Oaklin

Is the R&D business model still fit for purpose?

How can pharmaceutical companies deliver **faster, better and cheaper** innovation in a modern, increasingly complex environment: exploring the approaches of discovery leaders, innovation aggregators and investment engines.

Drug discovery has long been recognised as one of the most complex and capital–intensive processes in modern industry. According to the industry association PhRMA, the development of a single new medicine typically takes 10—15 years and costs approximately $2.6 billion, when accounting for the cost of failed development programmes [1].

Over the past three decades, the pharmaceutical development model has evolved continuously in an effort to improve both speed and cost efficiency. Today, the industry appears to be approaching another structural inflection point. Several forces are converging to intensify pressure on pharmaceutical companies to deliver new profitable therapies more efficiently than ever before:

First, patent expirations are placing sustained pressure on companies to replenish their pipelines. Between 2025 and 2030, pharmaceutical analysts estimate that products generating more than $300 billion in aggregate annual revenue will face global patent expiry [2].

Second, drug pricing has become an increasingly politicised issue across global markets. Governments and healthcare systems are scrutinising the sustainability of pharmaceutical pricing, particularly in the US. This is forcing companies to reconsider whether current levels of research and development investment, often approaching 20% of revenue, can be maintained.

Third, rapid technological progress, particularly in artificial intelligence and computational biology, is reshaping the possibilities for drug discovery, development and manufacturing.

Taken together, these pressures raise an important strategic question:

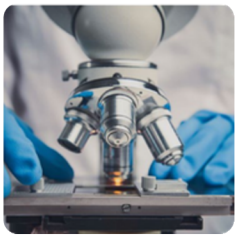
Is the current pharmaceutical model ready to respond to a rapidly changing technological, societal and geopolitical environment?

Through engaging with leaders in the industry, Oaklin has explored how the R&D model has evolved, the forces currently reshaping it, and what these trends mean for pharmaceutical companies defining and implementing the business model of the future. We explore this through the lens of 5 main areas undergoing rapid transformation: (1) digital drug discovery, (2) buying innovation, (3) clinical trials, (4) commercialisation and (5) manufacturing and supply chains.

Oaklin shares our vision of the future:

Pharmaceutical organisations will shift from primary discoverers, to innovation aggregators and investment engines.

Is the R&D business model still fit for purpose in pharmaceutical organisations?

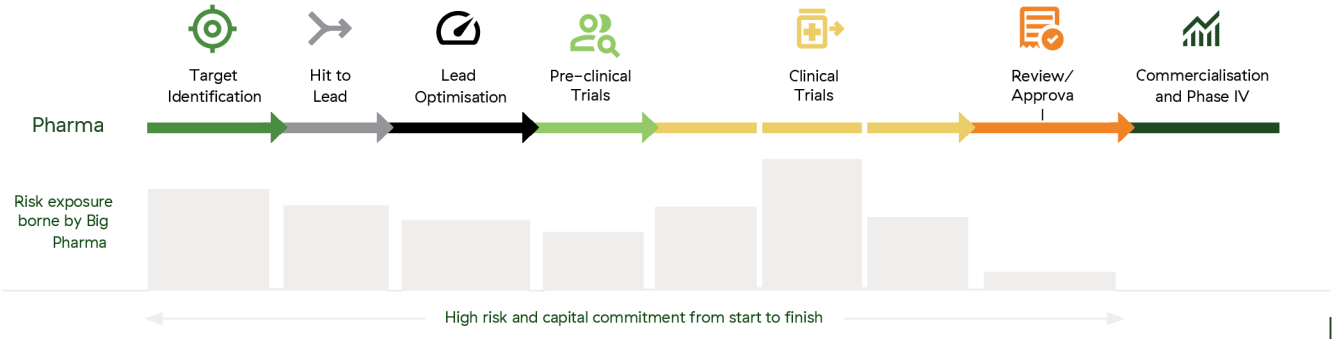


How can pharma deliver faster, better and cheaper innovation in a modern research ecosystem: as discovery leaders, innovation aggregators or investment engines?

1 The origins of pharma

Traditional, fully integrated model

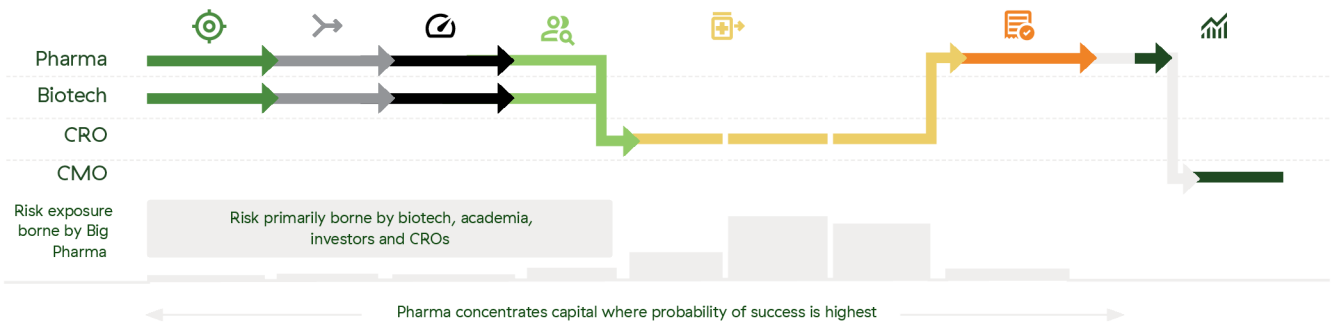
'Big Pharma' is the discovery leader, funding and bearing 100% of the risk across the entire end-to-end drug development pipeline, structured around the regulatory process.



