfolios with sufficient shots on goal to produce outlier mega-blockbuster assets that can feed their revenue growth requirements. This requires maintaining stringent portfolio prioritization processes.
- Investing in internal innovation by optimizing for access to early science, speed in clinical development, breadth of therapeutic application and development success rate. Large pharma drug candidates that are organically discovered or acquired at a preclinical stage on average are likely to be more productive in generating returns than those accessed externally at later stages of development given transaction costs.
- Deploying business development into more selective opportunities. While business development will remain essential for larger pharmas, it can be a costly way to drive R&D productivity. Large pharmas should therefore carefully weigh the contribution of their business development activities to R&D productivity and rely on it as needed, as opposed to the default approach.

On the other end, small-company executives should center their efforts on:

- **Sustaining and enhancing R&D efficiency.** Small companies have historically excelled due to their lean teams, constrained capital and focus on efficiency. However, as they grow and gain access to larger pools

of capital — fueled by recent high-value financings — they risk losing this critical edge. To maintain their R&D efficiency, these companies must continue to prioritize agile and financially disciplined management of early-stage programs, as well as well-designed experiments and trials that maximize impact while minimizing resource expenditure. By staying adaptive and disciplined, they can scale without sacrificing their innovative and nimble culture.

- **Rethinking clinical development of lead assets.** Too often, small companies focus their lead asset development on niche indications to secure early clinical proof of concept. While this approach is often dictated by financial constraints, it may limit long-term potential. Executives within these companies should consider a more ambitious strategy by targeting larger, higher-value indications when possible. Bold prospecting in these areas can deliver greater valuation and drive significant shareholder value, even if it requires creative financing or partnerships to achieve.
- **Exploring value-retaining deals.** Biotech platforms often present unpredictable therapeutic applications, necessitating a strategic balance between targeting smaller, independently manageable indications and addressing larger, more competitive markets that require collaboration with large pharma. When partnerships are necessary to maximize an asset's value, executives should avoid giving away too much value too early and structure deals to retain long-term upside, such as through co-development, co-commercialization agreements or attractive milestone payments.

By prioritizing these strategies, biotech and pharma executives can effectively navigate the evolving and competitive biopharma ecosystem, combining innovation with disciplined execution to drive R&D productivity and achieve sustainable success.

The authors would like to acknowledge Jenny Mackey and Ethan Hellberg from L.E.K.'s Healthcare Insights Center for their contributions to this article.

For more information, please contact us.

Endnotes

[1]The top 15 biopharma companies were categorized based on biopharma revenues >$25 billion in 2024 (Evaluate Pharma estimates). Non-top 15 biopharma is defined as all other innovative biopharma and biotech companies (excluding generics, devices, services and platform/technology companies).

[2]Genengnews.com, "The Great Pharma Wasteland." https://www.genengnews.com/topics/drug-discovery/the-great-pharma-wasteland/

[3]Nature.com, "Breaking Eroom's Law." https://www.nature.com/articles/d41573-020-00059-3

About the Authors

Pierre Jacquet
Pierre Jacquet, M.D., Ph.D., is a Managing Director and Vice Chairman of L.E.K. Consulting's Global Healthcare practice. Based in Boston, Pierre has more than 20 years of experience in corporate and business unit strategy consulting and in M&A advisory services. He has led numerous engagements across the biopharma, medtech and diagnostic sectors, helping companies identify and execute strategies that maximize shareholder value creation.

Ricardo Brau
Ricardo Brau is a Managing Director and Partner in L.E.K. Consulting's Boston office. Ricardo leads the firm's Life Sciences Biopharma practice and has experience across most therapeutic areas and industry segments, in both large and emerging biopharma companies. He joined the firm in 2008 as a Life Sciences Specialist and advises clients on a range of critical issues, including corporate and business unit strategy, innovation, R&D portfolio management and commercial planning.

Bradley Hagan
Bradley Hagan was formerly a Senior Engagement Manager in L.E.K. Consulting's New York office and a member of the firm's Life Sciences Biopharma practice. Bradley has extensive experience advising large pharma and biopharma clients on commercial M&A diligence and R&D strategy and prioritization.

EXECUTIVE INSIGHTS

Advanced In Vitro Models: Opportunities and Challenges for US Drug Development

Advanced in vitro models are an emerging approach for preclinical experiments

Pharmaceutical companies invest over $50 billion annually in drug discovery and preclinical development, yet only 3% of drug candidates gain approval.[1] A significant portion of this spending goes toward experimental systems that are overly simplistic (e.g., 2D immortalized cell cultures), insufficiently predictive (e.g., rodent models) or ethically sensitive (e.g., nonhuman primate models), failing to fully replicate human pathophysiology and accurately predict both safety and efficacy of drug candidates.

Much of this testing is also driven by IND-enabling guidelines that rely heavily on animal-based data, reinforcing legacy models. As a result, biopharma companies must navigate the drug development process with suboptimal experimental tools that convey partial insight into biologic function/phenotype, leading to costly development cycles where many drug targets or candidates prove ineffective and fail later in development. These inefficiencies result in pharma companies allocating significant resources (e.g., time, money, labor) to projects unlikely to succeed.

Advanced in vitro models are an emerging class of tools that, alongside in silico modeling and artificial intelligence (AI) insights, are poised to unlock better decision-making regarding candidates earlier in the preclinical value chain.[2] Over the past few years, efforts like the FDA Modernization Act 2.0 and the ISTAND program have begun to ease regulatory barriers and encourage validation of nonanimal methods.[3,4] More recently, the FDA's announcement that it would phase out animal testing requirements for monoclonal antibodies (mAbs) marks a significant step forward.

Although this guidance remains relatively high level, it signals growing regulatory momentum toward broader acceptance of advanced in vitro models in drug development.[5] These advanced in vitro models aim to bridge the gap between simplistic 2D cell models (in vitro) and costly, low-throughput and ethically sensitive animal models (in vivo) by closely mimicking tissues or organ systems and providing predictive safety and efficacy data for critical systems (e.g., liver, kidney, heart).

Depending on eliminate application and intended placement in the value chain, advanced models have various archetypes, including organoids (or spheroids), organ-on-a-chip (OOC) systems and tissue-engineered organs (see Figure 1):

• **Organoids** are made of small clusters of primary or immortalized cells and, depending on the organ system, can contain multiple cell types. Certain cell types naturally self-assemble into macrostructures, allowing for more physiologically relevant properties compared to their 2D counterparts. Due to organoids' small size, ease of use and inexpensive design, they can be highly scaled (96-384 wells) and are lower cost compared to other advanced in vitro systems, allowing utilization earlier in the value chain for activities such as hit-to-lead screening.

