



## Accelerating speed of time to value in R&D

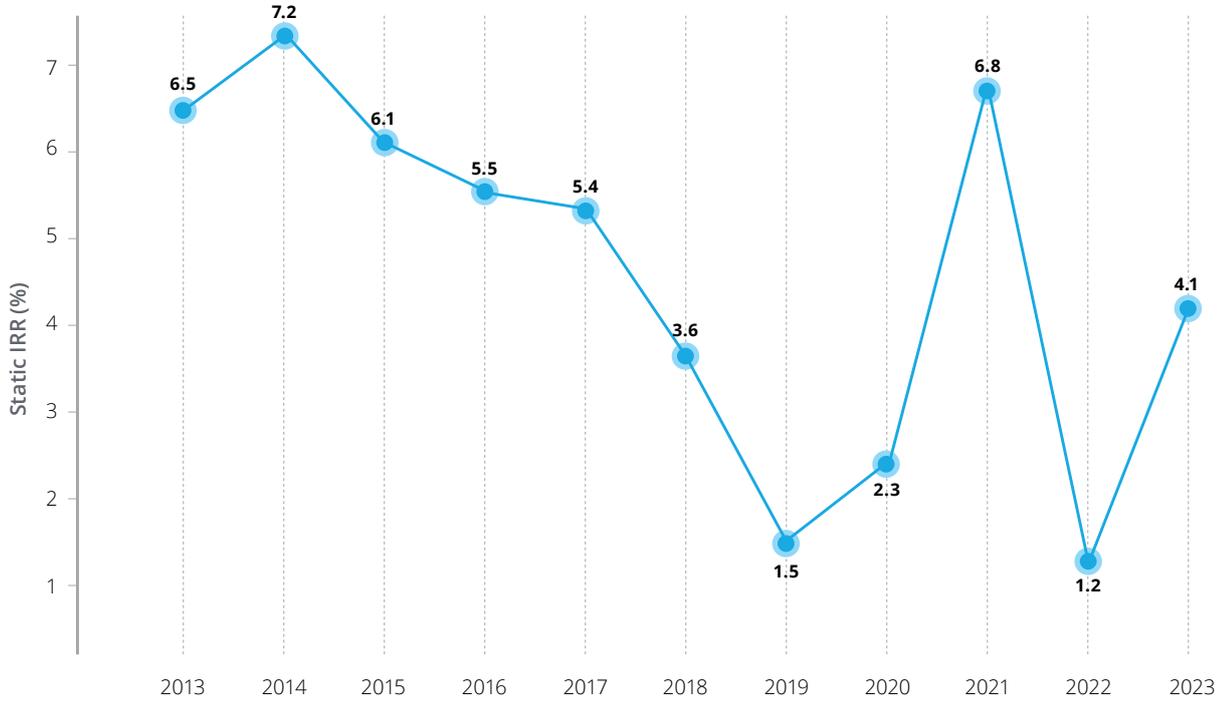
Large pharmaceutical companies account for almost two-thirds of total pharma research and development (R&D) investments<sup>1</sup> and spent a record total of US\$161 billion in 2023—an increase of almost 50% since 2018.<sup>2</sup> As a percentage of companies' net sales, spending reached a historic high of 23.4%.<sup>3</sup>

Since 2010, Deloitte's series on Measuring the return from pharmaceutical innovation has provided insights into the productivity of biopharma R&D and has now evolved to include the top 20 pharma companies by R&D

spend (determined in 2020).<sup>4</sup> For this cohort, R&D spend increased 4.5% from 2022 to 2023, while the average R&D cost to progress an asset from discovery to launch remained flat in this period at US\$2.284 billion per asset.<sup>5</sup>

This year's modeling, based on a dataset that includes an expanded scope of assets and line extensions, shows the internal rate of return (IRR) rising to 4.1% in 2023 from 1.2% in 2022—the lowest point for the cohort since our analysis began (figure 1).<sup>6</sup>

Figure 1. Internal rate of return of the late-stage pipeline



Source: Deloitte, "Unleash AI's potential: Measuring the return from pharmaceutical innovation – 14th edition," 2024.

