



R&D

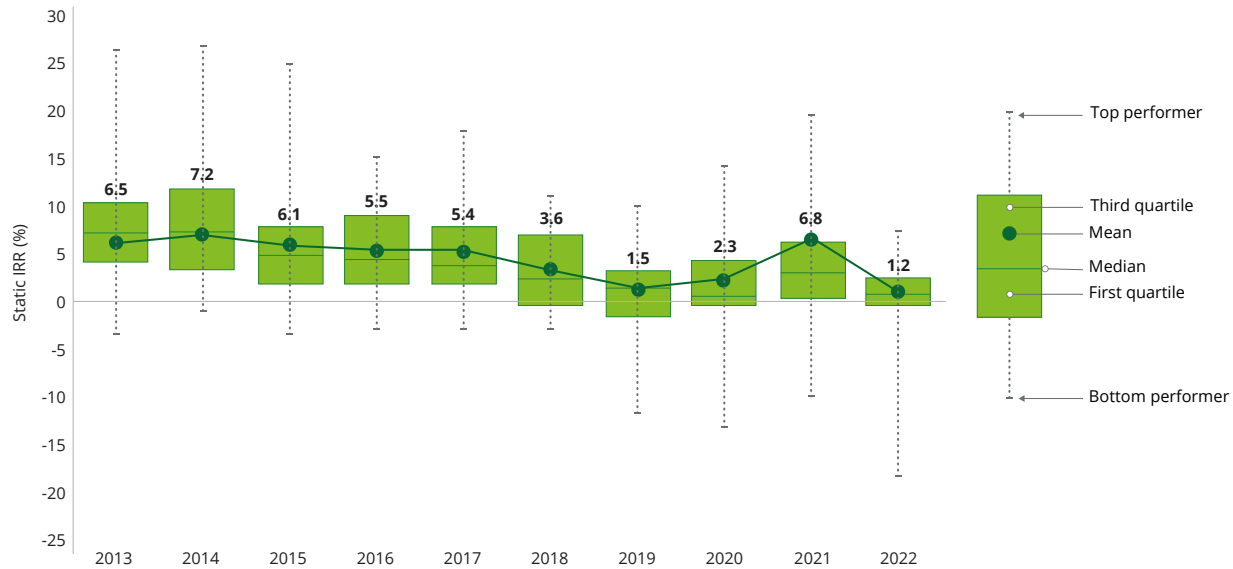
Innovation is fundamental to the global life sciences sector, even as pricing pressures, growing market share for generic drugs, and looming patent expirations remain significant challenges. In the coming year, life sciences companies will continue to build on advances such as translational medicine, big data analytics, and digital innovations in research and development. In addition, other advanced technologies will emerge to improve research and development (R&D) efficiencies, boost long-term returns, and enhance the patient outcomes and experiences.

R&D innovation is one of the top actions that 91% of life sciences organizations plan to invest in more heavily during 2023, according to a Deloitte survey of 60 senior life sciences executives from biopharmaceutical and medical device manufacturers with revenue of more than \$500 million.¹

Almost half — 48% — of the executives in the same survey said they are cautiously optimistic about the sector's outlook in the coming year. R&D investments in composition, drug pipelines, clinical trials, and processes for regulatory approval of new assets will play a critical role in the industry's success, but the financial challenges on achieving a return are significant. Deloitte's analysis of the top 20 pharma companies found that:

- Internal rates of return (IRR) for late-stage assets fell to 1.2 percent from 6.8 percent a year earlier. Indeed, IRRs have resumed a downward trend that began in 2014, slipping below the 1.5 rate achieved in 2019. (Figure 1)
- R&D spending among the 20 biggest companies fell to \$139 billion in 2022 from \$141 billion in 2021 (though it remains higher than it was in 2020).
- Average asset development costs increased in 2022 by \$298 million, to \$2.28 billion, compared with a year earlier. This increase was largely because of increased clinical cycle times, which were compressed during the pandemic.
- The average forecast peak sales per pipeline asset fell to \$389 million from \$500 million in 2021 because of the successful commercialization of high-value assets.²

Figure 1. Return on late-stage pipeline, 2013-22



Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 1 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.

