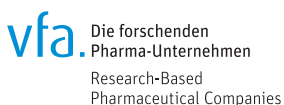




Modernizing the biopharma innovation engine

An essay collection about reinventing
pharmaceutical research and development today
to deliver therapeutic innovations of tomorrow



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Foreword

As the global pharmaceutical industry marches toward 2030, many CEOs are preparing for a bumpy ride through the second half of this decade. On one hand, the looming patent cliff of major biology therapy blockbusters will require substantial portfolio replacements to stabilize top-line growth. On the other, regulatory authorities in major markets across the world are expected to continue compressing policymaking timelines. And it all points toward raising the bar for market access and reimbursement in light of continuously tightening public healthcare funding.

Marry these trends with next-level understanding of cell and disease biology and manifesting opportunities from generative AI to reinvent drug discovery and development. For many CEOs, the result—already felt today—is increasingly heated boardroom discussions with key investors regarding rising expectations for innovation and productivity to sustain biopharma’s economic model. Together with the unpredictable geopolitical dynamics across the Americas, Europe, and the Indo-Pacific region, the perfect storm has arrived.

We at Kearney are proud to share the following series of thought-provoking essays on the future of biopharma innovation together with hand-selected senior executives from leading industry players Bayer, Boehringer Ingelheim, Roche, and the German Association of Research-based Pharmaceutical Companies (VFA). These articles are intended to provide leaders with inspiring perspectives on how to refine their innovation models—starting today.

All articles were originally published as a special in the prestigious *Harvard Business Manager* magazine in Q3 2024. We hope you enjoy reading them and find our perspectives insightful. And remember: there is time to strategize, but there’s also time to pivot from debate to action. Let us know if you want to dive deeper into what it takes to modernize biopharma innovation, research, and development. We want to be the difference between your big ideas and reality.



Marc P. Philipp

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How biopharma can shape tomorrow's innovation

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Over the past years, the pharmaceutical industry has achieved remarkable breakthroughs. Nevertheless, CEOs are under unprecedented pressure to innovate as expiring patents and more stringent regulations are forcing them to commit to increasingly larger investments into research and development to meet capital market's expectations. The result is fierce competition for therapeutic innovation, which comes with industry challenges that will require novel strategies and approaches to innovation, research and development.

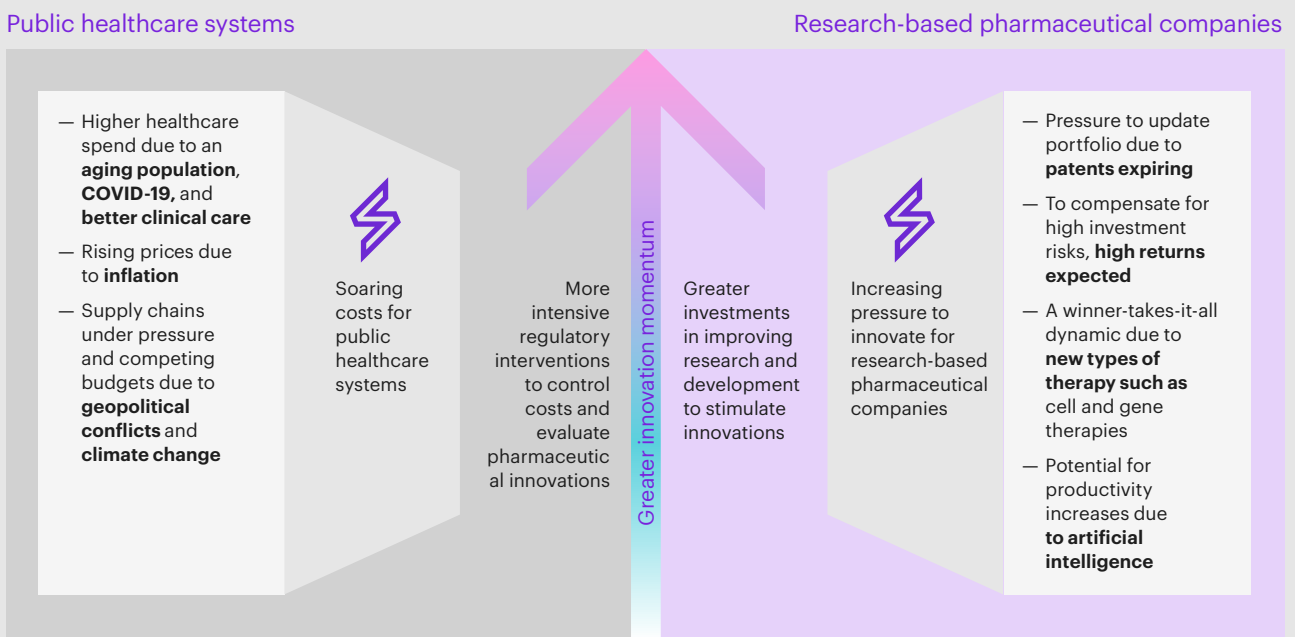
Pharmaceutical executives have reasons to be cheerful about the past few years' successes, including the following:

- The swift development of new vaccines saved millions of lives during the COVID-19 pandemic.
- Alzheimer's has long been a difficult disease to treat, but new therapies that slow down cognitive decline have yielded the first real successes in decades.
- A new generation of drugs to combat the obesity epidemic will reduce the condition's toll on individuals, improve mental health, lower cardiovascular risk, and prevent the occurrence of related illnesses.

And yet, the mood in many boardrooms is gloomy. As patents for major biologics expire, pharma needs to keep replenishing its portfolio of novel therapies to maintain their competitive edge. That's a lengthy, risky, and expensive business. Launching a new therapy takes an average of more than 10 years, and only one out of every 15 projects is successful.^{1,2} Recently, more than a record-breaking €260 billion was poured into research and development of new therapies globally, and there are no signs of a slow-down.²

¹ Research projects at phase 1 of clinical research that gain approval
² Kearney analysis based on Evaluate Pharma

Figure
Public healthcare systems are under pressure to innovate



Source: Kearney analysis

The financial squeeze on public healthcare systems worldwide is compounding the pressure to innovate. (see figure). In light of the many new drug launches, regulatory authorities are casting an ever-more critical eye over the additional therapeutic value these medications provide compared with the established standard of care, as more frequent price regulation interventions indicate. In 2024 for example, the United States—the world’s largest pharmaceutical market—introduced price negotiations for selected drugs for the first time. Germany established a tighter pricing regime for new medications, while the European Commission is in the midst of discussing raising the bar for intellectual property protection and market exclusivity.

The result is a snowballing effects. Unpredictable but eventually fundamental changes in the external regulatory environment decrease the plannability of long-term investments. At the same time, increased uncertainty will likely also raise investors’ expectations about compensation for the additional risk. Consequently, biopharma CEOs are facing more pressure to differentiate their companies with innovative products to avoid competing on costs. In addition, new scientific advancements such as cell and gene therapy that could cure diseases instead of just treating symptoms or delaying progression are creating an unparalleled winner-takes-it-all dynamic.

Now is the time for pharmaceutical companies to rethink their approaches to managing innovation, research, and development. Based on the vast amount of advisory work we’ve done with R&D leaders across the globe, we believe five dimensions deserve an overhaul:

Dimension 1: competitive positioning at the intersection of therapeutic areas and research technology platforms

For a sustainably successful market positioning, pharmaceutical executives should systematically compare and align their own competitive strengths with the unmet medical needs across different market segments and shore up internal capabilities accordingly.

Two core approaches have transpired: a strategic focus on certain therapeutic areas, physician, and patient segments and specialization in proprietary, biotech research platforms, drug classes, or modalities that can be used to address a broad set of very different disease areas, such as mRNA, cell, and gene therapies. Both approaches come with their own challenges that need specific management. Companies focusing on therapeutic areas typically need to boost external innovation to complement in-house research and development through acquisitions or in-licensing to continuously feed the commercial machine and avoid dependency on in-house drug discovery. On the other hand, biotech platform companies need to consciously reflect and decide which internal capabilities they have to strengthen across the value chain at what point in time to effectively drive innovation to the market or—alternatively—enter into partnerships to clinically develop, launch, and commercialize their products in the event of success.

However, these two approaches are not clear cut and start to converge. Several larger pharmaceutical companies with corresponding financial muscle experiment to get the best of both worlds by being more flexible in terms of their focus on certain disease areas. This balancing act requires strong leadership in strategic planning and capital allocation as well as the willingness to disrupt the status quo despite good short-term profitability levels.