In 2024, ongoing regulatory changes and loss of exclusivity of an unprecedented number of high-value assets are expected to challenge the existing biopharma operating model.<sup>7</sup> Pricing pressures from the Inflation Reduction Act's (IRA's) health provisions are already impacting R&D decision-making and portfolio strategies.<sup>8</sup> Ten R&D leaders interviewed by Deloitte expressed more concern about changing regulations than cycle times or R&D costs.<sup>9</sup>

Scientific and technological advancements present a significant opportunity for those willing to harness the power of innovation, but the rapid pace of innovation can also be a challenge.<sup>10</sup> Advances in AI, including Generative AI (GenAI), have the potential to demystify complex disease biology, expedite drug discovery, cut study timelines, revitalize the clinical trial experience and improve regulatory success. Realizing productivity improvements and unleashing AI's value could provide new sources of value.<sup>11</sup>

### Not just speed to market, but accelerating time to value

Speed to market has long been a leading priority for drug developers to accelerate patient access to life-saving therapies.<sup>12</sup> Since Deloitte first started analyzing pharmaceutical innovation in 2010, still only about one in ten new drugs entering human trials obtains regulatory approval.<sup>13</sup> Despite many advances in science and technology, this remains one of the leading challenges for the biopharma industry.<sup>14</sup>

"When you're facing an illness like cancer or heart disease, you don't want therapies 20 years from now—you want them now."

—David Reese, Executive Vice President, Research and Development, Amgen<sup>15</sup>

Speed to market is only part of a success formula; companies should also be looking at ways to accelerate time to value.<sup>16</sup> Leading biopharma companies are adopting new GenAI/AI technologies and other data innovations across the value chain, while forming new partnerships, collaborating early with regulators, and outsourcing for cost and time savings.

“Twenty-five percent of our projects entail working with partners, which has doubled research productivity as measured by dollars spent per clinical candidate and doubled our first-in-human entries.”

—**Paul Hudson**, CEO, Sanofi<sup>17</sup>

## Adopting a more agile mindset

### Accelerating people and processes

By adopting strategies to accelerate time to value, companies can start on their individual path to potential cost savings and competitive advantage<sup>18</sup> even if small gains are made in each step of the process.<sup>19</sup> With the pace and development of AI-enabled digital solutions only expected to accelerate, leaders should start reengineering with an agile mindset.<sup>20</sup>

Accelerating time to value in an agile manner means having the people and processes in place to change and adapt swiftly in response to market forces.<sup>21</sup> Successful companies are building strategies to reduce the time it takes to advance across the stages of R&D, commercialization, and post-marketing surveillance.<sup>22</sup>

“We are applying speed levers in multiple areas, from digital technology and innovative study designs to regulatory partnerships. Our goal is to help each drug development team integrate as many of these levers as possible to accelerate progress.”

—**Kimberly Clemenson**, Vice President, R&D Transformation, Amgen<sup>23</sup>

### Snackable AI for improving business functions

At the BioCentury China Healthcare Summit in late 2023, Sanofi CEO Paul Hudson discussed how Sanofi uses “snackable AI” to get rapid access to data by providing many people across the organization with “bits” of AI for real-time decision-making and reporting. He says snackable AI offers radical data transparency and may provide immediate and trustworthy feedback without hesitation or sugarcoating—unlike managers who may delay delivering data to leaders when uncomfortable with the results.<sup>24</sup>

### Use of AI in R&D expected to grow 106%

While the pharma industry is innovative in R&D, it is also true that it is often slow at embracing technological revolutions.<sup>25</sup> However, GenAI has brought more widespread attention to the current state of AI and jumpstarted many new initiatives.<sup>26</sup> Research shows that AI currently accounts for approximately 16% of drug discovery efforts and is

predicted to grow by 106% over the next three to five years.<sup>27</sup> It is the combination of domain specific LLMs, GenAI, AI/ML, deep learning, and data analytics that is positioned to accelerate time to value across biopharma R&D.

The R&D function represents the top value opportunity for large biopharma companies representing 30-45% of value creation. AI applied to novel drug identification and accelerating drug development could provide both cost savings and revenue uplift.<sup>28</sup>

Combining next-generation AI technologies with rich multi-omics data may close the loop across the R&D pipeline with rapid, automated generation and testing of hypotheses from bench to bedside.<sup>29</sup> Currently, GenAI may reshape the way life sciences organizations decide:

- Which disease areas to invest in,
- Which targets to pursue, and
- Which molecules to develop.<sup>30</sup>

### Incorporating GenAI in R&D, from novel target identification to regulatory approval

Experts have ambitions to apply GenAI technologies to novel target identification through to regulatory approval, and into commercialization.<sup>31</sup> To kickstart their GenAI programs, organizations should employ “no regrets bets” that can deliver value in a relatively short timeframe (figure 2).<sup>32</sup> These types of low-risk activities can accelerate progress, while de-risking investments.<sup>33</sup>

Figure 2. GenAI’s “no regrets bets” in R&D

	DESCRIPTION	VALUE TO THE BUSINESS UNIT	VALUE TO THE ENTERPRISE	WHY THIS IS NO REGRETS
<b>Research &amp; Development</b> 	<b>Scientific literature summarization</b>  Generates easy-to-consume summaries of scientific literature	<b>Greater productivity</b> from faster hypotheses testing	+ Cost reduction + Revenue uplift	GenAI can cut through research noise and go straight to insights with <b>minimal resource investment</b>
	<b>Intelligent study deliverable authoring</b>  Automate the drafting of clinical study report (CSR) deliverables	<b>Greater speed</b> from less rework and automated drafting	+ Cost reduction + Cost avoidance	Companies have a massive <b>treasure trove of past documents</b> that can be tapped into to automate creation

Source: Deloitte, “Realizing Transformative Value from AI & Generative AI in Life Sciences,” 2024.