2 The current R&D model

Modern distributed model

Risk has been increasingly distributed across a network of partners; pharma invests later in the development cycle to acquire de-risked assets.



3

The future model for pharma

A shift in the role of pharmaceutical companies

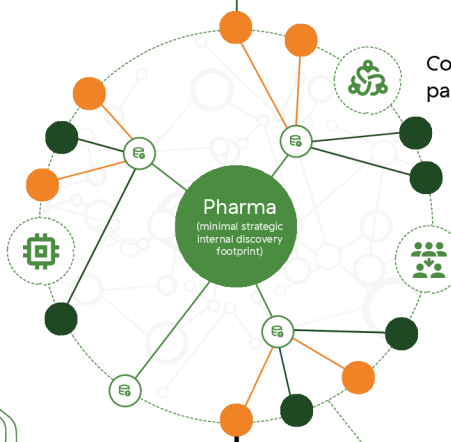
Rather than operating solely as vertically integrated discovery organisations, pharmaceutical companies may increasingly function as innovation aggregators across the drug discovery lifecycle.

Discovery and Pre-Clinical Development

Pharma as an innovation aggregator

Pharma participation

Increasing emphasis on partnerships with traditional technology firms



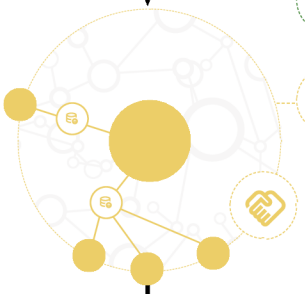
Complex multi-organisation partnerships

'Tech-bio' team composition

'Data motorways' for efficient data sharing between partnerships

Clinical Trials

Pharma participation



Increasing reuse of existing data in new regulatory submissions

Clinical trials managed exclusively through CRO partnership

Review/Approval

Pharma participation

IP ownership driving strategy and operations

Regulatory submission expertise retained in-house

Commercialisation and Phase IV

Pharma participation

Increasing focus on direct to patient and direct to business commercial models

Technology-enabled commercial approaches defined in-house

Dynamic 'supply grid' coordination across multiple geographic regions for manufacturing and distribution

1. Digital Drug Discovery

Failing faster and increasing investor confidence

Drug discovery is fundamentally high risk, with the vast majority of candidates failing before they ever reach clinical trials. As the cost of pursuing unsuccessful compounds continues to rise, pharmaceutical companies are under growing pressure to identify weak prospects earlier. This has driven constant demand for stronger validation methods and more effective approaches to scientific research.

Drug discovery has historically relied on highly specialised scientific disciplines, combining expertise in areas such as structural biology, medicinal chemistry, and both in vitro and in vivo experimentation.

For many years, technological advancements primarily enhanced the efficiency and quality of traditional laboratory processes rather than fundamentally transforming the discovery process itself. Data science and computational tools were largely viewed as supporting capabilities rather than core drivers of innovation.

This dynamic is now changing.

Computational models can simulate molecular interactions, predict biological activity and accelerate the identification of promising compounds. The U.S. Food and Drug Administration (FDA) has noted that the use of artificial intelligence in drug development and regulatory submissions has increased exponentially since 2016, significantly transforming early-stage drug discovery [3].

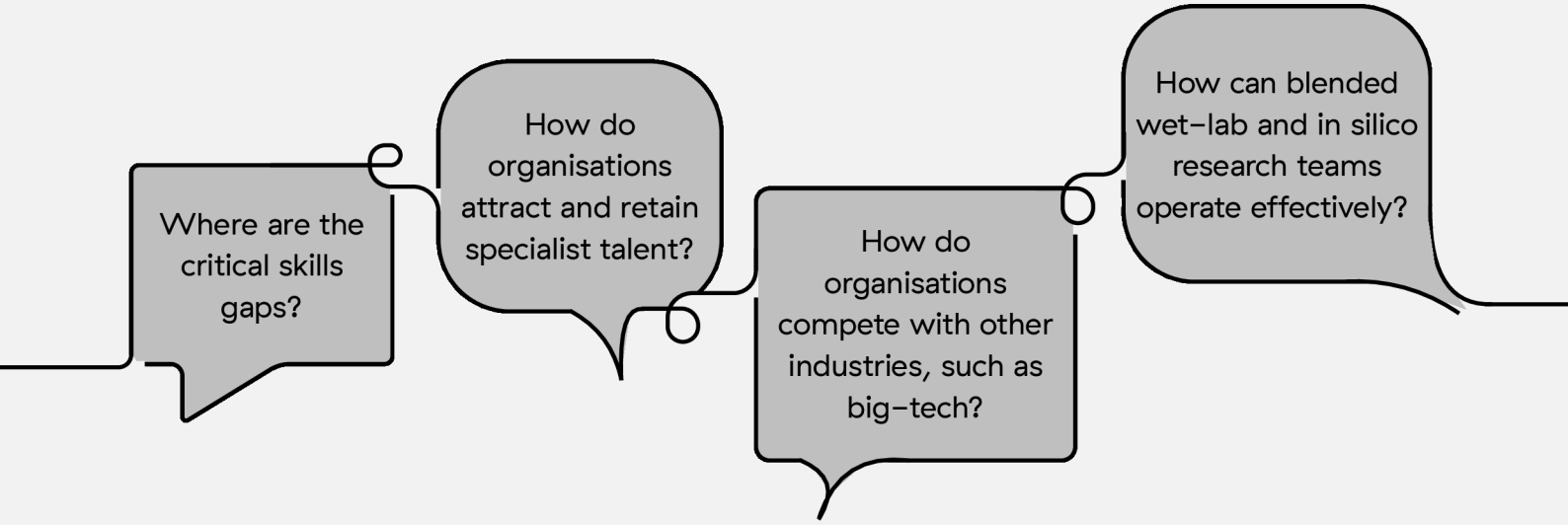
These technologies allow researchers to analyse extremely large datasets in order to identify potential therapeutic targets and generate candidate molecules. In practice, this can support the identification of novel early-stage hits, accelerate hit optimisation and enable earlier detection of potential failure risks. The importance of artificial intelligence and computational techniques lies not only in their ability to accelerate discovery but also in their potential to reduce costly late-stage failures.