Dimension 2: global capital allocation and footprint optimization balancing clinical development productivity and commercial success

To improve returns on investment and R&D productivity, pharmaceutical executives need to examine how and where they allocate R&D budgets and investments. Deciding where pharmaceutical R&D is conducted globally has become more complex and mission critical. Geographical locations greatly impact not only the probability of R&D success, speed-to-market and cost effectiveness, but also a new drug's commercial success.

Germany is a great example. As a recent study by Kearney and the German Association of Research-Based Pharmaceutical Companies (VFA)³ shows, the country has lost in attractiveness, particularly as a clinical development location compared with other countries over the past few years. It's true that the country still excels globally in terms of high-quality clinical research, patient care, and well-trained, skilled medical professionals, but bureaucracy, stagnating digitalization, and a lack of collaboration across the ecosystem have made R&D operations less attractive on the world stage. The German government, however, has heeded the warning and responded with a revamped pharma strategy. For instance, the nation's planned Medical Research Act aims to improve conditions for research by speeding up approval procedures.

Consequently, business leaders need to not only continuously "landscape" the global R&D environment to make the right capital allocation decisions but also contemplate how they can anticipate and leverage changing conditions within individual jurisdictions to create a competitive advantage.

Dimension 3: translational science and operations across discovery, development, medical, and commercial activities

To maximize value of innovation, pharmaceutical executives need to press ahead by fostering a much greater cross-disciplinary approach within their companies. Although the industry has been talking about it for a long time, becoming truly "translational" in the broader sense will become essential to success in the future. At any early stage, pharma leaders must already be fully aware of what it will take for their R&D results to become the standard of care for most patients. Therapeutic innovation that is not only scientifically effective and safe, but also commercially competitive with alternatives as long as possible will be paramount in a world where innovation cycles are continuously compressed.

In reality, many companies' key functions along the pharmaceutical value chain are still operating in a much too isolated manner. While R&D teams focus on obtaining market authorization as swiftly as possible, market access and the sales force is driven by negotiating pricing and reimbursement as well as maximizing prescriptions. The result is a frequent scenario where leaders find out too late that the proof of a drug's efficacy and safety during the research and development may not provide sufficient evidence to also effectively pitch the medication's health and economic benefits. This is especially true for diseases where high price points for a small patient population require extra justification. At this juncture, this shortcoming is virtually impossible to fix, which means valuable opportunities are wasted.

R&D leaders should thus feel equally responsible for laying the evidence foundation for novel therapy's success on the market. Pioneering companies have already developed effective blueprints for a more horizontally integrated approach that also includes overhauls of leadership performance management and governance systems.

³ Philipp et al. (2023). Pharma-Innovationsstandort Deutschland. Kearney and VFA, www.de.kearney.com

Dimension 4: inside-out, stakeholder-led R&D at the intersection of patient, caregiver, and clinician perspectives

This may seem obvious, given the fact that the industry has been talking about “patient centricity” for more than a decade: to accelerate drug R&D, minimize risks, and improve the probability of commercial success, pharmaceutical executives should look inside-out and consider stakeholder needs more systematically and strategically. This obviously includes the target patient’s needs and preferences but should also include opportunities for therapeutic differentiation and positioning with caregivers, clinical scientists, and prescribers. This is especially true for competitive, highly dynamic innovation scenarios and environments with already well-developed standard of care. As the war for patients has already started to become fierce in late-stage development, companies are dependent on patients participating in clinical trials. Trials tailored to patients’ needs have a good track record of attracting participants more quickly and retaining them. The impact isn’t just positive from a commercial standpoint. In highly competitive areas of research, such as oncology, where patients can often choose from numerous trials, patient engagement is pivotal to success. But in this case, there’s no room for afterthought because important decisions are often taken at an early stage. In other words, the patients’ perspective must take center stage in the design of research programs and trials.

Pharmal CEOs will need courage and persistence to find new answers to the innovation challenge.

Dimension 5: data and AI for more efficient research and development

The hype around data, analytics, digitalization, and artificial intelligence is not a new phenomenon. In a highly regulated, generally risk-averse industry with still above-average profitability levels, it is not a surprise that biopharma CEOs have long been reluctant to walk the talk and go all in on AI. Given the benefits and increasing pressure to disrupt and modernize R&D, we feel pharmaceutical executives need to expedite harnessing data and artificial intelligence now to conduct R&D more swiftly and affordably.

