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Unleash AI's potential
Measuring the return from
pharmaceutical innovation – 14th edition

April 2024

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Foreword

Welcome to *Unleash AI's potential*, Deloitte's fourteenth annual report in our Measuring the return from pharmaceutical innovation series. Our report explores the performance of the biopharmaceutical (biopharma) industry and its ability to generate returns from investment in innovative products in the development pipeline. The current biopharma R&D operating model faces several serious challenges, including ongoing regulatory changes, loss of exclusivity of an unprecedented number of high-value assets, and the rapid pace of scientific and technological advancements. However, advances in digitalisation and artificial intelligence (AI) present new opportunities to improve R&D productivity, paving the way for a new era of innovation and accelerating patient access to new therapies. As always, our report explores the industry's performance, the changing characteristics of the late-stage portfolios and the opportunities for biopharma companies to improve capital returns.

Between 2010 and 2023, our report series has provided insights into the productivity of biopharma R&D. In 2010, we analysed the expected return on investment from the late-stage pipelines of a cohort of 12 large-cap biopharma companies. Over subsequent years, the composition of our cohort has evolved to now include the top 20 companies by R&D spend in 2020. Our analysis in 2023 shows that following a long-term trend of declining returns that there are some welcome signs of improvement with the cohort's internal rate of return rising to 4.1 per cent.

Insights from our year-on-year analysis have demonstrated that transformational change in R&D productivity is essential if improvements in projected returns across the biopharma industry are to be sustained and grow. Our analysis this year shows that this conclusion is as relevant as ever given R&D projected returns remain below the cost of capital which will make R&D leaders' funding requests continue to be challenging.

Today, the industry is increasingly using technology-enabled approaches, including AI, to optimise the use of a wide range of proprietary R&D data to inform their decision making. However, the full benefits can only be obtained if relevant data are managed, processed and utilised to gain actionable insights. Advances in AI, including generative AI, can enable companies to demystify complex disease biology, expedite drug discovery, cut study timelines, revitalise the clinical trial experience and improve regulatory success. Ultimately, unleashing AI's potential could be the key to improving longstanding internal and external productivity challenges across the biopharma R&D industry but these activities need focus to ensure value is created.

We explore these themes in our report and, as always, welcome your feedback and look forward to discussing the implications of our findings.

Colin Terry
Partner
UK Life Sciences and Healthcare Consulting Leader

Kevin Dondarski
Principal
Life Sciences Strategy

Executive summary

Investments and advances in biopharma research and development (R&D) continue to fuel innovation, improve health outcomes and shape the future of health. This year's analysis shows signs of improvement in productivity following a steep decline in 2022. However, as biopharma companies work to sustain a profitable R&D pipeline and bring new therapeutics to market, they are navigating a complex landscape of regulations, looming patent expiries, technological advancements, and competitive pressures.

About this report

Since 2010, our report series *Measuring the return from pharmaceutical innovation* has provided insights into the productivity of biopharma R&D. Our inaugural report analysed the return on investment that 12 large-cap biopharma companies might expect to achieve from their late-stage pipelines. Over the past 14 years, the composition of our cohort has now evolved to include the top 20 companies by 2020 R&D spend.

This year, we have expanded the scope of our analysis to include an expanded range of assets, label expansions and line extensions and have increased the granularity of our data set. To supplement our data analysis and understand better the underlying drivers of change in internal rate of return (IRR), this year we interviewed ten R&D leaders as well as drawing on the expertise of Deloitte colleagues who operate in the R&D space and on an extensive literature review.

Measuring the return from pharmaceutical innovation

Our analysis over the past 14 years has shown a steady decline in productivity between 2010 and 2019, a short-lived improvement due to the impact of the COVID-19 assets in 2020 and 2021, followed by a dip in 2022, and in the 2023 cycle, we are beginning to see signs of some improvement. This year's modelling, based on a dataset which includes an expanded scope of assets and line extensions, calculates that the IRR has risen to 4.1 per cent from 1.2 per cent last year, which was the lowest point for the cohort since our analysis began.

IRR depends on both efficiency (cycle times and costs) and value creation (risk-adjusted forecast sales), each of which has multiple parameters that can improve outcomes. It is therefore important to understand both the trends in costs to develop an asset from discovery to launch and also the risk-adjusted forecast revenue of the assets in the pipeline.

Total reported R&D spend by our cohort has increased from $139.2 billion last year to $145.5 billion in 2023, an increase of 4.5 per cent. The average R&D cost to progress an asset from discovery to launch has remained flat for 2022-2023 at $2,284 million per asset, reflecting an expanded range of assets and line extensions in the analysis this year.

The cohort's average forecast peak sales per pipeline asset fell from $389 million in 2022 to $362 million in 2023. This continues the decline from the 2021 peak ($500 million) that was driven by high value COVID-19 assets. Reflecting the successful approval of high value assets which we have observed year-on-year, the total revenue for our cohort continues to trend upwards without interruption with reported top 20 pharma R&D sales increasing by 9.6 per cent in 2023.

Improving productivity in biopharma R&D will never be easy given the need to balance efficiency (cost) and value creation (sales), each of which depends on multiple factors that can influence the drivers of change. This year, regulatory changes, the impending and unprecedented scale of the loss of exclusivity of high value assets for many companies in our cohort, inflationary pressures, the rapid pace of scientific and technological advances and rising protocol design complexity are all placing significant pressures on the current R&D operating model but are also creating new opportunities to improve R&D productivity.

Realising efficiency opportunities

This rise in R&D costs can be attributed to several factors, including more complex trial requirements, regulatory changes, the impact of inflation, and continuing to operate in functional silos. Despite the increasing expenditure, the cost of a project very rarely deters a biopharma company from pursuing it, as ultimately the primary driver is to develop a successful product that benefits the intended patient population.

Long development cycle times have been a challenge for the industry for many years, reflecting the escalating trial complexity in delivering advanced therapies for niche and rare indications or complex neurological conditions. Developing more flexible and adaptable clinical trial processes can improve productivity and help companies respond more effectively to the rapidly evolving regulatory and commercial landscape, and in turn reduce costs, while bringing products to market more quickly and effectively. For a modernised trial to be successful, a clean, understandable and efficient process needs to be identified that enables clinical trials to represent the diversity of the intended patient population.

Regulatory compliance can be either a barrier to or an enabler of productivity in the highly regulated biopharma industry. Interpreting the new and evolving regulatory expectations and implementing any necessary changes in a coordinated, cost-efficient and timely manner, across a number of business functions, is a significant challenge for the industry. Most of our interviewees were concerned about the changing regulation landscape, and specifically called out the US Inflation Reduction Act (IRA). However, there are a plethora of other changes in regulatory requirements on clinical endpoints, diversity of trials and sustainability reporting, which differ across geographies, and can have a significant impact on R&D costs and productivity.

Biopharma companies are increasingly using technology-enabled approaches that use R&D data to inform their decision-making. As a result, the amount of data produced during clinical trials is growing exponentially; but the benefits can be obtained only if the data is managed, processed and utilised to gain actionable insights. Given the pace of technology innovation, and increasing use of AI-enabled technologies, the time is ripe for the industry to scale the use of digital technology to obtain enduring value.

Optimising the value of pipelines

We consider that the IRA in the US is likely to be an ongoing catalyst for change, rather than a one-time event. Eighteen months after being signed into law, the extent of its impact is yet to be realised, but it is front-of-mind for many across the industry. Despite the IRA being US legislation, there is and will continue to be a global ripple effect on biopharma strategies due to the international nature of the industry. EU patent law revisions will also impact development and launch strategies across multiple geographies.

With the greater incentives and penalties imposed by regulations, companies should map their commercial strategy for assets as early as possible in the development process. There is also a need to embed flexibility and a dynamic balance of internal and external sourcing in pipeline strategy. These strategies, developed through early cross-department engagement, need to look forward some five to ten years, develop a prediction of the commercial, regulatory and innovation landscape at the anticipated time of launch, and ultimately guide investment into those programmes most likely to be successful and high value. Harnessing advanced analytics in commercial potential and technical and regulatory risk assessments will support the development of these strategies and the 'go or no-go' decisions at various stages across the R&D cycle.

Strategies to improve productivity

AI-enabled digital transformation is fast becoming a strategic imperative for leaders in life sciences. The biopharma industry is on the brink of large-scale disruption driven by interoperable data, advances in AI and analytics, open and secure platforms and patient-centric care, which have the potential to deliver less costly and more productive drug development. When developing the business case for investment in digital and AI, the short-term costs need to be balanced against the long-term efficiency gains. Executing large-scale strategies requires setting up a governance function for making investments, assessing value realised, and monitoring ethical and legal risks from use of AI.

Competitive intensity, scientific breakthroughs and regulatory incentives have skewed R&D spending toward certain areas, particularly oncology and rare diseases. By 2023, 39 per cent of late-stage development programmes for our cohort were focused on oncology and the proportion has been consistently greater than a third of the pipeline since 2020. At the same time, a third of the cohort's development programmes were targeted at rare diseases in 2023. As competition in over-concentrated therapeutic areas heats up and the focus of payers on the equitable allocation of health care spending rises, the current dynamic could change.

Ultimately, transforming the productivity of R&D will require companies to work entirely differently, drawing on change management skills, as well as partnerships and collaborations. If biopharma succeeds in capitalising on AI's potential, the internal and external productivity challenges driving the decline in the IRR of biopharma innovation will be reversed and the industry will thrive. We outline the key questions for R&D leaders to consider in establishing a resilient and cost-effective technology-enabled R&D strategy in the final section of this report.

Measuring the return from pharmaceutical innovation

Our annual report series Measuring the return from pharmaceutical innovation analyses the projected IRR that biopharma companies can expect to earn from their late-stage pipelines. The past 14 years have demonstrated that transformational change in R&D productivity is required to reverse the declining trends in returns across the biopharma industry while continuing to deliver innovation to patients. Our latest analysis shows that this conclusion is more relevant than ever, given that companies are facing an evolving regulatory landscape, growing cost pressures, declining peak sales and difficulties in replenishing their pipelines, with the result that projected R&D returns continue to remain well below the cost of capital.

About the report

Our report series Measuring the return from pharmaceutical innovation has provided insights into the productivity of biopharma R&D since 2010. Our inaugural report analysed the return on investment that 12 large-cap biopharma companies might expect to achieve from their late-stage pipelines. Over the past 14 years, the composition of our cohort has now evolved to include the top 20 companies by 2020 R&D spend.

Methodology

This year, we have expanded the scope of our analysis to include an expanded range of assets, label expansions and line extensions and have increased the granularity of our data set. For each of the companies in our cohort, our new data provider, Evaluate, provides sales forecasts for assets and indications in the late-stage pipelines, estimates of the probability of technical and regulatory success (PTRS) and pipeline composition data such as therapy areas, modalities and the source of innovation.

We continue to use the same objective methodology, which focuses on each company's late-stage pipeline, using multiple inputs to calculate the IRR, which is our measure of R&D productivity. The inputs to our calculation include:

- the total R&D expenditure incurred by a company in bringing its assets to launch (based on publicly available information from audited annual reports and readily available data from third-party data providers)

- the impact of in-licensing and mergers and acquisitions (M&A) on R&D costs

- forecast estimates of the future revenue that will be generated from the launch of the late-stage assets (revenue forecasts provided by Evaluate)

- success rates in late-stage development to risk-adjust projections

- the cost of failure due to the inherent risks in undertaking R&D

- the impact of clinical cycle times.