Life sciences R&D organizations are under increasing pressure to generate sustainable returns on investment given shifts in the market, regulation, and reimbursement practices. While the industry has recently produced groundbreaking innovation such as mRNA vaccines and platform technology, which have the potential to truly transform global health, scaling the impact will require reinventing and realigning traditional R&D models.

Real-world evidence (RWE), new approaches to clinical trials and partnerships and artificial intelligence (AI) have the potential to transform R&D – from drug discovery and development to regulatory approval.

The growing benefits of RWE

RWE refers to clinical findings about the use and potential benefits or risks of medical products based on analysis of data such as patients' health status or the delivery of care. RWE helps life sciences organizations better understand disease progression, monitor patient safety, and assess clinical and cost effectiveness. RWE also can help organizations adjust instructions for how medications may be used, administered, or labeled.³

During the COVID-19 pandemic, RWE enabled the sector to innovate faster by understanding the incidence and severity of the virus and its variants for vaccine and drug development. RWE helped vaccine developers predict global hotspots, collect better data from diverse racial and ethnic groups, and understand vaccine effectiveness across age, gender, race, and ethnicity to determine the need for boosters.

Increasingly, RWE is playing an expanded role in R&D in helping life sciences organizations design clinical trials, understand the heterogeneity of treatment effects, and inform price and forecasting assumptions.

Though life sciences organizations lagged other sectors in adopting RWE, it now is a growing part of the decision-making process. Companies are getting faster at collecting and analyzing RWE. Ninety percent of the biopharma executives surveyed by the Deloitte US Center for Health Solutions said their organizations are using RWE to speed product life cycles and design synthetic control arms and adaptive trials. These processes are expected to increase in the next two to three years.⁴

Regulatory agencies are accepting the use of RWE in submissions. Over the past two years, the US Food & Drug Administration (FDA) has released guidelines on its use for claims, electronic health records, and registry data in submissions.⁵ As part of its RWE strategy, the FDA is working on projects exploring the role RWE could play in regulatory decision-making.⁶

For example, Eli Lilly collaborated with Flatiron Health to fill evidence gaps in its FDA submission for a new dosing regimen of cetuximab, which treats metastatic colorectal cancer (CRC). Analysis of real-world data from Flatiron Health’s database found no significant differences in the survival of CRC patients receiving weekly or biweekly doses of cetuximab. The findings were critical to the FDA’s approval of biweekly doses of cetuximab, and infusions can now be scheduled alongside other biweekly treatments, reducing patient visits to infusion centers.⁷