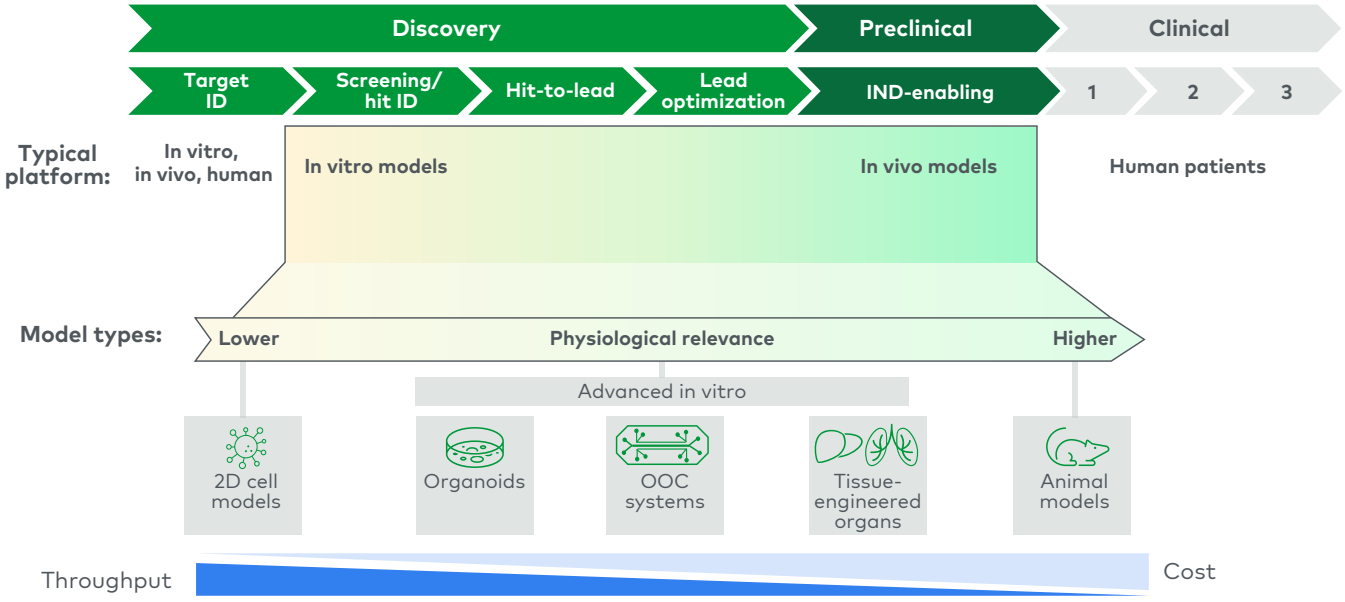
• **OOC** systems consist of microfluidic platforms seeded with organ-specific primary or immortalized cells (often multicellular with endothelial cells) and incorporate flow throughout the platform to mimic the body's vascular system, which may improve physiologic relevance. Their complex design and fabrication lead to higher costs and limited throughput (24- or 48-well formats), positioning them primarily in lead optimization.

• **Tissue-engineered organs** remain in an early stage of development and are primarily used in niche applications during later-stage optimization due to their complexity and cost.
These advanced in vitro systems have shown promising data that could improve decision-making and aim to improve each program's PTRS. For example, advanced liver organoids/chips have demonstrated the ability to produce physiologically relevant liver safety biomarkers (e.g., ALT, AST), and solid tumor organoids can replicate the tumor microenvironment to optimize therapeutic delivery and efficacy.

While applications for these technologies are extensive, they have historically faced significant headwinds to pharmaceutical adoption and widespread utilization. Many advanced in vitro tools have ended up stuck in the middle of legacy approaches, lacking the cost-effectiveness and throughput of 2D models as well as the validation and regulatory acceptance of animal models.

Figure 1

Advanced in vitro model utilization mapped across the discovery and preclinical value chain



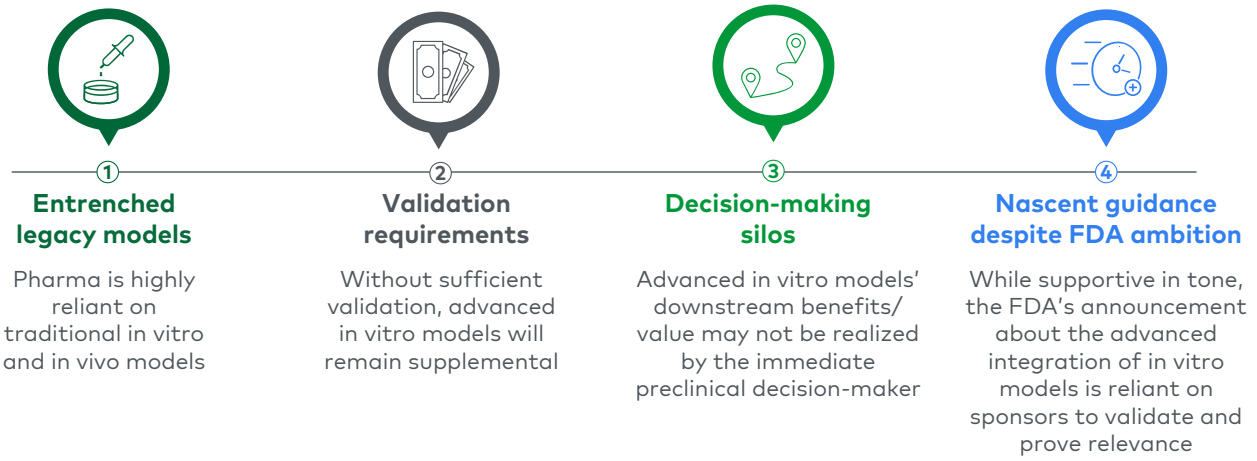
Note: ID=identification; IND=investigational new drug, OOC=organ-on-a-chip
Source: L.E.K. research and analysis

In this edition of *Executive Insights*, L.E.K. Consulting provides an overview of the headwinds impeding the adoption of these technologies and discusses some strategies to overcome these challenges.

Despite providing promising (albeit often incremental) human-relevant insights, advanced in vitro systems face a number of adoption headwinds as companies seek to expand the role these models play across both discovery and preclinical workflows. L.E.K. has identified four key challenges that must be addressed to unlock broader adoption and commercial impact for advanced in vitro tool suppliers (see Figure 2):

Figure 2

Key challenges faced by advanced in vitro tool suppliers



Note: FDA=Food and Drug Administration
Source: L.E.K. research and analysis

1. Current in vitro and in vivo models are highly entrenched within discovery and preclinical development workflows.

In vitro and in vivo models have long been foundational to pharmaceutical development, not because they are perfect but because they are trusted, are practical, and have consistently supported the discovery of clinically successful drugs. In vitro models typically consist of 2D cell models, and while these models are simplistic, pharma leverages them in high-throughput formats (384-well plates) in single-readout assays to assess efficacy or safety across large compound libraries. Often these 2D cell model assays recapitulate a disease state (e.g., breast cancer) or test a safety attribute (e.g., hERG ion channel safety). Although advanced in vitro models may offer greater accuracy, the acceptance, entrenchment and throughput of 2D models create a high barrier to adoption.

Additionally, the higher cost of these advanced in vitro systems may not be justified by their performance benefits, making practicality a key consideration. Recently, suppliers have focused on complex disease areas that lack a simple 2D model (e.g., I/O or muscular dystrophy) and where advanced models support a higher throughput not previously possible. Suppliers are increasingly integrating AI with advanced models to drive throughput and extract insights about disease mechanisms. AI and machine learning (ML) algorithms can help simplify complex data and identify early patterns of efficacy and toxicity.

In vivo rodent models are typically used starting in lead optimization to evaluate candidates in physiologically relevant systems. These models are leveraged for a suite of experiments (e.g., safety, efficacy and ADME studies), often with multiple readouts from a single animal.

For example, dose escalation studies will also enable toxicity and pathological assessment of organs (e.g., liver, kidney, heart).

While advanced in vitro models may be as predictive as in vivo models, their lack of physiological complexity/context (e.g., multi-organ systems) limits widespread utilization and has kept many researchers from replacing in vivo models. Animal models that are resource-intensive or offer limited translational value (e.g., nonhuman primates) are increasingly viewed as entry points for advanced in vitro approaches, and recently, suppliers have been targeting use cases where large numbers of animals are utilized for only a single specific readout (e.g., gene therapy, titer optimization).