We consider the late-stage pipeline to be assets in phase II with pivotal or breakthrough designation, in phase III, or filed for regulatory approval. As assets are approved, their forecast revenues move out of the late-stage pipeline into the commercial portfolio, and in doing so move out of scope of our analysis. At the same time, as assets progress through the development cycle into the late-stage pipeline, they enter the scope of our analysis. We are continually working to improve the methodology, modelling and scope of our analysis to ensure greater accuracy and more comprehensive insights while ensuring that a consistent and objective approach is applied across all companies each year.

To supplement our data analysis and understand better the underlying drivers of change in IRR, this year we interviewed ten R&D leaders, nine from companies in our cohort and one from a R&D platform technology company, as well as drawing on the expertise of Deloitte colleagues who operate in the R&D space and on an extensive literature review. For more details of the methodology and companies included in our cohort, see methodology annex.

**Projected returns from innovation have improved this year**

Last year's modelling of R&D productivity (as measured by IRR) showed that 2022 marked the lowest point for the cohort since our analysis began, as the result of the successful approvals and commercialisation of several high value forecast assets which left the scope of our analysis. This year's modelling, based on a dataset which included an expanded scope of assets and line extensions, calculates that the IRR has risen to 4.1 per cent, as shown in Figure 1. The distribution of IRRs across our cohort of 20 companies narrowed in 2023, with the lowest outlier sitting well above the large negative IRRs we witnessed for some companies across 2019-2022. Additionally, the bottom of the interquartile range in 2023 has a positive IRR for the first time in five years, excluding the 2021 COVID-19 skew.

In 2023, as in 2022, several high value forecast assets were approved, and on entering the commercial portfolio left the scope of our analysis. These include GLP-1 receptor agonists used for the treatment of type 2 diabetes, novel oral medication for plaque psoriasis, and the first single-dose preventative option for respiratory syncytial virus (RSV). However in 2023 we also saw a number of new high value forecast entries to our late-stage pipeline that target large patient populations. These include multiple single and combination GLP-1 receptor agonists targeting chronic weight management, monoclonal antibodies for early Alzheimer's disease, as well as infectious disease vaccines utilising mRNA platforms.

The scientific breakthroughs enabling the targeting of these large patient population indications has the potential to reignite the landscape of blockbuster assets and impact positively the health outcomes of a greater proportion of the global population. Nevertheless, as we discuss later in the report, executing sustainable pipeline replenishment remains a nuanced and complex strategy for biopharma companies.

The IRR depends on both efficiency (cycle times and costs) and value creation (risk-adjusted forecast sales), each of which has multiple parameters that can improve outcomes. It is therefore important to understand both the trends in costs to develop an asset from discovery to launch and the risk-adjusted forecast revenue of the assets in the pipeline.

Figure 1. Return on late-stage pipeline, 2013-2023
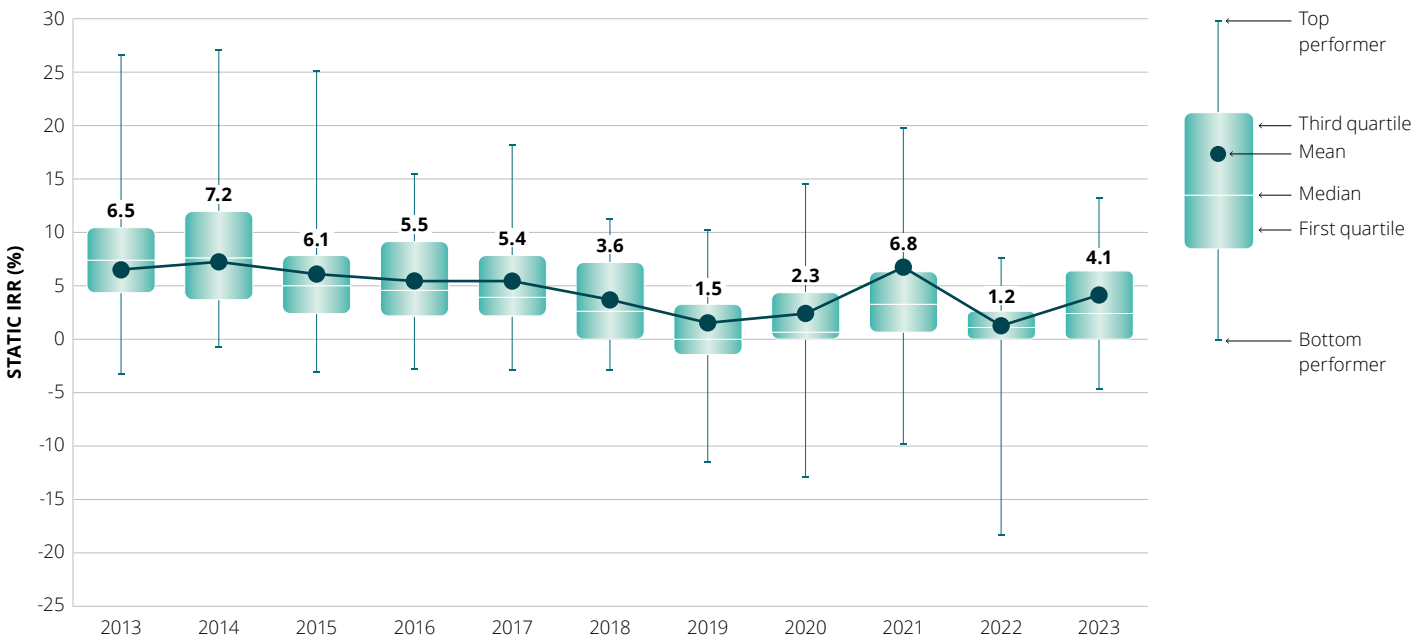
Note: 2013-2022 calculated from GlobalData dataset, 2023 data point calculated from Evaluate dataset
Source: Deloitte analysis, 2024.

While the total R&D expenditure has increased, the average cost to develop a pipeline asset is unchanged
Figure 2 shows that the average R&D cost to progress an asset from discovery to launch has remained flat for 2022-2023 at $2,284 million per asset. However, this plateau results from the larger number of assets in the 2023 portfolio due to the increase in the scope of assets and line extensions. When looking at the cost of R&D from discovery to launch all assets in their late-stage portfolio, the average company spend increased from $31.75 billion in 2022 to $48.54 billion in 2023.

Total reported R&D spend by our cohort increased from $139.2 billion in FY2021 to $145.5 billion in FY2022, an increase of 4.5 per cent. Three of the companies in our cohort increased their pharma R&D spend by over 25 per cent between FY2021 and FY2022.
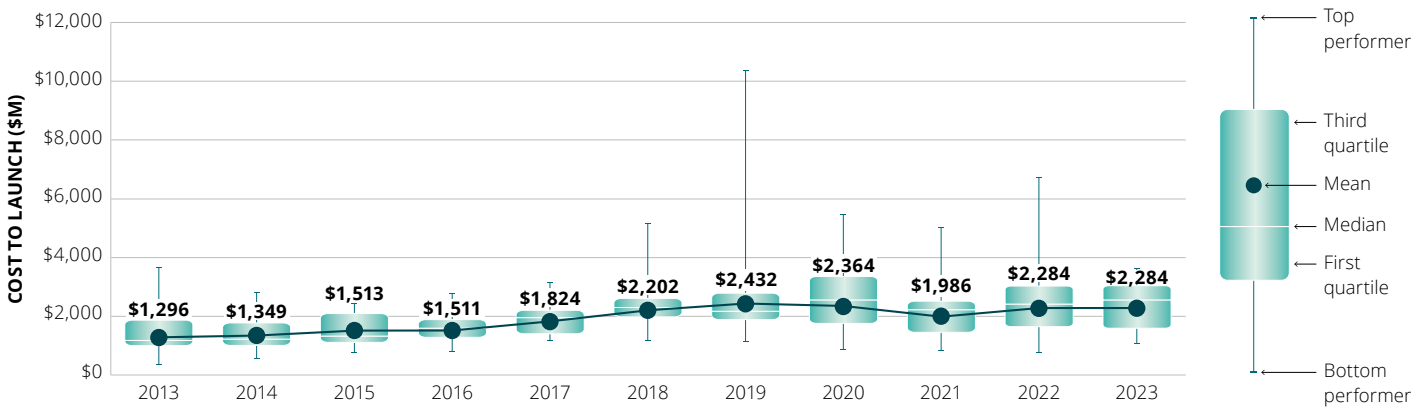
The average forecast peak sales per asset has decreased
In 2023 only one of the companies in our analysis is predicted to achieve forecast peak sales per asset of more than $1 billion. The cohort's average forecast peak sales per pipeline asset decreased from $389 million in 2022 to $362 million in 2023, as shown in Figure 3.

This continues the decline from the 2021 peak ($500 million) that was driven by high value COVID-19 assets. The distribution of the average forecast peak sales for the companies continues to converge after the disparate effect caused by high value COVID-19 assets of some companies.

Reflecting the successful approval of high value assets which we have observed year-on-year, the total revenue for our cohort continues to trend upwards without interruption. Reported top 20 pharma R&D sales in FY2022 increased by 9.6 per cent, to $719.2 billion from $656.2 billion in FY2021.

Figure 2. Average R&D cost to develop an asset from discovery to launch, 2013-2023

Note: 2013-2022 based on GlobalData dataset, 2023 data point calculated from Evaluate dataset
Source: Deloitte analysis, 2024.

