

Accenture Life Sciences
New Science. Transformative Patient Outcomes.

From Billions to Millions

Faster innovation.
Greater R&D productivity.

 accenture

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The biopharma industry stepped out of its comfort zone with its response to COVID-19, resetting expectations for the pace of innovation and bringing treatments to market.

These breakthroughs are taking place at a time when healthcare spend, and profitability pressures are also on the rise. Now is the time for the industry to embrace change and rewrite the productivity equation, bringing down the cost of discovering and developing new treatments from billions to millions.





The capabilities are in place to transform Research and Development (R&D) productivity exponentially—using data, advanced analytics and technology to reconfigure how it gets done. While cost reduction is a major driver for this push, the adoption of faster, better processes that enhance productivity will also increase R&D output, ultimately providing more impact for patients.

Three strategic plays for R&D can help biopharma companies make that leap from billions down to millions and critically change the makeup of their pipelines and path to commercialization: New Science portfolio, digital and data-led research, and faster, smarter development.

Companies are already in innovation mode, and now is the time to shift strategy and reimagine R&D with digitally powered and patient-centric design.

Price Pressures

The healthcare ecosystem is under significant price pressures at both the system and patient levels. In the US, healthcare spend is now more than 17% of GDP (up from 9% in 1990¹) and makes up almost a quarter of government spending². In emerging markets, patients are heavily exposed to pharmaceutical costs with most public healthcare programs focused on the provision of free or subsidized generics.³

The affordability gap in developed markets is predicted to reach an estimated \$300B by 2028⁴, suggesting that pharmaceutical sales forecasts dramatically overestimate the capacity of global health systems to afford the treatments currently under development.

Patient affordability is also under strain.

The average US premium for family coverage has increased 55% over the last ten years, and almost 30% of patients report not taking their medicine as prescribed due to cost.⁵

Meanwhile, the growth of New Science* and precision medicine means that each therapy is increasingly customized for a smaller patient population, limiting potential revenues.

For the biopharma industry, these trends are contributing to profitability challenges and underperforming sales targets, and a higher likelihood of policy and regulatory changes as the affordability gap widens. These pressures add to the urgency felt by biopharma leaders as they contend with the unsustainable economics of bringing medicines to market.



* **New Science** includes a spectrum of treatments that:

- Solve for a clear, unmet need through a new mechanism, modality or health technology, such as new cell therapies and curative gene therapies
- Often require a new technology device or diagnostics for their development or as a companion to treatment, or could describe the technology alone

R&D's Productivity Challenge

The cost of bringing a successful medicine to market is between \$2.6B⁶ and \$6.7B⁷ (including the cost of capital and cost of failure) depending on therapeutic area, treatment modality and disease complexity.

The growing price pressures on the healthcare ecosystem mean that this cost must come down exponentially, from billions to millions. R&D has a pivotal role to play in this transformation.

A central strategy for addressing the economics of bringing treatments to market is to rethink the discovery and development process. This requires a closer look at the longstanding productivity challenge that the biopharma industry has been working hard to address. The productivity problem hinges

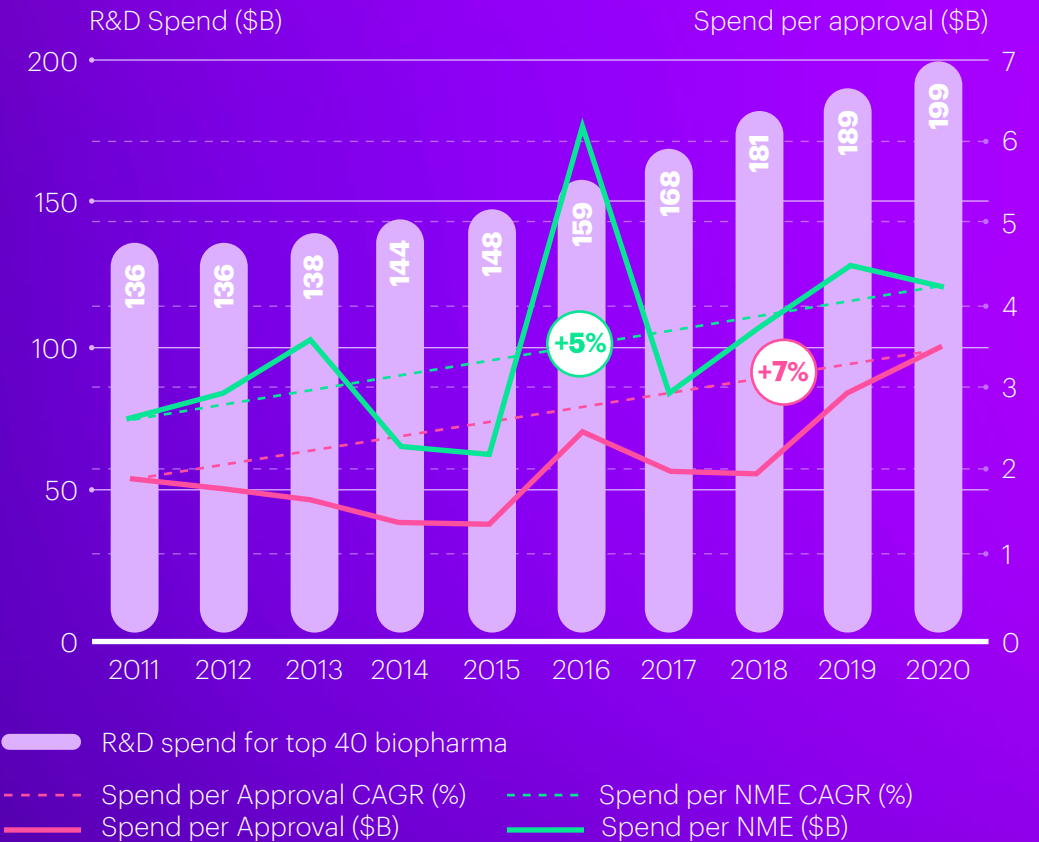
on the rising ratio of R&D spend per each new treatment approved, which has increased at 5% per NME and 7% per approval annually over the last ten years (see figure 1).⁸ Companies must shift this equation to drive competitiveness, by looking at how today's advanced capabilities can boost efficiency and effectiveness.