Suppliers are using AI/ML in combination with these systems to further help researchers model vector performance, predict optimal capsid design and understand transduction efficiency. Beyond gene therapy, AI and advanced systems are helping reduce animal use across complex and poorly predicted areas, such as cardiac toxicity and immune response, demonstrating that advanced systems may serve as a strong starting point toward supporting the FDA's goal of reducing and eventually eliminating animal testing.

2. Advanced in vitro systems are likely a supplemental cost until fully validated.
Validation is key to convincing stakeholders to choose an advanced in vitro model over the current gold standard; however, it remains a moving target. Without sufficient validation, researchers must still conduct legacy experiments, making advanced in vitro models a supplemental cost rather than a replacement. Stakeholders often require both retrospective and prospective validation. For retrospective validation, suppliers leverage therapeutics with known toxicity profiles to show that advanced in vitro models can predict similar specificity and sensitivity. Some models have shown toxicity from therapeutics that failed clinical trials but were not deemed toxic using traditional in vitro and in vivo models.

Pharmaceutical stakeholders also seek prospective validation, where other researchers successfully use this advanced in vitro tool to support a drug's progression to clinical trials and potentially eventual approval. Taken together, retrospective and prospective validation are costly, as they require high upfront investments and initial adoption by multiple champions. In today's cost-constrained and time-sensitive environment, studies are often hard to justify, particularly when they do not replace existing experiments. Justifying these extra costs remains a headwind for suppliers, and without broad validation, advanced in vitro models are likely to remain additive to development workflows.

To overcome this, suppliers must sharpen their value proposition to attract champions and clearly demonstrate practical utility. A growing number of suppliers are leveraging AI/ML to validate and benchmark their models against known clinical outcomes to enhance regulatory credibility and commercial adoption. AI/ML algorithms can analyze high-dimensional data (e.g., transcriptomics, phenotypic screens) to demonstrate that in vitro models align with relevant disease biology and drug response. The FDA's most recent guidance may accelerate broader collaboration across advanced in vitro approaches to build confidence and momentum.

3. Advanced in vitro model value accrues downstream and may go unrecognized by purchasing stakeholders

Discovery and preclinical teams are often siloed from their clinical counterparts, hindering the realization of advanced in vitro models' full value. This disconnect means the buying team may not recognize downstream benefits, such as improved PTRS, from better early-stage decisions. For example, if an organoid model helps discovery scientists eliminate candidates with hepatotoxic profiles, the benefit of delivering a lead candidate with a lower risk of liver damage to preclinical studies or clinical trials may go unnoticed.

This lack of cross-team visibility also applies to cost and time savings, as preclinical and clinical teams may not fully recognize the impact of early discovery failures. These efficiency gains and cost savings can be overlooked when transitioning candidates across stages of the value chain. Additionally, "kill quickly" is not always incentivized, as many researchers are evaluated based on the number of candidates, not necessarily the success of those candidates downstream.

To demonstrate value, advanced in vitro model suppliers must track how their tools have supported key decision points (e.g., deprioritizing candidates based on early safety or efficacy signals) and highlight the productivity gains (e.g., longer and more costly in vivo studies). This task can be difficult, as each clinical asset likely passes through multiple models and hundreds of experiments, and each advanced in vitro model must lean on its value proposition to convince the pharma industry of its impact.

4. The FDA's recent announcement signals progress, but broad replacement of animal models will be a cautious and slow process.

Despite the growing evidence supporting advanced in vitro models over traditional in vitro and in vivo testing, the FDA has been slow to fully embrace these technologies and integrate them into regulatory frameworks. While the agency has taken incremental steps in recent years, such as issuing guidance documents, supporting legislation (e.g., FDA Modernization Act 2.0), launching qualification programs (e.g., ISTAND) and supporting collaborative research, the pace of adoption remains cautious.

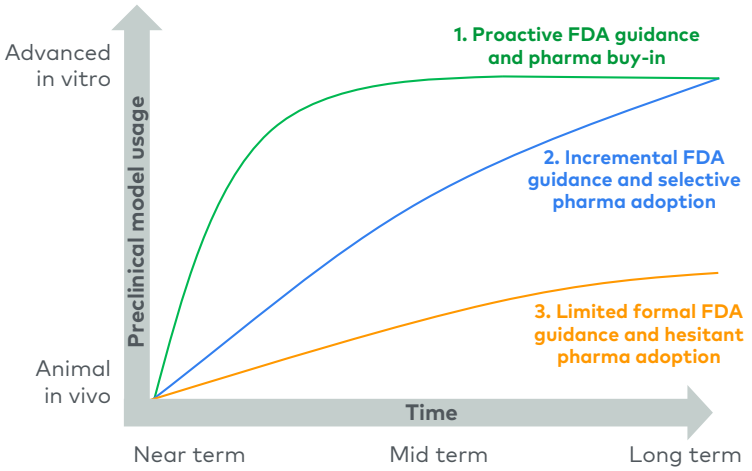
The most recent FDA guidance indicates a more active stance on reducing animal usage and relying on alternative models. However, beyond the reduction of primate study requirements for mAbs, the roadmap remains aspirational. Outside select, more mature applications (e.g., liver OOC), the advanced in vitro space is nascent, with many emerging models lacking validation and the confidence of sponsors. The FDA highlights early-stage concepts, such as whole-body-on-a-chip systems and AI/ML models for pharmacokinetics, but provides limited clarity on regulatory expectations or actionable pathways for adoption.

While the FDA's tone is supportive of a transition to more predictive tools, for now the burden of validation and regulatory evidence falls to pharma sponsors, which must determine whether the FDA is truly accepting of data from organoids or OOC systems. Additionally, the FDA and the pharma industry must account for other stakeholders such as clinical teams that may be hesitant to recruit for studies built on unfamiliar toxicology data.

Still, this guidance marks an important inflection point. Depending on how industry and regulators act in the near, mid- and long term, adoption could accelerate meaningfully or continue at a slower pace (see Figure 3). Pharma will play a critical role in generating the validation data needed to shift regulatory perception, especially in high-priority use cases where existing models are costly or poorly predictive. If adoption is effectively executed with coordinated validation, clearer expectations and support across advanced in vitro, in silico and AI/ML models, this recent guidance could drive broader adoption efforts across pharma company silos and organizations, offering meaningful tailwinds for suppliers if these efforts translate into real change.

Figure 3

Future advanced in vitro model adoption scenarios following the recent FDA announcement



1
- **FDA builds momentum** with clear guidelines and defined, efficient validation pathways
- **Pharma begins parallel validation** at scale
- **AI tools help generate supportive evidence** quickly

2
- **FDA supports advanced in vitro systems on a case-by-case** basis, without clear guidance
- Adoption and validation are focused on **high-burden or less-predictive use cases** in discovery and preclinical stages

3
- FDA supports advanced in vitro systems in tone only with **limited formal guidance** or qualification pathways
- **Validation costs remain high,** with pharma hesitant to adopt without regulatory clarity

Note: FDA=Food and Drug Administration
Source: L.E.K. research and analysis

To cultivate the adoption and impact of advanced in vitro models, both suppliers and users should consider several key success factors. Given these challenges, how can an advanced in vitro model supplier accelerate adoption and find success within this market? And with the FDA's recent announcement, how can pharma stakeholders drive meaningful efficiency and return on investment by integrating these models into the drug development process?