Figure 3. Average forecast peak sales per pipeline asset, 2013-2023
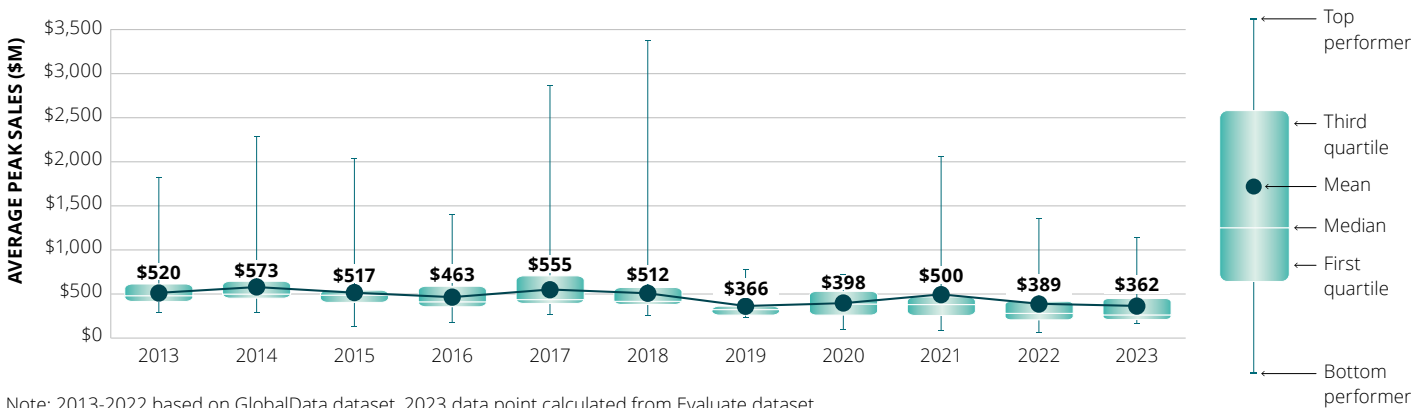
Note: 2013-2022 based on GlobalData dataset, 2023 data point calculated from Evaluate dataset
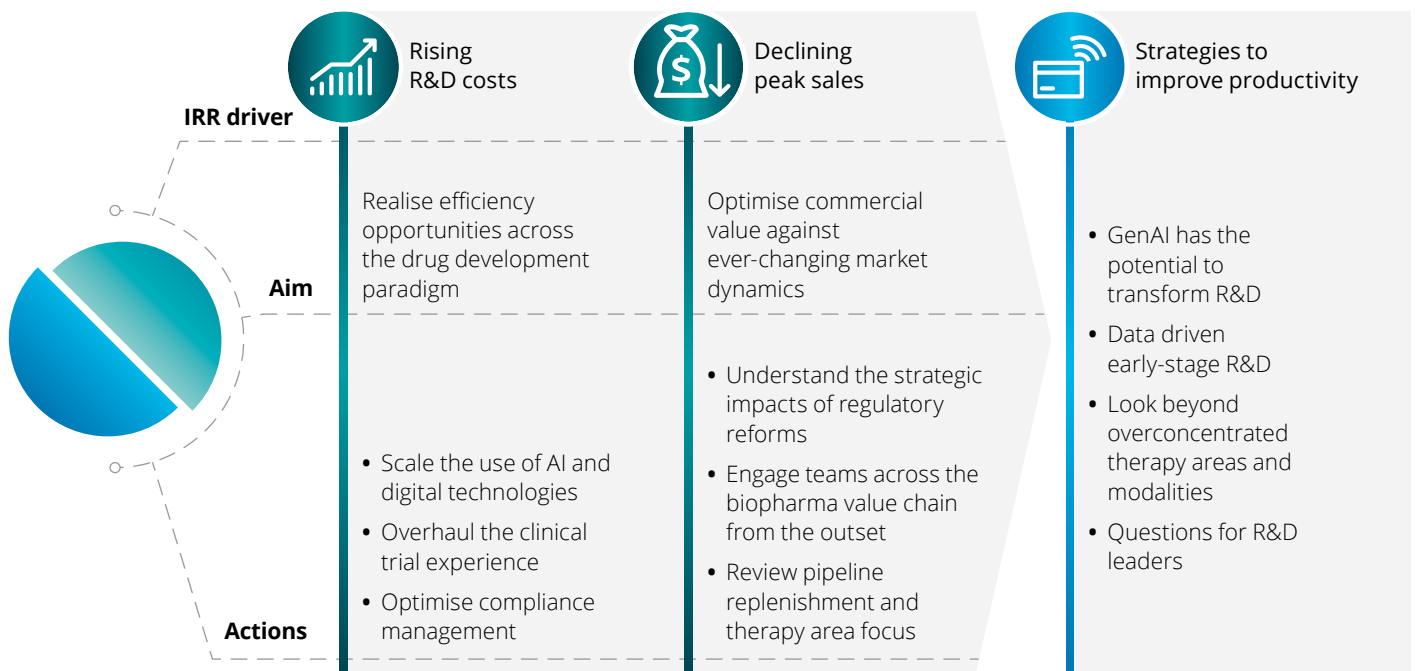Source: Deloitte analysis, 2024.

Drivers of the change in R&D productivity

Our analysis over the past 14 years has shown a steady decline in productivity (IRR) between 2010-2019, a short-lived improvement due to the impact of the COVID-19 assets in 2020 and 2021, followed by a dip in 2022, and in the 2023 cycle, we are beginning to see signs of some improvement. However, improving productivity in biopharma R&D will never be easy given the need to balance efficiency (cost) and value creation (sales), each of which depends on multiple factors that can influence the drivers of change.

This year, regulatory changes, the impending and unprecedented scale of the loss of exclusivity of high value assets for many companies in our cohort, inflationary pressures, the rapid pace of scientific and technological advances and rising protocol design complexity are all placing significant pressures on the current R&D operating model, but are also creating new opportunities to improve R&D productivity, see Figure 4.

In the rest of this report, we will explore each of these productivity drivers in detail, and dive into the levers that biopharma companies can pull to improve their rate of return on investment, and also the many issues that need to be addressed before a clear path ahead can be forged.

Figure 4. Opportunities to tackle the drivers of IRR and improve productivity

Source: Deloitte analysis, 2024.

Our analysis over the past 14 years has shown a steady decline in productivity (IRR) between 2010-2019, a short-lived improvement due to the impact of the COVID-19 assets in 2020 and 2021, followed by a dip in 2022, and in the 2023 cycle, we are beginning to see signs of some improvement.

Realising efficiency opportunities

While R&D executives prioritise expediting the time to market for drugs targeting unmet needs, they also have pressing concerns about the consistently high expenditure and rising costs of R&D. By scaling end-to-end digital transformation and the use of AI and other technology tools, companies have the potential to increase drug development efficiencies dramatically. However, investment in data infrastructure and AI capabilities needs to recognise the importance of maintaining 'the human in the loop' in realising value and efficiency gains.

Rising R&D costs are attributable to several factors

As stated previously, the R&D spend by our top 20 cohort increased by 4.5 per cent to $145.5 billion in FY2022, from $139.2 billion in FY2021. This rise in R&D costs can be attributed to several factors, including more complex trial requirements, regulatory changes, the impact of inflation, and continuing to operate in functional silos. Despite the increasing expenditure, the cost of a project very rarely deters a biopharma company from pursuing it, as ultimately the primary driver is to develop a successful product that benefits the intended patient population.

While long development cycle times have been a challenge for the industry for many years, our interviewees reflected that the expectations of the clinical trial experience are growing as trials become much more sophisticated. Long cycle times also reflect the escalating trial complexity in delivering advanced therapies for niche and rare indications or complex neurological conditions like Alzheimer's, which present challenges in agreeing endpoints. In 2023, half of the development programmes in our dataset involved advanced therapies and biologics, including cell and gene therapies, monoclonal and recombinant antibodies, protein and peptide therapies, and plasma-derived therapies. Additionally, 30 per cent of the development programmes of our cohort in 2023 are targeted at rare indications.

The need to recruit more specialised and diverse sub-populations for complex studies has compounded recruitment challenges, lengthening trial timelines.

Added to this is the lingering issue of high dropout rates due to poor participant experience, leading to loss of valuable trial data and additional costs and time to recruit replacements. But the challenges are not limited to patient recruitment. Our interviewees commented on the numbers of skilled medical professionals leaving the industry since the pandemic, leading to a shortage of experienced site staff required to conduct trials. The ripple effect has only intensified the struggle to retain skilled and experienced staff vital to R&D productivity, which in turn adds to the costs.

"We're now having to elucidate more and more complex science and do more and more complex studies. Recruiting patients for complex studies takes a long time. We are setting higher expectations of how patients should experience a clinical study. And hospital systems and medical systems don't want to share the data except for monetary reward. All these things lead to higher costs, if you are a company that is committed to innovative medicines."

**Former Vice President**, R&D IT, Top 20 Biopharma

R&D executives are most concerned about changing regulations

We asked our interviewees to rank their concerns about factors affecting drug development. Figure 5 shows that R&D executives were more concerned with changing regulations such as the Inflation Reduction Act (IRA) than with rising R&D costs and increasing cycle times. In fact, more challenging regulatory requirements which require biopharma companies to increase the quality and quantity of evidence generated during clinical trials are impacting the complexity of clinical trial design and development and therefore the costs and productivity of R&D. Developing more flexible and adaptable clinical trial processes can improve productivity and help companies respond more effectively to the rapidly evolving regulatory and commercial landscape, and in turn reduce costs, while bringing products to market more quickly and effectively. Ultimately, while rising R&D costs need to be tackled, it's important to strike a balance between cost considerations, the experience of patients and site staff, and the need to innovate and bring new products to market more quickly.

Effective management of regulatory compliance

Regulatory compliance can be a barrier to or an enabler of productivity in the highly regulated biopharma industry. It is a fundamental requirement for the safety and efficacy of product development, and provides a framework in which commercial objectives and patient access can be optimised. However, interpreting the new and evolving regulatory expectations and implementing any necessary changes in a coordinated, cost-efficient and timely manner, across a number of business functions, is a challenge for the industry.

Figure 5. Factors that are of most concern to R&D executives
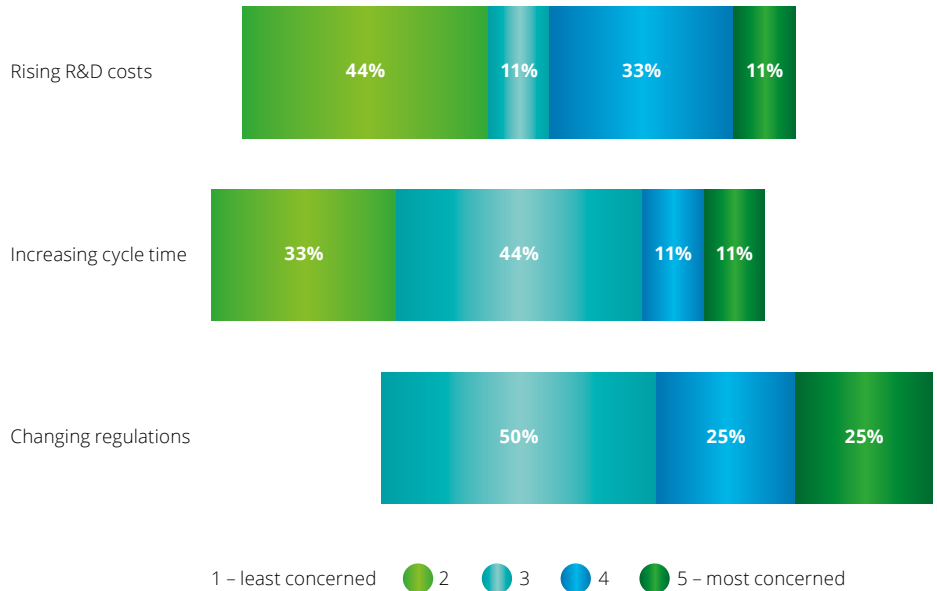
Note: N=9

Question: On a scale of 1 to 5, how concerned are you about the following factors impacting R&D productivity?

Source: Deloitte analysis, 2024.

"I see changing requirements globally that do not always align across regulatory bodies. More and more individual countries have specific requirements which is complicating development programmes. Sometimes you have to make tactical choices, deselecting specific countries or pushing intended commercial opportunities to a later time."

Executive Vice President, Development, Top 20 Biopharma

Most of our interviewees were concerned about the changing regulation landscape, and specifically called out the US IRA. However there are a plethora of other changes in regulatory requirements on clinical endpoints, diversity of trials and sustainability reporting, which differ to varying degrees across geographies, but which can have a significant impact on R&D costs and productivity. While the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are often considered as regulatory counterparts, our interviewees noted that they diverge in their requirements. Changing regulations like the IRA, if implemented as intended, is likely to introduce further misalignment across the major regulatory agencies, and pose challenges in clinical execution, hindering innovation and increasing the cost and time taken to ensure compliance.

