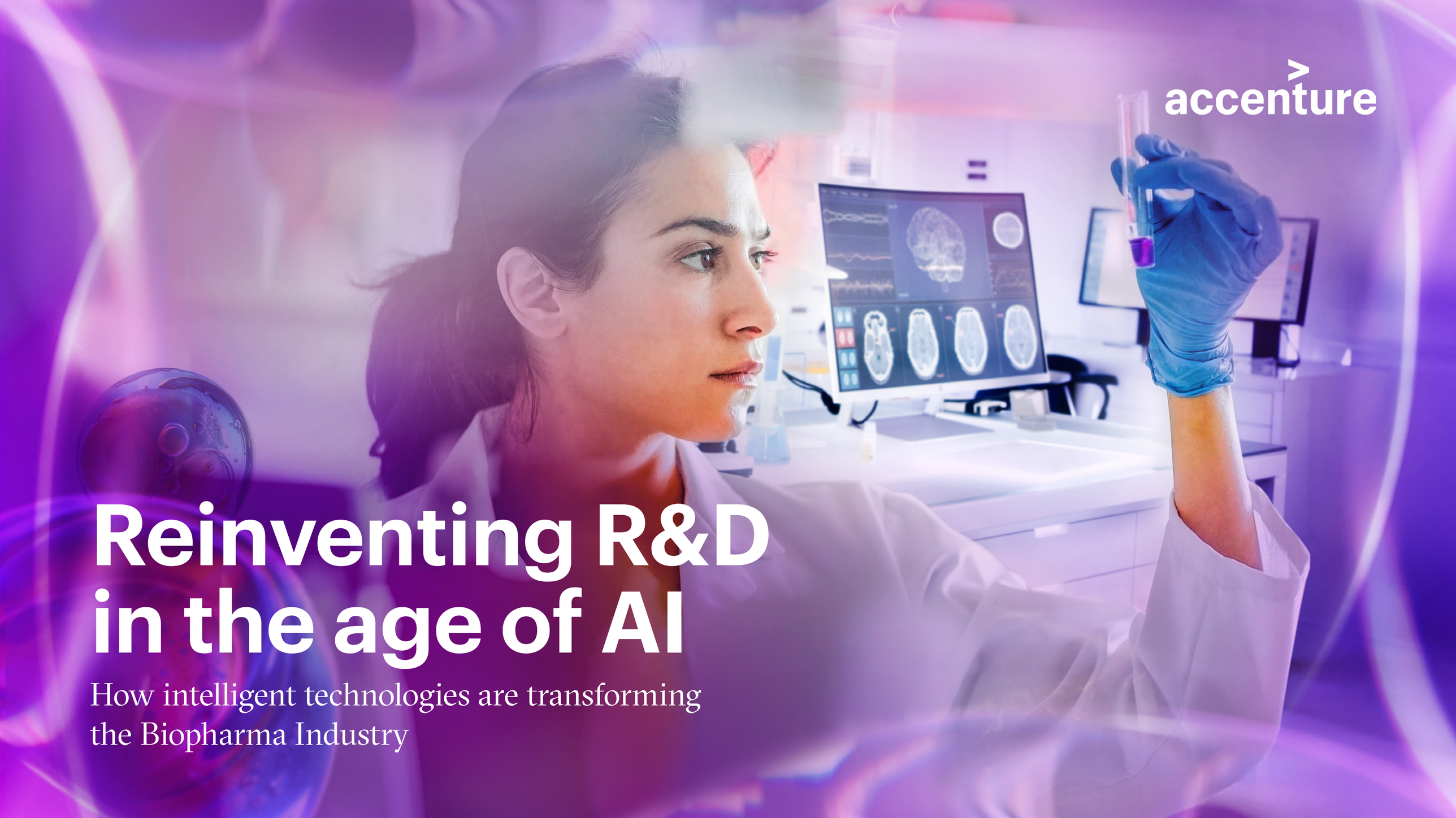


Reinventing R&D in the age of AI

How intelligent technologies are transforming the Biopharma Industry

Contents

Preface

R&D leaders across the industry are unanimous about the challenges ahead, voicing concerns like:

I now have to choose between investing in an asset (a clinical trial or external innovation) vs. an emerging technology.

I now have to take bigger risks to scale new technologies on high value assets because the upside is significant.

I now have to consider myriad factors (such as drug access, pricing, reimbursement and manufacturing scale challenges) in conjunction with choices around modality before an asset goes into first-in-human studies.

I now have to make investments that will create value in a short timescale so that I can fund essential technology and capability investments that will be critical to R&D reinvention and pay off in the longer term.

Life-changing interventions that have previously been pipedreams are now within reach for the biopharma industry, made possible through an increasingly sophisticated understanding of human biology coupled with unparalleled advances in technology. On the other hand, the industry's research and development (R&D) productivity has remained largely unchanged for a decade, while the complexities of biopharma's competitive market have continued to evolve. While intelligent technologies promise to accelerate scientific advances and address some of the fundamental R&D challenges that existed for a decade, they require capital investment and a thoughtful approach.

Creating therapies from basic science and making the best use of advances in technology requires companies to reinvent their R&D organization. Biopharma companies that embrace technology, reinvent their workforces and refocus their organizational priorities will improve R&D efficiency and patient outcomes, and ultimately secure growth in an increasingly challenging macro environment.

Authors

Tom Lehmann
Managing Director, Global Lead R&D
Accenture Life Sciences

Selen Karaca-Griffin
Thought Leadership Principal Director – Products and Life Sciences, Accenture Research

Nicole Paraggio
Managing Director, Accenture Strategy Life Sciences

Kailash Swarna
Managing Director, Global Research and Clinical Lead, Accenture Life Sciences

Alex Blumberg
Pharmaceutical Research Lead, Accenture Research

Acknowledgements

The authors would like to thank the following people for their contributions:

Barry Heavey for his expertise on developing and manufacturing new types of treatments.

Akash Trivedi for his expertise on optimizing clinical trials.

Joanna Lisiecka for her support on the AI-mediated drug discovery company analyses.

Nicole Crane and **Alexandra Brown** for their support on the development of the R&D executive survey.

Aran Bahl and **Biagio Paoletta** for their support on gathering Accenture Subject Matter Expert input.

About the research

In 2021, Accenture's "Billions to Millions: Improving R&D Productivity" highlighted the escalating costs and extended timelines of drug development amid profitability challenges. At that time, technologies like cloud computing and AI were just beginning to integrate into biopharma R&D, while intelligent technologies such as generative AI and large language models were in their infancy.

Today, these advances, combined with a deeper understanding of biology, have evolved biopharma R&D. Our latest research goes beyond the scope of "Billions to Millions," which focused solely on time, success rates, and potential cost savings. This comprehensive study incorporates factors such as enhanced revenue from extended commercialization periods.

Our research methodology was threefold:

1. We surveyed 75 R&D executives from the top 20 biopharma companies by annual revenue to understand the current landscape and the direction of change.

2. We conducted in-depth interviews with industry subject matter experts and used our internal expertise.

3. We developed custom analyses, including a model to quantify the uplift in future potential and an index to better understand the contributors to R&D success.

Our findings reveal that companies outperforming their peers in terms of relative cycle times and probability of technical and regulatory success (PTRS) rates generally experienced larger growth in enterprise values. However, these improved success rates and cycle times are no longer sufficient to generate future commercial value. To achieve that uplift, careful consideration of future potential and value of the assets must be done at earlier stages than traditional value discussions.

The R&D opportunity

All biopharma CEOs agree that R&D presents the most significant opportunity within the biopharma value chain when it comes to creating value with intelligent technologies.

An unprecedented understanding of human biology coupled with new advances in technology are allowing the biopharma industry to create life changing interventions we could only dream of until now. Personalized cell therapies are treating previously intractable cancers and showing potential for managing devastating autoimmune conditions.[1] Targeted treatments for ultra-rare diseases and genetic conditions with high unmet needs are emerging through antisense oligonucleotides (ASOs) and gene therapies.[2] Additionally, precision medicines developed through antibody drug conjugates (ADCs) and radioligand therapy have become a reality.