- **Pursue a more targeted approach and sharpened value proposition.** Suppliers must deeply understand the disease areas and use cases (e.g., safety vs. efficacy) where there is sufficient unmet need or market pain to overcome adoption barriers. This includes clearly defining where their technology fits within the drug development value chain (e.g., target identification, drug screening, candidate selection, lead optimization or clinical trial support). At the same time, pharma should actively assess where advanced in vitro systems can be introduced to add value, particularly in these high-cost, less-predictive areas, as an initial step toward broader integration.
- **Strategically build the necessary data sets to validate the value proposition.** Based on the key use cases, suppliers must identify the key pieces of evidence necessary to demonstrate how their solutions complement (e.g., addressing safety concerns) or replace (e.g., outperforming HTS on efficacy) current models or eliminate existing bottlenecks so that pharmaceutical companies can confidently integrate these systems into their workflow. Recent FDA guidance may begin to define a clearer path toward recognizing these models

as primary models, rather than supplemental tools, within drug development workflows. The pharma stakeholders should look to partner in this effort by generating or supporting validation in parallel with legacy tools, especially in their high-priority use cases.

- **Establish a clear deployment/business model (e.g., product, service or hybrid approach).** Suppliers must clearly define what is included in their offering — from core technologies to ancillary services such as data analysis, regulatory support and validation studies — and tailor their model to reduce adoption barriers for customers unfamiliar with advanced in vitro systems while clearly demonstrating the solution's value proposition. Pharma should seek supplier support to implement these models effectively within their existing R&D frameworks as the FDA transitions from animal models.

By refining their approach and aligning with industry needs, advanced in vitro model suppliers can overcome adoption barriers and demonstrate their value more effectively. Pharma should also prepare for a future where these models play a larger role, by identifying areas of fit and building internal readiness for adoption.

To explore how L.E.K. can help you navigate the opportunities and challenges in the advanced in vitro market, please reach out to our team. We can offer strategic guidance to set you up for success in this evolving space.

For more information, please **contact us**.

Endnotes

[1]LEK.com, "The Financial Ecosystem of Pharmaceutical R&D." https://www.lek.com/insights/sr/financial-ecosystem-pharmaceutical-rd

[2]LEK.com, "New Drug Discovery Paradigm: Advances in 3D Tissue Models and Applications." https://www.lek.com/insights/ei/new-drug-discovery-paradigm-advances-3d-tissue-models-and-applications

[3]Congress.gov, "S.5002 - FDA Modernization Act 2.0." https://www.congress.gov/bill/117th-congress/senate-bill/5002

[4]FDA.gov, "Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program." https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/innovative-science-and-technology-approaches-new-drugs-istand-pilot-program

[5]FDA.com, "FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs." https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs

About the Authors

Jeff Holder
Jeff Holder, Ph.D., is a Managing Director and Partner in L.E.K. Consulting's San Francisco office and a member of the Life Sciences practice. Jeff has experience helping clients develop, manufacture, supply and enable advanced therapeutic modalities, including cell and gene therapies. He has expertise in the life science tools, bioprocessing, biopharma services and diagnostics spaces, with a particular focus on growth strategy, portfolio planning, new product opportunities and business development support.

Alex Vadas
Alex Vadas, Ph.D. is a Managing Director and Partner in L.E.K. Consulting's Healthcare practice and co-leads the Life Sciences Enablers practice. Alex has worked with many financial and strategic clients from venture-backed to global multi-nationals in corporate strategy, product strategy and planning, as well as transaction support. He also specializes in life sciences tools and technologies, diagnostics and precision medicine, and advanced therapy bioprocessing and manufacturing.

Adam Siebert
Adam Siebert is a Partner in L.E.K. Consulting's New York office and a member of the Life Sciences Enablers practice. Adam focuses on the biopharma manufacturing and supply chain across therapeutic modalities, including radiopharmaceuticals. He supports clients in developing strategies (growth, go-to-market, manufacturing/ supply chain, pricing), provides transaction support and helps organizations realize operational efficiencies.

Adam Nover
Adam Nover, Ph.D., is a Principal based in L.E.K. Consulting's New York office and a leader in the firm's U.S. LSB P&MA practice. Adam joined L.E.K. in 2016 and is dedicated to the firm's Life Sciences and Pharma practices. His experience spans therapeutic areas and modalities. Adam supports clients across a broad range of functional areas, including corporate strategy and commercial assessment.

Paul Gehret
Paul Gehret is a Life Sciences Specialist in L.E.K. Consulting's New York office and dedicated to the Life Sciences practice. Paul has experience advising clients across biopharma and enabling technologies with a focus in advanced in vitro tools and diagnostics.

EXECUTIVE INSIGHTS

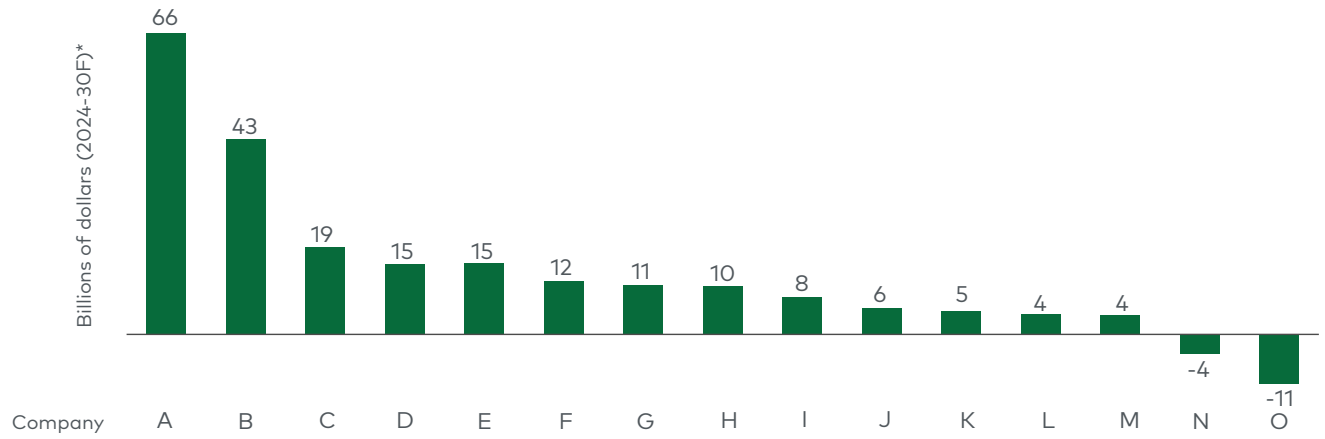
How Pharma Companies Are Driving the Next Wave of Revenue Growth

Introduction

The top 15 biopharma companies account for 75% of total industry revenue, making their future performance a defining factor for the sector at large. Their strategies, investment decisions and execution disproportionately shape the trajectory of innovation and the creation of shareholder value across the entire sector. Despite facing loss of exclusivity (LOE) risks impacting 25%-30% of 2024 revenue, these companies are projected to grow their combined revenue by approximately $200 billion — a 30% increase — by 2030 (see Figure 1).

Figure 1

Top 15 biopharma revenue growth (2024-30F)



*Total revenue includes Rx sales, Alliance/copromotion revenue, and royalty and licensing income, and excludes over-the-counter products
Note: Rx=prescription
Source: FDA; EvaluatePharma

Yet this growth is highly uneven. Nearly 80% of the projected revenue expansion is expected to come from just five companies, highlighting the growing divide between market leaders and the rest of the industry.

As executive teams navigate where and how to invest, a clear understanding of the underlying growth drivers — ranging from asset concentration and the mix of in-line versus pipeline contributions to life cycle potential, therapeutic focus and innovation sourcing — is critical for making informed decisions and sustaining long-term value creation.