Maximising the opportunity requires substantial organisational change, from workforce transformation, to scalable, compliant and ethical technology and data use.

A. Building a bilingual workforce

Pharmaceutical workforces will increasingly need to become "bilingual", combining deep scientific expertise with computational fluency. Organisations must develop talent capable of operating across both scientific and digital disciplines, while also attracting specialist expertise in areas such as machine learning and advanced analytics. Google DeepMind's computer programme AlphaFold tested this model, combining science with technology in an attempt to solve the protein-folding problem. With heavy competition from big-tech companies such as Google, traditional pharmaceutical organisations must develop an attractive employee proposition.

What questions do pharmaceutical organisations need to answer to deliver faster, better and cheaper?



A workforce strategy that addresses the critical gaps and market risks will be essential for building a competitive and relevant talent base.

B. Building the digital-physical hybrid bench

Beyond the workforce, laboratories themselves are also evolving. Concepts such as the "lab of the future" combine automated experimentation with computational modelling, enabling rapid feedback loops between digital simulation and physical experimentation. In addition, the rise of synthetic data could enable more accurate and faster demonstrations of drug efficacy, helping organisations to evaluate potential ROI earlier within the lifecycle.

This represents dramatic progress towards modernising highly specialised technology. For years, labs have consisted of disparate specialist machines that export data into static files. Lab books and data records can become an afterthought when juggling high-pressure research priorities. The lab of the future model puts a data ecosystem at the centre of research, regardless of the collection method.

This focus on data sharing is not new to pharmaceutical companies. The drive towards Findable, Accessible, Interoperable and Reusable (FAIR) data has already been prevalent, particularly in clinical research. We expect to see this concept extended into pre-clinical discovery to further support a blended wet-lab and computational approach. The most successful organisations will approach this change by designing for seamless data transfer and interoperability, supporting additional insights through new computational modelling and automation of traditional lab approaches to maximise discovery efficiency.

What questions do pharmaceutical organisations need to answer to deliver faster, better and cheaper?

01 Does this technology and data really help to demonstrate drug efficacy and ROI earlier than traditional wet-lab methods?

02 How do organisations build trust with regulatory bodies and the public when using computational methods to generate submission evidence?

03 How do we transform legacy systems to become more responsive and compete against nimble new entrants?

04 What checks and balances are needed to safely and compliantly share and use clinical research data, including public records?

For many organisations, the central challenge will be how and where to invest in traditional wet-lab research and scalable computational discovery platforms. As organisations shift to become more “tech-bio” than “bio-tech”, companies that remain overly reliant on conventional research models risk underutilising the economies of scale offered by computational discovery. Conversely, organisations that move too rapidly towards digital-first approaches may face regulatory uncertainty, operational disruption and ethical challenges, for example the risk of bias amplification, lack of transparency or manipulation from synthetic data. When operating under expanding pressure to deliver new market entrants quicker, and cheaper, this balance becomes increasingly important to navigate.

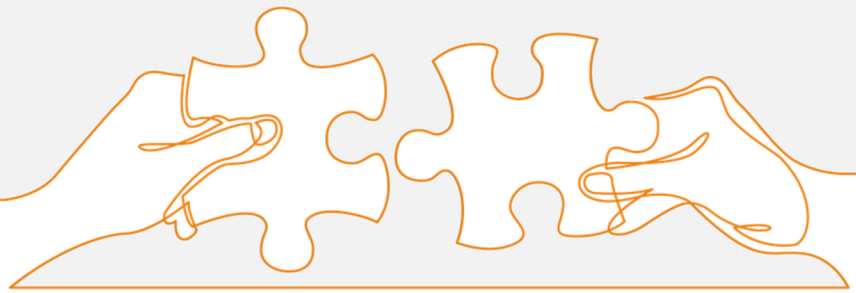
2. Buying Innovation

Accelerating discovery whilst hedging risk

Over the past two decades, pharmaceutical innovation has become increasingly distributed.