However, the industry's R&D productivity has remained largely unchanged for a decade, while the complexities of biopharma's competitive market have continued to evolve. Over half a trillion dollars in revenues will likely be at risk by the end of the decade, dialing up pressure on biopharma to bring new medicines to market—faster, at lower cost, and without compromising quality.[3,4,5] This is partially due to market forces such as the influence of pharmacy benefit managers and insurance companies on reimbursement, access and pricing. Other factors include government policies like the Inflation Reduction Act in the U.S, and loss of exclusivity on major revenue sources.

Technologies such as artificial intelligence (AI), generative AI, machine learning, and next-generation computing are pushing science forward at a pace never seen before, while simultaneously enabling better business and patient outcomes. Our research indicates that harnessing technology for these outcomes has become the top priority for biopharma CEOs in 2024.

It's time to reinvent biopharma R&D.

Combined with rapidly advancing technologies, the expected revenue gap we've described is triggering an intelligent technology wave and creating a palpable urgency to reinvent biopharma R&D.

> If intelligent technologies are used at scale and workflows are reinvented appropriately, companies can bring a new medicine to market four years faster, earning an extra $2 billion per successful drug.

In this new scientific age, huge volumes of high-quality human data from sources such as global biobanks and electronic medical records (EMR) can revolutionize the drug development process, from target selection to clinical trial design and patient recruitment. Our analysis shows that if intelligent technologies are used at scale and workflows are reinvented appropriately to reduce the cost of failure and shorten discovery and development timelines, companies can bring a new medicine to market four years faster, earning an extra $2 billion per successful drug.[6]

Typically, the cost of bringing a successful medicine to market is between $2.6 billion and $6.7 billion (including the cost of capital and cost of failure) depending on therapeutic area, treatment modality and disease complexity.[7] We expect this cost to be cut by 35–45% using intelligent technologies.[8]

Executing a reinvention strategy will require dedicating 8–10% of the annual R&D budget to digital transformation initiatives over the next five year.[9] For a $5 billion R&D budget, this equates to $400–500 million per year. It's a substantial investment.

However, the potential value is even more significant. Even a 1% improvement in clinical success rates would yield hundreds of millions in additional revenue. Key risks include technological, talent, cultural and regulatory complexities. The AI and digital technologies being bet on are still maturing, and there will inevitably be failures and setbacks. To mitigate this, maintaining a balanced portfolio of initiatives by pursuing the right mix of near-term, high-confidence opportunities and longer-term, higher-risk/reward projects is crucial.

An evolved definition of success:

In this new era of R&D where science and intelligent technologies are rapidly converging, it is essential to reevaluate how value is created and R&D success is defined. (see Figure 1)

Measure 1: Probability of technical and regulatory success (PTRS): Unsurprisingly, our recent survey confirms that R&D organizations have predominately focused on the PTRS measure. This makes sense, as slight improvements in PTRS lead to a significant reduction in the cost of failures and an uptick in R&D productivity.

Measure 2: Cycle times: It is crucial to replenish revenue gaps caused by loss of exclusivity, continuously declining net prices and government pressure on drug pricing. This acceleration is necessary to keep pace with the competitive market and ensure sustained revenue growth. Based on our survey, this measure is currently underappreciated despite the CEO focus on accelerating R&D.

Measure 3: Future potential: Companies must carefully consider both commercial and manufacturing aspects of drug candidates early on to select drug candidates with the highest future potential. This is more critical now than ever due to 1) increasing new modalities and the associated manufacturing challenges, 2) the economic implications of pursuing different modalities and the impact of the Inflation Reduction Act in the US and 3) an increasingly complex access and reimbursement environment requiring early alignment on the clinical and economic value of the product.

Figure 1

R&D organizations must consider three important value levers when defining success.

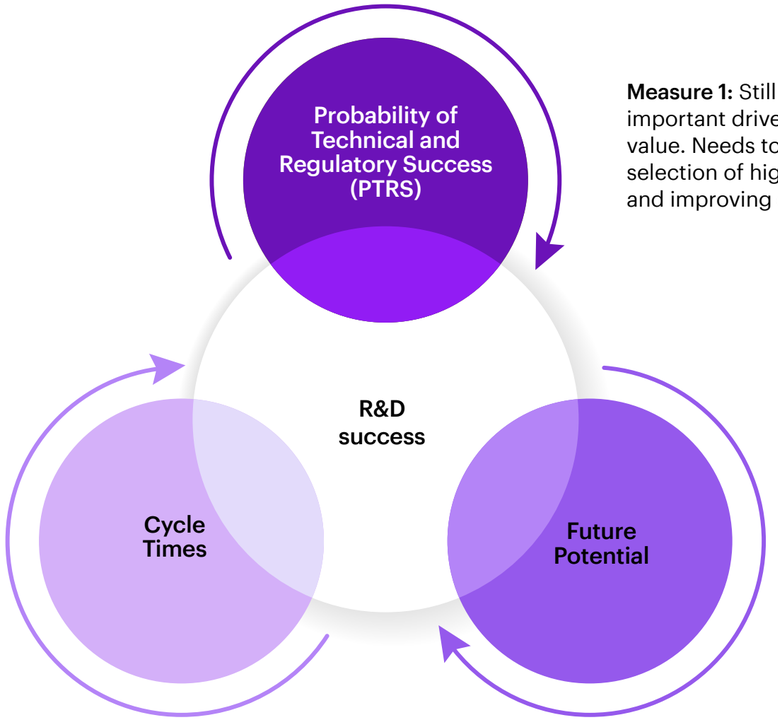


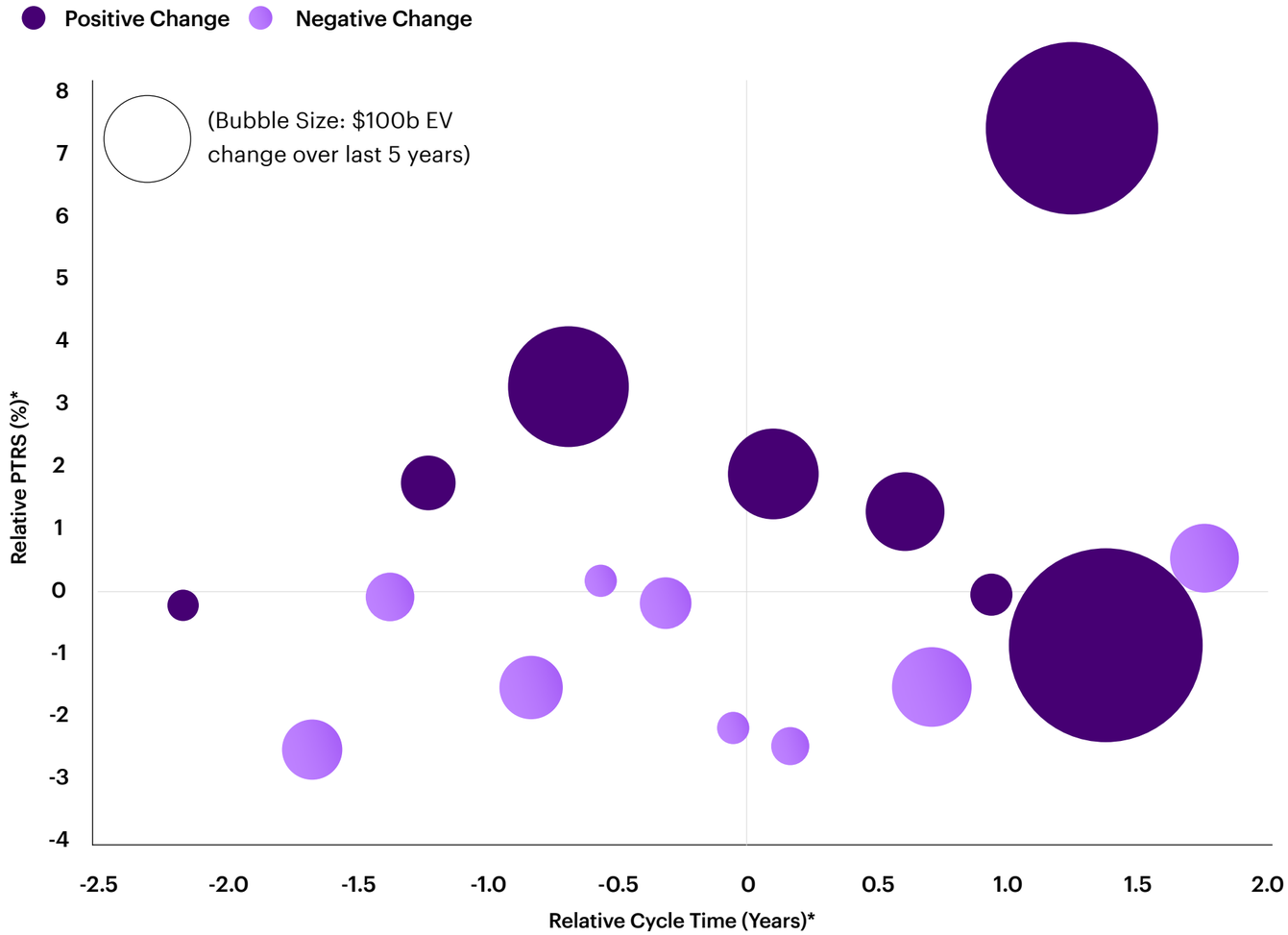
Figure 1: Historically, PTRS has been the primary measure of R&D success. While PTRS remains important, there also needs to be a focus on improving speed and future commercial potential.