The following model illustrates three horizons of innovation in pharma R&D with the development of GenAI (figure 3). Throughout the evolution of GenAI, experts say that keeping a human-in-the loop where possible will be critical to maximizing productivity gains without significant risks, even in high stakes applications.<sup>34</sup>

Figure 3: R&D transformation horizon

Areas of Change	Horizon 1 Today 	Horizon 2 18 Months 	Horizon 3 5 Years 
<b>How is data managed and accessed?</b> 	<b>Disjointed ecosystem of non-standardized data sources</b> aligned to specific business processes  <i>Example: RWE for omics analysis; CTMS for clinical study conduct processes etc.</i>	<b>Amazon-like marketplace</b> where purpose-built R&D data products or extracts can be searched and accessed  <i>Example: Research scientists can search for biomarker analysis data from past studies clinical trials data and request access</i>	A <b>dynamic data fabric</b> that seamlessly connects data assets across functions to provide a single source of truth  <i>Example: Clinicians can readily leverage real-time data from safety, commercial, and regulatory systems to meet their business needs</i>
<b>How are insights curated and consumed?</b> 	Insights are generated from discrete analytical models and <b>interpreted by data analysts</b> to support clinical processes  Scientists <b>manually review and synthesize</b> scientific literature (e.g., publications, patents) to create research insights  <i>Example: Clinical study managers rely on data analysts to contextualize outputs of site selection analytical models</i>	Business users leverage <b>GenAI to interpret outputs</b> of complex analytical models that provide them with more flexibility and context  Scientists can access <b>summary insights</b> from vast amounts of scientific literature enabling them to rapidly adapt research priorities  <i>Example: Clinicians can interact with GenAI chatbots to understand population health insights to optimize inclusion criteria</i>	Insights are <b>readily-embedded into business workflows</b> with little to no need for human intervention  Insights from external research are <b>rapidly contextualized and disseminated</b> across the enterprise  <i>Example: Research, Clinical, Finance, Commercial, Regulatory teams are provided with contextualized impact summaries of a competitor's patent</i>
<b>How are research operations conducted?</b> 	Experiments are highly manual and expensive due to <b>iterative hypothesis development and compute-intensive validation</b>  <i>Example: Scientists manually create and test hypothesis, going back to the drawing board only after confirming failed hypotheses</i>	Scientists use <b>AI-powered simulations</b> to parallelize generation, testing, and optimization of thousands of hypotheses  <i>Example: Scientists generate 3D biomolecular structures by rapidly testing and optimizing new molecules to treat breast cancer</i>	Research scientists prioritize leads by <b>amplifying decisions</b> with impact on downstream functions  <i>Example: Researchers prioritize leads for treating breast cancer based on likelihood of regulatory approval and commercial viability</i>
<b>How are clinical trials managed?</b> 	Complex trial processes and systems result in <b>highly manual, linear, and siloed decision-making leading to suboptimal outcomes</b>  <i>Example: Disjointed decisioning around study design and site selection lead to expensive delays in trial execution</i>	Clinical <b>processes are streamlined &amp; simplified</b> through AI / GenAI automation to deliver efficiency and experience gains  <i>Example: GenAI copilots optimize study design decisions by incorporating insights from downstream patient enrollment and site selection processes</i>	Clinical trials are autonomously run through GenAI copilots that <b>optimize outcomes across the end-to-end value chain</b>  <i>Example: Real-time participant attrition insights generate recommendations to modify upstream study design choices</i>
<b>How does R&amp;D interact with other functions?</b> 	<b>Operations within different part of R&amp;D are often siloed</b> and insights are not shared across all R&D teams  <i>Example: Clinical data and analytics are rarely readily available to upstream research scientists</i>	<b>Seamless data and insight connectivity</b> enables greater collaboration across all R&D functions  <i>Example: Research, clinical, and regulatory teams work together to solve problems and create new products</i>	Hyper-connected enterprise where all <b>enterprise functions work together</b> to optimize enterprise outcomes  <i>Example: R&amp;D, regulatory, commercial, and manufacturing functions collaborate to seamlessly launch new drugs</i>
<b>How do R&amp;D organizations navigate regulatory landscapes?</b> 	Diverse regulatory rules are <b>manually interpreted</b> by local market and process teams in non-standardized, highly manual review cycles  <i>Example: Regulatory teams spend weeks manually reviewing new clinical regulations in EU and assessing impact on ongoing and upcoming trials</i>	R&D teams leverage <b>GenAI capabilities</b> at scale to automate monitoring, synthesis, and impact assessment of regulations  <i>Example: GenAI copilots identify and synthesize trial diversity requirements in the US and flag impacted studies</i>	Business processes limit human error and regulatory cycle time by building <b>AI-enabled regulatory checks</b> into processes  <i>Example: GenAI copilots ensure new protocols are compliant with the latest regulatory policies during the drafting process</i>