There are distinct components to R&D productivity including unit cost, probability of technical success, time to market and selection of treatments with high market potential. While these components are interdependent and can be difficult to address simultaneously, here we explore strategic plays which address all the components and calculate cost and revenue opportunities to understand the comparative value of those strategic plays.

Figure 1

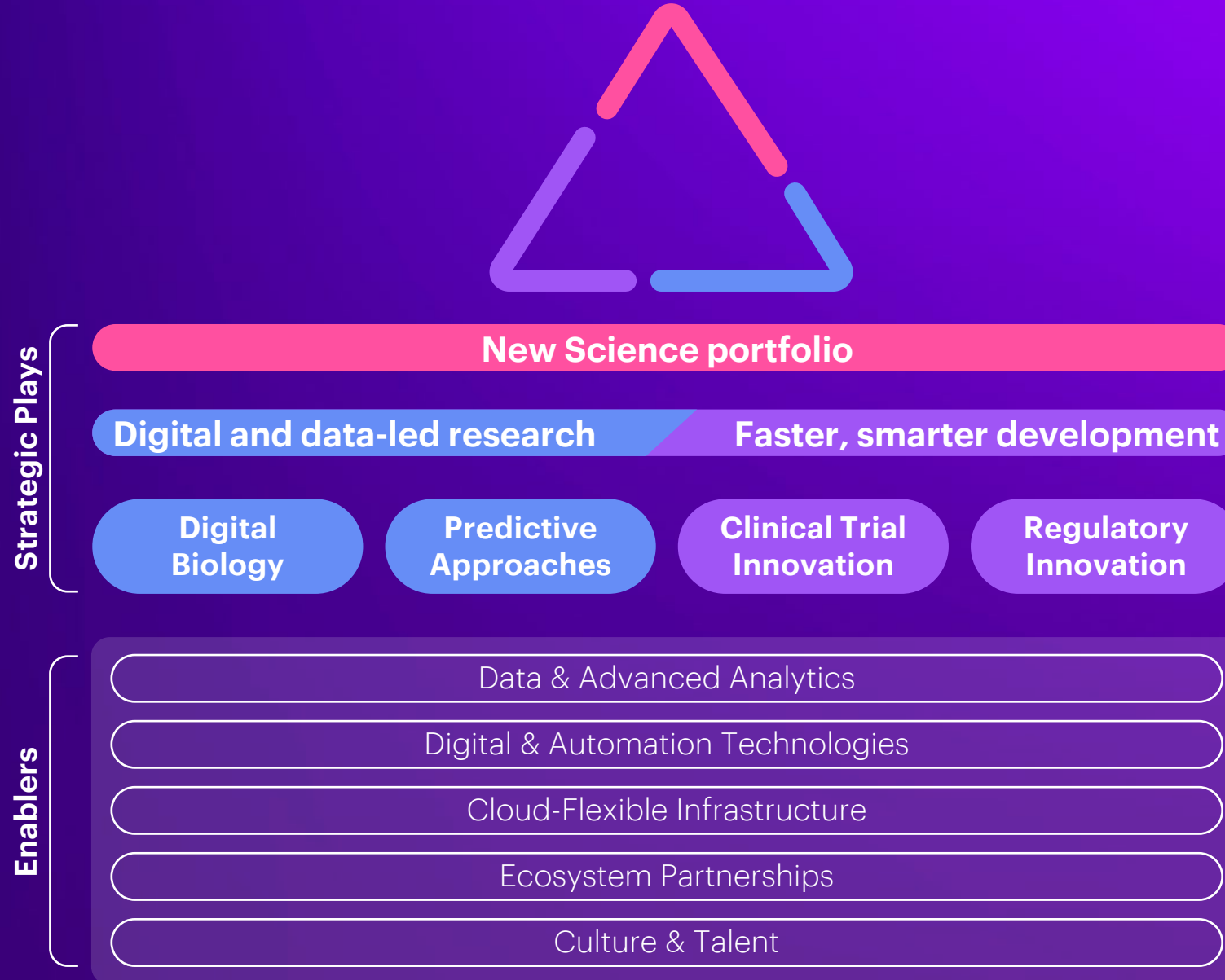
Overall R&D spend is increasing and putting pressure on biopharma to improve R&D Productivity

Biopharma R&D spend vs. spend per approval

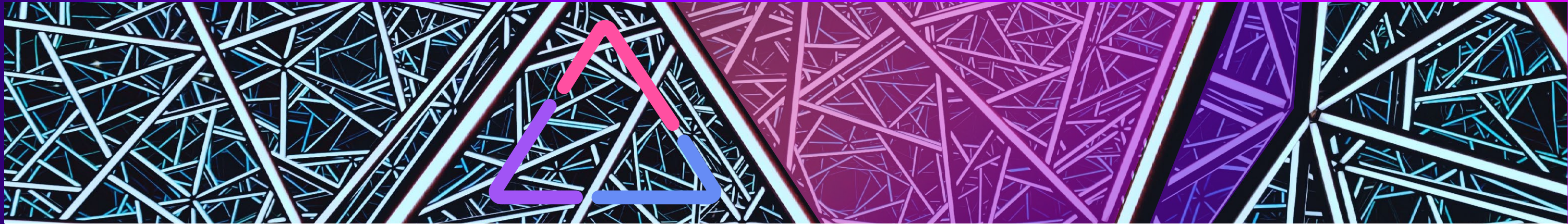


Notes: Evaluate Pharma; Top 40 by 2020 WW Sales (\$B)
 "All Approvals" defined as NDA and BLA, excludes biosimilars and generics
 Abbreviations: NME – New Molecular Entities, NDA – New Drug Application, BLA – Biologics License Application, CAGR – Compound Annual Growth Rate

Strategic plays



To disrupt the current R&D productivity equation, biopharma companies should intensify their focus on three strategic plays and the critical enabling capabilities.