The R&D Success Index

Our R&D Success Index is a retrospective analysis over the past 10 years that illustrates part of this new model, considering the impact of PTRS and cycle times on enterprise value (Figure 2).[10] Notably, companies that outperform their peers in terms of relative cycle times and PTRS have generally experienced larger growth in enterprise value (over the past five years).

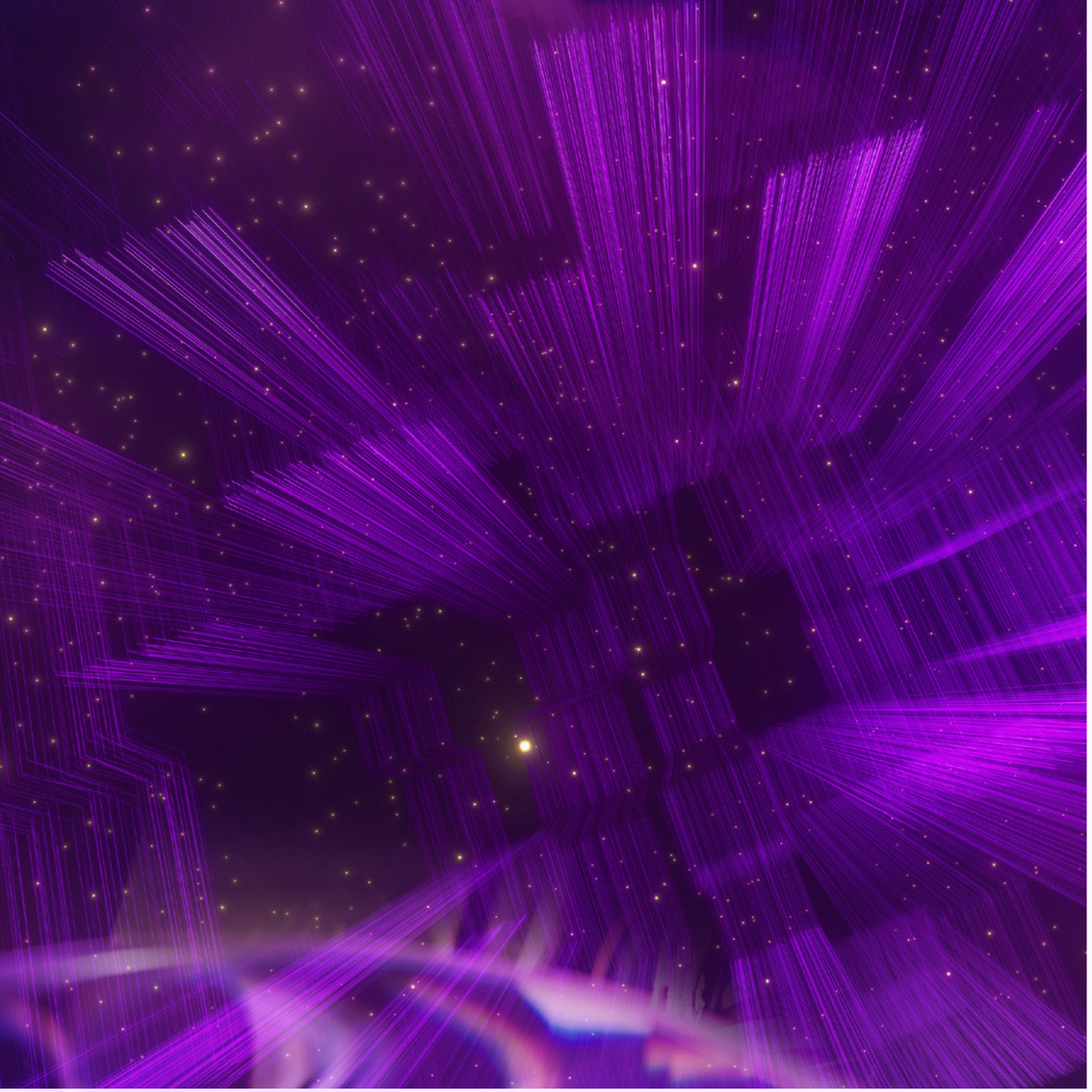
Figure 2

Large Biopharma - Relative PTRS and Cycle Times vs. Change in Enterprise Value



Source: Accenture Research.
*PTRS and Cycle Times over the last 10 years of the top biopharma companies compared to the peer group average, weighted by phase and therapeutic category to remove variability.

Figure 2: The X-axis shows how quickly companies' drugs move through the pipeline and the Y-axis shows companies' success rates, both of which are relative to their peers and are weighted by company pipeline phases and therapeutic categories. Those farther to the right are faster than expected and those farther up have better success rates than expected. This data was derived from PharmaPremia and CapIQ. Bubble Size shows the change in enterprise value over the past five years.



Intelligent technologies offer all companies an opportunity to enhance PTRS and cycle times further. Additionally, companies must now develop their understanding of the future potential of their pipeline assets pre-IND.

To be successful in the future, R&D organizations should adopt a comprehensive approach, prioritizing four areas of reinvention supported by three foundational building blocks. This strategy can improve R&D productivity and accelerate the cost-effective delivery of innovative therapies to the market.

The rest of this report focuses first on these four key capabilities and, second, on the foundational building blocks that underpin them, setting out a roadmap for biopharma companies to thrive in this rapidly evolving landscape.

Reinventing the R&D organization

To address the challenges faced by CEOs, Heads of R&D and CTOs, reinventing the R&D organization requires prioritizing two overarching tasks:

1/ Identifying reinvention opportunities

Four key capabilities for significant focus and capital investment to drive competitive advantage for prioritized assets.

1.1 Using AI for discovery

1.2 Developing and manufacturing new types of treatments

1.3 Optimizing clinical trials

1.4 Dynamic portfolio management

2/ Addressing the imperatives that power reinvention

Three foundational building blocks that underpin and guide reinvention strategy.

2.1 A secure, AI-ready digital core

2.2 Talent and leadership

2.3 A culture of continuous reinvention

1. Identifying reinvention opportunities

Four key capabilities for significant focus and capital investment to drive competitive advantage for prioritized assets.

Turning new knowledge and technologies into a competitive advantage and future success requires new thinking and new processes. Our experience tells us that the top-performing companies stand out because they invest heavily in four reinvention opportunities. According to our survey, the first three are already viewed as crucial for R&D success; using AI for discovery, developing and manufacturing new types of treatments, and optimizing clinical trials. However, success will be further enhanced by dedicating more focus to a fourth area; dynamic portfolio management.

1.1 Using AI for discovery

- **64% rank new drug discovery methods among the top three most important capabilities for driving future success.**
- **61% say it has been a top area of investment.**
- **72% rank their capability as mature, but our research finds that while most companies are experimenting with these technologies, they rely on partnerships to scale their use.**

Source: Accenture's Biopharma R&D Executive Survey[11]

AI enables a new way of working, where multidisciplinary teams of computational and scientific experts collaborate, using diverse data sets that are managed and enhanced by AI and machine learning. This makes it possible to identify targets that are more likely to succeed in the clinic and use predictive modeling for lead identification and optimization.