The US Inflation Reduction Act (IRA)

The IRA, passed in 2022, has empowered the Center for Medicare and Medicaid (CMS) to negotiate directly with manufacturers on the price of some high cost Medicare drugs. It caps out-of-pocket spending at $2,000 per year, and puts penalties in place for drug manufacturers that increase their Medicare prices by more than the rate of inflation.[1] Prior to the IRA, Medicare was forbidden from negotiating drug prices. Now, the CMS is empowered to negotiate the maximum fair prices for biologics 13 years after approval and small molecule drugs nine years post-approval.[2] We have calculated that it takes an average of over eight years for a small molecule to recoup investment cost and over seven years for a biologic.[i]

In August 2023, the CMS released a list of the 10 drugs, that are no longer covered by patent exclusivity, for the first round of price negotiation. Together these 10 drugs accounted for $50.5 billion in Medicare spending from June 2022 to May 2023.[3] This could shorten the economic product life cycle, impact future revenue, and drive changes in R&D and commercial strategy. Expert analysis of the likely response of companies is that they may rebalance portfolios towards biologics and single indication orphan drugs.[4]

In 2023, half the development programmes in our dataset involved biologics and advanced therapies, including cell and gene therapies, monoclonal and recombinant antibodies, protein and peptide therapies, and plasma-derived therapies. Advanced therapies have created challenges for regulators and pharma companies in agreeing surrogate endpoints, and also in design, manufacturing, and supply complications in the conduct of the trials themselves. The resultant complexities in clinical trial design can increase cycle times, but uncertainty about regulatory requirements can cause further delays and increase costs. When specific regulatory requirements do not align with clinical practice, this can be a disincentive to innovation and decrease the willingness to invest. Companies are increasingly partnering and working more closely with regulatory bodies and relevant patients to develop surrogate endpoints during the early R&D stages that can be agreed for individual development programmes. We will return to the impact of changing regulations, particularly the IRA, on the potential commercial value of assets in the next section of this report.

> *"We haven't figured out a way to have surrogate endpoints agreed by regulatory authorities.... How are we going to move the needle in Alzheimer's? It's clear that earlier treatment will be better. But who can sign up for many thousands of patients for 15 years? It's more of a policy barrier than a scientific one because we actually know what to do."*
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> **Executive Vice President**, Research and Development, Top 20 Biopharma

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i   Assuming 40 per cent operating expense, average R&D cost per asset at $2.3 billion and recouping R&D investment cost from a net cashflow perspective.

Scaling the use of AI and digital technologies

The traditional linear, randomised clinical trial process is inherently labour-intensive (using high cost human capital), complex, and highly regulated. We have highlighted in previous reports that digital technologies, automation tools, and patient-experience solutions can reduce the need for manual activities, and in turn reduce the overall cycle time and cost. However, these digital tools have so far had only an incremental, rather than transformational, impact on the productivity of clinical trials. The potential wide-scale adoption of generative AI (GenAI) to process and learn from terabytes of structured and unstructured data is seen by many as a potential game-changer in R&D. We cover this in our final section, *Strategies to improve productivity.*

Today, pharma companies are increasingly using technology-enabled approaches that use R&D data to inform their decision-making. As a result, the amount of data produced during clinical trials is growing exponentially; but the benefits can be obtained only if the data is managed, processed and utilised to gain actionable insights. In 2021, according to Tufts Center for the Study of Drug Development (CSDD), Phase III clinical trials generated an average of 3.6 million data points, three times the amount of data collected by late-stage trials ten years ago.[5]

There is growing evidence of successes in applying AI and digital technologies, all with humans in the loop, to the massive amounts of data that are collected during clinical development. This covers the entire R&D value chain from expediting target discovery, helping identify and select potential site and trial participants, recruiting and retaining trial participants, aggregating and analysing patient-generated data, and automating document generation, such as protocols and case safety reports, through to helping compile the dossiers for regulatory approval.

Nevertheless, to ensure that differentiation and value are obtained from digitalisation, decisions need to be made about the type, scale and reliability of clinical data collected– as well as how this data is to be managed, stored and utilised so that it can be optimised for research purposes. Digital clinical trial recruitment solutions, data platforms and AI-enabled tools contribute improvements to clinical research techniques, promoting a more patient-centric, cost-effective and manageable approach. Companies across our cohort are already realising the efficiency potential:

- TrialHub is a data intelligence platform for clinical trial planning that uses large language models and natural language processing to improve data usability, compatibility and flexibility. TrialHub provides a centralised access point for all participating teams in the trial planning phase to dependable data, ensuring it can be tailored for their unique purposes, thus avoiding fragmented analysis and siloed decision making and has been used in the planning of more than 6,000 trials:

  - a top 10 contract research organisation reported an increase in the speed of collecting standard of care insights by 20 times and save 170,000 hours of manual research.
  - a top 10 biopharma company avoided at least one substantial amendment and months of unsuccessful patient recruitment, all estimated at $1.6 million.
  - a consultancy company and their biopharma client needed a rescue strategy for a Phase III study and were able to develop a plan for the best countries, sites and DCT elements that can make the patient experience better and ended up having three times faster patient recruitment compared to before.[6]

- For the first time, an AI-designed drug targeting idiopathic pulmonary fibrosis, developed by Insilico Medicine, is in the second phase of clinical trials. The drug (ISM018_055) involved multiple AI-methods throughout its entire development process. Using Insilio Medicine's drug design platform Pharma.AI, the team used multiple AI methods to find a potential target for the disease and then generated promising drug candidates. ISM018_055 stood out for its ability to reduce scarring in cells and in animal models. Last year, the drug successfully completed a Phase I clinical trial in 126 healthy volunteers in New Zealand and China. The drug has reached this stage after three-and-a-half years compared to the normal timeline of around seven years from finding a target to completion of Phase I clinical trials. The company launched Phase II clinical trials in June 2023, which will further investigate the drug's safety and begin to test its efficacy in people with the disease.[7]

- AI can also reduce the number of patients needed for a trial. Unlearn, a start-up, creates digital twins of patients in clinical trials. Based on an experimental patient's data at the start of a trial, researchers can use the twin to predict how the same patient would have progressed in the control group and compare outcomes. This method typically reduces the number of control patients needed by between 20 and 50 per cent. Digital twins benefit not only researchers, but also patients who enrol in trials, because they have a lower chance of receiving the placebo.[8]

> *"With the level of investment that has gone into digitalisation, I don't think the full return has been seen. There have been a lot of failures. While we see continuous progress, it's not dramatic progress. We've had in the last half decade or so an enormous number of very fun and illuminating pilot experiments in the industry. But the number of things that have been scaled is far fewer."*
>
> **Executive Vice President**, Research and Development

Given the pace of technology innovation, and increasing use of AI-enabled technologies, the time is ripe for the industry to scale the use of digital technology to obtain enduring value. Our interviewees considered that despite the heavy investment into applications of AI, it has not yet become a game-changer and a full return is yet to be seen. This can be attributed to most companies investing in AI on an ad hoc basis, and they are yet to determine a clear, long-term strategy. Many interviewees acknowledged the hard work that is beginning to get enduring value from AI, but that deciding what to scale is a challenge.

Success requires a strategic focus and enterprise-level buy-in, both top-down and bottom-up, but our interviewees also recognised that it's hard for digitalisation to be top priority, given the explosion in science that is happening. Despite the lack of dramatic progress, interviewees recognised that continuous progress is being made across the industry, which is now accelerating with the adoption of GenAI and its potential to improve the productivity of R&D. We consider the impact of GenAI in the final section of this report, *Strategies to improve productivity.*

Overhauling the clinical trial experience

Today's standard patient-centric approaches are insufficient to resolve the recruitment and retention challenges that add to trial timelines and costs. Our interviewees recognised that there are higher expectations across the industry about how patients should experience a clinical study. By adopting a human-centred approach, companies can draw on patient needs, experiences, and community relationships to tackle unique issues with awareness, access, and trust. Building community relationships can help biopharma companies cultivate trust in medical research, reduce hesitancy to participate in research, and improve trial diversity.[9] Large language model-based apps that enable conversational interfaces with patients can help answer questions about studies at pivotal moments, such as during recruitment or consent, resulting in increased engagement and compliance.

One aspect that is often overlooked is the immense burden that clinical trials can place on investigators, site staff and patients, creating an unwillingness to participate in future research. Decentralised clinical trials (DCTs) were used during the pandemic, and although scaled adoption has yet to be realised, there is transformative potential for DCTs, or hybrid trial models that incorporate elements of decentralisation, such as e-consent, telehealth and sensors for virtual check-ins and remote assessments. Patient engagement in trials can be greatly enhanced, but this requires trial sponsors and site staff to adapt how they conduct clinical trials to serve patients better, without compromising data collection or evaluation tools, offering solutions such as mobile clinical research units to improve patient centricity, diversity and inclusion.[10, 11]

DCT capabilities include virtual training, telehealth, direct-to-patient shipments, patient reimbursement, connected devices, and image capture focused on meeting study participants in or near their homes, instead of requiring them to travel to trial sites for evaluation. An increase in the use of wearables that enable access to a wider range of communities across diverse age groups, ethnicities, and locations, could dramatically increase the flexibility of how trials are executed and the collection of real-world trial data. Devices like the Apple Watch, the Oura Ring, and smart clothing enable data collection in ways that increase accuracy and minimise historical trial burdens that participants have to navigate. Going forward we expect to see patient-centric DCT solutions incorporated as part of study design, which in turn should improve protocol compliance, patient recruitment and retention, and R&D productivity.[12]

However, remote monitoring and decentralisation is not a straightforward solution. Aspects of decentralisation can be burdensome. Recent research by the Tufts Center for the Study of Drug Development, which conducted an online survey among clinical research sites worldwide and gathered 355 responses, found that a high percentage of investigative sites (50.5 per cent) have had no experience with DCT solutions and only a small percentage (6.6 per cent) have participated in fully decentralised clinical trials.[13] Overall, half of respondents view DCT solutions as more burdensome than traditional clinical trials.[12]

In general, activities related to operational and managerial aspects of trial implementation were viewed as less burdensome when done remotely, while clinical procedures or elements that require study team-patient interactions were viewed as more burdensome when using DCT approaches rather than in-person or traditional methods. However, DCTs can still be operationally very complex when multiple systems and platforms are used.

While it is critical to balance the additional site burden against decreasing the patient burden, the industry can reduce complexity through other means, such as creating synthetic control arms, which can increase speed and support the inclusion of under-represented groups.[13]

Importantly, when it comes to clinical trials saving time translates into saving lives, or at least improving them, through faster availability of treatments. While these innovations enhance speed, precision, and cost-efficiency in drug development, patient safety remains paramount, necessitating a 'human-in-the-loop' and equity centred design approach.

This requires companies to invest in agile data processing, engage with regulators early, collaborate with external partners and prioritise portfolio management. The combination of GenAI, machine learning (ML), deep learning, and data analytics is positioned to enhance time to value across biopharma R&D, with a myriad of opportunities to enhance speed, productivity, quality and sustainability. Combining next-generation AI technologies with rich multi-omics data — capturing the 'language of life'— can close the loop across the R&D pipeline, with automated generation and testing of hypotheses from bench to bedside.[15]

For a modernised trial to be successful, a clean, understandable and efficient process needs to be identified that enables clinical trials to represent the diversity of the intended patient population. As identified in previous research reports, the clinical trial of tomorrow will be built on:

- purpose-led digital innovation

- establishing clinical trial networks

- an ingrained focus on sustainability (sustainability by design)

- extensive collaboration

- extensive data interoperability

- application of FAIR (findability, accessibility, interoperability and reusability) data standards

- and robust protection and privacy (security by design).[16, 17, 18]

Optimising the value of pipelines

As biopharma companies work to sustain a profitable R&D pipeline and bring new therapeutics to market, they navigate a complex landscape of regulations, looming patent expiries, technological advancements, and competitive pressures. Today the IRA, EU patent laws and the rapid advent of AI across the industry are demanding fast-paced, flexible and collaborative R&D operating models to stay ahead of the curve.