Companies using data and AI can cut the time for new drug development many times over and therefore revolutionize drug research in the long term. For example, analysis of patient omics data can help identify new targets, pathways, and lead drug candidates, and the use of synthetic data in clinical trials can cut down on time-consuming patient recruitment.

So it should come as no surprise that in light of the sheer number of opportunities to pursue, radical prioritization concerning value and feasibility is crucial to success. Unfortunately, the past few years have been dominated by pharmaceutical companies either being in a “wait and see” mode for too long or having invested in building their own large, proprietary in-house comprehensive AI capabilities. Many of these high-cost digital programs with the intent to create platforms that “solve for everything” were unable to sufficiently demonstrate their value and were often abandoned after millions had been invested. To reduce complexity, pharmaceutical managers should instead focus on their companies’ own strengths and purpose. It’s vital to spot strategic areas with high value propositions along with ones that quickly produce results and build confidence and trust in data-driven insights. Partnerships with technology companies are one of the keys to success.

All of these five dimensions prove one thing: pharmaceutical CEOs will continue to need courage and persistence to find new answers to the innovation challenge. To achieve sustainable success in the competition for innovation, incremental adjustments to current approaches are no longer enough.

Farewell complexity, hello customer focus in clinical development

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Complexity in drug development unnecessarily ties up capacity for most stakeholders—be it clinical researchers, businesses, or government departments. It's a vicious circle that needs breaking across the board.

To minimize risks and ensure patient safety, the clinical development of novel pharmaceutical products is heavily regulated. The upshot is a rising number of local and regional regulations and regulatory requirements worldwide, for example, from health authorities such as the US Food & Drug Administration (FDA) or the European Medicines Agency (EMA).

For many years, this has meant a significant increase in complexity for pharmaceutical companies as businesses have come up with a whole host of standard operating procedures designed to meet regulations specified by the authorities, curtail risks, or eradicate safety shortcomings. These internal processes are subject to consistent audits, leading to complexity in corporate structures and requiring resources. In turn, this complexity is also reflected in internal decision-making processes. Because many relevant players are involved, decisions can take longer to make. Despite the advance of digitalization and automation in clinical development, mandatory steps to validate and ensure the quality of processes, systems, and clinical data often delay new product launches. In response, the industry has created external bodies and consortia that provide advice on effective R&D compliance.

Not surprisingly, a complex submission process to the authorities can mean that important pharmaceutical innovation take months or even years to reach patients as extra bureaucracy shifts management's focus to in-house processes. This takes precious time and, ultimately, slows down organizations from providing patients with what they urgently need: treatment options that are quickly available, innovative, or scientifically advanced.

Rethinking the development process

Greater awareness about complexity when dealing with internal processes and regulations can help reduce unnecessary complexity. Clear and continuous risk assessments must go hand in hand with the desire to make decision-making processes more effective. Ultimately, outcomes will be more successful when several clinical development scenarios for novel therapies are simulated early in the process and the organization focuses on optimizing for speed and efficiency.

However, progress in emerging yet poorly researched and complex areas, such as cell and gene therapy, inherently spawns new regulations on clinical trials in particular and not just across domestic borders. All parties—government authorities, medical investigators, and research-based pharmaceutical companies—need to join forces to identify an area to do battle together. There's plenty of debate on this subject, but few answers.

Bayer Pharma's future portfolio concentrates heavily on personalized medicine and cell and gene therapies. Alongside knowledge of the therapeutic area concerned, these approaches and mechanisms require in-depth scientific understanding to make new and suitable therapies possible in the first place. Getting these new therapies through clinical development in a less complex way requires companies to step up in establishing close-knit networks of scientists and clinical investigators. Integrated clinical approaches that incorporate clinical data and patient requirements into the design of clinical trials are a must. This is the only way to save time and accelerate the approval of innovative new therapies.

Conclusion

To reach new therapy destinations quickly and successfully, we need to depart from well-trodden paths and set out on new ones. Processes need simplifying and rejigging; internal rules and decision-making channels need to be questioned and simplified. It's vital to integrate all players and combine internal and external expertise in therapy development. Our medical and scientific experts need to interact more, and new technologies need to be applied to achieve new results more quickly.

This would allow pharmaceutical companies employees to depart from traditional paths and branch out into uncharted territory. They could adopt new mindsets, work more flexibly, review existing responsibilities, and take on new ones to develop therapies faster.