With an AI-led discovery strategy, companies can reduce discovery cycle times by two-thirds and design therapies that have been impossible until now. AI-driven insights also help generate robust, comprehensive pre-clinical data sets to support trials, improving the chances of success.

Companies must build cross-functional teams and equip them with diverse, well governed data sets to enable efficient target identification and validation, lead optimization and molecule design. Through simulating experiments *in silico*, scientists can discover new links between genes and diseases.

Further, integrating AI platforms into the scientific operating model will allow companies to create a fully scaled R&D portfolio enhanced by AI-led discovery. Critical to all initiatives that deploy AI and generative AI is a dedication to applying responsible AI principles that manage risks of data set bias and other unintended consequences.

Leaders must facilitate cross-functional data governance, management, connectivity and a “FAIRification” strategy, which refers to data and research that is Findable, Accessible, Interoperable and Reusable. They must also work to build a robust partnership ecosystem that supports niche, highly differentiated capabilities and the strategic sourcing of new data sets to generate insights.

All of this comes with a set of challenges, however. For instance, while AI-mediated drug discovery is growing in importance, the industry doesn’t yet have enough people with the right skills to drive progress forward.[12] And although quality data is fundamental to developing these models, many companies do not have an AI-enabled, strong digital core that allows them to make best use of the data they have, or to capture new data from clinical trials and lab notes.

There is a symbiotic relationship between nimble AI-mediated drug discovery companies and large biopharma organizations. These companies excel in developing models and architectures, and attracting top AI talent, while biopharma companies have extensive therapeutic area expertise, pipelines and vast amounts of data necessary for creating the most effective models. Collaboration between them is both logical and opportunistic, presenting significant potential for advancing innovation and enhancing outcomes.

The AI-mediated drug discovery landscape continues to grow

Defining AI-Mediated Drug Discovery Companies

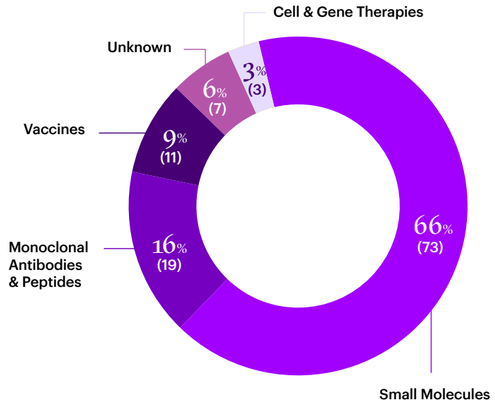
Accenture Research conducted an analysis of the AI-mediated drug discovery landscape. Assets in this analysis include those where the AI-mediated drug discovery company was either the lead or partner.

We recognize that there is a considerable amount of variability in the type and sophistication of AI/ML methods used across these companies and a disagreement on how to define what an AI discovered drug is.

Therefore, companies were classified as such if they identified or marketed themselves as leveraging AI in the following areas:

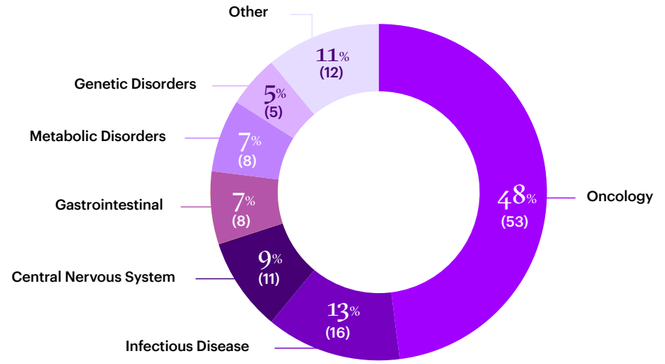
- lead design and optimization
- target prediction and identification
- drug repurposing
- biomarker identification

Small molecules represent two-thirds of the drugs in clinical development, with 73 assets, followed by monoclonal antibodies and peptides with 19 assets. Of the small molecules, 30 are focused on oncology and 9 are in Central Nervous System (CNS).



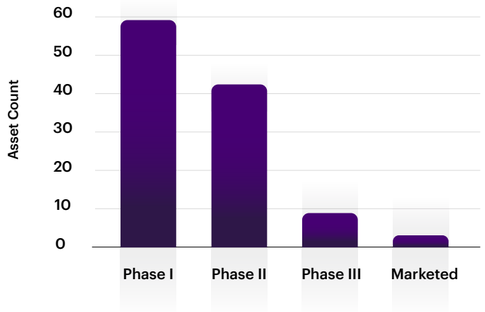
Source: Accenture Research 2024 leveraging GlobalData

Across all modalities, the focus remains on oncology, accounting for nearly half of the assets in clinical development with 53, followed by infectious disease and CNS with 16 and 11, respectively.



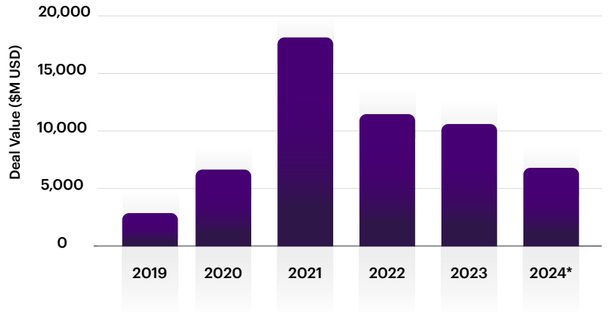
Source: Accenture Research 2024 leveraging GlobalData

The majority of assets are in phase I, accounting for 59 of 113. Three assets have reached the market so far.



Source: Accenture Research 2024 leveraging GlobalData data and companies' websites

Large biopharma companies have struck deals potentially worth over $55b since 2019. Deals for 2024 are on pace to eclipse the last two years.



Source: Accenture Research 2024 leveraging GlobalData and Citeline data *2024 Data as of 5/24/2024

1.2 Developing and manufacturing new types of treatments

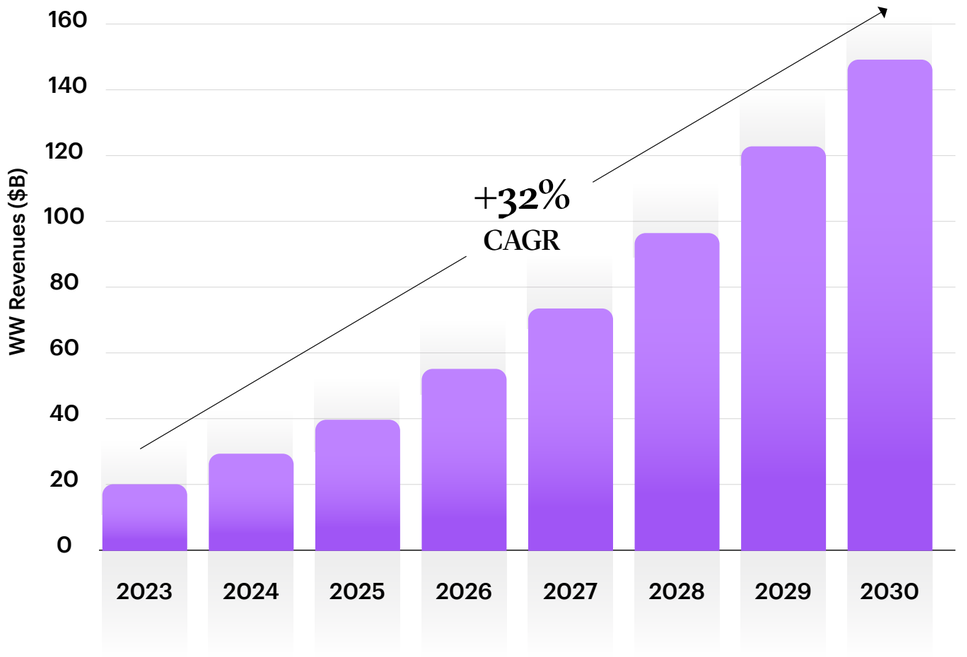
- **69% say that this capability is key to achieving success.**
- **75% rank it as a top 3 investment over the past 12 months.**
- **92% are focused on creating platforms for the rapid development of next-generation therapies.**
- **61% note that the establishment of new modalities and the ability to support new modalities is most critical.**

Source: Accenture's Biopharma R&D Executive Survey[14]

Developing a consistent and scalable production process for new new medicines is critical once they reach clinical trials. For instance, shortages of radioligand therapies have caused clinical trial delays and access issues for patients already on therapy. As R&D advances, producing more specific and complex drugs (like multi-specific antibodies) leads to more intricate recipes and assays. The increasing speed of clinical trials leaves less time for optimizing and scaling these complex recipes, impacting a drug's commercial potential. With sales of new modalities projected to grow from $22 billion in 2023 to $152 billion by 2030[15], the ability to quickly develop and scale production becomes even more crucial.