New Science portfolio

Shift the portfolio strategy to be more heavily weighted towards New Science⁹. While these treatments have high initial development costs, they also have a higher probability of success in clinical trials, lowering overall cost of failure. They also bring greater potential value as assets that have scientific novelty, address an unmet need, and/or leverage technology convergence to generate value.

Digital and data-led research

Transform the way research is done, collapsing the layers of separation not only between scientists and patient data but also between biopharma, biotechnology and academic institutions. Identify disease-specific signatures and biomarkers through real-world data including -omics, outcomes and histology data to improve disease understanding and identify, validate and optimize targets that have a lower risk of failing during development. Speed up lead identification, selection and optimization through predictive modeling and AI. Build an ecosystem strategy beyond therapeutic area (TA) adjacent partnerships to continuously create new sources of value through new modalities, platforms, capabilities or ways of accessing patients.

Faster, smarter development

Reimagine clinical development by leveraging machine learning and multi-modal, real-world data to power patient-centric design, formulate trial strategy and assess risks to maximize benefit while reducing operational costs with smaller cohorts, faster timelines and fewer sites. Scale trial innovation such as decentralized trials to meet patients where they are, improving patient enrollment, retention and diversity. Engage differently with health authorities, reducing the time and effort to file, and generate additional revenue opportunities through a faster time to market.

Driving billions to millions

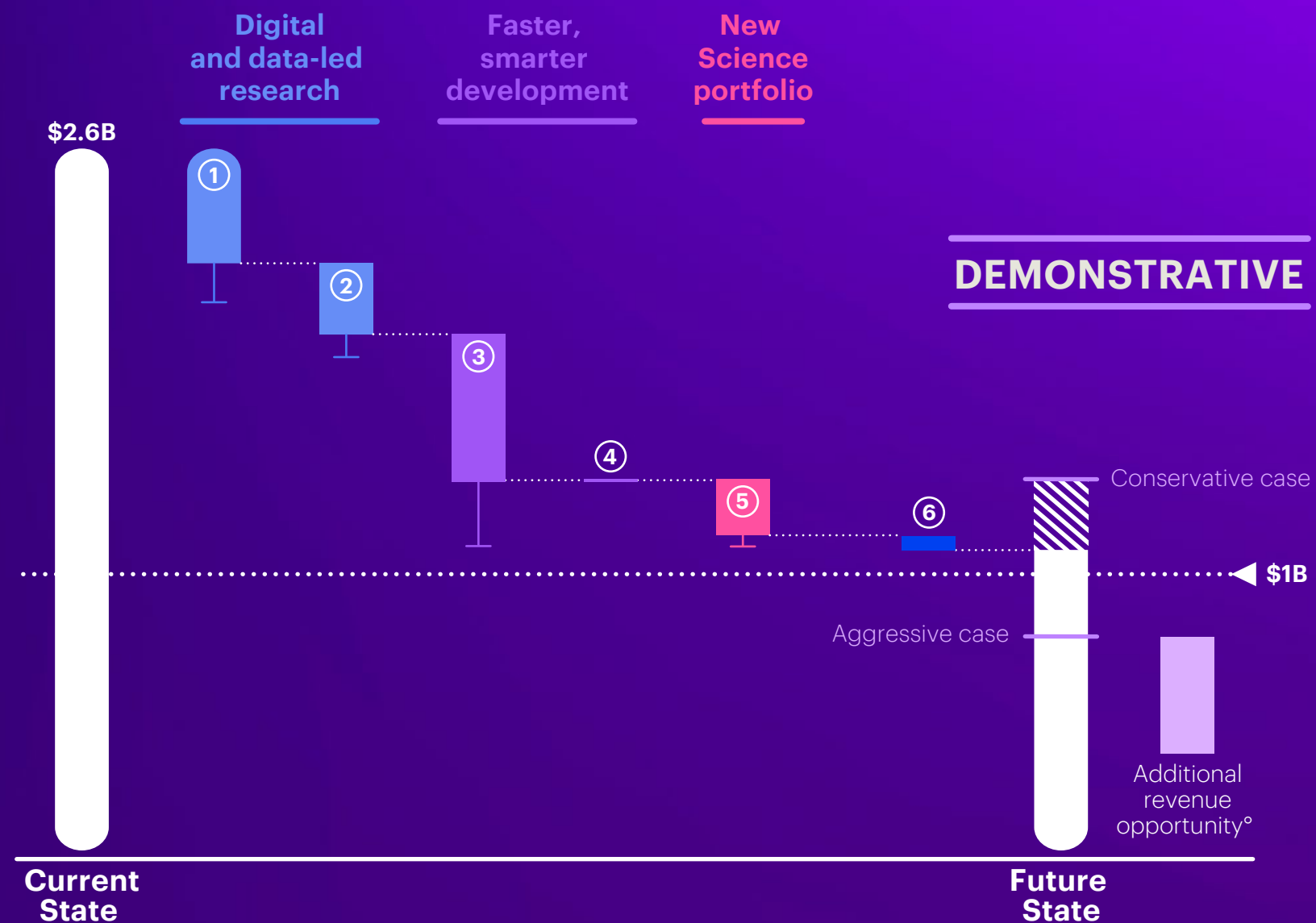
Our research demonstrates that when executed with the right enablers, these three strategic plays significantly impact costs and time to market. We modeled quantifiable impacts for each strategic play on the average cost of bringing a medicine to market. Baseline assumptions are leveraged from peer-reviewed productivity models¹⁰ widely accepted by the industry.