At the end of the day, all of this would mean putting a greater focus on clinical development goals for those that matter most: our patients.

All parties need to join forces to identify an area to do battle together.

Patient-centric approaches in clinical trials: no longer data subjects, but collaborators

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Given the rising complexity of the healthcare sector, research-based pharmaceutical manufacturers need to explore new avenues. One increasingly popular method is to include customers—the patients—and their needs at early stages of clinical trial development. Roche demonstrates how consistent and early engagement of patients leads to better quality clinical research outcomes and faster and broader market launches.

A patient-inclusive approach has enormous potential at various phases of drug development.

Why is engaging patients in the initial stages of clinical trials important?

Clinical trials underpin medical progress by evaluating the safety and effectiveness of new treatments and are the basis for drug approvals. Patients do derive direct benefit from participating in clinical trials as they receive in-depth medical care and innovative treatment options early on. However, 80 percent of trials are completed later than expected,¹ and trial results are often not fully representative of the real world.² Unfortunately, patients' willingness to participate in trials has sunk to below 50 percent.³ Meanwhile, research-based pharmaceutical manufacturers are encouraging faster research and development of innovative therapies, thanks in part to data and artificial intelligence. Of the 5,000 to 10,000 substances produced and investigated by researchers, an average of only nine make it to the first clinical trials with humans, of which only one medication actually reaches the market. The pressure from organizations and those footing the bill to verify cost effectiveness is growing. More than half of market launches have underperformed in the past three years,⁴ while the pharmaceutical sector's spending on research and development in Europe is estimated at around €44.5 billion per year.⁵

Patient centricity in clinical trials is a core approach in this respect. Tailoring trials to patient needs has led to better recruitment results, a greater willingness to take part, improved adherence to trial protocols, and, ultimately, better treatment results and patient satisfaction. From an economic perspective, a patient-inclusive approach has enormous potential at various phases of drug development. It accelerates recruitment by three months on average,⁶ improves launch probability by 20 percent,⁷ and increases the net present value following market launch by an average of \$25 million.⁸ Patient focus makes clinical research faster and more successful.

Regulatory authorities such as the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) have also upped their collaboration with patients.^{9,10} Health technology assessment (HTA) bodies, responsible for pricing and reimbursement of medicines and healthcare technologies in a particular country, are creating opportunities for patient involvement at various stages in the process worldwide.¹¹ This institutional support underscores the relevance of patient centricity in medical research today.

¹ Clinical Trials ARENA Clinical Trial Delays: America's Patient Recruitment Dilemma. 2012. Jul 18. Available from: <https://www.clinicaltrialsarena.com/buyers-guide/clinical-trial-patient-recruitment-companies/>

² [https://www.sciencedirect.com/science/article/pii/S0092867419310025#:~:text=A%20disproportionate%20majority%20\(%3E78%25\),United%20Kingdom%2C%20and%20Iceland%20\(Mills](https://www.sciencedirect.com/science/article/pii/S0092867419310025#:~:text=A%20disproportionate%20majority%20(%3E78%25),United%20Kingdom%2C%20and%20Iceland%20(Mills) [78% of participants in GWAS are of European descent]

³ <https://www.centerwatch.com/articles/24924-patient-willingness-to-join-clinical-trials-drops-dramatically-new-data-show> [Historical trends have been roughly around 85 percent, with a steep drop in 2020 in 49] <https://pharmaintelligence.informa.com/resources/product-content/2021-clinical-development-success-rates> [The current success rate of a drug candidate, from the beginning of the clinical trial to receiving marketing approval, is about 10%–20%, and it has not changed during the past few decades]

⁴ <https://de.statista.com/statistik/daten/studie/70870/umfrage/pharmaindustrie-ausgaben-fuer-forschung-und-entwicklung/#:~:text=Ausgaben%20f%C3%BCr%20Forschung%20und%20Entwicklung%20der%20europ%C3%A4ischen%20Pharmaindustrie%20bis%202022&text=Die%20Statistik%20zeigt%20die%20Ausgaben,rund%2044%2C5%20Milliarden%20Euro>

⁵ Economist Intelligence Unit. The Innovation Imperative: The Future of Drug Development, 2018.

⁶ Economist Intelligence Unit. The Innovation Imperative: The Future of Drug Development, 2018.