Figure 3

Advanced Modality Growth



Source: Accenture Research 2024 leveraging Evaluate Pharma data

To meet this demand, advanced techniques such as computational fluid dynamics must be applied more upstream. These methods enhance understanding of the biology and chemistry needed for producing and purifying active pharmaceutical ingredients (APIs). Leveraging increased computational power allows for in silico simulations on producer cell lines for gene therapy or stem cells, reducing the need for wet-lab experiments. This results in optimized recipes with higher yields and consistent processes, ultimately streamlining recipe development and scaling. By reducing delays, clinical testing and commercial availability can be accelerated, ensuring that groundbreaking treatments reach patients faster.

The current operating model presents another opportunity for improvement. Traditionally, process development teams reside in R&D, while Manufacturing Science and Technology (MSAT) teams sit within commercial manufacturing. This division hinders collaboration and knowledge sharing, leading to inefficiencies and overextension of specialized teams during critical development phases. Integrating recipe development within manufacturing—rather than keeping it siloed in R&D—could significantly enhance collaboration and efficiency. A unified "Development and Manufacturing" team focused on recipe development, scaling, optimization and troubleshooting would provide full lifecycle ownership, better knowledge management, and reduce the likelihood of recipe issues.

Tech transfer is another critical phase, vulnerable to problems particularly when manufacturing processes shift between teams or sites. This transition is fraught with risks at all stages of development, but it's especially challenging when moving from clinical to commercial scale. Effective tech transfer requires continuous communication, standardized plans, and clear protocols, including thorough risk assessments and quality control strategies. Prioritizing tech transfer will speed up development and commercialization, ensuring smoother transitions and reducing the strain on MSAT teams.

Outsourcing manufacturing to contract development and manufacturing organizations (CDMOs) is increasingly common, projected to rise from 28% in 2023 to 37% in 2030[16], with 70–80% of ADC development now outsourced.[17] While outsourcing provides flexibility and access to specialized equipment, it also introduces risks such as dependence on specific vendors and reduced control over the process. Building strong relationships with CDMOs, maintaining some degree of independence, and having robust MSAT teams can effectively manage these risks. Strategic in/outsourcing decisions and strong supplier relationships can enhance operational agility, prevent material shortages and ensure timely release of commercial batches.

Ultimately, the biopharma industry must adapt to the growing complexity of drug development and manufacturing. By investing in intelligent technologies to streamline recipe development, adjusting operating models to integrate recipe development within manufacturing, prioritizing tech transfer and making intentional in/outsourcing decisions, the industry can enhance efficiency, reduce risks and ensure the timely delivery of new treatments to the market. Taking these steps very early in both drug design and dynamic portfolio management decisions is crucial for keeping pace with the rapid advancements in drug development and ensuring that innovative treatments are available to patients when they need them most.

1.3 Optimizing clinical trials

- **60% rank clinical trial optimization among the top three most important capabilities for driving future success.**
- **68% say it has been a top area of investment.**

Source: Accenture's Biopharma R&D Executive Survey[18]

As the number of clinical trials for smaller, more focused indications increases (clinical trials for rare diseases have increased 77% from over 600 in 2017 to nearly 1,100 in 2023[19]), biopharma companies must design trials that reduce patient burden and attract participants. They must adapt to changing healthcare dimensions and scientific advancements while managing the complexity of large trials in areas like cardiovascular and metabolic diseases.

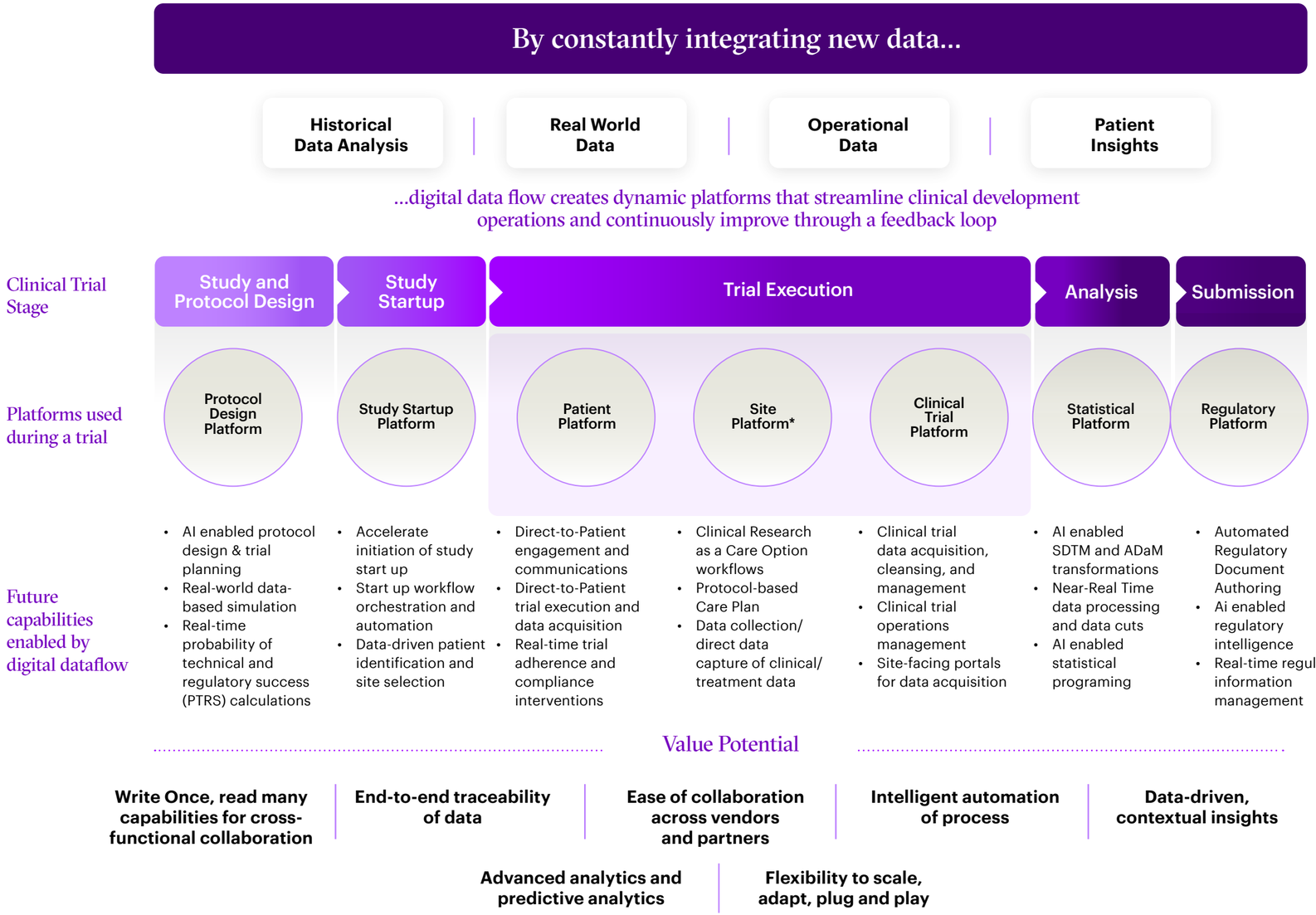
Biopharma companies targeting scientifically challenging diseases face extensive procedures, numerous endpoints, and multiple subgroups to analyze. Protocols often exceed 150 pages with intricate requirements, making trials burdensome and sometimes unrealistic. Additionally, the global expansion of trials—aimed at accessing diverse patient populations and reducing costs—adds significant logistical complexity. Stricter regulatory requirements, while essential for patient safety, also increase the cost and duration of trials.