Source: Deloitte analysis

## Low-hanging fruit, GenAI replacing many manual processes

Google demonstrated the capabilities of its multimodal platform, Gemini, to aid research scientists in extracting data from scientific literature, often an arduous, time-consuming process done by hand.<sup>35</sup> In one example, Gemini read through 200,000 papers, filtered relevant studies down to 250, extracted the key data needed, annotated, and created graphs—and the entire process took about an hour.<sup>36</sup> In the near term, the ability to access knowledge rapidly and transform manual processes opens up an opportunity for GenAI in clinical trials.<sup>37</sup>

“The clinical trial space is an area where we have a lot of repetitive and very time-consuming tasks. GenAI is really a tool that enables an acceleration in some of these tasks, where before it would be a very manual prolonged process for both sponsors and sites.”

— **Silvia De Carvalho**, Clinical Studies lead at AXON

To achieve the necessary increases in R&D productivity, some of the sweet spots are drug discovery and early clinical development, from target selection to clinical proof-of-concept.<sup>39</sup> Synthetic data is one way to accelerate access to data to start prototyping models quickly, and generative chemistry combined with a platform of tools and human expertise may help speed up drug design and identify better candidates. Work is being done with GenAI in de novo protein design, such as antibody design.<sup>40</sup>

## GenAI model, SyntheMol, creating recipes for chemists to synthesize drugs in the lab

Researchers at Stanford Medicine and McMaster University are utilizing a new GenAI model for synthesizing molecules, dubbed SyntheMol.<sup>41</sup> The model created structures and chemical recipes for six novel drugs aimed at killing resistant strains of *Acinetobacter baumannii*, one of the leading pathogens leading to antibacterial resistance-related deaths.

Older computational models were able to yield some results by sifting through 100 million known compounds. However, this only scratched the surface in finding all the chemical compounds that could have antibacterial properties—estimated as close to  $10^{60}$  possible drug-like molecules. The work is being expanded with other research groups, using the model for drug discovery for heart disease and to create new fluorescent molecules for laboratory research.<sup>42</sup>

While a number of biotech companies are developing AI-designed drug molecules, none have received US Food & Drug Administration (FDA) approval.<sup>43</sup> It will take time to collect and analyze the data needed to demonstrate the safety and efficacy of these drugs through clinical trials.<sup>44</sup>

## Accelerating clinical trials with GenAI

As it develops, GenAI offers several possibilities for accelerating clinical trials, including:

- Automating document generation activities to increase velocity,
- Increasing study retention by amplifying patient engagement, and
- Improving regulatory engagement with tailored submissions.<sup>45</sup>

### Tracking speed, productivity, quality, and sustainability of GenAI applications

Reviews of potential applications for GenAI along the R&D pipeline should consider linking strategic value to metrics in speed, quality, productivity, and sustainability.<sup>46</sup> Use cases that improve the quality of data, assets, and decision-making have the potential to reduce failure rates across R&D phases.<sup>47</sup>

Productivity and quality may offer the largest gains provided by GenAI in the near term, followed by speed, then sustainability over the next decade.<sup>48</sup> Considering individual use cases along these metrics may help determine an optimal string-of-pearls strategy—where use cases are combined to unlock the full value of

GenAI.<sup>49</sup> Strategic applications of AI can be found all across the R&D value chain (figure 4).

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 realized, and monitoring ethical and legal risks from the use of AI.<sup>50</sup>

For more information on the string-of-pearls strategy, read the **Extracting value from Generative AI and emerging technologies** section of the 2024 Global Life Sciences Sector Outlook.