Our model suggests that the three strategic plays will deliver savings of \$1.2–1.7B per successful medicine (including the cost of capital and cost of failure), and will create additional future revenue opportunities of \$150–450M (see figure 2, next page).

We report on quantitative cost and time savings, which are directional rather than precise since every company is unique. We identified areas with the highest value creation potential—specific savings and revenue opportunities could vary depending on where the biopharma companies are in their journeys.



Levers to reduce the cost of discovering and developing new treatments from billions to millions



Levers

- ① Reduced cost of failure due to higher PTRS** achieved by **digital biology**
- ② Reduced research costs due to the use of AI-driven **predictive approaches** to target validation, lead identification & optimization
- ③ Impact on clinical development costs due to **clinical trial innovation** to achieve maximum patient benefit, simplicity, optimal size & duration
- ④ Impact on clinical development costs due to **regulatory innovation***
- ⑤ Reduced cost of failure due to the higher PTRS** of **New Science**
- ⑥ Reduced cost of failure due to higher PTRS** achieved by operating model changes to **portfolio progression**

° Additional revenue opportunity due to earlier time to market

* While regulatory innovation does not significantly reduce cost, it is included as a lever due to its greater impact on revenue opportunities

** PTRS: Probability of technical and regulatory success

Figure 2: Accenture Research 2021, From Billions to Millions. For more information on the methodology, see page 26.

Digital and data-led research

Change the way that data, analytics and ecosystem partnerships are used across the entire drug discovery value chain, leading to improved clinical and patient outcomes, accelerated time to clinical trial and reduced costs.

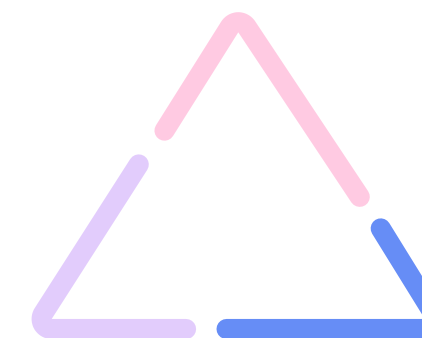
The components of this strategic play are:

① Digital Biology:

Leverage technologies such as -omics and imaging analysis to deepen the fundamental understanding of disease and improve target identification and validation at early stages. This applies to target assessment aspects now in frequent use (linkage between disease and target, understanding of future target patient population) and less frequent use (genetic target modulation approaches, application of biomarkers, target assayability, safety issues). Improved target identification and validation leads to better clinical strategies and trial designs down the line, boosting the probability of success. Our model estimates the savings from higher probability of clinical trial success due to better target identification and validation at 31% of overall cost savings.

② Predictive Approaches:

Use predictive methods and existing data with machine learning techniques and artificial intelligence to optimize drug candidate design and the selection of compounds to progress through the pipeline. This accelerates identification, optimization and selection of lower-risk clinical candidates and minimizes experiments that will not succeed. While we see predictive modeling as an opportunity for all modalities in the future, today the major impact can be realized on small molecules, which currently make up 40% of the industry pipeline.¹¹ Our model estimates the savings from utilizing predictive methods at 17% of overall cost savings.



A flexible ecosystem approach is essential to build differentiated capabilities supporting digital biology and predictive approaches.

For example, Celgene, (now part of BMS), entered into a partnership agreement with an AI drug discovery pharmatech in 2019; earlier this year BMS and Exscientia announced that they were able to identify a drug candidate molecule within 11 months of starting drug design.¹²

Faster, smarter development

Utilize a patient-centric and data-driven approach to the drug development process—optimizing trials for size, duration and maximum patient benefit; reducing overhead associated with overly cumbersome processes and technology; and generating rich insights from new sources of data.

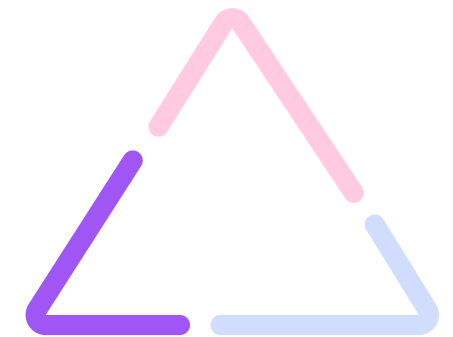
The components of this strategic play include:

③ Clinical Trial Innovation:

Taking a patient-centric approach to trial design to optimize trials for maximum patient benefit, simplicity, size and duration. This includes leveraging artificial intelligence and synthetic data to eliminate control arms and to reduce operational costs through better patient profiling, which was discussed in a recent Accenture article with Phesi, “[Better Clinical Trials: Benefits of Synthetic Data](#).” In addition, utilizing decentralized methods or virtual trials and other simple solutions significantly reduce patient burden and attrition. Clinical trial innovation benefits both the patient and the sponsor, with smaller cohorts, better retention, fewer amendments, reduced site costs and shorter time to market, all of which reduce cost. It also improves patient diversity.