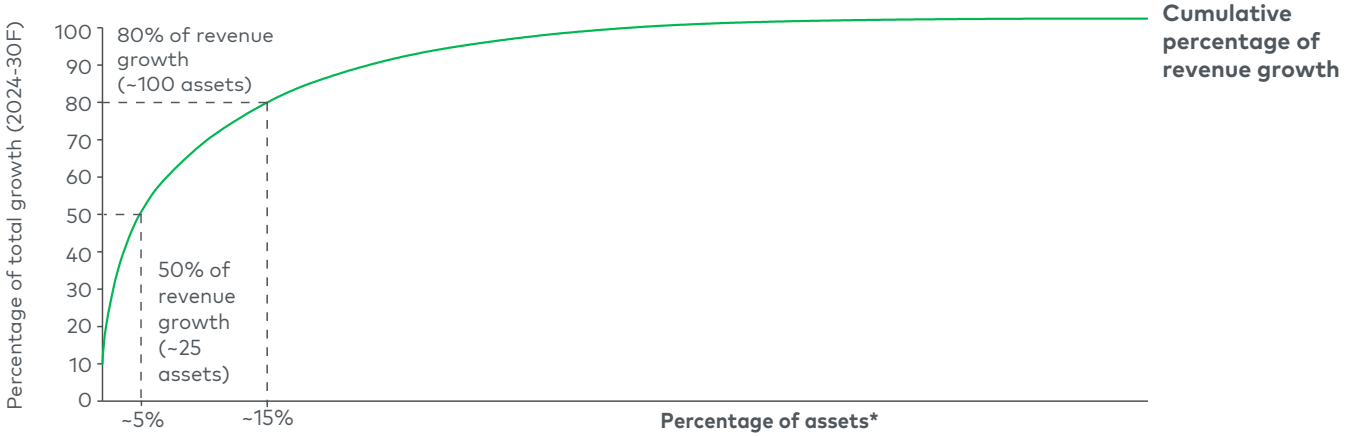
Growth is concentrated — not evenly distributed

Growth through 2030 for the top 15 biopharma companies is driven by around 600 assets, half of which were marketed in 2024 and half of which are expected to be approved between 2025 and 2030.[1] Yet revenue growth remains highly concentrated: Just 15% of top-performing assets are expected to drive 80% of the industry's projected growth through 2030. Even excluding glucagon-like peptide-1 agonists (GLP-1s), which account for nearly half of the top 15's projected growth, the pattern holds, with 20% of non-GLP-1 assets generating 80% of the remaining growth (see Figure 2).

Top-performing companies don't just aim for more product approvals; they strategically channel capital and resources into assets with the greatest potential for outsize commercial returns. These high-impact assets tend to scale well beyond their initial launch, often driven by geographic expansion, label extensions or significant differentiation in clinical outcomes. For leadership teams, the imperative is clear: Identify high-conviction opportunities early and commit decisively. Spreading investments too thinly across a broad portfolio may dilute impact and prove less commercially effective.

Figure 2

Concentration of revenue growth among top 15 biopharma assets



*Assets experiencing declining sales or LOE are not included in analysis
Note: LOE=loss of exclusivity

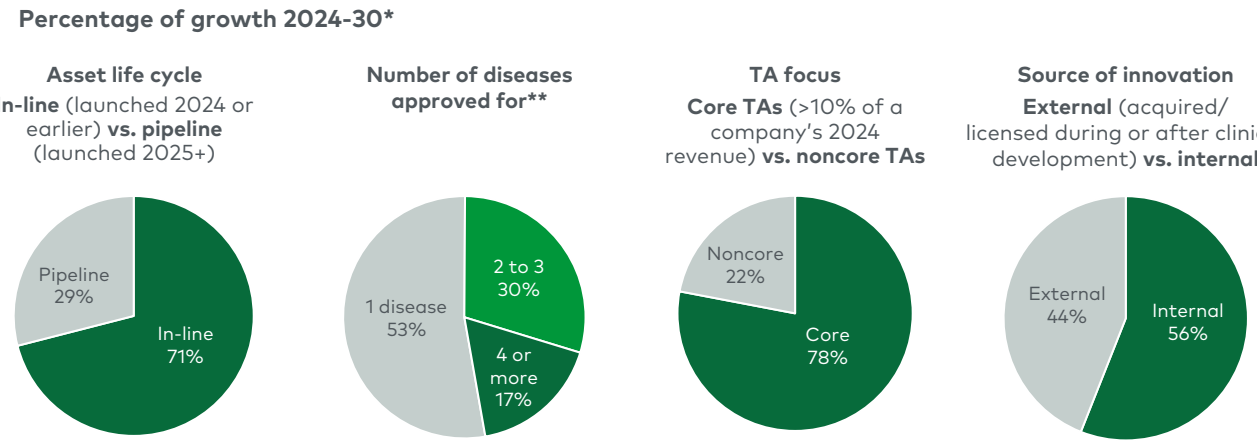
In-line assets are the backbone of growth

Over 70% of projected revenue growth through 2030 will come from in-line assets already on the market as of 2024 (see Figure 3). This places a premium on execution and life cycle management. To fully capture this value, companies must excel in launch performance, optimize market access and expand geographic reach. Sustained growth will depend less on new approvals and more on maximizing the potential of existing assets — ensuring they meet revenue expectations and then exceed them.

Relying exclusively on existing products is not a viable strategy for long-term growth. Even the strongest in-line portfolios will inevitably face pressure from market saturation and LOE. To sustain momentum, companies must complement in-line growth with a consistent cadence of new product launches — not only to offset revenue decline but also to refresh the portfolio, maintain commercial relevance and reinforce investor confidence in the company's innovation engine.

Figure 3

Composition of top 15 biopharma 2024-30F revenue growth



*Does not include collaboration, copromotion or licensing revenue, and excludes assets losing exclusivity or decreasing revenue 2024-30
**Number of diseases per asset based on EvaluatePharma "indication-level" data
Note: TA=therapeutic area
Source: FDA; EvaluatePharma

Multidisease assets drive disproportionate value

"Portfolio-in-a-product" assets — therapies with the potential to address multiple diseases — are emerging as some of the most powerful growth drivers among the top 15 companies. Although they represent only about one-third of the combined portfolio density, these multi-indication assets are expected to account for nearly half of total projected revenue growth. Notably, just 13 such therapies, each spanning four or more indications, are set to deliver nearly 20% of topline expansion through 2030. Their outsize impact is a key differentiator between

higher- and lower-growth players: The top five companies alone anticipate over $100 billion in growth from these assets — more than double the combined contribution expected from the bottom 10.

This underscores a critical strategic consideration. Therapies with the potential to scale across multiple diseases should be prioritized, as they offer not only greater revenue potential but also improved return on R&D and commercial investment.

Core therapeutic areas drive the majority of growth

Nearly 80% of projected revenue growth through 2030 is concentrated in core therapeutic areas — those already accounting for at least 10% of a company's revenue. This trend highlights the strategic advantage of building from a position of strength. By doubling down on familiar territory, companies can leverage established scientific expertise, trusted stakeholder relationships and existing commercial infrastructure to develop evidence strategies that resonate, accelerate launches, optimize access and gain share more efficiently than in less-familiar therapeutic areas.

In an environment defined by growing scientific complexity and mounting commercial pressure, companies that deepen their presence and enhance execution in core areas will be best positioned to drive consistent, capital-efficient growth.

Finding the right balance between external innovation and organic growth

External innovation — through M&A, in-licensing or strategic partnerships — remains a critical engine of growth in biopharma. Projections through 2030 show revenue growth is nearly evenly divided between internally developed assets and those sourced externally during or after clinical development. This balance does not yet reflect future deal activity, which is likely to tilt the mix even further toward external innovation over time.