Figure 4. Strategic applications of AI across the R&D value chain

	Role of AI	Value levers
 <b>Drug repurposing</b>	Perform meta-analysis of clinical trial and research data to generate high quality hypothesis for drug repurposing	<ul style="list-style-type: none"> <li>• Reduced pre-clinical costs</li> <li>• Reduced time to market</li> <li>• Higher NDAs</li> </ul>
 <b>AI-driven drug discovery</b>	Optimize target and biomarker identification and shortlisting candidates while assessing toxicity and therapeutic efficacy	<ul style="list-style-type: none"> <li>• Improved clinical success rate</li> <li>• Lower failure rates</li> <li>• Higher number of NDAs</li> </ul>
 <b>Rapid design and setup</b>	Automated protocol generation, drafting of study documents (consent form, agreements) and regulatory submissions	<ul style="list-style-type: none"> <li>• Lower average protocol authoring time</li> <li>• Lower average time to first enrollment</li> </ul>
 <b>Digital data flow</b>	Collate and standardize trial data elements to create analysis-ready data sets and to auto-populate tables and charts in trial artifacts (e.g., case report forms)	<ul style="list-style-type: none"> <li>• Reduced total time per phase</li> <li>• On-time database lock</li> <li>• Faster documentation creation</li> </ul>
 <b>Regulatory intent and submission excellence</b>	Identify regulatory requirements across geographies, generate drafts of dossiers, and understand competitor regulatory strategy	<ul style="list-style-type: none"> <li>• Higher regulatory success</li> </ul>
 <b>Participant experiences</b>	Enhancing participant experiences with strategic nudges to revolutionize recruitment and retention strategies	<ul style="list-style-type: none"> <li>• Reduced drop out rate</li> <li>• Faster recruitment</li> <li>• Lower terminations for insufficient recruitment</li> </ul>

Source: Deloitte UK, “Unleash AI’s potential - Measuring the return from pharmaceutical innovation,” April 2024.

## Setting near-term GenAI objectives

Small molecule de novo generation is already delivering value, and the next wave of opportunities being developed are in the clinical arena, from operations and delivery to patient experience.<sup>51</sup> In the near term, organizations should look to organize data more effectively, in addition to identifying early wins from productivity gains across functions.<sup>52</sup> The quality and comprehensiveness of proprietary data that these algorithms are trained on are expected to be a differentiator. As GenAI becomes a core capability within R&D data science teams, organizations should also have strategies in place for developing their future workforce.<sup>53</sup>

## Accelerating speed in clinical trials

The pace for scientific and technological advancements is accelerating, from gene therapy to AI, but challenges in clinical research remain, including:

- The ability to recruit and retain a representative patient population
- The delayed response to operational problems
- The reliance on incomplete or un-insightful data sources

Ultimately, transforming clinical trials could require companies to work in very different ways, drawing on change management skills as well as partnerships and collaborations. This may require companies to develop highly skilled interdisciplinary leadership and AI experts who can innovate, organize, and guide others as well as AI-friendly CEOs and board members to push for the adoption of AI.<sup>54</sup>

## Strategic CGT partnerships trigger speed to value

### Discovering how fast novel treatments can reach rare disease patients

In late 2023, the US FDA approved the first cell and gene therapy (CGT) treatment using CRISPR gene-editing technology to treat sickle cell disease—Vertex Pharmaceuticals' Casgevy.<sup>55</sup> The treatment is being viewed as a test case for how fast these trailblazing

medicines can reach patients (in 2024, experts will be tracking the results).<sup>56</sup> Some suggest that if more than 2%, or about 2,000 US sickle cell patients, benefit from CGT over the next year, it may be a marker of progress for the disease.<sup>57</sup> There are 100,000 sickle cell disease patients in the US.<sup>58</sup> Tracking the speed at which revolutionary medicines reach patients may provide new insights and value.<sup>59</sup>

*"I think this is a pivotal moment in the field. It's been really remarkable how quickly we went from the actual discovery of CRISPR, the awarding of a Nobel Prize, and now actually seeing it being an approved product."*

— **Alexis Thompson**, M.D., Chief of the Division of Hematology at Children's Hospital of Philadelphia<sup>60</sup>