Industry research and case studies reveal the following challenges:

- One-third of Phase III clinical trials are terminated due to difficulties in enrollment, and around 80% of clinical trials cannot meet enrollment timelines.¹³
- Phase II and III protocol procedures have increased 44% since 2009 and trial sites have increased substantially as well, signaling a rise in trial complexity.¹⁴
- More than half of the 836 studies completed between 2010-2013 had at least one substantial protocol amendment, nearly half of which were avoidable. The average direct cost to implement a substantial amendment was US\$535,000 for a Phase III protocol. Development leaders in biopharma report that this cost is even higher today.¹⁵



- Synthetic data is increasingly being accepted by the US FDA. Merck KGaA and Pfizer’s Bavencio (avelumab) was approved in 2018 for Merkel cell carcinoma. The trial used data from electronic medical records in a synthetic control arm.¹⁶
- A convenience sample of Phase II and III protocols had 36% (140 days) shorter average treatment duration for decentralized trials compared to traditional trials.¹⁷

The key to success is to implement these approaches at scale. Our model estimates the savings from clinical trial innovation at 35% of overall cost savings. We also estimate that 50% of the \$150–450M revenue opportunity achieved through an earlier time to market would be realized from clinical trial innovation.



Faster, smarter development

④ Regulatory Innovation:

Simplifying submissions and leveraging data-sharing environments with global health authorities (HA) to accelerate time to file, increase objectivity and decrease effort. This means real-time engagement of health authorities through continuous information-sharing, managing simultaneous conversations with multiple HAs, and leveraging AI to build better regulatory intelligence and anticipate what information a specific HA may request. We see increasing interest from both health authorities and biopharma companies for regulatory innovation. The FDA Oncology Center of Excellence (OCE) launched the Project Orbis initiative in 2019 to provide a framework for simultaneous submission and review of oncology products among international partners.¹⁸

According to a survey of 22 biopharma companies, 91% agreed that AI offers significant opportunity for data processing for regulatory intelligence, with expected benefits that include operational efficiencies, enhanced quality and speed to market.¹⁹

We assumed that operating expenses only account for 25% of overall regulatory expenditure, and our model estimates minimal impact (less than 1%) to operational costs per successful launch. Investing in regulatory innovation will realize benefits through accelerated submission time, which accounts for 7–10% of the \$150–450M in total revenue opportunities we identified.

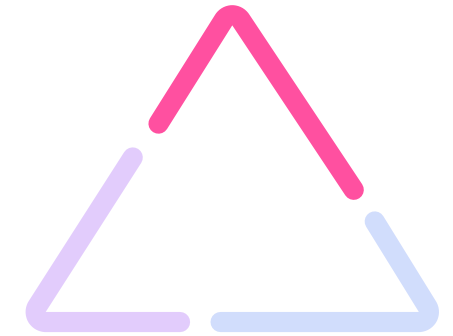
While the two biggest opportunities from faster, smarter development are in clinical trial innovation and regulatory innovation as described above, there are other pockets of opportunities, such as reducing redundancies in processes and governance by leveraging AI and right-sizing resources based on operational and regulatory risk.

For example, Pfizer automated the source data verification (SDV) process for their COVID-19 vaccine through AI and deep learning, which saved them an entire month and resulted in an earlier time to market.²⁰



New Science portfolio

Shift the portfolio strategy towards New Science. While these treatments have high initial development costs, they also have a higher probability of success in clinical trials, lowering overall cost of failure.



The component of this strategic play includes:

⑤ New Science:

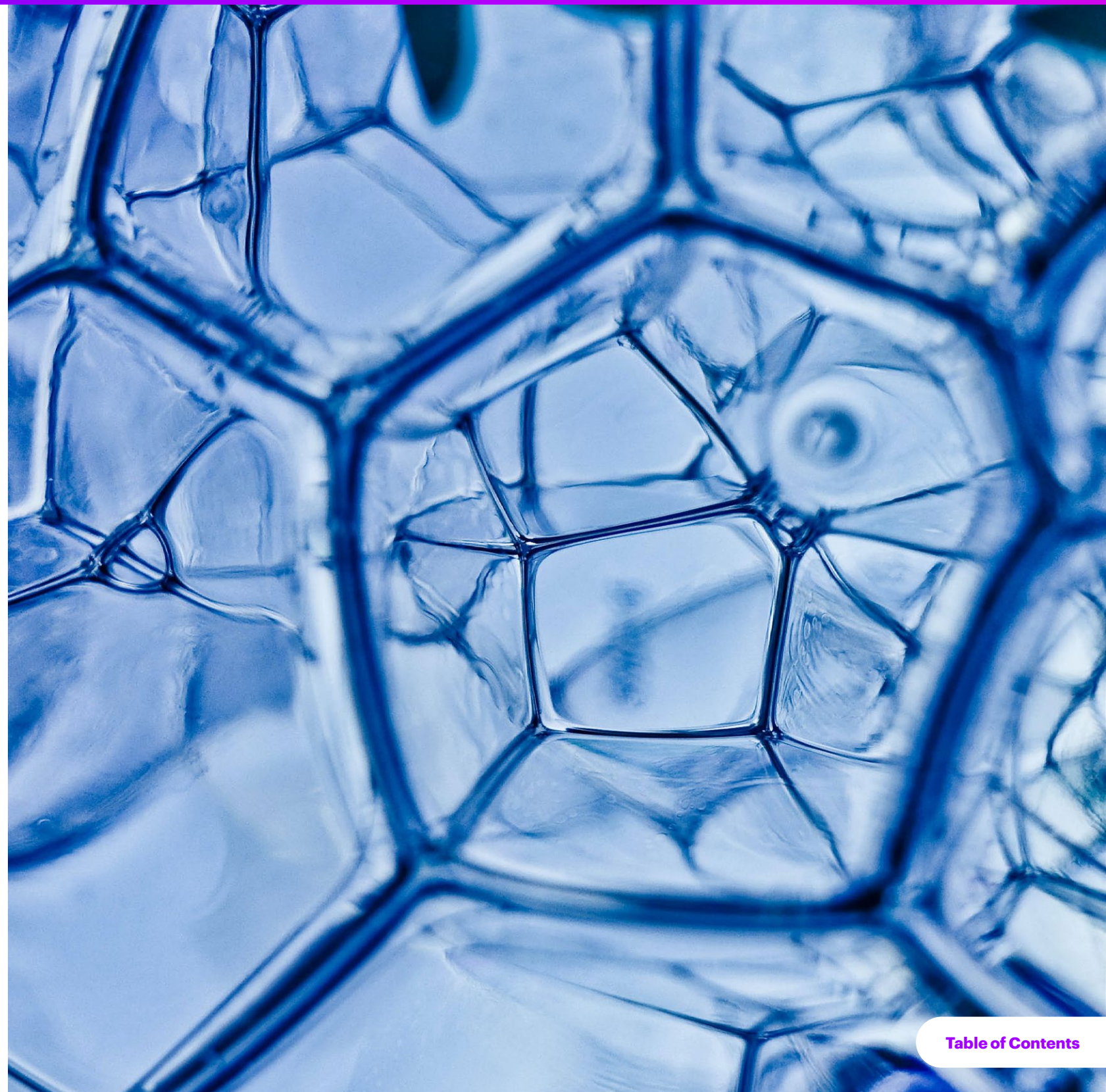
New Science portfolio positions the organization for higher future value. New Science is projected to drive 81% of biopharma industry revenue growth and 61% of all revenues from 2021 to 2026. The net present value (NPV) of New Science treatments is also expected to outshine that of conventional therapeutics—the average NPV of New Science treatments launched in 2022–2026 is expected to be 69% higher than traditional products.⁹