⁷ Levitan B, et al. Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI's Patient Groups and Clinical Trials Project. *Ther Innov Regul Sci*. 2018 Mar;52(2):220-229. doi: 10.1177/2168479017716715. Epub

⁸ Levitan B, et al. Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI's Patient Groups and Clinical Trials Project. *Ther Innov Regul Sci*. 2018 Mar;52(2):220-229. doi: 10.1177/2168479017716715. Epub 2017 Jul 17. PMID: 29714515; PMCID: PMC5933599. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5933599/>

⁹ <https://www.nature.com/articles/d41573-019-00164-y>

¹⁰ <https://www.fda.gov/patients/learn-about-fda-patient-engagement/fda-and-european-medicines-agency-patient-engagement-cluster> <https://www.ema.europa.eu/en/news/ema-fda-reinforce-collaboration-patient-engagement>

¹¹ https://partners4access.com/wp-content/uploads/2021/01/ISPOR-poster-PDF_FINAL_28th-January-2021-3.pdf and <https://onlinelibrary.wiley.com/doi/full/10.1111/hex.13191>

What form does patient focus in clinical trials at Roche take?

At Roche, our credo is “doing now what patients need next.” Consequently, we engage with patients systematically at an early stage of trial planning (see figure).

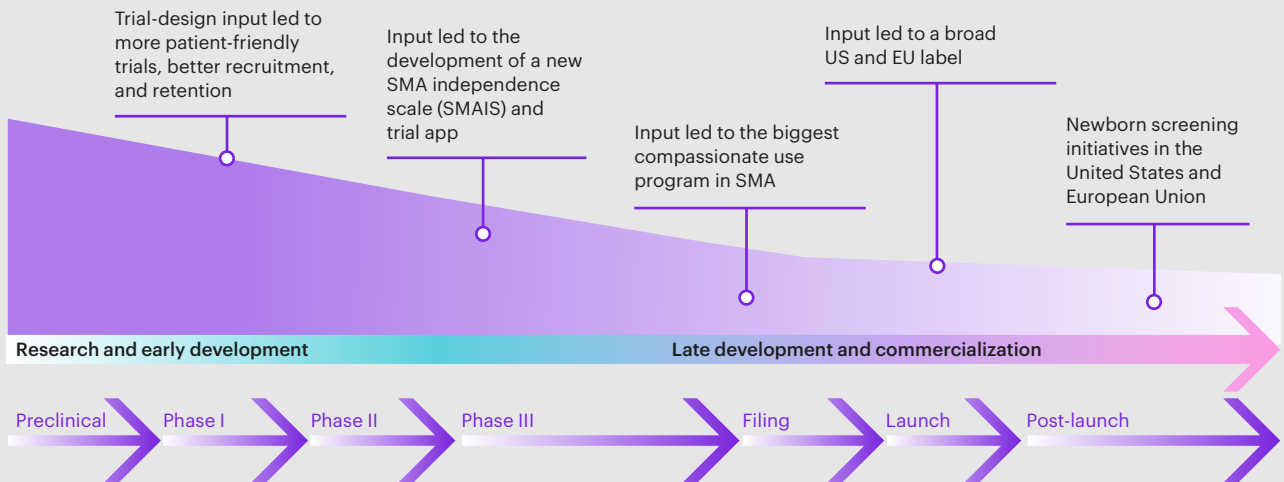
Roche collaborates with patient representatives to define the research objective, select the right clinical endpoints, and design how the trial is carried out. This helps us ensure that trial results faithfully reflect the reality of patient care. Consequently, Roche aims to incorporate patient opinions from phase 1 of all clinical programs. In Germany, for example, this means Roche puts patient representatives in touch with opinion leaders from the medical profession and the Roche’s global trial teams at an early stage. As a result, this ensures that the German healthcare market’s requirements are also brought to bear. Roche also includes patient representatives in designing and communicating national trials, often observational studies following market approval.

Roche is also very keen to improve communications between researchers and patients. The company is focusing on co-created informed patient consent to trials along with innovative technologies such as mobile apps, wearables, and online platforms to improve the flow of information through the trial. For years, Roche has also been sharing information about all recruiting studies and the results of completed trials transparently with patients, relatives, and the public in layman’s terms via the ForPatients.com platform (klinische-studien-fuer-patienten.de in Germany). Patients are always kept informed about the progress and results of trials and can be involved in decisions that affect their participation.

Roche engages with patients systematically at an early stage of trial planning.