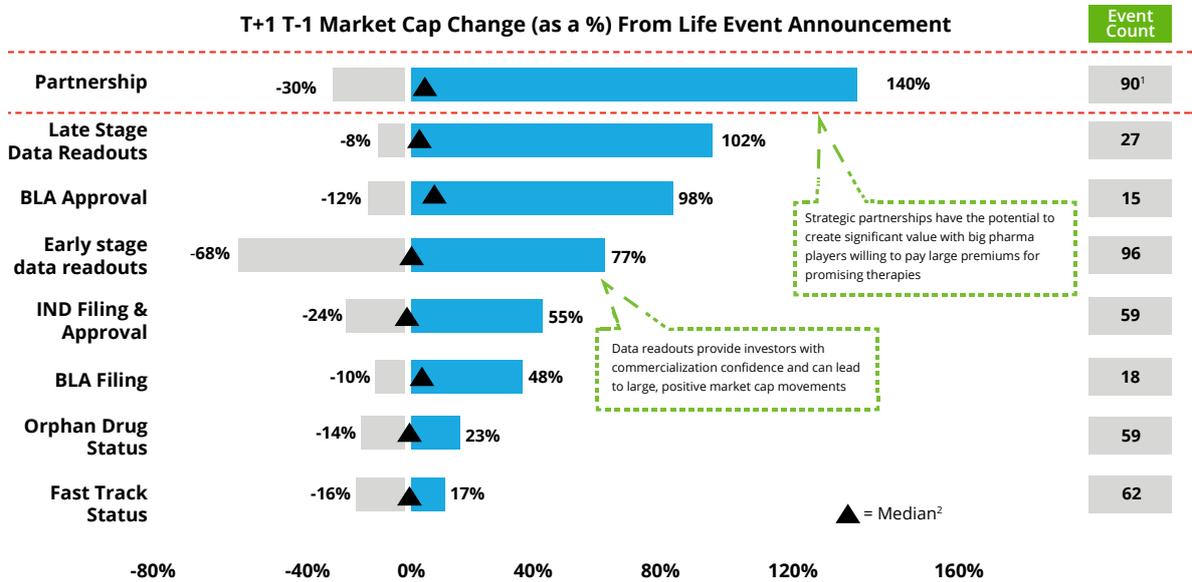
The Casgevy approval was quickly followed by another CGT approval for sickle cell disease, Bluebird Bio's Lyfgenia.<sup>61</sup> In 2023, Bluebird Bio said that its study for Lyfgenia was the longest follow-up of sickle cell patients to date—following 47 patients over 5 years<sup>62</sup>—and the National Heart, Lung, and Blood Institute (NHLBI) points to its transparency and collaboration as laying the groundwork for other technologies to follow.<sup>63</sup> The company says a validated access and reimbursement strategy is driving a favorable insurance coverage landscape.<sup>64</sup>

### Successful partnerships involve a combination of commercial and R&D arrangements

What moves the needle for CGT investors after regulatory approvals is what happens when a company is closer to having a commercial product, according to Deloitte US' CGT Market Index research team.<sup>65</sup> Strategic partnerships top the list of triggers, with market cap increasing by as much as 140% for companies announcing partnership arrangements with another, typically large pharma company (figure 5).<sup>66</sup>

Figure 5. Deloitte CGT Market Index™ value triggers

Limited number of triggers correlate with an increased market value for CGT companies, data as of 2023



Source: Deloitte US analysis

Research demonstrates that the most successful partnerships involve a combination of commercial and R&D arrangements, not one or the other. These partnerships typically combine the technological expertise of CGT companies with the asset development experience, clinical trial know-how, market access, and distribution channel infrastructure of larger companies.<sup>67</sup>

On the other hand, manufacturing partnerships did not trigger positive results, while contract manufacturers did derive more value than a company undertaking construction of its own costly

facility.<sup>68</sup> Overall, companies stringing together multiple milestones realized continued high-impact value creation multiples over those hitting just one milestone and then moving on.<sup>69</sup>

### Outsourcing for time and cost savings

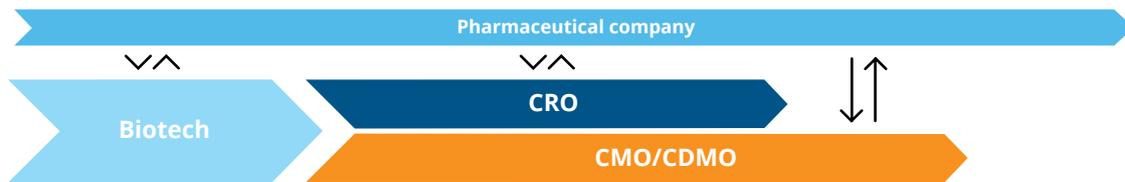
Outsourcing is on the rise for both biotech<sup>70</sup> and pharma companies to accelerate speed to market.<sup>71</sup> Like the semiconductor segment, the pharmaceutical ecosystem has a mature horizontal division model of drug discovery and manufacture by biotech and pharmaceutical companies (figure 6).<sup>72</sup>

Figure 6. Horizontal division of roles in pharma

### 1 Vertical integration model in the pharmaceutical industry



### 2 Horizontal integration model



Source: Copyright © 2022 Kurata, Ishino, Ohshima, and Yohda, "CDMOs Play a Critical Role in the Biopharmaceutical Ecosystem," *Frontiers in Bioengineering and Biotechnology*, 21 March 2022.