Rather than owning every stage of the discovery and development process, pharmaceutical companies now collaborate extensively with specialised external partners across the innovation lifecycle. This shift reflects a strategic response to the inherent risks and complexity of drug development.

Early-stage discovery is frequently conducted by venture-backed biotechnology companies, which focus on specific technological platforms such as gene editing, RNA therapeutics or advanced biologics. These firms assume a significant portion of early scientific risk while pursuing highly specialised research strategies.



This dynamic is evident in the origins of innovative medicines. Research suggests that approximately 65% of FDA-approved drugs marketed by large pharmaceutical companies originate from external innovation sources, primarily biotechnology firms [4].

This reflects a broader strategic shift. Large pharmaceutical companies are no longer the sole engines of scientific discovery. Instead, they increasingly source innovation through acquisitions, licensing agreements, strategic partnerships and venture investment.

As computational discovery expands, the nature of these partnerships may evolve further. A new set of actors is entering the pharmaceutical ecosystem, including artificial intelligence companies and data analytics providers associated with 'Big Tech'. These organisations bring highly specialised capabilities, such as large-scale computational modelling and AI molecular design.

At the same time, therapies are becoming more complex. Combination therapeutic approaches involving multiple modalities, blending delivery mechanism and disease area expertise, often require specialised knowledge and skills.

The shift towards increasingly specialised discovery forces organisations to think more critically about the value of in-house capability development. In order to balance pipeline profitability with intellectual property (IP) expansion, pharmaceutical companies may increasingly act as integrators of specialised capabilities, combining technologies and expertise accessed through multiple partners to develop new therapeutic solutions.

This is already evident in the rapid evolution of alliances across the industry. While such partnerships were relatively uncommon two decades ago, they are now a central and attractive mechanism for pooling specialist expertise and supporting strategic portfolio development. At the same time, alliances are becoming more sophisticated, with multi-partner arrangements growing in both frequency and complexity.

At the core of these collaborations is IP ownership, which continues to underpin alliance strategy. Large pharmaceutical companies remain focused on expanding and strengthening their IP portfolios; however, looking ahead, much of the operational development may be delivered through increasingly complex networks of specialised partners.

> **"SCIENTIFIC KNOWLEDGE REMAINS THE BEDROCK OF ALLIANCES, WITH IP THE MAIN FACTOR STEERING ALLIANCE STRATEGY"**
> *– Katherine Kendrick (Head of Alliance Management at Jazz Pharmaceuticals)*

Katherine Kendrick is Executive Director and Head of Alliance Management at Jazz Pharmaceuticals, where she leads global partnerships across development and commercialisation to deliver value for patients with serious diseases. She joined Jazz in 2019 after leadership roles at Eli Lilly & Company and Elanco Animal Health, where she built and led alliance management functions.

With over 25 years of experience in clinical development and strategic partnering, Katherine is known for building high-performing alliance teams and driving patient-focused, value-based collaboration. She holds a BS in Biomedical Science from Texas A&M University and is a Certified Strategic Alliance Professional (CSAP).

As a result, the role of large pharmaceutical organisations is evolving. Although internal research capabilities will remain essential for maintaining scientific depth, companies must strike the right balance between in-house innovation and external collaboration.

One of the challenges already emerging is data sharing, which becomes increasingly complex across multi-partner networks. Success depends on effective data transfer that is both compliant and meaningful . Current research into existing data models and standards indicates further progress is needed to achieve a unified global approach [5]. The success of partnerships may therefore be determined by their ability to establish "data motorways," facilitating seamless movement of information between organisations that rely on different systems and data structures. This creates a significant opportunity for the industry to advance alignment around common approaches which, beyond strengthening partnerships, also supports research collaboration across borders on a global scale.

What questions do pharmaceutical organisations need to answer to deliver faster, better and cheaper?

Q1

Which capabilities are critical to a pharmaceutical company's competitiveness, and should remain core internal competencies?

Q2

Which technologies are more effectively accessed through partnerships? And which are more suitable for acquisitions?

Q3

How can organisations efficiently manage increasingly complex networks of collaborators?

Q4

What does an effective "externally networked" R&D organisation look like?

Q5

How do pharmaceutical companies manage alliances in a way that delivers ROI while meeting regulatory requirements?

Q6

How do you shape "win-win" relationships that effectively share risk and reward across multiple parties?

Ultimately, success will depend on the ability to navigate this distributed innovation ecosystem. Leading organisations will be those that can effectively orchestrate a diverse network of partnerships, acquisitions, and joint ventures to maximise their therapeutic portfolios.

3. Modern Clinical Trials

Improving speed and efficiency, whilst remaining compliant and safe

Clinical trials remain among the most expensive and time-consuming phases of drug development. Estimates suggest that trial costs range from approximately $4 million for Phase I studies to over $100 million for Phase III trials [6].

Over the past two decades, much of the operational execution of clinical trials has been outsourced to contract research organisations (CROs). These partners support pharmaceutical companies across a wide range of activities, including trial management, patient recruitment, regulatory compliance and data management.
This model allows pharmaceutical companies to scale clinical trials globally while reducing operational complexity.