Figure

Early and systematic patient involvement in clinical trials adds value



“We have the feeling that this is a molecule that was developed by patients, with patients, and for patients.”
— SMA Europe

Sources: Roche Pharma; Kearney analysis

We talk with patient organizations and patients themselves from the get-go. As a result, we gain valuable insights into the day-to-day lives of patients and can reflect their concerns and priorities adequately. To ensure interaction isn't just ad hoc, Roche relies on advisories and steering committees worldwide. It wants to ensure that both the perspective of the care provider and the patient are reflected in the design and implementation of the trial and materials. This approach is both global and local to embrace the specific needs and priorities of patients in each market in the best possible way. To systematically track the patient benefit and societal impact of activities, Roche has developed a standardized framework called the Patient Benefit and Societal Impact Model (PBSI). The model covers various aspects such as diseases and treatment, influence on the patient pathway in care, health-related quality of life, patient empowerment, and the commercial and societal impact of activities.

Patient involvement exemplified by spinal muscular atrophy¹²

An example of patient involvement across the full product life cycle at Roche is the development of a product for spinal muscular atrophy (SMA), a rare genetic neuromuscular disease. When it comes to living with the disease, people with SMA and their relatives are the experts. A trial steering committee and specific working groups ensured that the perspectives of those affected played a role in decisions made about the clinical development program of the drug. The SMA Foundation (a permanent member of the steering committee), SMA Europe, and Cure SMA provided input on all components of the Roche-sponsored SMA trials from the outset. This included defining research priorities, contributing to trial protocols, and reviewing consent forms, assessment methods, and support materials for affected families. Their feedback led to the development of seamless phase II/III trials (combining phases II and III into one continuous trial), incorporating broader inclusion and less restrictive exclusion criteria, and reducing the burden on patients and their families. Findings from qualitative interviews with SMA patients and caregivers helped to select and develop patient-relevant trial endpoints, for example, to develop the SMA independence scale, a new scale to assess the need for support during everyday life. The patient organizations facilitated participation in and recruitment to the pivotal trials by helping families relocate to places running trials in other countries. During the COVID-19 pandemic, good liaison allowed measures, such as home delivery of medication and home care services, to be put into place and enable trials to continue despite restrictions.

However, early patient involvement is not only vital for the development program. Frequent input from patient organizations helps make it easier to understand healthcare in the real world and to develop joint solutions for approval applications and negotiations with organizations footing the bill.

What do these findings mean for other players?

By more clearly understanding our customers (people with a disease and their families) and focusing our research and development on their needs, we can make better products more quickly that transform patients' lives. This customer-driven approach can create added value in other sectors too. Roche is demonstrating how consistent and early engagement of patients in clinical trials leads to better quality research outcomes and faster and broader market launches with satisfied customers.

What's the next-level ambition? To boost patients' rights when decisions are made, such as reimbursing the costs of medication or treatment options, our goal is to take a patient-centric approach throughout the healthcare system. We want genuine examples of healthcare in the real world to be taken into account, a reduction in bureaucracy, and patient-relevant endpoints to gain importance.

“We're proud of the role we've played in the development of Risdiplam and our partnership with Roche. It's crucial that we continue to work with health authorities, regulators, and industry to ensure patients have access to the treatments they urgently need.”

Dr. Nicole Gusset, president of SMA Europe

¹² Patient involvement in the development, regulation and safe use of medicines Report of the CIOMS Working Group XI Council for International Organizations of Medical Sciences (CIOMS), Geneva 2022, <https://cioms.ch/publications/product/patient-involvement/>

Ready, steady, go! Winning the clinical development race

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As a leading global pharmaceutical company, Boehringer Ingelheim has always taken an integrated approach to speed up clinical development and rapidly provide patients with innovative medication. To do so, the company reorganized its infrastructure and collaborations. Better conditions for clinical research and reimbursement are essential to provide innovative therapies to patients as early as possible.

A continuous stream of innovation has enabled disease prevention, improved patients' quality of life, and reduced mortality. Research and development typically occurs in a fiercely competitive, global environment where health policies, commercial, regulatory, medical, and ethical requirements are in a state of flux. Successful development is quantified by the added value to patients, development costs, cost-effectiveness to the healthcare system, and the time taken to develop the product and bring it to the market.

A continuous stream of innovation has enabled disease prevention, improved patients' quality of life, and reduced mortality.