As many pharma companies adopt digital practices to shorten development timelines and reduce R&D costs, more are forming strategic alliances, outsourcing, or acquiring early and late-stage capabilities. There appears to be proliferation of collaborative research agreements/partnerships in the early drug discovery and preclinical drug development stages. In clinical trials, patient recruitment and clinical lab and diagnostics testing areas are seeing more outsourcing.<sup>73</sup> The number of contract research organizations (CROs) are growing,<sup>74</sup> and pharma companies are turning to flexible manufacturing in response to changing regulatory and market needs.<sup>75</sup>

### Proliferation of CROs facilitate experimentation

CROs and other contract service firms allow chemical expertise to be acquired rather than developed, which may enhance speed to market.<sup>76</sup> These molecule-on-demand firms have altered experimentation as artificial intelligence and machine learning help to design new drugs.<sup>77</sup>

The growth in CROs is behind a renaissance in small molecule discovery with developers learning novel ways to use small molecules to target disease.<sup>78</sup> In 2023, sales of the top 10 selling drugs were split 40/60 between small molecules and larger, more complicated biologics where sales were dominated by a few biologic blockbusters.<sup>79</sup>

### Globalization of contract development organizations (CDMOs)

Life sciences and medtech companies are considering new ways of working to help ensure product safety and quality without sacrificing speed. Companies adopting cutting-edge technologies, employing advanced process automation/continuous manufacturing, and incorporating real-time monitoring and modular facilities designs, may quickly and efficiently adapt production processes to accommodate varying product types, volumes, and customer demands.<sup>80</sup>

While some pharma companies in Europe favor regional CDMO services for close proximity to markets, innovation capabilities, and talent, CDMO services are being globalized by China and India. These two countries are projected to experience the largest CAGR growth in the CDMO industry—9.63% in China and 11.34% in India.<sup>81</sup>

### C "R" DMO outsourcing model emerges globally to accelerate therapies

As drug makers seek to increase efficiency and productivity and gain access to advanced technologies, there is a growing demand for outsourcing technology solutions that provide more integrated end-to-end services.<sup>82</sup> Drug makers are starting to seek out contract research development manufacturing organizations (CRDMOs). These operators consider

themselves science and technology platforms that also bring the “R,” or research, into the CDMO mix.<sup>84</sup>

CRDMO facilities are starting to spring up around the world—including in China, Singapore, the US, and Italy. By consolidating and unifying the CRO and CDMO models, companies see an opportunity to accelerate the time it takes to bring new therapies to market.

“Building end-to-end capabilities and offering integrated solutions in the small molecule space is our vision. Clients and the market want a one-stop shop and a partner who can take care of the entire project.”

—Giovanni De Filippo, Fine Chemicals Sales & BD head, Angelini Pharma SpA<sup>85</sup>

### New drug approvals and launches

A total of 69 novel active substances (NASs) were launched globally in 2023,<sup>86</sup> led by the US, with 55 compared to 37 in 2022.<sup>87</sup> Over the past five years, NAS

launches around the globe totaled 362.<sup>88</sup> The tally of NAS launches in China is on the rise, but an increasing number are not available outside China, reflecting an increasingly domestic industry.<sup>89</sup>

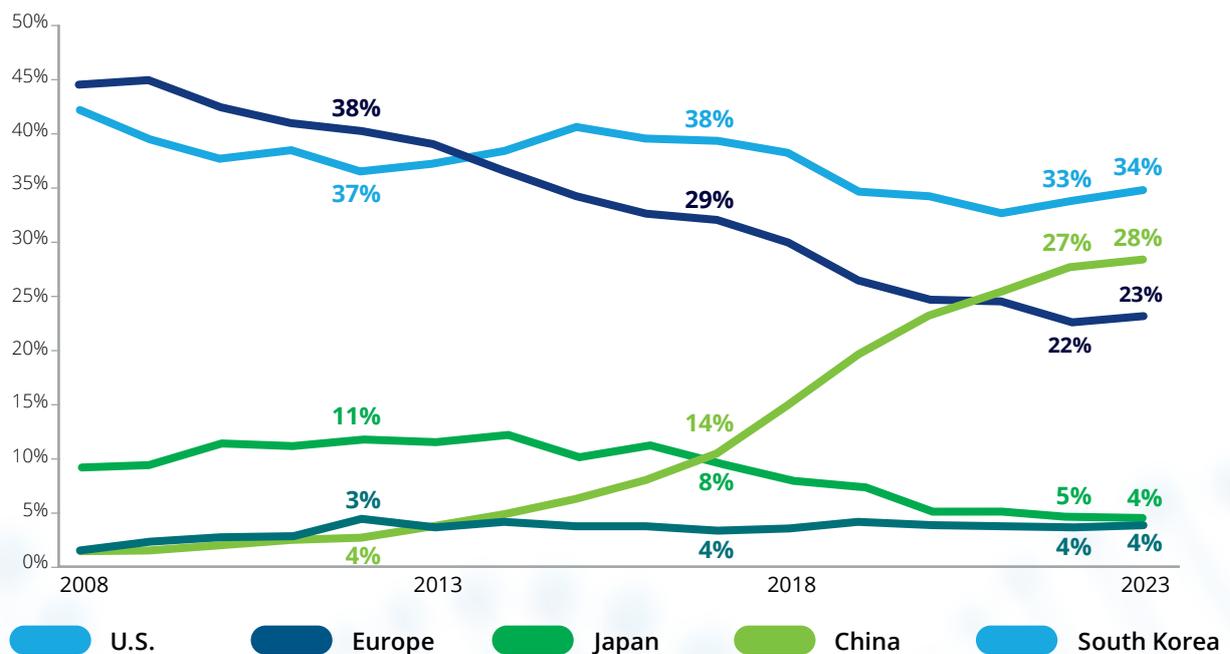
### China eclipsing Europe and gaining on the US in R&D