Despite this, patient recruitment and population bias remain two of the most significant challenges in clinical research. Some figures show that nearly 1 in 5 oncology clinical trials fail to recruit enough participants to yield reliable results [7]. This is further exacerbated by the rise of personalised therapies and increased focus on rare diseases, where smaller and more targeted trial populations require new approaches to statistical design and regulatory evaluation.

Regulators are already evolving supported evidence-generation models to enable decentralised and hybrid clinical trial designs to address these challenges. The FDA has indicated that such approaches may improve accessibility for participants and enable the recruitment of more representative populations [8]. The MHRA has also launched a system-wide overhaul of disease regulation aimed specifically at faster approval, with a rare-diseased focused implementable model launching in 2026 [9].

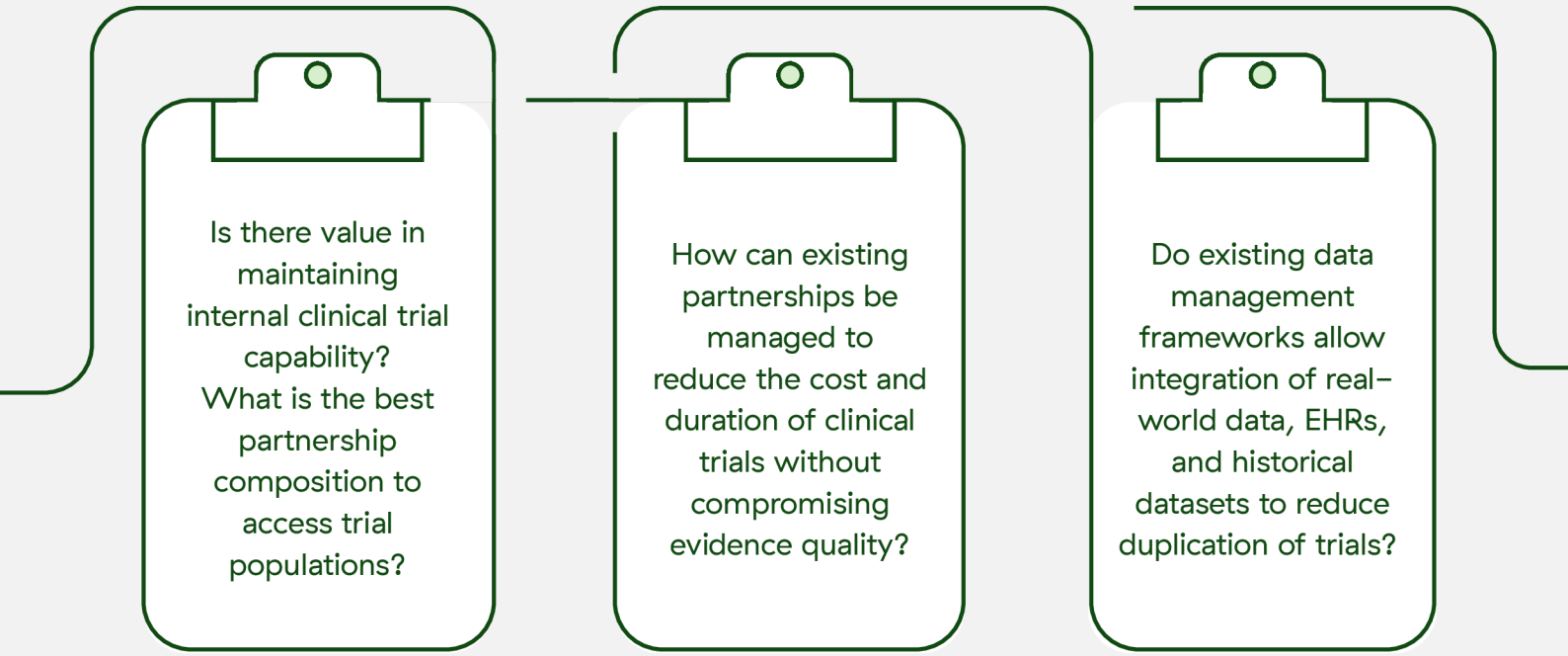
Artificial intelligence may also support trial design through improved patient stratification and recruitment strategies. However, further evidence is required to demonstrate if these approaches improve patient representation or inadvertently reinforce existing biases.

New technological approaches may further reshape how clinical evidence is generated. Advances in digital monitoring present important opportunities to enhance data quality and, increasingly, organisations are exploring ways to integrate historical clinical datasets with real-world evidence and electronic health records.

These approaches could enable greater reuse of richer clinical data, reducing the need to recruit entirely new patient populations for each study. Pooling patient data may help identify specific patient subgroups or biomarkers associated with improved therapeutic response.

Data reuse must be managed in a way that is compliant with its original capture. This puts additional focus on having robust data governance mechanisms that act as enablers for the business, helping increase the pace of discovery without risking the huge financial and reputational costs of data misuse. The long-term implication is that clinical development is likely to become more adaptive and data-rich. Scaling will depend on regulatory confidence, data governance, patient privacy and the careful management of bias in AI-supported methods.

What questions do pharmaceutical organisations need to answer to deliver faster, better and cheaper?