This dynamic highlights a key strategic imperative: Companies must carefully balance internal R&D with external sourcing to remain competitive. Overdependence on internal pipelines can limit exposure to novel modalities and emerging science, while excessive reliance on external innovation may compress margins, introduce integration challenges and reduce long-term pipeline visibility. Striking the right balance is essential for sustained, capital-efficient growth in an increasingly complex and competitive landscape.

Key implications for pharma executives

Future growth in biopharma will depend on deliberate, insight-driven portfolio choices. The next generation of outperformers will distinguish themselves by reconfiguring their portfolios around a few core strategic principles:

- **Elevate post-launch execution and life cycle management**
  Treat post-launch execution with the same strategic rigor as clinical development. Prioritize indication expansion, global market penetration and long-term value creation to fully realize the potential of in-line assets.
- **Double down on high-impact, scalable assets**
  Focus investment on a select group of high-conviction programs with label expansion potential. Concentrating capital behind these assets can unlock disproportionate returns and build momentum across the portfolio.
- **Leverage strength in core therapeutic areas**
  Deepen presence in therapeutic areas where scientific expertise, stakeholder relationships and commercial infrastructure already exist. Avoid the dilution and complexity that come with overdiversification into unfamiliar domains.
- **Balance internal R&D with external innovation**
  Maintain sourcing agility through a dual-engine model that combines internal research with targeted M&A, licensing and strategic partnerships. This approach ensures access to innovation across modalities and development stages while managing risk and capital efficiency.

Companies that align their commercial, development and investment strategies with these principles will be best positioned to drive sustainable, high-quality growth in an increasingly competitive environment.

For more information, please **contact us**.

Author's note: Almost 50% of forecast revenue growth is attributed to the GLP-1 class. This concentration, however, does not impact the core findings and recommendations in the article.

Note: AI tools were used in the drafting of this article.

Endnote

[1]The number of assets is not risk-adjusted for likelihood of approval

About the Authors

Pierre Jacquet
Pierre Jacquet, M.D., Ph.D., is a Managing Director and Vice Chairman of L.E.K. Consulting's Global Healthcare practice. Based in Boston, Pierre has more than 20 years of experience in corporate and business unit strategy consulting and M&A advisory services. He has led numerous engagements across the biopharma, medtech and diagnostic sectors, helping companies identify and execute strategies that maximize shareholder value creation.

Ricardo Brau
Ricardo Brau is a Managing Director and Partner in L.E.K. Consulting's Boston office. Ricardo leads the firm's Life Sciences Biopharma practice and has experience across most therapeutic areas and industry segments, in both large and emerging biopharma companies. He joined the firm in 2008 as a Life Sciences Specialist and advises clients on a range of critical issues, including corporate and business unit strategy, innovation, R&D portfolio management and commercial planning.

Jenny Mackey
Jenny Mackey is the Director of L.E.K. Consulting's Healthcare Insights Center, where she is focused on generating insights and thought leadership on topics and trends with major impact across the healthcare industry. Prior to this role, Jenny was a Principal in L.E.K.'s Biopharma practice, where she advised clients on a range of issues, including R&D portfolio prioritization, new product planning, forecasting and valuation, and organizational performance and development.

Ethan Hellberg
Ethan Hellberg is a Consultant in L.E.K. Consulting's Boston office dedicated to the Life Sciences practice. Ethan has extensive experience across infectious diseases, ophthalmology, neuroscience and oncology. He advises clients on a broad range of issues, including growth strategy, forecasting and valuation, portfolio prioritization, M&A and due diligence.

EXECUTIVE INSIGHTS

Behavior-First Biopharma Go-to-Market Strategies

Start with the right question

Biopharma go-to-market planning today demands a new level of precision and flexibility. Commercial leaders are facing mounting pressures from rising costs, constrained budgets and intensifying competition. Meanwhile, richer claims datasets, greater computing power and an expanding menu of engagement approaches provide more insights and options than ever, making it more complex to choose which levers matter most.

Despite this, companies may be tempted to rely on benchmarks and inherited frameworks to design their go-to-market strategies. But in our experience advising on a broad range of launches, we recommend starting by asking one deceptively simple question first:

Which behaviors, in which stakeholders, need to be changed for patients to start and stay on treatment?

Approaching the challenge through a behavior-first lens naturally sharpens decision-making. It encourages functions to align around shared outcomes rather than siloed tasks and deploy the right interventions at the moments that matter most. Too often, this behavioral lens is applied only later — for example, at the brand planning stage — rather than earlier when it can shape go-to-market strategy itself. Capturing these insights up front requires more investment than most organizations are used to, but it pays dividends in sharper execution later.

In this edition of L.E.K. Consulting's *Executive Insights,* we propose a five-step process for developing and continuously refining the go-to-market strategy (see Figure 1).

Figure 1

Behavioral-driven process for developing a go-to-market strategy

Note: GTM=go-to-market; FTEs=full-time equivalents
Source: L.E.K. research and analysis

1. Determine (reassess) adoption drivers and barriers

We suggest companies begin by defining the full set of stakeholders whose behaviors influence adoption — core groups like prescribers, patients and payers, as well as caregivers, referring physicians, clinic administrators, nurses, distributors, pharmacies, genetic counselors, professional societies or associations, and patient advocacy groups. The next step is to map the journey each stakeholder takes, from symptom recognition to treatment initiation and ongoing use, and to pinpoint the specific behaviors required at each stage to drive adoption and persistence. This process identifies both barriers that block adoption and drivers that substantiate it, providing the foundation for go-to-market design by showing where momentum builds and where it breaks down (examples of barriers for some key stakeholders are shown in Figure 2).

Figure 2

Examples of barriers to adoption across select stakeholders

NONEXHAUSTIVE

	Symptom recognition and care seeking	Referral, testing and diagnosis	Treatment initiation	Treatment experience and monitoring
Patient and caregiver	× Low disease awareness × Symptom normalization × Misinformation × Complex travel logistics	× Complex travel logistics × High financial burden × Test invasiveness	× Side effect concerns × High financial burden × Confusing onboarding × Confusing self-admin	× Side effects × High financial burden × Treatment burnout
HCP/ center		× Misdiagnosis × Lack of referral relationships	× Safety concerns × Tx not in guidelines × Poor buy-and-bill economics	× Difficulty interpreting response markers × High admin load for reauthorization
Payer		× Poor coverage of Dx testing × Payer-preferred labs do not offer the test	× Restrictive prior authorization and/or reauthorization × Step edits through less expensive alternatives × Unclear criteria for retreatment or dose adjustments	

Note: HCP=healthcare provider; Tx=therapeutics; Dx=diagnostics
Source: L.E.K. research and analysis

2. Prioritize stakeholders and behaviors to change

No product launch can — or should — target every potential prescriber, patient or influencer equally. The starting point is identifying those who will most directly drive adoption and, within each group, the subset that could have the largest impact with focused engagement. For healthcare providers (HCPs), that might mean the 20%-30% of specialists who account for the majority of prescribing or patient volume in a category; for patients, it could mean those most likely to switch therapies within the next 12 months rather than the entire diagnosed population. It is also critical to identify the stakeholders that determine or influence the therapy's market access — payers, institutional decision-makers and clinical guideline committees — since their choices determine how broadly adoption is even possible.

With priority stakeholders identified, teams should next prioritize the behavior changes needed to drive adoption. Each behavior should be viewed through two lenses: the impact if successfully changed and the ability to influence that change.

The impact should be linked to measurable outcomes, such as incremental treated patients, revenue per claim or avoided discontinuations. Doing this well requires strong business insights and analytics capabilities to translate claims data and market research into clear implications for go-to-market strategy.