> *"The IRA has quite a limited scope on a small number of drugs. It's only the very largest drugs. It's probably an incremental impact and headwind, but it's not a real game-changing headwind. But if they scale that up, doing it for all drugs, we're going to have a shorter period of exclusivity. It becomes a slippery slope to more and more negotiation by Medicare. Then I think it will really stifle all kinds of innovation."*
>
> **Executive Vice President**, R&D IT, Top 20 Biopharma

The R&D executives we interviewed are more concerned with changing regulations such as the IRA than rising R&D costs and increasing cycle times. This is due, in part, to the relatively unknown impact of these regulations and the fact that other regulators, for example the EMA, are also introducing new and more stringent regulations impacting the revenue potential of assets. Having explored the impact of regulations on R&D costs and clinical trials in the previous section, we will look in this section of the report at the impact of regulation on optimisation of the commercial value of assets in development.

Regulatory reforms are likely to impact on indication expansion strategies

We consider that the IRA in the US is likely to be an ongoing catalyst for change, rather than a one-time event.[19] The ultimate goal of the IRA is to lower healthcare costs for American citizens through price negotiations and higher inflationary cap prices. However, the changes it will enact on Medicare prescription drug pricing will have far-reaching effects on the global biopharma industry.[20] Eighteen months after being signed into law, the extent of the impact is still yet to be realised, but it is front-of-mind for many across the industry. At present, the scope of the IRA is limited to ten drugs, taking effect from 2026, but these drugs are all blockbusters in our cohort's commercial portfolios.[21] By 2030, the number of drugs approved for price negotiations is expected to reach 80.[22]

In terms of launch and commercial strategies, many of our interviewees reflected on the difficult decisions around multi-indication launches that the IRA has the potential to impose on the industry. The traditional strategy for blockbuster assets is to market quickly with a narrow indication and then follow with much larger indications two or three years post-launch. However, biopharma companies may want to avoid triggering the IRA clock, the reduced time period before price negotiations, too long before the blockbuster indication launch. The alternative route of launching the biggest possible indication so the pre-negotiation window is maximised carries far more risk, with the potential for high investment followed by failure. There is no one-size-fits-all answer.

To mitigate exposure to negotiation, manufacturers may begin to favour drugs likely to be blockbusters outside the current scope of the Medicare market. This could entail a shift to drugs targeting conditions impacting younger people, as Medicare is primarily for the over-65s, or a greater focus on single indication orphan biologics which are out of scope of the IRA negotiations. A further strategy may be to not pursue post-approval trials to expand indications to avoid potentially being eligible.[23]

There is much more uncertainty if, or more likely when, the scope of the IRA expands. Our interviewees raised concerns that the IRA may stifle innovation because the incentives will be lower and profitability will be reduced, so that biopharma companies are likely to take fewer and smaller risks when progressing assets. However, this is not to say that biopharma R&D will involve fewer risks in total. Instead, those fewer assets progressed through the development cycle will likely be pressured into accelerated timelines, with clinical development efforts run in parallel in order to reduce time to market and recoup the cost before opening to price negotiations. Lessons from the very short development timelines of the COVID-19 therapeutics and vaccines, as covered in our 2021 and 2022 *Measuring the return from pharmaceutical innovation* reports, can be applied across portfolios to progress assets at greater pace.[24, 25]

Despite the IRA being US legislation, there is and will continue to be a global ripple effect on biopharma strategies due to the international nature of the industry. However, it is not the only impending change for the industry's regulations. The European Commission proposed in April 2023 to revise the EU's pharmaceutical legislation, described as the largest reform in over 20 years.[26] Similarly to the IRA, the proposed EU revisions focus on improving access to medicines while cutting down on market exclusivity and ultimately championing multi-indication products – incentivised by a one year extension to patents if the product targets more than one indication. Products will also receive a patent extension of two additional years if the products are launched across all the EU's member states (targeting the disparity in access to medicines across the EU).

Engage launch and commercial teams from the outset

With the greater incentives and penalties imposed by regulations, companies should map their commercial strategy for assets as early as possible in the development process. Novel scientific breakthroughs are not sufficient alone to guarantee market success. Many of our interviewees highlighted the operational silos between teams across the biopharma value chain. Without insights from across the company about the product, market landscape, regulations and patient population characteristics that will drive success if the drug progresses through to launch, strategic decisions about asset progression and launch and commercial strategies may not be as fully informed as they should be.

Early cross-department engagement and determination of the commercial value earlier in the development cycle, then following through with an aligned therapy area strategy and individual study design to ensure tracking to the market, will enable a more successful launch and commercial outcome to be achieved. Ultimately, if companies understand the commercial potential of a drug at the earliest possible stage in R&D, they can focus their resources on those drugs that are most likely to succeed.

Traditionally, large biopharma companies have relied on high value blockbuster assets to keep the industry afloat and counteract the 90 per cent of assets which fail during the development cycle and the high proportion which don't recoup the cost expended to get them to market. One-third of today's drug launches miss analysts' forecast expectations.[27] Additionally, the nature of patents, and the eventual loss of exclusivity and the development of lower cost generics, mean that biopharma companies rely on producing a steady stream of blockbusters to replace lost revenues. The loss of exclusivity is likely to have a bigger impact on our cohort over the next few years.[28] Deloitte's 2023 Life Sciences M&A trends report highlighted that M&A deal value grew by 46 per cent in 2023 and predicts that with big pharma continuing to face loss of exclusivity events across various therapeutic areas, 2024 will be another strong year for big pharma to plug portfolio gaps through M&A.[29]

Big pharma are suspected to continue to target late-stage development and early-stage commercial assets that can contribute material revenue growth in 2026 through to 2030.[30]

The strategy for launching blockbusters is likely to change. However, in a shifting market with a growing focus on targeted therapeutics, assets that meet unmet needs while having the potential to generate big profits are likely to remain a priority. Companies that engage commercial teams to develop therapy area strategies to guide R&D investments will support the identification and successful progression of high value assets. These strategies need to look forward some five to ten years, develop a prediction of the commercial, regulatory and innovation landscape at the anticipated time of launch, and ultimately guide investment into those programmes most likely to be successful and high value. Harnessing advanced analytics in commercial potential and technical and regulatory risk assessments will support the development of these strategies and the 'go or no-go' decisions at various stages across the R&D cycle.

Adopt sustainable pipeline replenishment strategies

By 2030, patents will have expired for 190 drugs, 69 of them current blockbusters, and almost every major pharma company will be impacted.[31] This equates to $236 billion in pharma sales at risk before 2030.[32] For an industry that invests around 20 per cent of its revenues in R&D, the need to replenish the commercial portfolio to maintain the pace of innovation is clear.[33]

When combined with the potential impact of IRA price controls, the projections indicate that there will be almost $160 billion less to invest in R&D at a time when the opportunities for breakthroughs have never been greater.[34] Therefore, biopharma companies should implement flexible sourcing strategies to plug revenue gaps, explore opportunities beyond over-concentrated therapy areas to minimise potential IRA impacts and implement data-driven R&D strategies to increase the likelihood of success.

To fuel sustainable pipeline replenishment, companies need to consider the trade-offs between internal and external sourcing. Internal innovation, as interviewees pointed out, has become increasingly risky, as companies target complex unmet needs. To develop first-in-class therapies, companies need to invest in understanding biology, finding targets, and building modalities and tools – biomarkers, assays, and endpoints – all in parallel. Validation of these efforts occurs in late-stage clinical studies, where asset termination rates have been rising.

For our cohort, the number of terminated late-stage assets more than tripled between 2021 and 2023. However, internal asset development may lend itself to greater success, given stringent asset progression guidelines, and enable the creation of deep internal expertise.

We have looked at the composition of the cohort's pipeline with our new dataset back to 2020. For these companies, the proportion of expected revenue from internally sourced assets has remained relatively steady since 2021, at just over half the proportion of forecast revenue 50 per cent, see Figure 6.

Figure 6. Proportion of late-stage pipeline forecast sourced from internal and external sources, 2020-23
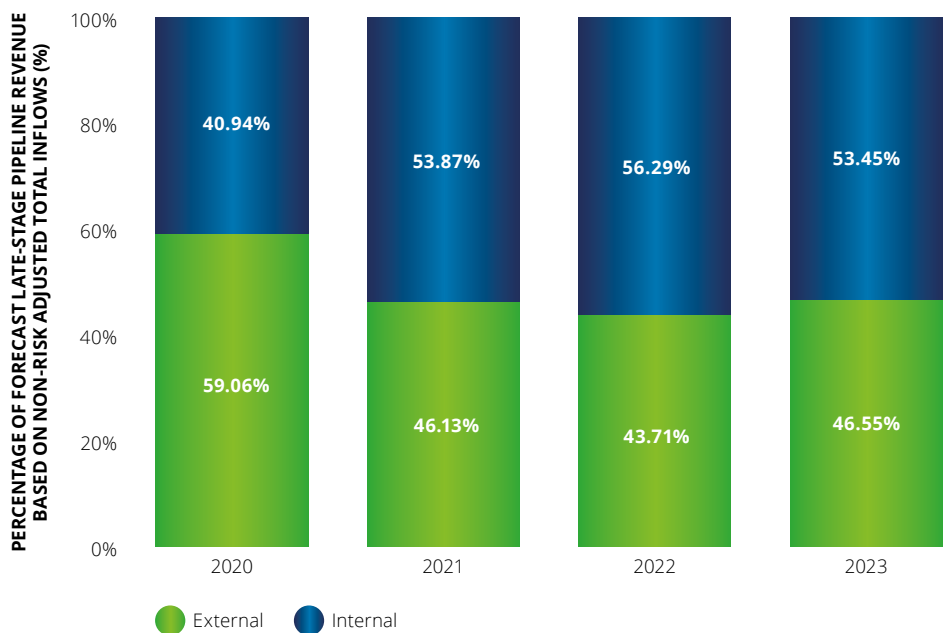
Source: Deloitte analysis, 2024.

"To source external innovation, you want enough proof. When the seller gets that much proof, the price skyrockets. The entire industry is always trying to figure out how far to go. Companies are willing to pay a lot more than they were. And prices on acquisition have really skyrocketed to the point where it becomes hard to understand how to get the return on their investments."
R&D Chief of Staff and Vice President, Portfolio Program Management, Top 20 Biopharma

To fuel sustainable pipeline replenishment, companies need to consider the trade-offs between internal and external sourcing.

In the past decade, biopharma companies have relied on external innovation to refuel pipelines. In terms of volume, externally sourced assets (assets acquired through M&A, purchases, joint ventures, or licensing) formed around 60 per cent of the cohort's late-stage pipelines since 2020. The upcoming patent cliff is also likely to increase the focus on external sourcing as companies look to plug portfolio gaps and supplement the loss of commercial inflows.[35]

Externally sourced assets require the development of internal teams or finding the right partners to progress to commercialisation, depending on when in the development cycle they are acquired. Our interviewees also cautioned that an over-reliance on acquiring late-stage de-risked assets reduced the return on investment due to soaring acquisition prices. Striking a balance between high likelihood of success and paying a high acquisition price depends on having knowledgeable teams in place to agree the deal at the pivotal point.

"I have seen companies moving into being almost 100 per cent dependent on external innovation. I think that's the road towards failure. However, I don't think you can or should do everything in-house. But if you don't have a clear foundation and capability for innovation in-house, including deep knowledge of what to acquire, I don't think you will be successful."