Our analysis shows that New Science demonstrates lower risk and a higher probability of technical and regulatory success (PTRS) compared to other New Molecular Entities (NMEs) and New Biologic Entities (NBEs). The cost savings of the improved PTRS for each New Science treatment in our model amounted to 13% of overall cost savings.

© Portfolio progression

Evolve the portfolio progression model such that it shifts power to asset teams and provides more accountability, creating an environment where treatment candidates fail fast and only those with higher probability of success progress through the pipeline, thereby reducing the cost of failure. While each organization should tailor their approach, Accenture identified the following features to be essential for a future portfolio progression model: independent and decentralized asset teams, fit-for-purpose development pathways, expertise and partnership networks, shared learnings, and data-driven decision-making²¹.

We see these benefits in mid-size players taking an asset-based approach to innovation with the ability to make quick changes to adjust their portfolio to strategic needs. Our model estimates the savings from an evolved portfolio progression model to be 4% of overall cost savings.



In summary, three major type of benefits—PTRS improvements, direct cost savings, and accelerated time to market—were converted to cost savings or revenue opportunity*.



The greatest opportunity is through improving PTRS. Two of our strategic plays, New Science portfolio and digital and data-led research, combined with the operating model changes to portfolio progression, achieve higher PTRS. These complement each other and should be considered as a cohesive initiative to reduce cost of failure. We calculated total savings from these three combined elements as 47% of overall cost savings.