Patient recruitment is a major bottleneck, causing delays for nearly 80% of trials.[20] Outdated technology exacerbates the problem, as core technologies for executing clinical trials have not fundamentally improved in two decades, leading to siloed data and manual processes. Economic factors also contribute to high costs, including rising costs at clinical trial sites, higher salaries for clinical research associates (CRAs) and project managers, increased costs from contract research organizations (CROs), and macroeconomic impacts like regulatory changes and inflation.

Biopharma companies must urgently accelerate clinical programs to minimize impending revenue losses from the expiration of drug patents, market forces and governmental policies. As patents expire, the loss of exclusivity threatens revenues, making it critical to bring new therapies to market faster. Also, for those companies with an increasing number of molecules resulting from enhanced research productivity and a higher PTRS, a pipeline bottleneck can develop with more molecules vying for development than there is capacity or budget to handle.

Meeting these challenges demands a comprehensive strategy focused on clinical trial design and optimization. This includes establishing a digital transformation office to drive strategy and coordinate initiatives; launching a major data infrastructure program to enable seamless, secure data flow across R&D; developing an enterprise AI platform for shared tools, algorithms and compute infrastructure; implementing a comprehensive master data management strategy to ensure data quality, consistency and governability; implementing an end-to-end digital data flow (see Figure 4); and creating an AI governance board to oversee responsible AI policies.

Figure 4



*The Electronic Medical Record system is the platform for Care Delivery/ Medical facilities

Digital data flow describes the thread of data that connects all aspects of a clinical trial, from the Integrated Evidence Plan to regulatory submission. This thread contains the context required for automating and augmenting clinical development. As a result, organizations can conduct simulations on study designs (including eligibility criteria, endpoint rationalization, and assessments), automate clinical IT system builds (such as electronic data capture and clinical databases), perform appropriate SDTM transformations, and generate regulatory documentation. Digital data flow ensures seamless integration, standardized procedures, and accelerated progress from protocol inception to study completion.

High-impact AI projects in areas like protocol optimization, patient-trial matching and real-time safety monitoring can make a significant difference. Redesigning processes to embed AI and automation across the clinical development value chain; piloting AI-native trial designs that are faster, more adaptive and more patient-centric; and establishing a personalized medicine initiative to use AI and multi-modal data to match patients to therapies can all contribute to improvements. Scaling successful AI pilots into full adoption with robust processes for model validation, monitoring and continuous improvement, can deliver up to a 30% reduction in nonperforming clinical sites and reduce costs by up to 15%, with study-time improvements of up to 18% in certain trials.[21]

The future of clinical trials will be data-driven, digitally enabled and AI-powered. Technology has the potential to transform clinical trials by optimizing protocol design, identifying the right patients and sites, monitoring risks and analyzing safety signals. However, realizing this potential requires overcoming challenges such as data accessibility, algorithmic bias, explainability, regulatory acceptance, privacy and security, and organizational acceptance. This is an opportunity to fundamentally transform how clinical trials are designed and conducted. While the road ahead will demand significant investment, unwavering focus and a willingness to disrupt long-standing norms, the potential rewards—for patients, for business, and for society—are immense. Organizations that commit will be prepared for the future and positioned as leaders in the digital age of medicine.

1.4 Dynamic portfolio management

- **32% list it as a top capability for driving future success.**
- **35% say it has been a top area of investment.**
- **73% of companies rank their capability as mature, but our research reveals significant gaps.**

Source: Accenture's Biopharma R&D Executive Survey[22]

Traditionally, biopharma portfolio prioritization decisions focused on discussions of assets within a therapeutic area, which ensured a sound strategy but also led to isolated decision-making. Portfolio prioritization discussions are now becoming more comprehensive to encompass bio-platforms, new modalities, AI capabilities, digital health solutions and economic factors like reimbursement pathways, value propositions and evidence generation plans. This shift necessitates a dynamic approach that continuously integrates new data to make informed decisions.

Adopting dynamic portfolio management is crucial for future success, especially in an environment of budget restrictions and market fluctuations. Companies need to be agile and reprioritize their pipelines effectively. C-suite executives face tough decisions on whether to invest in strategic capabilities and technologies—such as generative AI—or drug programs and platforms. Currently, half of C-suite executives do not consider intelligent technologies as part of their overall capital allocation decisions.[23] By appropriately prioritizing investments, companies can significantly improve efficiency, success rates and trial times, even though these investments may limit funds available for drug programs.

Despite current efforts, commercial risk assessment remains a significant gap in portfolio prioritization across many companies. Biopharma companies often evaluate a drug's commercial potential around phase II or the proof-of-concept stage, using net present value and a mix of epidemiological and real-world data. However, experts we spoke with suggest starting this evaluation earlier during the creation of the target product profile, integrating access and pricing considerations with market share and epidemiological data—which often remain siloed—to avoid an incomplete understanding of commercial potential. Emerging technologies promise to enable advanced "what if" analyses with sensitivity models, significantly improving assessments. Using extensive data from real-world evidence, epidemiological studies and market research, these technologies make commercial risk assessments more accurate, enabling companies to make more informed decisions and balance immediate pipeline needs with long-term technological investments.

Additionally, companies must take a holistic approach to financial portfolio management, bringing together both drug project (direct spend) and non-drug project (indirect spend) considerations. Balancing capital expenditures and operational expenses strategically is crucial to supporting long-term growth and innovation. For example, investing in capabilities to accelerate specific high-priority programs within the portfolio can ensure that investments are aligned with strategic goals and deliver maximum impact. And given how quickly both pipeline competitive landscapes and technology advancements are shifting, the status quo of quarterly portfolio assessments is insufficient.

Integrating external assets into the portfolio management process is another challenge. The industry needs to streamline external scouting efforts and ensure that external opportunities are seamlessly integrated into the portfolio. This requires a more logical and consistent application of external data sets to assess new product portfolio prioritization. Additionally, the lack of an R&D-wide data platform to combine and analyze disparate data sets, including real-world evidence, hinders the ability to make successful PTRS predictions. In addition, most R&D organizations have not digitally captured their historical decisions, assumptions and outcomes to augment their future decisions. They continue to rely heavily on instincts and portfolio decision-making based on traditional approaches.

The implementation of AI and other advanced technologies is still evolving. While there are promising developments in drug discovery and clinical trial design, the application of AI for portfolio optimization and commercial calculations remains in its early stages. Nonetheless, these technologies hold significant potential to improve decision-making processes and overall efficiency, improving commercial potential.

To conclude, biopharma companies should consider these integrated strategies to address the challenges and opportunities: broadening portfolio management to include diverse elements like bio-platforms and AI-driven discovery; adopting dynamic portfolio management for agility; prioritizing technology investments for efficiency; enhancing commercial risk assessments with advanced AI tools; integrating access and pricing considerations early; streamlining decision-making processes; and taking a holistic approach to financial management.

> "We need to be more dynamic. We need to continue that shift and better optimize the use of real-world data."
>
> R&D VP, Top 10 Biopharma Company

2. Addressing the imperatives that power reinvention

Three foundational building blocks that underpin and guide reinvention strategy.

Future success requires a degree of reinvention for biopharma companies. For their reinvention to succeed, they must be properly supported. The right talent and working processes will drive progress forward efficiently and cohesively. A culture of continuous reinvention nurtures open minds and is important for enterprise agility and adaptability. And a secure, AI-ready digital core that is fueled by data and supported by a robust technology ecosystem will make the previously impossible a reality.

2.1 A secure, AI-ready digital core

- **87% say that AI and machine learning are imperative to their organization's success.**
- **65% of leaders say that using the right tools and technologies to improve productivity is most important for R&D success, but only 55% of organizations make it a priority.**
- **32% stated that generative AI has been highly or fully adopted for both medical and regulatory affairs, versus 93% for research and discovery and 89% for clinical development.**
- **We've seen companies who embrace a tech-enabled innovation philosophy experience 6.5X faster growth, 2.2X more profitability and 4.2X more cost efficiency.[25]**

Source: Accenture's Biopharma R&D Executive Survey[24]

To take advantage of the latest analytical tools and intelligent technologies, companies need a strong, modern, highly interoperable data and AI foundation, supported by an agile digital infrastructure. This flexibility will enable the use of both general models accessible to all employees and specialized models for specific tasks. Essential elements of this framework include security, a modern data platform, a model switchboard, domain expertise, and a commitment to responsible AI. A robust digital core brings numerous benefits such as the ability to implement next-generation AI models, streamline operations, and reduce data silos across the organization.