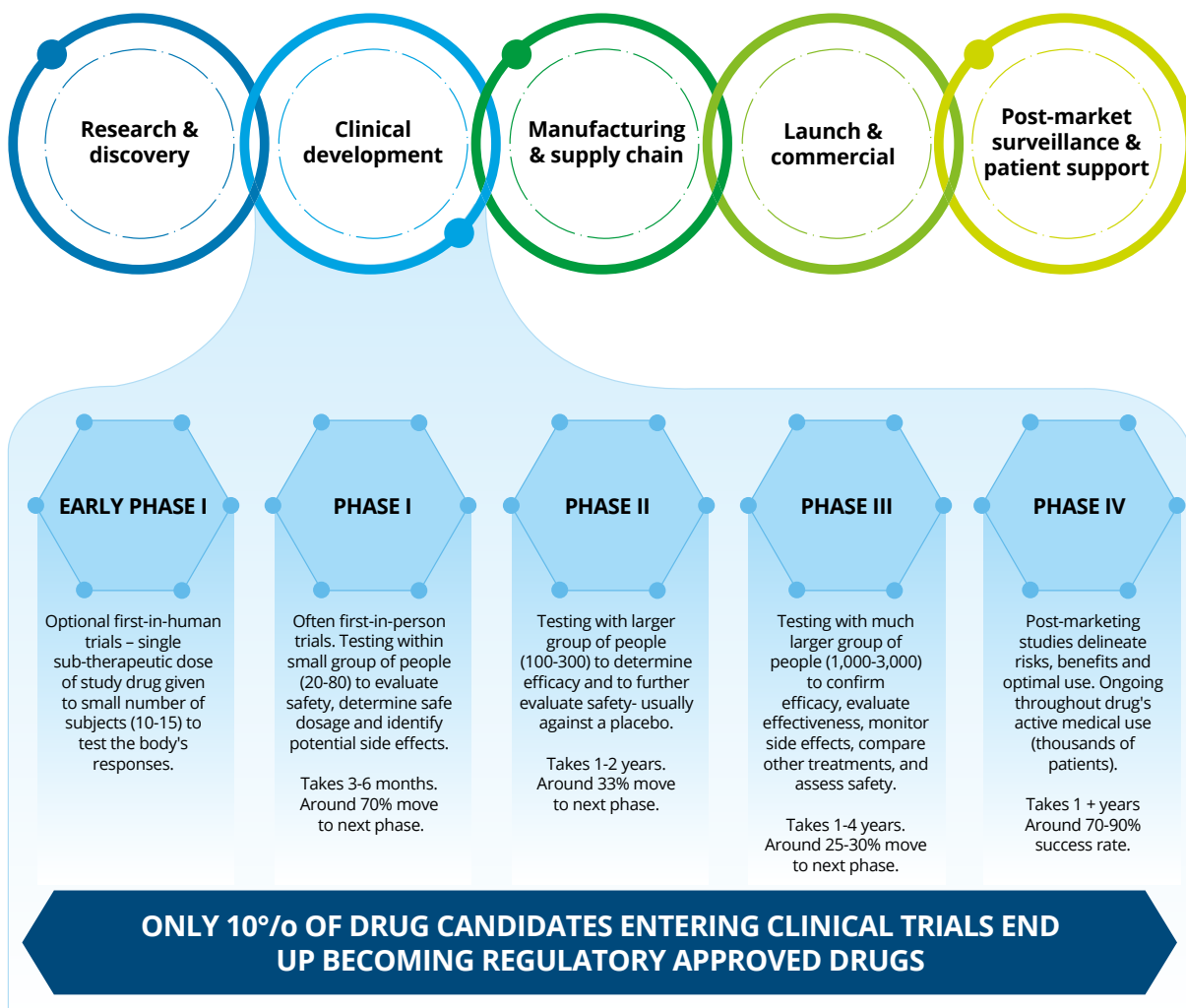
The European Medicines Agency (EMA) and the National Medical Products Association in China also are attempting to expand RWE use to expedite patient access to innovative therapies.⁸

With new regulatory pathways for real-world data, advanced information management and analytics, technologies can enable R&D organizations to access, analyze, and meaningfully act on RWE to advance drug discovery.

Reshaping clinical trials

Clinical trials remain vital to life sciences’ R&D, but the lengthy process of discrete and fixed phases in randomized controlled trials (RCTs) has changed little in recent decades and was designed principally for testing mass-market drugs (Figure 2).

Figure 2. The traditional approach to clinical development is a lengthy process with only 10 percent success rate



Source: Deloitte analysis.