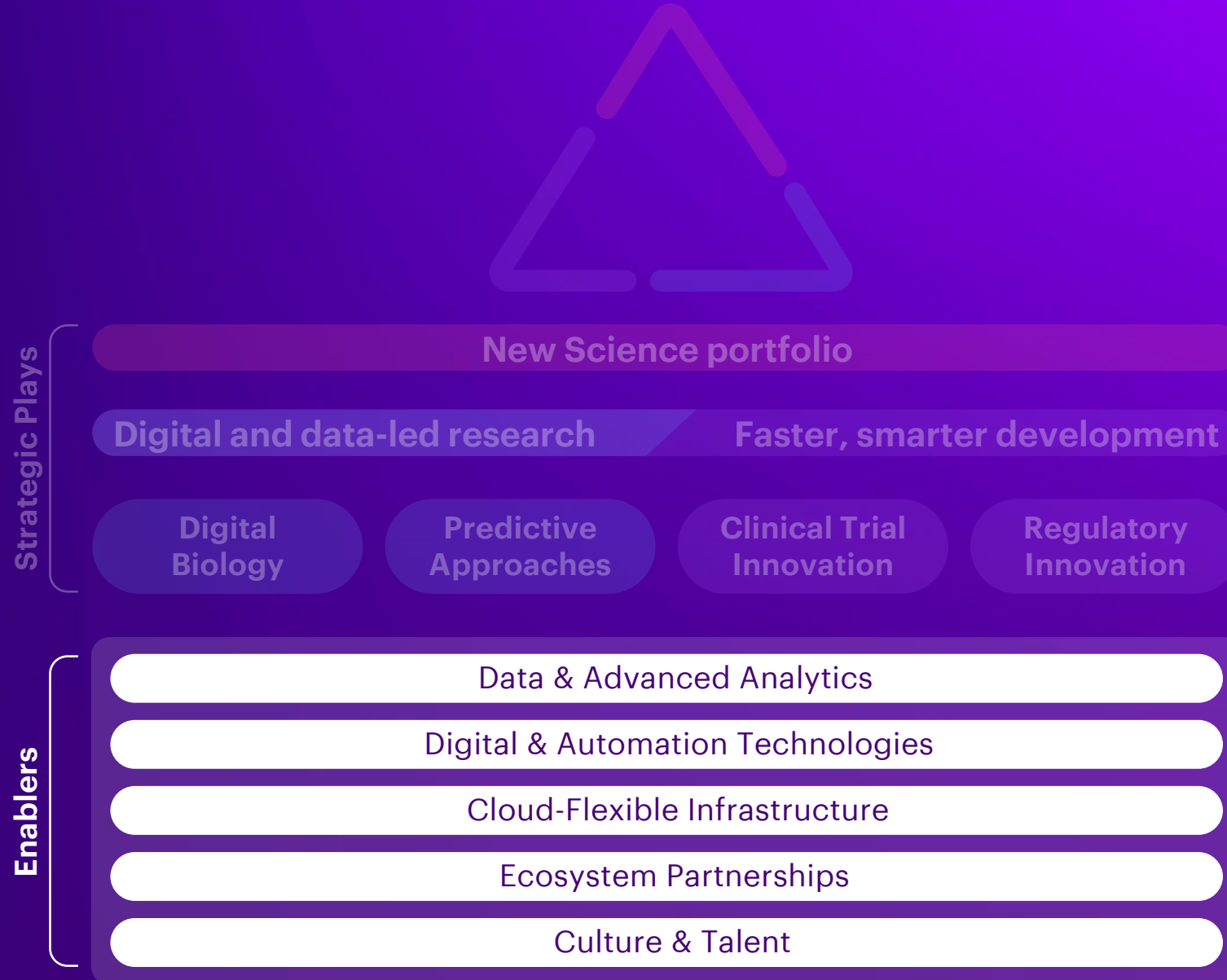


The second largest opportunity for cost savings comes from faster, smarter development, specifically clinical trial innovation. We modeled the benefits of leveraging in-silico data to eliminate control arms, the use of smaller treatment cohorts, and better trial design and operations to improve patient enrollment timelines and patient retention, as well as reduce site-related costs, trial complexity, and the number of protocol amendments. According to our model, this accounts for 35% of overall cost savings. We believe these savings from lowering cost of discovering and developing new treatments could be passed on to patients and help address the affordability gap.



The third largest opportunity is the accelerating time to market that offers additional revenue opportunities. Our analysis shows that specific strategies would accelerate time to market by 1–5 years. This corresponds to \$150–450M of revenue upside opportunity based on assumptions of a drug's average first year revenue. These time savings are realized through predictive approaches (digital and data-led research ~40%), clinical trial innovation (faster, smarter development ~50%), and regulatory (faster, smarter development ~10%).

Enablers to capture value



To realize the potential value of the strategic plays, coordinated investments across specific technologies and critical enabling capabilities are needed. These investments could change the very foundation of how biopharma companies are organized and operate, collapsing silos to systematically and seamlessly provide the data, tools and operating mindset that enable transformation of the company's pipeline and ways of operating.

The technologies and enabling capabilities needed to actualize the three strategic plays are: Data & Advanced Analytics, Digital & Automation Technologies, Cloud-Flexible Infrastructure, Ecosystem Partnerships, and Talent & Culture.

Data & Advanced Analytics

Global biopharma companies have historically focused on generating and guarding their own data, but external data will be increasingly important to R&D success.

Insights from data and advanced analytics would enable high performers to gain advantage in how they identify targets, how quickly they develop and market them, how they adjust developmental plans to reduce failure, and doing all of these not just faster, but cheaper.

Various types of patient data, such as genomic data to enable better target selection, and RWD for in-silico modeling during discovery, would facilitate accelerated timelines and better drug candidate selection. Patient data from clinical trials or electronic medical records would be used to construct synthetic control arms. Decentralization of

clinical trial implementation could create continuous streams of data collected passively and actively between clinic visits.

AI/ML capabilities would be increasingly used as the only feasible technology to extract signals from these expanded data sources, generating novel insights from unstructured data such as notes in patient electronic medical records or from disparate fields of scientific study, and in feature detection in continuous patient monitoring data.

This exponential increase in data volume requires more robust data governance models to ensure the cross-functional decisions and validity of data used in analysis. It also requires a continuous evolution of data analytic capabilities streamlined across functions to keep up with the explosion of data types.





Digital & Automation Tools

Digitizing analog processes such as collection of patient-reported outcomes is a step that many biopharma companies have already taken and is vital to support new modes of remote operations, create new collaboration opportunities and enable automation. Intelligent automation would increasingly relieve the burden of repetitive and low-value-added tasks, transforming the human role in the data process and enabling improved R&D productivity.

The trend towards more digitally-enabled trials would continue, with digital and automation tools used at every stage of a study to streamline the ways that patients are identified, enrolled and engaged, and how sponsors interact with investigators and sites. As decentralized and remote trial models are more widely adopted, the use of remote devices and in-home diagnostic tools to collect patient data would also increase. Companies must reimagine their processes to incorporate and leverage automation in areas where they can shift non-value-add steps from talent to digital tools.

Cloud-Flexible Infrastructure

All three strategic plays require executing external collaborations at speed, with partners such as academia and technology disruptors. They also require that digital solutions work cohesively from any location. To enable this, a robust and comprehensive cloud infrastructure supported by pervasive APIs is an essential requirement.

The next generation of technology supporting R&D would be a platform that connects disparate data sources, applications and external partners, and organizes that data to be easily accessible to enable collaboration and rapid data-driven decision-making.

By building this platform in the cloud, R&D organizations will benefit from cloud value levers such as:

- Elasticity: Providing scalable computing power to analyze massive volumes of data with machine-learning models
- Ubiquity: Enabling global teams to collaborate at any time, from any place, without the need to access on-premise systems
- Innovation: Democratizing access to cutting-edge tools like AI and machine learning for researchers and asset teams



Ecosystem Partnerships



Flexible ecosystem partnerships underpin the three strategic plays. These relationships allow companies agile but controlled access to new data and innovation, enabling them to experiment and create value for both themselves and their partners. The need to innovate rapidly is driving the adoption of multiparty systems. Life Sciences companies are innovating faster than ever before due to a shifting emphasis from “building” and “buying” to partnerships. As a result, companies are seeing faster time-to-insight.