As R&D organizations gather more data, building data fabrics and warehouses becomes increasingly important. This data serves both internal stakeholders and external partners, especially science-tech companies focused on AI-enabled drug discovery. Generative AI also allows for the creation of synthetic data using the vast amounts collected daily from all areas of R&D. While these ideas aren't entirely new, they can now be executed at incredible scale and speed, thanks to modern digital and AI platforms. Multimodal data types like voice, video, and unstructured text from labs or clinical trials can now be quickly analyzed, opening up a new range of applications. Our report, "Reinventing Life Sciences in the Age of generative AI," explores digital core strategy for the biopharma industry in more detail.

A robust digital core brings numerous benefits such as the ability to implement next-generation AI models, streamline operations, and reduce data silos across the organization.

2.2 Talent and leadership

- **31% of respondents say their organization ranks the development of and investment in talent as a top three priority for success.**
- **100% say their R&D organization is focused on developing AI- and machine learning-literate talent.**

Source: Accenture's Biopharma R&D Executive Survey[26]

Transforming talent is important. Launching an AI/Digital Talent Strategy to assess gaps, upskill existing staff and acquire key talent through hiring and partnerships can drive reinvention. Strategic partnerships with leading academic institutions and tech companies can provide access to cutting-edge research and innovation, while a comprehensive change management program can build awareness, engagement, and adoption of the digital transformation agenda.

The impact of intelligent technologies on talent in core R&D functions is transforming roles: traditional biology roles have evolved into separate biology and data science roles; lab technicians are now focusing more on automation and robotics rather than routine tests; and protein scientists have shifted from creating new molecules to understanding diseases and their mechanisms from a data science perspective.

New roles are emerging as the lines between traditional science and computational science blur. This convergence—including analytics and data science—is making scientists more effective and productive, with an estimated 20% productivity gain.[27] This boost can improve company performance, reduce employee burden, or enable talent upskilling.

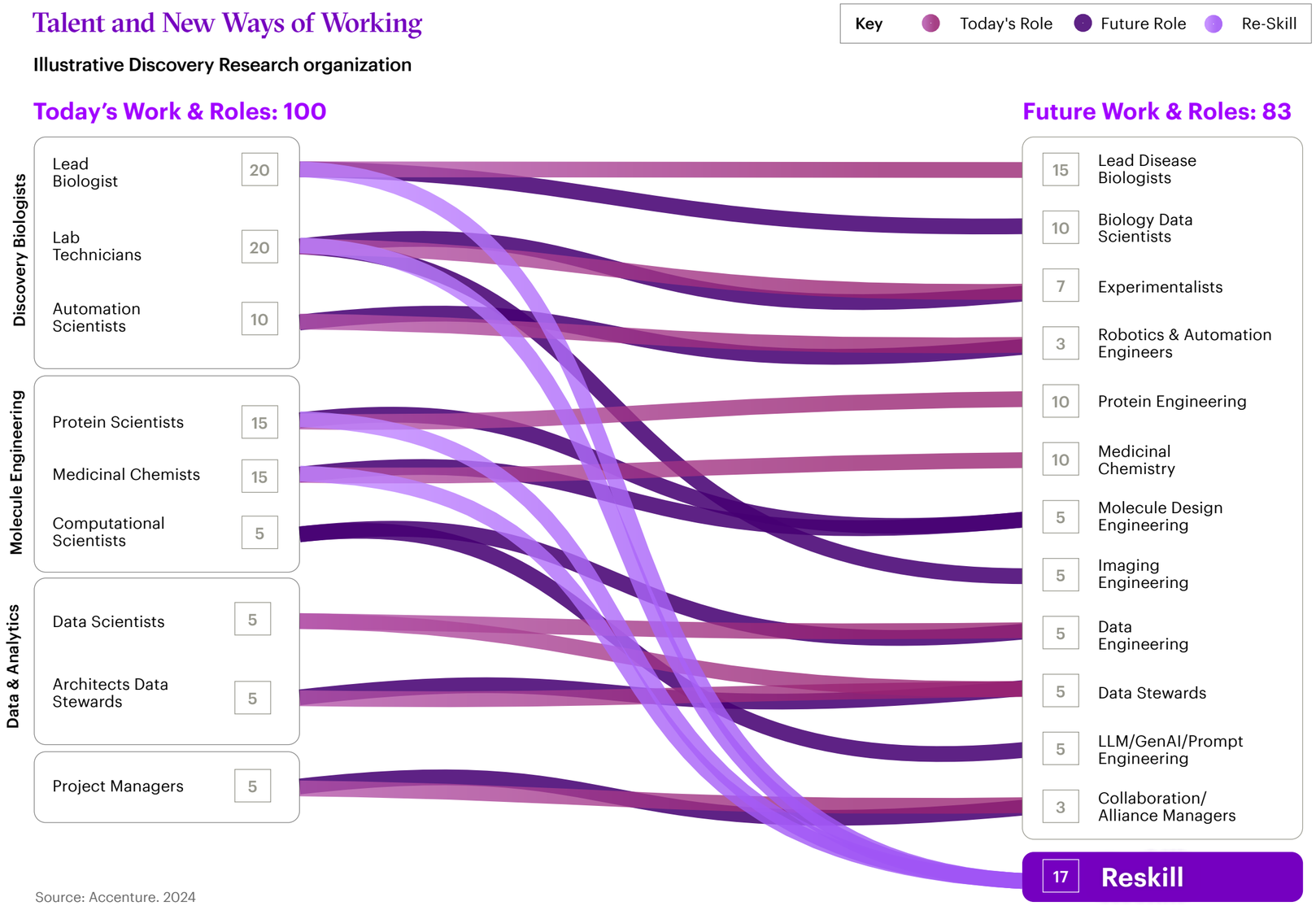
These changes demand new skillsets. Scientists are no longer just conducting basic research and discovering new molecules—they now spend about a third of their time managing data and integrating it with their lab experiments, meaning they need to be fluent in both traditional science and data science.

The question is whether companies are ready for this shift. This transformation requires a new skill and talent profile (**Figure 5**). The skills required for a biologist today differ profoundly from those needed just two years ago. Understanding biology is no longer enough, as scientists must also understand disease, develop and implement generative AI models, and be able to recognize when a model is faulty. Companies must find this new talent and upskill their current workforce to ensure they have the capabilities to embrace the next generation of technology.

Figure 5

Talent and New Ways of Working

Illustrative Discovery Research organization



Source: Accenture. 2024

Figure 5: As generative AI and other advanced technologies are increasingly leveraged, new ways of working will emerge, requiring the reallocation of current talent, the creation of entirely new roles, and reskilling the current workforce.

Multi-disciplinary talent is essential for driving R&D organizations into the future. Biopharma companies must expand their recruitment horizons beyond scientific talent to include those who are skilled in technology and AI—a trend that is already gaining speed. Life Sciences technology hires have doubled in the past five years, and AI-specific roles have increased fourfold.[28] At the same time, technology companies are starting to recruit more scientific talent, making recruitment more competitive.

2.3 A culture of continuous reinvention

- **99% agree their R&D organization is open to change and embraces creativity, but only 68% say people are encouraged to take risks.**
- **Research shows that a safe, open culture can improve productivity by 50% and collaboration by 57%.**

Source: Accenture's Biopharma R&D Executive Survey[29]

Reinvention in the R&D organization shouldn't be seen as a contained, one-time initiative. It should be embraced as an ongoing strategy, set in the broader context of the evolving regulatory landscape. Establishing a digital academy to provide tailored training programs for staff at all levels—from basic AI literacy to advanced data science certifications—and implementing agile ways of working across R&D can foster a culture of innovation.