The most successful organisations will be those that put sufficient emphasis on their internal data ecosystem to safeguard quality and interoperability, and those that actively manage partnerships with CROs. This will allow them to maximise data reuse, improve patient recruitment and accelerate trial timelines, reducing the cost to meet regulatory submission requirements.

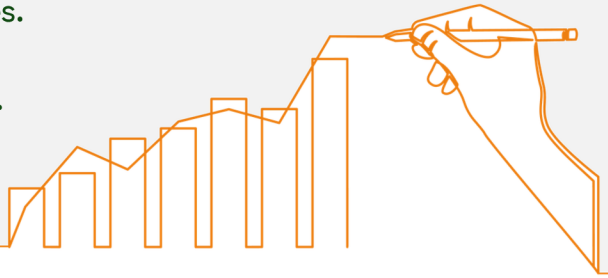
4. Flexible Commercialisation

Commercial agility powered by broad engagement

While many areas of the pharmaceutical value chain have undergone substantial transformation, the commercial model has remained comparatively stable.

In the United States, pharmaceutical commercialisation continues to rely heavily on sales representatives engaging directly with healthcare professionals, supported by market research and targeted marketing initiatives.

This model is increasingly under pressure.



Healthcare systems are becoming more complex, payer scrutiny is intensifying and digital technologies are reshaping how healthcare professionals and patients access information.

Artificial intelligence and advanced analytics are already beginning to transform commercial decision-making. AI-driven research tools can synthesise vast quantities of clinical, scientific and market data, enabling more sophisticated insights into treatment adoption and patient pathways.

Pharmaceutical companies must reconsider how they engage with healthcare professionals. Digital engagement models are expanding rapidly, but organisations must carefully balance technology-enabled outreach with the importance of trusted relationships between clinicians and industry experts.

There is also growing evidence in the academic literature that omnichannel engagement can positively affect physician engagement and prescribing behaviour, supporting the case for a commercial model that blends digital capability with human relationships rather than replacing one with the other [10].

In addition, patients themselves now have significantly greater access to medical information and are increasingly engaged in treatment decisions. This growing transparency can have substantial market implications.

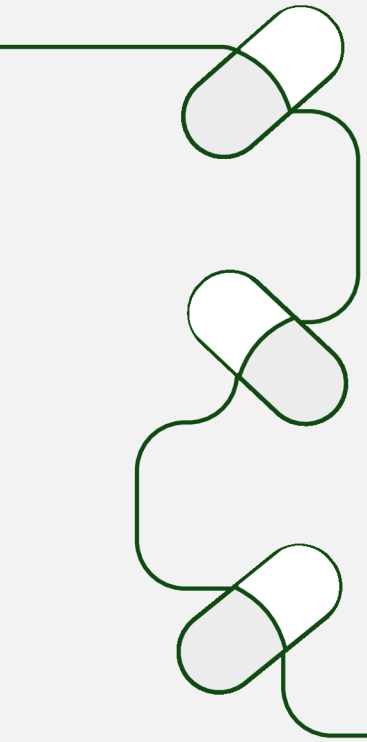
For example, in the rapidly evolving GLP-1 treatment market, early investor expectations were broadly similar for therapies from Novo Nordisk and Eli Lilly. Once efficacy data indicated stronger weight-loss outcomes for Eli Lilly's therapy, investor sentiment shifted rapidly, affecting market momentum for competing treatments.

Future commercial models will need to place greater emphasis not only on product promotion but also on patient engagement and access strategies.

This becomes particularly significant when considering how patients access information about potential treatments. The rise of social media as a source of medical information, and misinformation, has changed the competitive landscape for traditional pharmaceutical organisations. They must now compete with wellness brands when vying for patient attention, making direct to patient engagement increasingly important.

When considered in total, the industry will be forced to fundamentally reconsider how therapies ultimately reach patients. Pharmaceutical companies are entering a phase of commercial architectural innovation, exploring models such as direct–to–business or direct–to–consumer approaches to improve market penetration.

What questions do pharmaceutical organisations need to answer to deliver faster, better and cheaper?



How flexible does a commercial strategy need to be across different products and markets? How prepared are organisations for competitive shifts?

Where will patient preferences and behaviours shape demand and adoption? How do organisations engage, educate, and support patients?

Where can technological advancements meaningfully improve effectiveness and patient access? Where do they add complexity?

Successful organisations are likely to adopt flexible commercial strategies rather than committing exclusively to a single model. This flexibility will allow companies to tailor their commercial approach to the specific characteristics of individual therapies and markets.

5. Dynamic Manufacturing Supply Chains

Reducing risk in increasingly complex delivery models

Pharmaceutical manufacturing has undergone significant structural transformation.

Contract manufacturing organisations (CMOs) now provide specialised capabilities across areas such as biologics production, advanced therapy manufacturing, fill–finish operations and small–batch manufacturing.

Outsourcing manufacturing enables pharmaceutical companies to avoid large capital investments while maintaining operational flexibility across their production networks. Historically, however, the global pharmaceutical supply chain has been designed primarily for cost efficiency rather than resilience.