As of September 2022, more than 16,000 clinical trial studies were underway, and non-COVID study starts through August were on pace to top 5,500, a 17% increase from the 4,700 starts in 2021.⁹

The need for large numbers of studies, however, are hampered by difficulty finding subjects to enroll, and the time it takes to complete them: The average trial time for Phase 3 trials in 2022 was 3.5 years, up slightly from 3.4 years in 2021.¹⁰

The pandemic taught the sector that technology can be used to collect and monitor patient data more quickly. Dublin-based ICON ran a COVID trial in Argentina with 5,000 subjects. Monitoring the data onsite would have been too time-consuming, so the company monitored the data from Japan to ensure it was being collected properly. "That's sort of technology [that] can now become part of trials in the future," CEO Steve Cutler said.¹¹

It's also important to note that despite slow changes in the trial process, the pandemic accelerated the use of virtual trials, wearables and RWE, and we expect this trend to continue, leading to more widespread adoption.

Digital trials

Trials are being conducted at sites that are more convenient for patients, rather than at centralized testing facilities. Data is gathered remotely through wearables, mobile engagement apps, and medication management. For example, Curebase, a US clinical research firm, conducts decentralized clinical trials without a traditional testing site. Data is collected through wearables, home visits, telemedicine, and reminders sent by apps.¹²

Meanwhile, companies such as Novotech and Obviohealth are working to develop decentralized clinical trials in the Asia-Pacific region, which accounts for more than 60% of the global population and represents the fastest-growing market for pharmaceutical sales.¹³

These remote testing capabilities not only increase the amount of data collected, but they also can give manufacturers greater insight into patient safety by identifying risks. While standards are needed for data collection, analysis, and collaboration, the data gathered could provide better understanding of disease and a broader view of the patient experience before, during, and after dosing.¹⁴

Trial simulation

Digital technology can conduct trials via computer simulations and use analytics to verify trial feasibility. These digital studies can simulate organ response to drugs, employ AI to optimize dosing, and predict disease progression.

Paris-based Ariana Pharma, for example, designs and executes precision medicine clinical trials using AI. The company integrates pre-clinical, clinical, and RWE data, then uses that information to select patients for trials, determine best dosages and even suggest alternative clinical indications.¹⁵

Trial simulation can help identify clinical outcomes in the discovery or development phase, long before any human trials. Life sciences organizations are adopting modeling and simulation to understand the complexity of human physiology and predict human response to therapies. One key area for growth is addressing relapses from drug resistance in diseases such as cancer, tuberculosis, and other bacterial infections.¹⁶

As a result, the biosimulation market, which was \$3.17 billion in 2021, is expected to grow at an annual rate of 15%, reaching \$6.13 billion by 2026.¹⁷

Retail clinics

Some 80% of clinical trials are delayed because of recruitment issues, and about one-third of patients who sign up drop out before a trial is completed. Most clinical trials are conducted in academic medical centers, which may require a patient to travel

as much as two hours each way. One solution: bring the trials closer to the patients, most of whom live within 10 or 15 minutes of a pharmacy or grocery store with clinics that often are open at nights or on weekends. Retail outlets are not suitable for all types of clinical trials, but they are well-suited for drugs to treat skin cancer, diabetes, asthma, or hypertension. The use of retail locations – such as pharmacies, grocery stores or urgent care facilities — could expand the number of trial sites and improve patient access. Using retail locations may also address health equity issues by attracting more racially, ethnically, and economically diverse participants.¹⁸

For example, the health division of the US grocery store chain Kroger established a clinical trial site in partnership with pharmaceutical companies, research organizations and health systems. The first trial began at a Kroger pharmacy in Toledo, Ohio, in early 2023 and enrolled an initial cohort of 55 people in a study to identify microbiome-based biomarkers indicative of colorectal cancer.¹⁹

Intelligent trials

Using real-world data, predictive AI algorithms can accelerate the understanding of diseases, identify suitable patients, assist in site selection, and support novel study designs. The algorithms also collect and analyze clinical data more quickly and from more inputs while also reducing the potential for human error. AI can also improve patient monitoring, medication adherence and retention.