New and complex science, enabled by technology, is driving a scientific renaissance. By continuously reinventing themselves, biopharma companies can improve patient outcomes, streamline clinical trials and increase clinical success rates, boosting their commercial potential.

Similarly, building a digital core to support reinvention and create competitive advantage also must be considered an ongoing focus. It requires ongoing investment to incorporate the latest technologies and business capabilities across the R&D organization. If companies treat their digital core as something to be completed, it will quickly become obsolete. They must stay on the leading edge of technology to enhance core aspects of their R&D operations.

Continuous adoption of new capabilities and technology is impossible without the right talent, so investing in people is crucial to maintaining a competitive advantage. Modern leaders must have the skills and behaviors to guide their companies through continual reinvention—they must embrace new ways of working and build expertise in technology, data, and analytics. Ongoing investment in new skills both for themselves and for the broader R&D workforce is essential.

Conclusion

The biopharma industry is sitting on a proverbial golden egg. Technology now has an incredible capacity for enhancing human ingenuity on a scale never imagined before—let alone seen in reality. The potential for life changing and life enriching treatments is broader than ever. To harness this potential fully, biopharma companies must undergo a comprehensive reinvention of their R&D organizations. This involves embracing intelligent technologies, reimagining work processes and talent, and fostering a culture of continuous innovation. Companies can become more competitive in a rapidly evolving market by prioritizing developing and manufacturing new types of treatments using intelligent technologies for discovery, optimizing clinical trials, and dynamic portfolio management.

The companies most able to realize this potential are those that adopt a reinvention strategy encompassing the recommendations laid out in this report. They will be well-positioned to deliver transformative therapies, drive substantial growth and establish themselves as leaders in the next generation of medical treatments.

Methodology

R&D Success Index Methodology

Accenture Research developed this success index leveraging PTRS and Duration data from Pharmapremia (January 1, 2024 – December 31, 2023) and Enterprise Value from CapitalIQ (2018-2023). The X-axis shows how quickly companies' drug-indication pairs moved through the pipeline and the Y-axis shows companies' success rates. Those farther to the right achieved shorter cycle times and those farther up achieved higher success rates relative to their expected performance.

For each company, we created an "Expected PTRS" and "Expected Cycle Time" based on the proportion of their pipeline focused on disease group and phase pairs (for example, phase I oncology, phase II oncology, phase I cardiovascular, and so forth) to normalize for varying levels of duration and success rates across phases and therapeutic areas. We then compared this to the actual success rates and durations that they experienced.

Survey Methodology

We surveyed 75 R&D executives globally from the top 20 biopharma companies by 2023 annual revenue to understand the current R&D landscape and the direction of change. Roles included Head of R&D/Chief R&D Officer, VP/SVP, Senior/Executive Director, and Chief Science Officer. The survey was conducted in January 2024. Our primary focuses were on how executives and R&D organizations define R&D success; the factors and capabilities required to achieve that success; and the level at which organizations embraced intelligent technologies.

Time Savings and Revenue Uplift

Time savings based on industry case studies as well as expert and client discussions. Almost three years of time savings during target discovery and validation and lead ID and optimization using AI-methods and workflow reinvention. 18 months of time savings during the clinical trial period that comes from accelerated clinical protocol design and better patient selection and recruitment.

Revenue uplift was calculated based on the additional four years of exclusivity period in market with average peak sales of $500 million. This calculation does not take into consideration other qualitative factors such as first mover advantage. As such, we believe this number to be conservative. Additionally, revenue uplift can vary dramatically depending on indication and potential peak sales.

Cost savings are based on Accenture's "Taking R&D From Billions to Millions" model. Cost savings come from the uplift in probability of success of clinical trials based on factors such as better target validation, understanding of the disease mechanisms, trial design and patient selection. Reported cost savings are per successful drug including cost of failure and cost of capital.

AI-mediated Drug Discovery

Landscape: We initially identified over 200 AI drug discovery companies using Pitchbook and other internal resources. However, we recognize that there is a considerable amount of variability in the type and sophistication of AI/ML methods used across these companies and a disagreement on how to define what an AI discovered drug is. Therefore, as we refined the list, companies were classified as such if they identified or marketed themselves as leveraging AI in the following areas:

- lead design and optimization
- target prediction and identification
- drug repurposing
- biomarker identification

Once we finalized the list of companies, we extracted all pipeline assets from GlobalData. We focused on assets where the identified AI-mediated drug discovery companies were involved as either the originator/licensor or developer.

The analysis is limited by the coverage of our databases. As such, in some cases, the role of the AI-mediated drug discovery company may be minimal or not fully detailed.

Deals: We compiled a comprehensive list of AI partnership deals from Citeline's Biomedtracker and GlobalData leveraging keyword searches. The dataset includes all completed partnership deals from January 1, 2019 – May 24, 2024. From this list, we identified companies classified as AI mediated drug discovery companies based on our previous definition. We further categorized the deals to identify those involving Big Pharma companies, which we defined as the top 20 pharmaceutical companies by 2023 Rx sales according to Evaluate Pharma.

References

1. Potential treatment for rare autoimmune disorder adapted from CAR-T therapy
2. FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease
3. Inflation Reduction Act's Price Controls Are Deterring New Drug Development: IRA effects on revenue loss range from $237b (CBO) to $450b
4. Accenture Research Analysis of Evaluate Pharma data as of 6/1/2024: $300 billion+ of revenues at risk between 2026-2030 due to loss of exclusivity
5. Four Trends That Will Pop the $250 Billion Gross-to-Net Bubble—and Transform PBMs, Market Access, and Benefit Design
6. Accenture Research analysis leveraging Billions to Millions model. Please see methodology for more details
7. Innovation in the pharmaceutical industry: New estimates of R&D costs, DiMasi et al.
8. https://www.accenture.com/gb-en/insights/life-sciences/from-billions-to-millions-transformation
9. Based on internal Accenture work, industry case studies, and expert & client discussions
10. Accenture Research analysis of top biopharma companies leveraging Pharmapremia and S&P Capital IQ data
11. Accenture Resarch's Global Biopharma R&D Executive Survey
12. Accenture Life Sciences CEO Forum 2024 research
13. Accenture Research analysis. All facts and figures are derived from GlobalData and Citeline's Biomedtracker. Please see methodology section for additional details
14. Ibid.
15. Accenture Research analysis of Evaluate Pharma data
16. Goldman Sachs Equity Research, April 29, 2024
17. Jeffries Research, Insights with Expert, January 2, 2024
18. ibid.
19. Accenture Research analysis of GlobalData's Clinical Trial Database. Rare diseases exclude oncology and were selected using GlobalData's definition
20. ibid.
21. ibid.
22. ibid.
23. Survey of 1000+ C Suite Executives, Accenture's Innovation Unleashed Report
24. ibid.
25. ibid.
26. ibid.
27. Accenture Research analysis leveraging occupation level data from the U.S. Bureau of Labor Statistics and O*NET.
28. ibid.

About Accenture

Accenture is a leading global professional services company that helps the world's leading businesses, governments and other organizations build their digital core, optimize their operations, accelerate revenue growth and enhance citizen services—creating tangible value at speed and scale. We are a talent and innovation led company with 743,000 people serving clients in more than 120 countries. Technology is at the core of change today, and we are one of the world's leaders in helping drive that change, with strong ecosystem relationships. We combine our strength in technology with unmatched industry experience, functional expertise and global delivery capability. We are uniquely able to deliver tangible outcomes because of our broad range of services, solutions and assets across Strategy & Consulting, Technology, Operations, Industry X and Accenture Song. These capabilities, together with our culture of shared success and commitment to creating 360° value, enable us to help our clients succeed and build trusted, lasting relationships. We measure our success by the 360° value we create for our clients, each other, our shareholders, partners and communities.

Visit us at **www.accenture.com**.

About Accenture Research

Accenture Research creates thought leadership about the most pressing business issues organizations face. Combining innovative research techniques, such as data-science-led analysis, with a deep understanding of industry and technology, our team of 300 researchers in 20 countries publish hundreds of reports, articles and points of view every year. Our thought-provoking research developed with world leading organizations helps our clients embrace change, create value and deliver on the power of technology and human ingenuity. For more information, visit Accenture Research on **www.accenture.com/research.**