The industry relies heavily on globally distributed manufacturing networks, with significant concentrations of active pharmaceutical ingredient (API) production in regions such as China and India. Analysis from the United States Pharmacopeia (USP) indicates that global API manufacturing remains highly concentrated. Its 2025 Medicine Supply Map analysis identified 92% of API drug master file holder locations and highlighted continued manufacturing concentration in India and China [11].

Recent global disruptions have exposed vulnerabilities within these supply networks, making supply resilience an increasing strategic priority. The UK parliament has recently presented medicine security as a national priority, highlighting growing concern around the ‘fragile global supply chain’ [12], and similar political direction is being seen in the US [13].

Future pharmaceutical supply chains will need to evolve toward dynamic supply grids, consisting of multi–vendor production networks distributed across multiple geographic regions.

Supported by digital monitoring and predictive analytics, these systems could allow companies to shift production between facilities, allowing them to respond more rapidly to disruptions and maintain regulatory compliance across distributed manufacturing networks.

As therapies become more complex, particularly biologics and personalised medicines, manufacturing systems will also need to become more technical and scaling must be managed with care. Achieving this will require greater visibility across the entire supply chain, in particular the “last mile” of product distribution.

This points toward a different future-state supply model: less a static low-cost network, and more a dynamic, digitally enabled supply grid with regional optionality, improved visibility and greater resilience to geopolitical, regulatory and operational disruption.

What questions do pharmaceutical organisations need to answer to deliver faster, better and cheaper?

01 How do organisations redesign supply chains from cost-optimised models to resilience-first models, without losing competitiveness? How can this be used to diversify risk effectively?

02 How can digital monitoring, data integration, and predictive analytics be leveraged to enable real-time supply chain visibility and decision-making?

03 What operational changes are required to support the manufacturing of complex therapies such as biologics and personalised medicines at scale?

04 What governance, partnerships, and strategies are needed to build and sustain a robust, future-ready pharmaceutical supply network?

Successful organisations will focus on building diverse supply networks to allow more rapid adaptation to changing regulations and geopolitical forces. A focus on end-to-end visibility, particularly in the “last mile,” will help prevent disruptions in product delivery to patients.

The emerging model: Pharma as innovation aggregator

Taken together, these trends point toward a significant shift in the role of pharmaceutical companies within the innovation ecosystem.

Rather than operating solely as vertically integrated discovery organisations, pharmaceutical companies will increasingly function as: innovation aggregators and investment engines.

CURRENT	FUTURE
"Bio-tech" approach with heavy focus on wet-lab environment, with some capability borrowed from big-tech.	"Tech-bio" approach with orchestration of scientific, synthetic and real-world information to drive down financial risk and fail fast.
Large retained internal discovery footprints with minor augmentation through partnerships.	A network of alliances and acquisitions to accelerate and amplify discovery and share investment risk.
Outsourced arms-length capabilities (e.g. CROs) to deliver within a linear and regulatory-framed environment.	A cyclical orchestrator across CRO, technology and bio-tech companies to deliver economies of scale.
Point-to-point B2B service provision heavily focused on HCPs.	Bespoke B2B2C commercial models that place emphasis on patient engagement and experience.
High dependence on a few key suppliers with a focus on low cost and margin.	A web of interconnected and resilient supply chains that deliver a more resilient delivery model.

In this emerging model, pharmaceutical organisations would focus on:

01 | Identifying promising technologies across biotech and traditional technology organisations

02 | Integrating discoveries into a managed network of scalable research, clinical development and manufacturing partners

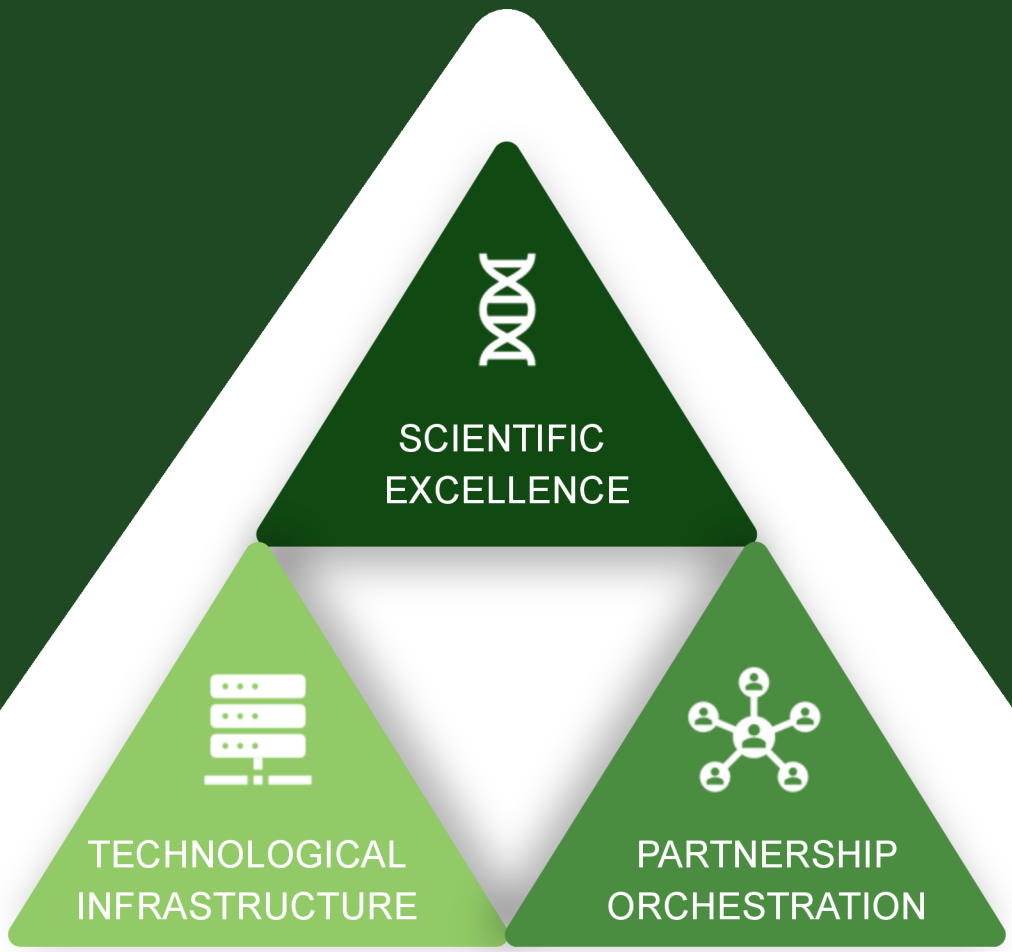
03 | Improving agility and interoperability of enabling functions, such as legacy systems and data