The ability to influence then screens for feasibility: which barriers sit within the manufacturer's realm of control and which demand broader policy, infrastructure or socioeconomic shifts. For example, rural clinics may lack access to advanced imaging required for diagnoses; expanding regional scanner capacity would accelerate uptake, but the manufacturer cannot feasibly build or finance new facilities.

Finally, companies must take a balanced approach to addressing the behavior changes. For instance, a campaign focused on the therapy's value proposition versus its competitors will have limited impact if the disease remains highly undiagnosed upstream or has significant payer coverage restrictions.

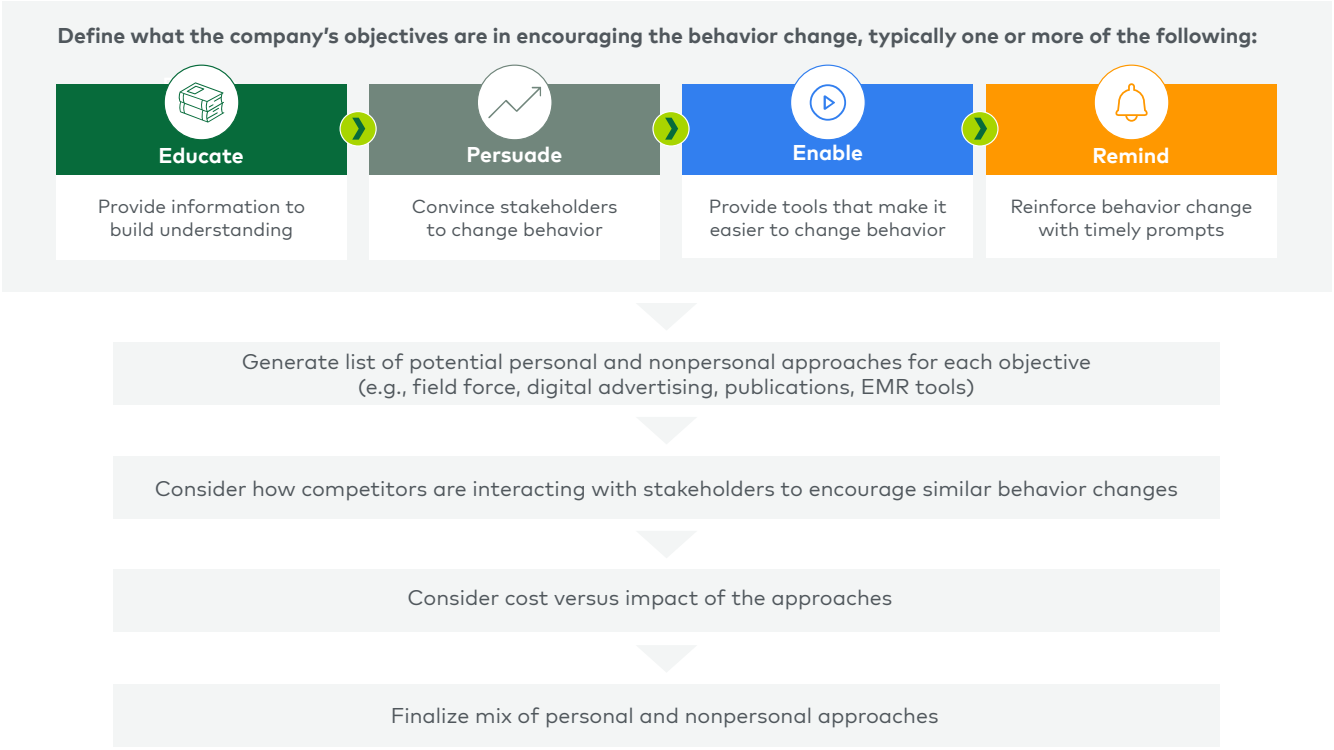
3. Identify engagement approaches required

With priority behaviors identified, behavior change is most often supported by a combination of personal and nonpersonal engagement. Except where personal engagement is restricted or cost-prohibitive, high-performing go-to-market plans choreograph both forms of engagement around each behavior change.

The process typically starts by clarifying what is needed to shift the behavior — educating, persuading, enabling or reminding — and then weighing potential approaches, competitor activity and cost versus impact before settling on the right mix (see Figure 3).

Figure 3

Selecting the mix of personal and nonpersonal engagement approaches



Note: EMR=electronic medical record
Source: L.E.K. research and analysis

For behaviors that require persuasion through nuanced, individualized dialogue — such as deciding to prescribe a therapy with complex risk-benefit trade-offs — personal promotion is the anchor. A live conversation with a medical science liaison (MSL) can surface concerns no digital banner could. Even so, nonpersonal tools — like a short explainer video, follow-up text or concise evidence digest — help educate prior to making a decision and reinforce the exchange after a decision has been made.

When the barrier to the behavior change stems from a straightforward information gap, recognition lapse or procedural misstep, scaled digital tactics focused on educating, enabling and/or reminding can shoulder more of the load. Take physician office activation for prior authorization as an example: Interactive microlearning modules, autopopulated checklists in the electronic medical record (EMR) system and real-time status alerts can standardize submissions and cut cycle time. A field reimbursement manager remains on call for escalations, providing a targeted human touch when digital alone is not enough.

Personal engagement: Design the customer-facing model

Delivering the personal side of engagement requires a clear customer-facing model with a blueprint for which roles engage which stakeholders and how those interactions are coordinated.

Certain roles — sales representatives, MSLs and national account managers — form the backbone of nearly every launch. During go-to-market planning, companies must decide which additional roles to layer on and at what scale.

This should be dictated by the behaviors the company has prioritized and the skills required to shift them. If diagnostic inertia is a constraint, deploy diagnostic specialists who can walk clinicians through test-ordering workflows. If access friction is resulting in patient drop-off, plan for a robust field reimbursement manager force to navigate prior authorization appeals and benefit investigations. When administration is complex, nurse educators equipped to train infusion sites and coach patients become critical.

Equally important, coordinate these specialists' outreach so stakeholders experience a seamless dialogue — not a barrage of overlapping touchpoints.

The customer-facing model assigns the right roles to the right behaviors, maintains the necessary share of voice and reserves human expertise for the moments when personal engagement drives outcomes.

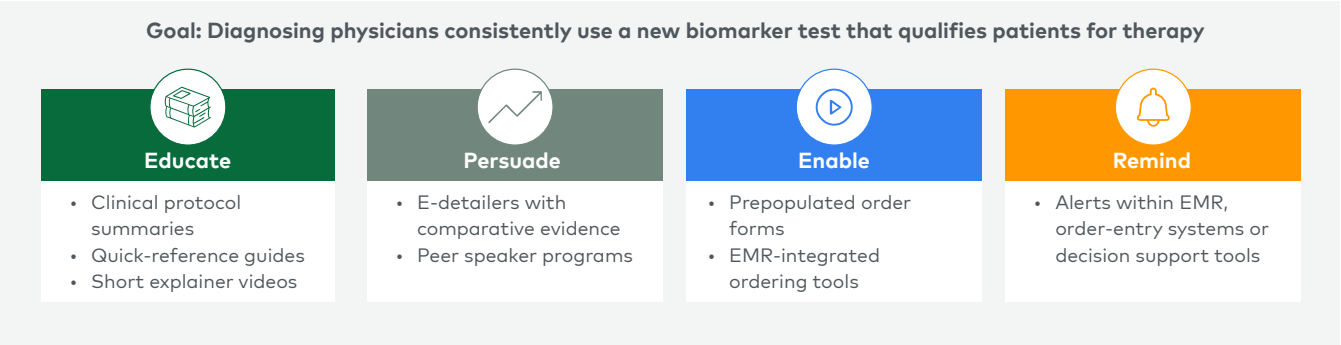
Deploy nonpersonal engagement

Nonpersonal engagement is also critical for behavior change and demands the same disciplined planning as personal engagement. At the go-to-market strategy stage, the goal is to match each prioritized behavior with the nonpersonal approaches most likely to shift it, gauge the investment those approaches will require and surface net new capabilities — such as EMR system integration or modular content operations — so budgets and roadmaps are grounded before detailed tactical planning begins.