Executive Vice President, Development, Top 20 Biopharma

M&A will continue to play a critical role in the biopharma industry and the upcoming patent cliff will remain a crucial driver. As companies seek to build therapy area depth, the competition for high value acquisitions validated with strong data will only intensify. Indeed, we analysed the M&A deals executed by our cohort of companies in 2022 and 2023. The value of deals executed by the top 20 biopharma companies doubled from 2022 to 2023, as shown in Figure 7. In 2023, the companies allocated a higher proportion of capital to acquiring later-stage R&D assets, particularly those in phase II and phase III, increasing from 17 per cent of deal value in 2022 to 45 per cent in 2023.

For long-term success, there is a need to embed flexibility and a dynamic balance of sourcing in pipeline strategy alongside building and maintaining a strong knowledge base and expertise in therapy areas of strategic focus. Such a knowledge base hinges on the ability to attract and retain talent with years of expertise to guide decisions such as acquiring assets earlier before valuations rocket. Most interviewees indicated their companies are struggling with this challenge due to typical career patterns of today that involve working in multiple companies with much greater diversification of roles. It is no longer standard for scientists to stay 30 to 40 years with one company and build deep knowledge of a single mechanism in one therapy area.

Figure 7. Top 20 biopharma M&A activities by leading phase, 2022-2023
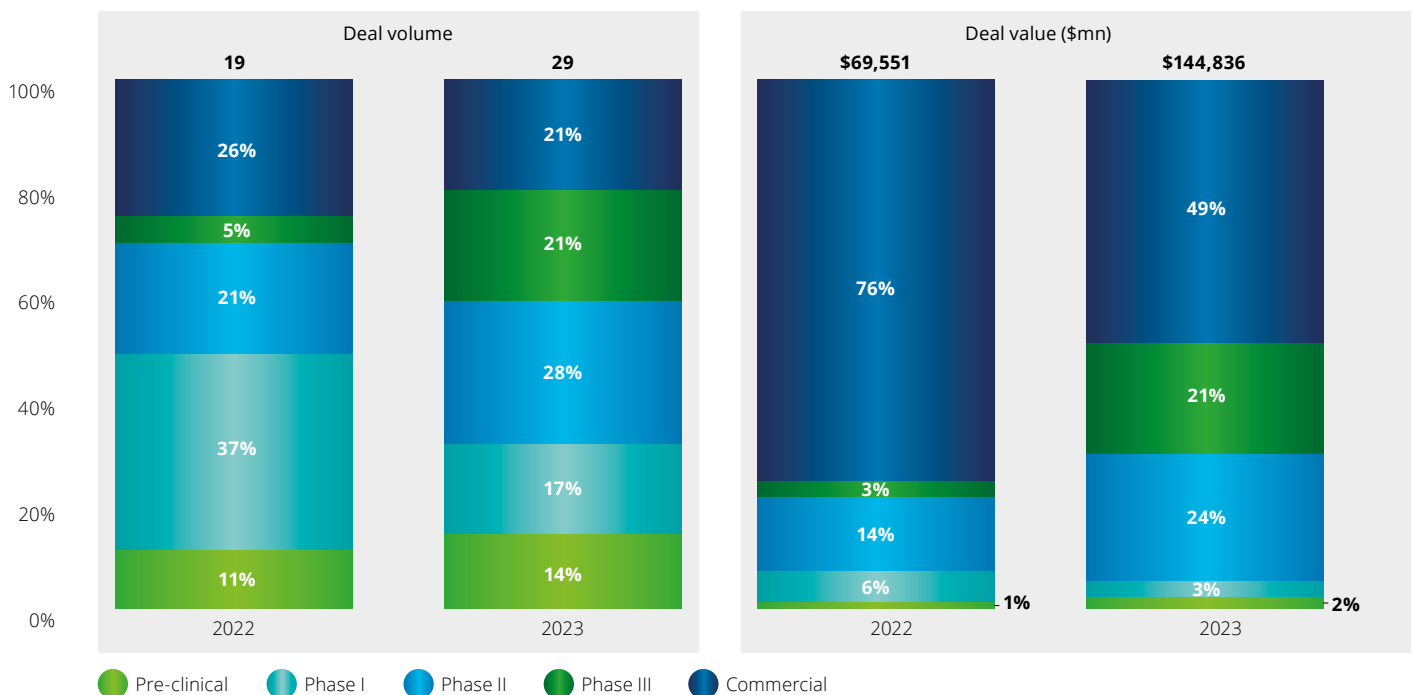
Note: Reflects biopharmaceutical-related deals only and excludes transactions without publicly disclosed deal value

Source: Capital IQ, company websites, Deloitte primary research and analysis.

Strategies to improve productivity

Since 2010, our cohort of companies have struggled to replenish their R&D pipeline with new assets at the same pace, and to the same value, as the assets leaving the pipeline due to successful regulatory approval or late-stage termination. With rising costs, long cycle times, looming patent expiries, a complex M&A landscape and changing regulations, biopharma is nearing the point where the commercial portfolio is unable to sustain innovative R&D and support long-term growth.

The life sciences and health care industries are on the brink of large-scale disruption driven by interoperable data, open and secure platforms and patient-centric care, which have the potential to deliver less costly and more productive drug development. AI will accelerate the identification of new, more precise and targeted therapeutics, designed to be highly specific, precise and with less risk of side effects. Indeed AI, together with enhanced computer simulations and advances in personalised medicine, will lead to in-silico trials, which use advanced computer modelling and simulations in the development and regulatory evaluation of a drug. The potential of AI to improve the patient experience will also help deliver the ambition of biopharma to embed patient-centricity more fully across the entire R&D process. Consequently, AI-enabled digital transformation is fast becoming a strategic imperative for leaders in life sciences.

GenAI's transformative potential in R&D

There is a growing consensus that AI, and specifically, GenAI, may finally be the transformative technology innovation that accelerates decision making. In 2020, our report Intelligent clinical trials explored the role that AI was beginning to play in enhancing clinical trial productivity, improving the patient experience and accelerating regulatory decision-making.[36] Today, continuing developments in GenAI, together with machine learning and predictive analytics, have the potential to go much further and create an end-to-end business value stream—from clinical study startup through clinical study close-out.

R&D presents the top value creation opportunity by scaling the use of AI, followed by commercial, manufacturing & supply chain, then enabling areas according to our recent research.[37] To date, the most common use of GenAI is in transforming the way pharma companies decide which disease areas to invest in. It is also being used to identify targets, develop molecules, and improve the accuracy, predictability and speed of drug discovery.[38]

Research shows that GenAI currently accounts for approximately 16 per cent of drug discovery efforts and its use is predicted to grow by 106 per cent over the next three to five years.[39]

Moreover GenAI, with the 'human in the loop', has the potential to slow rising costs and accelerate tasks across the entire R&D value chain and bring a greater proportion of services back within the four walls of biopharma companies, while improving experiences for internal staff and patients alike, and ultimately contributing to more efficacious therapies.[40]

Deloitte experts note that many companies in our cohort have built internal capabilities and partnerships to explore how this technology could impact various operational processes. But how can GenAI best be leveraged as a strategic tenant for transformational change? Figure 8 highlights some strategic applications that could enable companies to demystify complex disease biology, expedite drug discovery, cut study timelines, and revitalise the clinical trial experience.

Figure 8. Strategic applications of AI across the R&D value chain

	Role of AI	**Value levers**
Drug repurposing	Perform meta-analysis of clinical trial and research data to generate high quality hypothesis for drug repurposing	• Reduced pre-clinical costs • Reduced time to market • Higher NDAs
AI-driven drug discovery	Optimise target and biomarker identification and shortlisting candidates while assessing toxicity and therapeutic efficacy	• Improved clinical success rate • Lower failure rates • Higher number of NDAS
Rapid design and startup	Automated protocol generation, drafting of study documents (consent form, agreements) and regulatory submissions	• Lower average protocol authoring time • Lower average time to first enrollment
Digital data flow	Collate and standardise trial data elements to create analysis-ready data sets and to auto-populate tables and charts in trial artifacts (e.g., case report forms)	• Reduced total time per phase • On-time database lock • Faster documentation creation
Regulatory intel and submission excellence	Identify regulatory requirements across geographies, generate drafts of dossiers, and understand competitor regulatory strategy	• Higher regulatory success
Participant experiences	Enhancing participant experiences with stategic nudges to revolutionise recruitment and retention strategies	• Reduced drop out rate • Faster recruitment • Lower terminations for insufficient recruitment

Source: Deloitte analysis, 2024.

> *"I think the companies that are most successful and getting the most from their data are the ones that are investing in building mature capabilities for data architecture and the implementation of FAIR principles in their data architecture."*
>
> **Former Vice President**, R&D IT, Top 20 Biopharma

When developing the business case for investment in digital and AI, the short-term costs need to be balanced against the long-term efficiency gains. Executing large-scale strategies requires setting up a governance function for making investments, assessing value realised, and monitoring ethical and legal risks from the use of AI. Our recent publication highlights the need for cultural, leadership, and mindset within biopharma companies to scale transformation through AI and GenAI use.[41]

Successfully scaling technology adoption also entails addressing user anxiety, scepticism, and resistance to integrating these technologies into established workflows. Frequent demonstrations to users explaining how the technology helps to overcome frustrations in workflow and actively responding to user feedback during scale-up can help encourage widespread adoption.

Data-driven early-stage R&D to enhance likelihood of success

Despite the large investments in time and money needed to develop a drug, nine out of ten drug candidates that enter trials fail to make it to market.[42] Research shows that the cost of trial failure represents some 60 per cent of all development costs.[43] However, recent research by IQVIA suggests the potential for improvement with the composite success rate reaching 10.8 per cent, the highest since 2018.[44] While not sufficient alone, improving the analytical insights from early stage R&D could enable companies to progress a greater volume and proportion of high quality candidates.

As innovation becomes increasingly complex, investments in translational science can enable companies to better understand target protein binding, safety profiles, and efficacy, and to validate proof of mechanism pre-clinically or in early-stage R&D.

Analysing this depth of knowledge through quantitative decision frameworks could enable R&D organisations to reach 'go or no go' decisions earlier and with deeper insights, and ultimately reach a stage where phase III studies are confirmatory rather than pivotal.

Our interviewees predict that over the next few years, AI and ML algorithms will expedite drug discovery activities (from target identification, molecular design, and lead validation) making them increasingly commoditised. The differentiator is likely to be the quality and comprehensiveness of proprietary data these algorithms are trained on and continue to use. Building analytical engines that make it easy to manage internal clinical trial data, publicly available multi-omics datasets, and patient-generated data (e.g. data from wearables) are likely to transform how companies use data for insight generation. Companies that invest today in building data architecture to use and securely share multiple data sets could realise significant benefits.

Developing digital human cell models that closely mirror the biology of human health and disease can also enable an earlier and better understanding of the safety and efficacy of drug candidates. Furthermore, simulating outcomes from clinical studies can improve drug development by allowing researchers and scientists to test different scenarios and outcomes in a controlled and efficient manner. By using computer models, researchers can simulate the effects of different doses, treatment regimens, and patient populations on a drugs safety and efficacy. This can help identify potential safety concerns and optimise dosing and treatment strategies before clinical trials are conducted. Models can also be used to create digital twins of trial participants and simulate what would happen if a trial participant was in the control group thereby reducing the numbers of control candidates needed.

"So if we could get beyond the eight per cent to 10 per cent success rate of drugs entering human testing that actually make it across the finish line... Just imagine if we failed 80 per cent of the time, we would be the best by a mile."