AI-powered simulations and computer modeling will advance the development and regulatory evaluation of new drugs, while reducing the time and costs of clinical trial cycles and improving patient safety.²⁰

AI's growing role in drug development

AI has the potential to transform drug discovery by extracting concepts and relationships from data. It also can cross-reference published scientific literature with alternative information sources, such as clinical trials information, conference abstracts, public data, and unpublished datasets. By mining such information, AI applications in drug discovery have already delivered new candidate medicines, in some cases in months rather than years.²¹

Whiz.AI, a US startup, uses AI to provide data insights gleaned from patient history, remote patient monitoring, and results of previous trials. Life sciences organizations can use the information to expedite R&D and time to market, while also more accurately forecasting development costs.²²

AI's ability to crunch large amounts of data allows it to rapidly identify drug targets, such as molecules and proteins associated with specific diseases, that can be made into medicine. Biotech companies such as Exscientia, Evotec, and Insilico Medicine have announced clinical trials for drugs developed with AI, and Verge Genomics, a US biotech, recently started clinical trials of novel therapy for ALS that it developed using AI to analyze brain tissue databases.²³

“

Data science has now closed the gap with chemistry, biology and physics and really driving innovation in the pharmaceutical industry,” said Frank Nestle, global head of research and chief scientific officer for Paris-based Sanofi. “The predictive models, what we call AI, will give us novel hypotheses, and those novel hypothesis will speed up drug discovery, make it more affordable, and cheaper and also get us better quality medicines.”²⁴

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As the number of compounds identified using AI increases, drugs capable of treating specific pathologies will become available. By 2030, more drug discovery will be done using AI-controlled simulations in collaboration with academia. The time from screening to preclinical testing will be reduced to a few months and new potential drug candidates identified at increasingly lower costs.²⁵

Collaboration and shared services

Prior to the pandemic, developing, testing, and releasing a new vaccine, therapy, or medical device in less than 10 years was almost unheard of. Today, companies, shareholders, and consumers all want faster cycles, but they can't do it alone. Long drug and device development times can add significant human, health, and economic costs to R&D efforts. By working to reduce those times through international interagency collaboration, regulators could help mitigate those costs.

During the past two years, regulators globally have been working more closely together than ever. While many regulatory bodies were involved in working groups prior to COVID-19, the pandemic accelerated those relationships, which are likely to continue in the years to come.

Regulators also stepped up information sharing with private companies. These collaborations focus on creating clusters of technical experts, sharing research results, leveraging inspection reports, and disseminating information. Regulators also showed they were willing to relax certain requirements, lower barriers to entry, and accelerate approval processes for new products to facilitate faster and more comprehensive responses from both the public and private sectors.²⁶

This newfound sense of collaboration is particularly important in Europe, where biopharma products must receive regulatory approval from the EMA, and the UK's Medicines and Healthcare products Regulatory Agency (MHRA). The EU recently changed regulations for clinical trials and medical devices, for example, and cross-border collaborations remain challenging.²⁷

Collaboration also has increased within the industry. Biopharma companies and medtech manufacturers are sharing information in ways they never have. In March 2020, after COVID-19 was declared a pandemic, companies such as Eli Lilly, Novartis, Gilead, and AstraZeneca formed a research group that shared knowledge and resources to accelerate development of vaccines and treatments.²⁸

And life sciences organizations are turning to external providers for services such as robotic cloud labs, or lab-as-a-service (LaaS). In these labs, companies provide proprietary hardware, single-platform software, and services that allow automated research to be done remotely. Researchers log in to a dashboard, specify the experiments they want to run, and configure the equipment remotely. The labs can run experiments around the clock, greatly reducing the time it takes to develop new drugs.^{29,30}