Discovery itself will remain the bedrock of the industry, but it will increasingly occur across a distributed network of biotechnology firms, technology platforms and specialised service providers.

The pharmaceutical R&D model has already begun to evolve from fully integrated research institutions to complex innovation networks. The next phase of transformation may be driven by regulatory changes and technological developments.

If this trajectory continues, pharmaceutical companies will increasingly compete not only on their ability to discover new therapies, but also on their ability to orchestrate innovation across a complex global ecosystem.

The most successful organisations will be those that combine three critical capabilities:



For pharmaceutical leaders, the central strategic question has shifted. It is no longer how to improve R&D productivity, but rather its role in a system that is more distributed, more digital and more interdependent than the one that came before.

Organisations that are smaller may be better able to adapt to this change and have an automatic advantage over the larger, more traditional 'Big Pharma' firms.

Will this mean that, after years of thinking it was too big to fail, the age of 'Big Pharma' is coming to an end?

Supporting the Future of Pharma

At Oaklin, we help pharmaceutical organisations navigate change by addressing outdated, fragmented operating models and enabling them to respond to evolving demands. We work side-by-side with clients in focused, experienced teams, bringing cross-sector insight and unconstrained thinking to solve critical strategic challenges and deliver lasting change. Our connected workforce keeps us agile and adaptable, allowing us to deliver tailored solutions without relying on off-the-shelf thinking.

Recognised by the Financial Times in 2026, Oaklin has a strong track record of guiding pharmaceutical organisations through complex transformations.

We shape, deliver and assure complex operating model transformations, drawing on our expertise that spans multiple areas critical to the future pharmaceuticals, including:

- Data and AI strategy
- Digital transformation
- Workforce planning and people optimisation
- Operating model design
- Commercial and procurement advisory
- M&A strategy and alliance management

By helping organisations align technology, talent and operating models, we support pharmaceutical companies in defining and realising their vision for the future.

Get in touch

Do you want to learn more about managing operational changes in the pharmaceutical industry?

Connect with our team:

Barry Hahn
barry.hahn@oaklin.com

Nick Palmer
nick.palmer@oaklin.com

Josh Carhart
josh.carhart@oaklin.com

Miriam Grant
miriam.grant@oaklin.com

FT FINANCIAL TIMES statista UK'S LEADING MANAGEMENT CONSULTANTS 2026 Chemicals & Pharmaceuticals

Oaklin

Wild about ideas,
serious about business

www.oaklin.com

Sources:
[1] https://www.phrma.org/policy-issues/research-development#:~:text=On%20average%2C%20it%20takes%2010,Drug%20Administration%20(FDA)%20approval.
[2] https://www.drugpatentwatch.com/blog/predict-the-patent-cliff/
[3] https://www.fda.gov/news-events/press-announcements/fda-proposes-framework-advance-credibility-ai-models-used-drug-and-biological-product-submissions
[4] https://www.nature.com/articles/d41573-023-00102-z
[5] https://pmc.ncbi.nlm.nih.gov/articles/PMC12616946/
[6] https://www.abacum.ai/blog/clinical-trial-costing
[7] https://www.medicalnewstoday.com/articles/304607
[8] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements
[9] https://www.gov.uk/government/publications/rare-therapies-and-uk-regulatory-considerations/rare-therapies-and-uk-regulatory-considerations
[10] https://academic.oup.com/jphsr/article/14/1/55/7058752?utm_source=chatgpt.com&login=false
[11] https://qualitymatters.usp.org/global-manufacturing-capacity-active-pharmaceutical-ingredients-remains-concentrated
[12] https://publications.parliament.uk/pa/ld5901/ldselect/pubserv/252/252.pdf
[13] https://www.federalregister.gov/documents/2025/05/08/2025-08267/regulatory-relief-to-promote-domestic-production-of-critical-medicines