Executive Vice President, Research and Development, Top 20 Biopharma

Figure 9. Late-stage pipeline composition by therapy area, 2020-2023
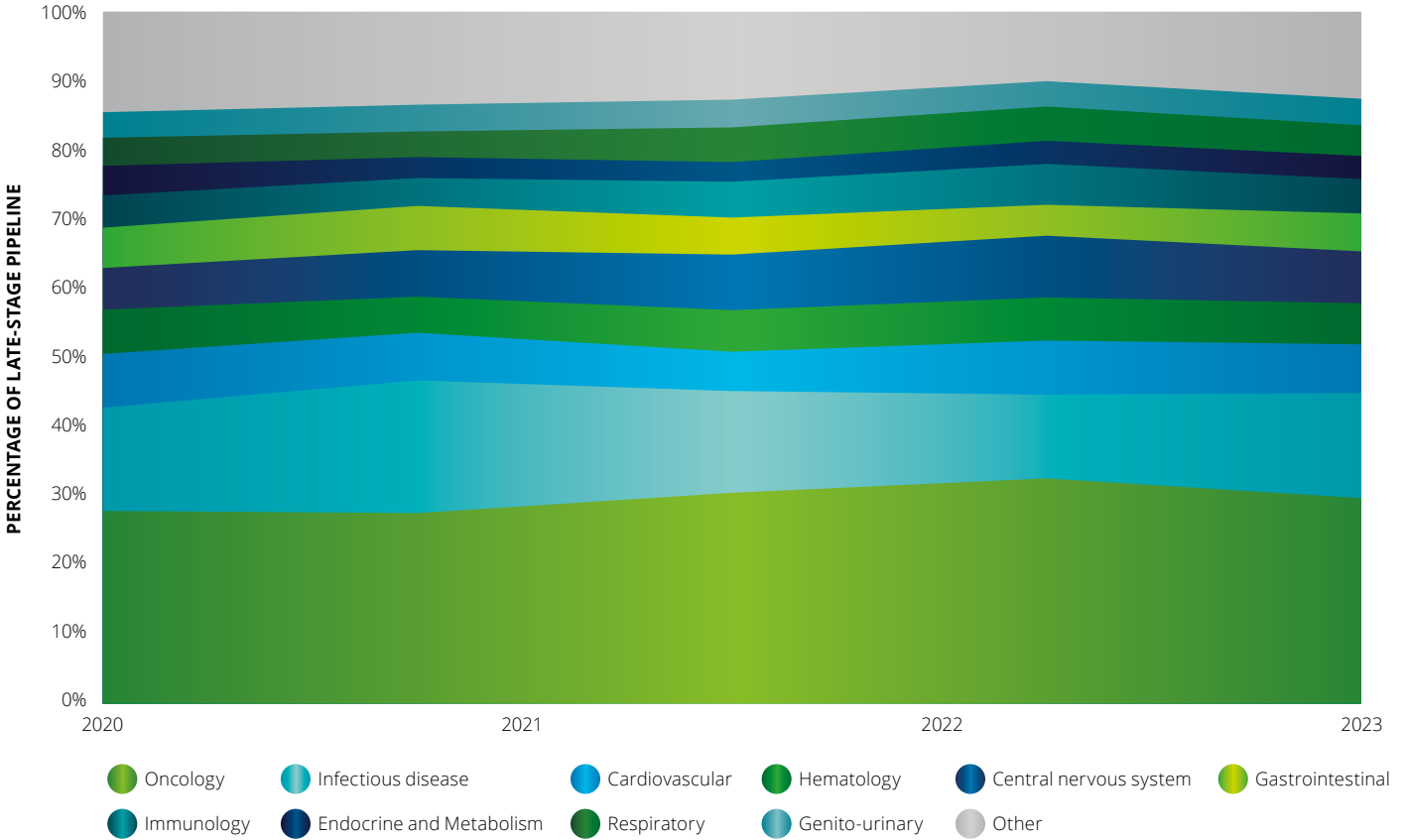
Source: Deloitte analysis, 2024.

Looking beyond over-concentrated therapy areas and modalities
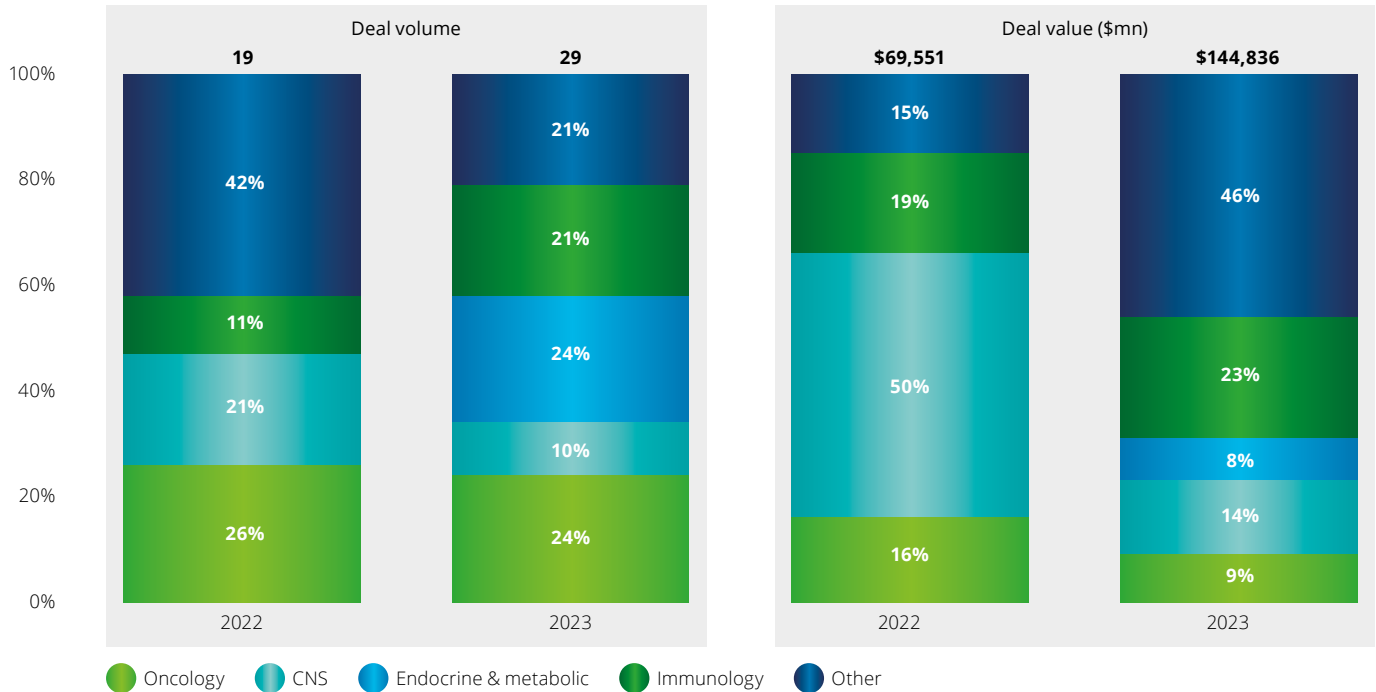
Competitive intensity, scientific breakthroughs and regulatory incentives have skewed R&D spending toward certain areas, particularly oncology and rare diseases. By 2023, 39 per cent of late-stage development programmes for our cohort were focused on oncology and the proportion has been consistently greater than a third of the pipeline since 2020, see Figure 9. At the same time, a third of the cohort's development programmes were targeted at rare diseases in 2023. One interviewee highlighted the remarkable similarity of portfolio strategies across companies, that has driven competition to buy and develop similar assets within specific therapy areas.

As competition in over-concentrated therapeutic areas heats up and the focus of payers on the equitable allocation of health care spending rises, the current dynamic could change. We expect the focus on high burden and large patient population diseases such as diabetes, cardio-metabolic disorders, and mental health conditions to increase. The aging populations in many countries could also add to the demand for therapies in areas such as neurodegenerative diseases, cardiovascular diseases, and non-rare cancers to enhance both longevity and quality of life.

"The challenge is that there are a lot of me-too. The 9th anti-PD1 got approved. Is it productive for a company to put out money and for regulators to approve another anti-PD1 when we already have so many? It doesn't help the field because you get a lot of me-toos or there's no innovation because you're all struggling in the same pool, but you're not sharing information."

Senior Director, Top 20 Biopharma

Figure 10. Top 20 biopharma M&A activities by therapeutic area, 2022-2023

Deal volume		Deal value ($mn)	
19	**29**	**$69,551**	**$144,836**
42%	21%	15%	46%
11%	21%	19%	23%
21%	24%	50%	8%
26%	10%	16%	14%
	24%		9%
2022	2023	2022	2023

● Oncology ● CNS ● Endocrine & metabolic ● Immunology ● Other

Note: Reflects biopharmaceutical-related deals only and excludes transactions without publicly disclosed deal value

Source: Capital IQ, company websites, Deloitte primary research and analysis

Our M&A analysis shows the continued focus on oncology, mirroring the late-stage pipeline composition, see Figure 10. However, there is also considerable investment across other therapy areas, notably immunology and CNS with 23 per cent and 14 per cent respectively of deal value in 2023.

Recent breakthroughs have spurred greater interest and investments in certain disease areas. For instance, the approval of Novo Nordisks' anti-obesity drug put obesity in the limelight as a public health emergency and a lucrative franchise, creating a race to bring a new class of anti-obesity medications to market.[45] In 2023, antibody-drug conjugate has become a centrepiece of platform-driven acquisitions, 25 per cent of deals by our cohort targeted endocrine & metabolic assets.

Looking at the top-grossing drugs, many were not planned from the outset, but were serendipitous findings that companies had the experience and ability to capitalise on. When opportunities arise, pipeline replenishment efforts are likely to be the most successful, when underpinned by flexible operating models and supported by a versatile toolbox to make investments across multiple disease and therapy areas.

Beyond therapy area focus, late-stage pipelines today contain advanced modalities created from a handful of once-novel platform technologies (including cell therapies, RNA interference, and m-RNA). Interviewees expressed a view that there is an over-concentration of capital in many of these advanced modalities.

As the next wave of technologies and technology platforms evolves (such as gene editors and microbiome therapeutics), being purposefully selective could enable companies to be differentiated while building capabilities to tackle hard-to-drug targets. One company executive highlighted how their company chose strategically to stay away from cell and gene therapies while building capabilities through partnerships in anti-sense RNA. Such trade-offs are likely to be essential as companies choose bespoke partnerships and build roadmaps to explore new technology platforms.

Actions for R&D leaders

Biopharma companies face serious headwinds: delays in technology adoption, looming patent expiries and increasing regulatory complexities. As the pace of scientific and technological advancements accelerates, from gene therapy to AI, the industry continues to face the same challenges in clinical research, including:

- recruiting and retaining a representative patient population

- delayed response to operational problems

- reliance on incomplete or un-insightful data sources.

These challenges will continue to plague the industry, unless a way is found to transform the existing culture of competitive behaviours to develop and share open source access to centralised operational data from across the entire industry, including academic medical centres and site networks, contract research organisations (CROs), trial sponsors, and patients.

Ultimately, transforming clinical trials will require companies to work entirely differently, drawing on change management skills, as well as partnerships and collaborations.

This will require companies to develop highly skilled interdisciplinary leadership and AI experts who can innovate, organise and guide others, as well as AI-friendly CEOs and board members to push for the adoption of AI. If biopharma succeeds in capitalising on AI's potential, the internal and external productivity challenges driving the decline in the IRR of biopharma innovation will be reversed and the industry will thrive. However, before adopting AI solutions, there are a number of key questions that biopharma companies need to consider carefully in developing their strategies.