Clinical trial starts are increasingly global with Asia experiencing the largest growth in recent years. China moved ahead of Europe in NAS launches as well as in clinical trials to reach the number two spot behind the US globally.<sup>90</sup> While China’s NAS launches are domestic, China’s clinical trials are increasingly global.

Only about a third of all clinical trials are being held in the US as the US clinical research footprint shifts overseas.<sup>91</sup> China is only a few points behind the US, with 28% of all clinical trial starts from China-headquartered companies in 2023—a significant jump from only 3% a decade ago (figure 7).<sup>92</sup>

Notably, China also reached the number two spot for worldwide R&D expenditures across all industries, surpassing the EU (17.5%) with 17.8%, mainly as a result of its tech sector.<sup>93</sup> For China’s pharma companies, high expenditures on R&D and procurement are shrinking profit margins.<sup>94</sup>

Figure 7. Number of Phase I to III trial starts based on company headquarter location, 2008-2023



Source: IQVIA, “Global trends in R&D 2024,” 2024.

Currently, the US leads biopharmaceutical innovation, supported by its large domestic market, IP protections, limits on government drug price setting, supportive science policies, and supportive innovation clusters.<sup>95</sup> However, the US is experiencing rising drug pricing pressures and US policies may weaken foundational IP protections.<sup>96</sup>

Critics point to lessons learned as a result of the US decline in semiconductors and telecommunications, where the US originally held leadership positions. Policy analysts suggest policymakers should not attack pharmaceutical companies but focus more on how to win the global battle for pharmaceutical sector competitiveness.<sup>97</sup>

### Funding biopharma R&D

How biopharma R&D unfolds depends on the ability to effectively partner across geographies and between the public and private sectors. This highly collaborative process can affect decision-making about R&D investments.<sup>98</sup> Ultimately, financing for R&D can play a major role in whether the medicines and treatments that patients need are developed.<sup>99</sup>

Researchers recently explored how pharmaceutical R&D is financed and how this may evolve in the future.<sup>100</sup> Of the total US\$300 billion spent on pharmaceutical R&D, large pharmaceutical companies represent almost two-thirds of investments.<sup>101</sup> Public and not-for-profit sectors contribute a quarter of the total (US\$75 billion).<sup>102</sup> These essential scientific

advances may then flow downstream for private R&D sector investment.<sup>103</sup> Venture capital currently accounts for about a tenth of the total investment.<sup>104</sup>

### Calls for more research into drug development productivity/value creation

Some AI researchers say that more funding should go to academia to study ways to cut costs and improve pharmaceutical R&D productivity as there is scant research on how value is actually created.<sup>105</sup> The US Congressional Budget Office (CBO) also recently called out a need for more research.<sup>106</sup>

The CBO uses a simulation model of drug development to analyze legislative proposals and incorporates feedback from academic and industry experts to inform its model. Life sciences and medtech leaders should be aware that the agency recently expressed interest in researching:

- How changes in the future profits of pharma companies might affect the development of drugs with differing characteristics (e.g., small and large molecules),
- How changes in the number of new drugs can affect health outcomes, and
- How policies—such as price negotiation or accelerated drug approvals—could affect companies' decisions about which indications to target for approval.<sup>107</sup>

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[Drug launch success](#)

# Endnotes

## Accelerating speed of time to value in R&D

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