In addition, a shift from the “adjacency” approach used by most biopharma companies to a “value pool” approach that aims at creating different optionalities is also essential. The biopharma executives we interviewed reported that most business development targets are selected based on therapeutic area (TA) gaps, focused primarily

on new assets that are anchored to the existing pipeline, which results in incremental innovation. A value pool approach looks beyond TA-adjacent partnerships to new platforms and capabilities for innovations such as a new understanding of a disease, a new drug delivery mechanism or a new way of reaching patients.

Finally, ecosystem players must institutionalize their partnerships across the R&D value chain to ensure quick and seamless collaboration. Effective partnerships overcome institutional barriers through thoughtful procurement and contracting strategies and are built on a foundation of trust and mutual value.

Culture & Talent

The critical enabling capabilities require new ways of working and an updated set of specialized skills. Computational biologists who use cutting-edge protein folding techniques for digital biology are highly specialized and scarce resources in the labor market, as are data scientists who can wrangle continuous time-series data to execute predictive use cases. Integrating intelligent automation approaches into the workflow would require adapting the skill sets of those whose jobs will be redefined in this shift.

An evolution of cross-functional teaming is needed to embrace a more agile and adaptive mindset where decisions are made in real time/near time and “failing fast” is embraced and aligned with incentives and rewards.

As functional silos begin to collapse and the organization moves towards a more elastic and fluid patient-centric model, the organizing principle becomes a rigorous focus on value creation rather than functional processes.

Transition to these new ways of working is occurring as biopharma companies move towards hybrid working models. The focus must be on embracing these changes in the context of deconstructing tasks to understand what activities could be enacted ‘anytime, anywhere.’ Cultural and structural barriers exist in many biopharma companies that could inhibit the rapid execution of the transformation necessary to enable the three strategic plays. The challenges cut across business units and require C-suite focus to address in a cohesive and coordinated manner.



Realizing value from transformation

To create the right environment needed to effectively enable the three strategic plays, companies must move away from siloed, incremental change and embrace full-scale transformation of the R&D pipeline and operations by:

Establishing enterprise-level strategy, budget, and oversight for strategic plays and foundational capability maturation for enablers through redistribution of budget for the enterprise and tracking of value realization.

Focusing on creating asset-centered teams with the objective of delivering business and patient value. To make this happen, companies need to evolve how teams operate and align incentives to asset outcomes rather than function-specific objectives.

Assessing the current maturity of enabling capabilities and making coordinated cross-enterprise investments to lay the foundation necessary to scale the strategic plays.

We believe biopharma can achieve greater value at speed by going through a “compressed transformation”, by simultaneously transforming research & development organizations and their portfolio across five enabling capabilities in what previously would have been sequential and siloed programs. This requires replatforming their businesses in the cloud, implementing digital & automation technologies while making operating model changes and reskilling their people all at once.



A modernized holistic approach to transforming R&D would deploy strategic plays to generate a new “future-fit” biopharma R&D organization.

Our research shows that this investment could bring discovery and development costs down from billions to millions—rewriting the productivity equation and enabling price reductions that broaden the access and impact of the coming wave of New Science treatments.

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Research Methodology

Accenture Research based the “From Billions to Millions” current state baseline for probability of success, cycle time, and cost assumptions primarily on two articles which are frequently cited by the industry for their approach to R&D productivity: [Paul, S. et al.](#) and [DiMasi J.A. et al.](#)

The impact of levers on the “From Billions to Millions” baseline, in particular the probability of success, unit cost, and cycle time, were modeled based on assumptions that were derived from both primary and secondary research including expert interviews, analysis of data from syndicated data partners, and literature review.

Quantitative cost and time savings reported in this research are directional with an objective of identifying areas with the highest value creation potential. Specific savings and revenue opportunities will vary depending on where the biopharma companies are in their journeys.

Lever	Impact drivers	Measured impacts
1 Digital Biology	Probability of success	Cost of failure
	Operational costs	Unit cost
2 Predictive Modeling	Operational costs	Unit cost
	Cycle time	Revenue opportunity
	Removing control arms	Unit cost
3 Clinical Trial Innovation	Cohort size	Revenue opportunity
	Site related costs	
	Operational costs	
	Protocol complexity	
	Protocol amendments	
	Cycle time	
4 Regulatory Innovation	Operating costs	Unit cost
	Cycle time	Revenue opportunity
5 New Science	Probability of success	Cost of failure
6 Portfolio progression	Probability of success	Cost of failure

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Accenture’s Life Sciences group is committed to helping our clients make a meaningful impact on patients’ lives by combining new science with leading edge technology to revolutionize how medical treatments are discovered, developed and delivered to people around the world. We provide end-to-end business services as well as broad range of insight-driven services and solutions in strategy, consulting, digital/analytics, technology and operations in all strategic and functional areas—with a strong focus on R&D, Sales & Marketing, Patient Services and the Supply Chain.

We have decades of experiences working with the worlds most successful Biopharma, Biotech, MedTech, Distributor, Digital Health, Contract Research and Manufacturing companies to innovate and improve their performance and across the entire Life Sciences value chain to better serve patients and stakeholders. Accenture’s Life Sciences group connects more than 20,000 skilled professionals in over 50 countries who are personally committed to helping our clients achieve their business objectives and deliver better health and economic outcomes.

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