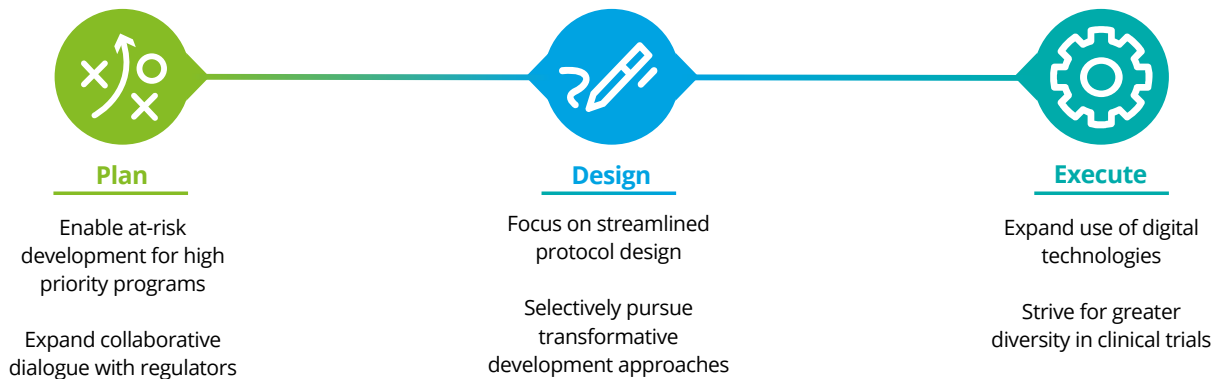
Life sciences organizations are increasingly seeking to augment their drug development pipelines through collaborations and scientific partnerships. A Deloitte survey of 15 life sciences companies found that they relied on external sources for innovation for more than 50% of late-stage revenue.³¹

Ipsen CEO David Loew said French biopharma company has almost stopped doing internal research. "We have only very little internal research left, and we partner now on the three years before entry into human space...with biotechs or with universities," he said.³²

The post-COVID outlook

The response to the COVID-19 pandemic has created new opportunities for innovation in the life sciences sector (Figure 3). In the coming years, it should continue to explore and embrace these new approaches, such as identifying programs with a high probability of success and ensuring they progress seamlessly from one phase of development to the next.

Figure 3. Incorporate the lessons from the R&D approaches adopted for COVID-19 into routine clinical development



Source: Deloitte analysis.

Other benefits from the pandemic response include expanding dialogue with regulators to accelerate development of urgently needed therapies, streamline trial protocols to avoid deviations, and speed development time, and strive for greater diversity in clinical trials to ensure subjects match the prevalence of diseases across racial and ethnic groups.³³

COVID-19 has highlighted the vulnerability of R&D to the traditional, site-based clinical trial system. Deloitte surveyed R&D and commercial leaders at both large and small biopharma companies, most of whom said they expect the shift to decentralized, patient-centric trials to continue for the long term. They also anticipate more reliance on innovation and both real-time and remote monitoring tools and diagnostics. Organizations also may develop extensive data and intelligent workflow to support improved decision-making.³⁴

Organizations that can continue to capitalize on the momentum gained by accelerating digital transformation programs, strategic shifts, and commercial reorganization before or during the pandemic, will be well-positioned to benefit from the more agile post-COVID market in 2023.

Considerations for the C-suite

To drive a more productive future for R&D, with more equitable and quicker access to new therapies, life sciences leaders should ask themselves these key questions:

- Is our R&D capital allocation sufficiently balanced to foster sustainable pipeline flow?
- Are we investing enough in the new capabilities and way of working that will transform our ability to execute the pipeline?
- Are we making the most informed project-level investment decisions given the shifting scientific, commercial, and reimbursement landscape?
- Can we unlock the power of data sharing? How can we build on emerging knowledge, reduce duplication of research efforts, and curate data in the cloud that be accessed by our organizations and our partners?
- Can we create a digital talent pool with the skills to expand the use of data-driven approaches? How do we rethink our talent strategies to leverage alliances for accessing talent? How do we best invest in retraining the talent pool we already have? Can we incorporate patient centricity to improve health equity and develop more comprehensive clinical trials that better assess the impact of our products for all races and ethnicities?
- How can we meet society's expectations about equity of access to experimental and approved therapies?

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