Key questions for an optimum R&D strategy

What are the main cost drivers of your clinical trial process? Where could AI have the most impact?
Patient recruitment and data management are among the largest cost drivers of clinical trials and are currently where AI shows the most promise.

How are you adapting your M&A strategy?
There is a need to balance sustainable long-term portfolio value and near-term revenue needs and at the same time account for regulatory scrutiny, such as the IRA and EU patent laws.

Have you developed a robust and sustainable AI strategy for clinical development and considered the extent to which you should partner with leading AI companies for drug discovery and development?
Biopharma companies benefit from selecting reliable partners to leverage their extensive knowledge and expertise gained from repeated experience, and in having AI solutions that are specific to their own proprietary data.

Have you prioritised consideration of how you can both incorporate patient perspectives throughout study design and also deploy open communication channels during study execution?
AI-enabled engagement during and after the conclusion of the study will attract, engage, and improve the retention of committed patients throughout the study.

Have you established effective strategies for engaging with regulators, and is your regulatory function seen as a strategic asset?
As the variety, velocity and volume of RWD submitted to regulators increase, regulators will also increase the use of AI tools in their processes. For biopharma, early engagement with regulatory authorities to align on objectives, study design and use of digital biomarkers or surrogate endpoints will be of critical importance. Regulatory relationships need to be based on a win-win approach.

Do you understand the legal and compliance requirements needed to protect the increasing volume of R&D data?
GDPR compliance in Europe and similar requirements in the US and elsewhere will be important, especially as failure to comply could have significant financial and reputational consequences. Moreover, biopharma companies need to ensure that any patient data used has specific consent for the specified purpose and that it remains private and secure.

Do you have a strategy for developing the future workforce that includes the necessary skills and talent to integrate AI technologies into your clinical development?
The adoption of AI innovation will require an internal team of experts, comprising biologists, chemists, engineers, data scientists and bioinformaticians, working in cross-functional teams. The aim should be to promote an 'intrapreneurship culture', providing these teams with the freedom and resources to create innovative solutions. As discrete tasks are increasingly shifted towards using GenAI, you will need to put established 'guardrails' in place to ensure the integrity of the outputs, including human validation of outputs.

Do you have a clear understanding of the completeness, accuracy and potential bias in historical trial data?
Clinical development has historically faced challenges in creating diverse clinical trial cohorts, meaning that leaders in R&D need to take care not to highly rely on historical clinical data or risk amplifying biases inherent in existing data sets. Ensuring that trustworthy AI frameworks and governance arrangements are in place can mitigate the potential for bias and unintended outcomes.

Before embarking on study startup have you automated document generation activities, to increase productivity?
Using previous examples of clinical trial protocols, site contracting agreements, clinical report forms, and other key pieces of paperwork required to jumpstart clinical trials, biopharma organisations can quickly draft and refine the documentation required to establish new test sites. This can be a critical step in creating diversity within patient cohorts, allowing sites in under-served geographies to be established more quickly and for less effort.

Endnotes

1   Inflation Reduction Act and Medicare, Centers for Medicare & Medicaid Services. Accessed on 1 April 2024. See also:
    https://www.cms.gov/inflation-reduction-act-and-medicare

2   How the Inflation Reduction Act Will Impact the Biopharmaceutical Industry, LEK, 9 September 2022. See also:
    https://www.lek.com/insights/ei/how-inflation-reduction-act-will-impact-biopharmaceutical-industry

3   HHS selects the first drugs for medicare drug price negotiation, U.S. Department of Health and Human Services (HHS), August 29, 2023. See also:
    https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html

4   How the IRA will affect drug development, BioSpace, 6 April 2023. See also:
    https://www.biospace.com/article/how-the-ira-will-affect-drug-development/

5   Rising protocol design complexity is driving rapid growth in clinical trial data volume, according to TUFTS center for the study of drug development,
    GlobeNewswire, 12 January 2021. See also:
    https://www.globenewswire.com/news-release/2021/01/12/2157143/0/en/Rising-Protocol-Design-Complexity-Is-Driving-Rapid-Growth-in-Clinical-Trial-
    Data-Volume-According-to-Tufts-Center-for-the-Study-of-Drug-Development.html

6   Case example developed with proprietary TrialHub data. See also: https://trialhub.com/

7   An AI-designed drug is moving toward approval at an impressive clip, Singularity Hub, 18 March 2024. See also:
    https://singularityhub.com/2024/03/18/an-ai-designed-drug-is-moving-toward-approval-at-an-impressive-clip/

8   How AI is being used to accelerate clinical trials, Nature Index, 13 March 2024. See also: https://www.nature.com/articles/d41586-024-00753-x

9   Broadening clinical trial participation to improve health equity, Deloitte, accessed on 1 April 2024. See also:
    https://www.deloitte.com/global/en/our-thinking/insights/industry/health-care/increasing-diversity-clinical-trials.html

10 Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022, Deloitte, January 2023. See also:
    https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf

11 What is the future of virtual clinical trials, Deloitte, 13 September 2022. See also:
    https://www2.deloitte.com/us/en/blog/health-care-blog/2022/what-is-the-future-of-virtual-clinical-trials.html

12 Ibid.

13 Florez, M., Smith, Z., Olah, Z. et al. Quantifying Site Burden to Optimize Protocol Performance. Ther Innov Regul Sci 58, 347–356 (2024). See also:
    https://doi.org/10.1007/s43441-023-00602-5

14 New Horizons: Pioneering Pharmaceutical R&D with Generative AI from lab to the clinic – an industry perspective, Arxiv, 21 December 2023. See also:
    https://arxiv.org/pdf/2312.12482.pdf

15 Ibid.

16 Embedding environmental sustainability into pharma's DNA, Deloitte, October 2022. See also:
    https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-embedding-environmental-sustainability-into-
    pharma-dna-updated.pdf

17 Predicting the future of healthcare and life sciences in 2025, Deloitte, accessed on 1 April 2024. See also:
    https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/companies-have-reversed-the-decline-in-the-returns-from-pharma-r-and-d.
    html

18 Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022, Deloitte, January 2023
    https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf

19 Biopharma's IRA readiness: From What? To Now what?, Deloitte, 22 June 2023. See also:
    https://www2.deloitte.com/us/en/blog/health-care-blog/2023/biopharmas-ira-readiness-from-what-to-now-what.html

20 How might IRA's drug-pricing provisions affect stakeholders?, Deloitte, 28 September 2023. See also:
    https://www2.deloitte.com/us/en/blog/health-care-blog/2023/how-might-iras-drug-pricing-provisions-affect-stakeholders.html

21 HHS Selects the First Drugs for Medicare Drug Price Negotiation, U.S. Department of Health and Human Services (HHS), August 29, 2023. See also:
    https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html

22 What does the US Inflation Reduction Act mean for pharma, LGT, 26 September 2023. See also:
    https://www.lgt.com/global-en/market-assessments/insights/investment-strategies/what-does-the-us-inflation-reduction-act-mean-for-pharma--172682

23 Strengthening The Inflation Reduction Act By Predicting Drugmakers' Avoidance And Gaming, Health Affairs, 2 March 2023. See also:
    https://www.healthaffairs.org/content/forefront/lawmakers-can-strengthen-inflation-reduction-act-predicting-pharmaceutical-companies

24 Nurturing growth: Measuring the return from pharmaceutical innovation 2021, Deloitte, January 2022. See also:
    https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/Measuring-the-return-of-pharmaceutical-innovation-2021-
    Deloitte.pdf

25 Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022, Deloitte, January 2023
https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf

26 European Health Union: Commission proposes pharmaceuticals reform for more accessible, affordable and innovative medicines, European Commission, 26 April 2023. See also: https://ec.europa.eu/commission/presscorner/detail/en/IP_23_1843

27 Drug launches reflect overall company performance, Deloitte Insights, accessed on 1 April 2024. See also:
https://www2.deloitte.com/us/en/insights/industry/health-care/key-factors-for-successful-drug-launch.html

28 Biopharma Facing Two Major Crises – A Huge Patent Cliff And Price Controls, Forbes, 26 June 2023. See also:
https://www.forbes.com/sites/johnlamattina/2023/06/26/biopharma-facing-two-major-crisesa-huge-patent-cliff-and-price-controls/?sh=3b8c7e5312a7

29 Life sciences M&A: 2023 trends, Deloitte, accessed on 1 April 2024. See also:
https://www2.deloitte.com/content/dam/Deloitte/us/Documents/mergers-acqisitions/us-mars-lshc-bi-annual-report-2024-final.pdf

30 Ibid.

31 How steep is pharma's patent cliff, PharmaVoice, 14 June 2024. See also:
https://www.pharmavoice.com/news/pharma-patent-cliff-Merck-Keytruda-Pfizer-Seagen-Humira/652914/

32 Ibid.

33 R&D spending as revenue share of leading 10 pharmaceutical companies in 2022, Statista, 23 October 2023. See also:
https://www.statista.com/statistics/309471/randd-spending-share-of-top-pharmaceutical-companies/

34 Biopharma Facing Two Major Crises – A Huge Patent Cliff And Price Controls, Forbes, 26 June 2023. See also:
https://www.forbes.com/sites/johnlamattina/2023/06/26/biopharma-facing-two-major-crisesa-huge-patent-cliff-and-price-controls/?sh=3b8c7e5312a7

35 Ibid.

36 Intelligent clinical trials: Transforming through AI-enabled engagement, Deloitte Insights, accessed on 2 April 2024. See also:
https://www2.deloitte.com/content/dam/insights/us/articles/22934_intelligent-clinical-trials/DI_Intelligent-clinical-trials.pdf

37 Realising transformative value from AI & generative AI in Life Sciences, Deloitte, April 2024. See also:
https://www2.deloitte.com/content/dam/Deloitte/us/Documents/us-realizing-transformative-value-from-ai-and-genAI-in-life-sciences-040924.pdf

38 Intelligent drug discovery: Powered by AI, Deloitte Insights, accessed on 1 April 2024. See also:
https://www.deloitte.com/content/dam/assets-shared/legacy/docs/insights/2022/DI_Intelligent-Drug-Discovery.pdf

39 Leveraging AI and ML in Drug R&D: Current and Future Impacts on the Life Sciences Industry, LifeSci Search, 9 October 2023. See also:
https://lifescisearch.com/leveraging-ai-and-ml-in-drug-rd-current-and-future-impacts-on-the-life-sciences-industry/

40 Can life sciences companies unlock the full value of GenAI, Deloitte, 3 October 2023. See also:
https://www2.deloitte.com/us/en/blog/health-care-blog/2023/can-life-sciences-companies-unlock-the-full-value-of-genai.html

41 Algorithm to lab, explore generative AI's impact in life sciences, Deloitte, accessed on 1 April 2024. See also:
https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/gen-ai-life-sciences.html

42 Probability of Success in Drug Development, ASCPT, 19 April 2022. See also: https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.2568

43 Achieving end-to-end success in the clinic: Pfizer's learnings on R&D productivity, Science Direct, March 2022. See also:
https://doi.org/10.1016/j.drudis.2021.12.010.

44 Global Trends in R&D 2024: Activity, productivity, and enablers, IQVIA, 22 February 2024. See also:
https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2024-activity-productivity-and-enablers

45 World Preview 2023: Pharma's Age of Uncertainty, Evaluate, 14 August 2023. See also:
https://www.evaluate.com/thought-leadership/world-preview-2023-pharmas-age-uncertainty/

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