The most effective programs anchor nonpersonal engagement in the behavior that needs to shift and what it will take to make that happen. Take the example of slow adoption of a new biomarker test despite guideline inclusion, where nonpersonal engagement approaches are coordinated to collectively educate HCPs about the biomarker test, persuade them of the benefits of using it, enable them to easily order it and remind them on an ongoing basis when patients are appropriate for that test (see Figure 4).

Figure 4

Examples of nonpersonal engagement approaches mapped to a behavior to change



Note: EMR=electronic medical record
Source: L.E.K. research and analysis

The best-performing companies treat nonpersonal engagement as a precision tool — designed, budgeted and measured with the same rigor as personal engagement. They ensure that nonpersonal engagement is highly personalized, with messages customized and channels tailored to individual stakeholders' needs and preferences. They also monitor and rapidly integrate emerging innovations into the engagement mix as appropriate.

4. Determine (adjust) go-to-market scale and investment level

With priorities and engagement approaches defined, teams must right-size the effort. This means translating the strategy into the required investment, talent, technology and vendor support. That assessment should also account for the technology (e.g., customer relationship management platforms, modular content platforms, omnichannel orchestration platforms and data integration capabilities) that will be needed to execute engagement efficiently and at scale. If the plan exceeds available resources, adjustments might include narrowing the target audience, phasing deployment or substituting lower-cost tactics that still address the barrier. The aim is not simply to fit the budget but also to ensure resources are sufficient to overcome key barriers without overspending on low-impact activities.

5. Execute and track impact

Next, the focus shifts to execution and ongoing measurement. Uncertainties are inevitable — competitor entry, evolving stakeholder needs and the emergence of new barriers can alter the market landscape. Teams should anticipate these possibilities through scenario planning and establish clear decision triggers in advance. The impact should be measured against prespecified outcomes-based key performance indicators, not just activity levels.

This measurement process feeds directly into the next cycle — reassessing progress against existing barriers, identifying new ones and refining the engagement plan accordingly. Teams should continually assess which approaches are delivering impact and which are not and adjust the mix as needed. Adjustments must be made carefully, particularly where established stakeholder relationships could be disrupted, but also decisively and with agility. Taking a cyclical, data-driven approach to go-to-market strategy ensures it remains responsive, targeted and effective over time.

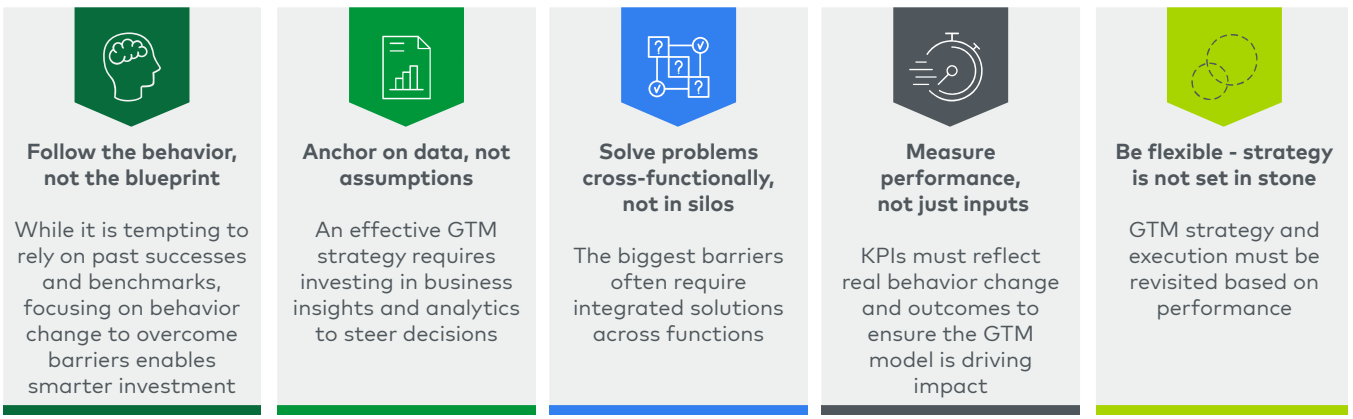
Takeaways for executives

In today's fast-moving market, it is easy to default to familiar tactics executed within individual functions without stepping back to ensure they are aimed at the highest-priority stakeholder behaviors to change. A behavior-first go-to-market approach counters that tendency by focusing on the most important adoption barriers and aligning resources to overcome them. It also empowers teams to address downstream workflows, especially brand planning, allowing them to build on this base and consider the attitudes and emotions that are so important for personalizing messages and channels to each stakeholder.

To put this approach into practice, executives should focus on five imperatives (see Figure 5).

Figure 5

Imperatives for behavior-first go-to-market strategy



Note: GTM=go-to-market; KPIs=key performance indicators
Source: L.E.K. research and analysis

When applied with discipline, effective go-to-market strategies can cut through the noise of competing priorities and keep the organization focused on what will truly drive adoption. The companies that revisit those priorities regularly and act on them in a coordinated and decisive way will be the ones that turn intent into sustained market impact.

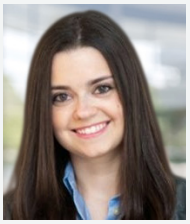
Note: AI tools were used to support this article.

For more information, please **contact us**.

About the Authors

Peter Rosenorn
Peter Rosenorn is a Managing Director and Partner in L.E.K. Consulting's Boston office. Peter specializes in the life sciences and pharma sectors with a focus on growth strategy and O&P. He advises clients on a range of critical business issues, including organizational scale-up and development, launch planning and commercialization, transaction support, forecasting and valuation, and postmerger integration.

Max Cambras
Max Cambras is a Managing Director and Partner in L.E.K. Consulting's New York office and a member of the Life Sciences practice. Max has over 17 years' experience working with biopharmaceutical companies on commercialization strategy, innovation planning and management, drug delivery and digital health, and patient engagement.



Jenny Mackey
Jenny Mackey is the Director of L.E.K. Consulting's Healthcare Insights Center, where she is focused on generating insights and thought leadership on topics and trends with major impact across the healthcare industry. Prior to this role, Jenny was a Principal in L.E.K.'s Biopharma practice, where she advised clients on a range of issues, including R&D portfolio prioritization, new product planning, forecasting and valuation, and organizational performance and development.

Linnea Tilberg
Linnea Tilberg is a Principal in L.E.K. Consulting's Boston office and a member of the firm's Life Sciences Biopharma practice. Linnea focuses on commercial excellence and advises clients ranging from emerging biotechs to scaled pharma companies on a range of topics, including GTM strategy development, launch readiness planning, organizational scale-up and operating model refinement.

Emily Vogel
Emily Vogel is a Senior Manager in L.E.K. Consulting's Boston office focused on the Life Sciences practice. Emily supports biopharma clients across a range of projects from strategy to operations and performance, with a particular focus on key aspects of commercialization. She has extensive experience evaluating market positioning, determining GTM strategy, planning launches and scaling commercial capabilities.

For questions or further discussion,
please contact L.E.K. Consulting.

LEK