Boehringer Ingelheim has expedited the clinical development time of innovative medicines, which takes an on average of 11 years to reach approval. Since 2021, the company has drastically reduced the time by 12 months through the following measures:

- Establishing and empowering agile asset teams to make quick decisions on development strategies
- Creating a data structure to enable selection of the best countries with rapid interaction with authorities and trial centers that offer high-quality and efficient infrastructure
- Building a standardized IT system landscape that allows for trial planning, execution, and submission all the way to optimizing an end-to-end flow of data
- Close collaboration with patient representatives and trial centers to plan and carry out trials

Rethinking the development process

It is essential to effectively consider current and future patient needs as well as requirements and expectations of health authorities and those paying the costs of innovative therapies early.

From 2025, the European Health Technology Assessment (EU-HTA) will come into play. Manufacturers will have to submit an additional dossier for the EU-HTA and thus need to initiate associated groundwork earlier. Further analysis by Germany's Federal Joint Committee (Gemeinsamer Bundesausschuss) need to be expected and European and domestic dossier need close coordination and alignment. Swift consultation with domestic HTA agencies is critical because they define the requirements of the clinical EU assessment. Both processes will require more resources in the short to mid-term. Harmonizing national and European requirements could get innovative medicines to patients in Europe faster, as trials are planned and conducted globally.

A positive outlook for clinical research in Germany

Unfortunately, Germany has slipped from second to seventh place in the international clinical research ranking, with decreasing per capita trial participation and fewer early trial phases. Germany's new Medical Research Act is currently undergoing the legislative process with its purpose to eliminate the national roadblocks that a recent Kearney report¹ identified and to harmonize with European countries in terms of clinical trial approval.

The hopes and promises are that principal investigators will be able to use social media and online recruitment platforms to enroll suitable patients in trials, that patients will be able to use online tools to find suitable trials and trial centers, and that investigators are better able to identify trial participants in their clinical networks, such as through electronic health records.

Early, close collaboration is key to success

Within the boundaries of a pharma company, strategic and timely collaboration between clinical development and medical affairs departments is an essential success factor. By leveraging existing relationships and creating synergistic insights on clinical scientists and clinical sites, the process of selecting the right centers for conducting clinical trials can be a lot more effective. If medical investigators, patient representatives and the pharmaceutical company liaise, they can enable patient-centric trial planning and implementation.

When clinical development and medical affairs departments work hand in hand, they can optimize stakeholder support throughout the life cycle of a therapeutic product, which in turn minimizes disruption in patient care. In an era where the pharmaceutical sector is facing constant change and rising competition, this type of collaboration is integral to the clinical development race.

¹ Philipp et al. (2023). Pharma-Innovationsstandort Deutschland. Kearney/VFA, www.de.kearney.com

Why Germany is indispensable as a pharmaceutical innovations hub

Author



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The German pharmaceutical research landscape is known for its vast range of medical disciplines and technological expertise. Every year, the country's research-based companies spend more than €9.4 billion on research and development. Nevertheless, it's still not exploiting its full potential, especially in terms of clinical pharmaceutical trials. However, to overcome some of the underlying handicaps, a political solution is currently underway.

How we got to where we are today

When it comes to developing new drugs, after the United States and China, Europe is the third biggest region worldwide. Germany is partly responsible for this ranking. Between 1970 and 2000, the focus was on cardiovascular, blood pressure and diabetes medications, antibiotics, and hormonal contraceptives. This changed fundamentally in the years that followed. Oncology became increasingly important and is now the number one R&D area. The development of therapeutic products to combat autoimmune and neurodegenerative diseases as well as vaccines for infectious diseases has also increased. Continuity is evident in heart diseases, for which new drugs from Germany have repeatedly received approvals or extensions.

German pharmaceutical labs pioneered the development of direct oral anticoagulants and specific antibodies for oncology as well as SGLT2 inhibitors, which were first widely used for type 2 diabetes and then also for heart failure. The range of research-based pharmaceutical companies in Germany has also changed markedly. Until the dawn of the millennium, pharmaceutical research was primarily carried out by larger companies, mostly headquartered in Germany. Nowadays, numerous players headquartered outside Germany (the United States, United Kingdom, France, Japan, Denmark, and Switzerland) also have research labs in Germany, and a significant level of pharmaceutical research is carried out by biotechs and mid-sized companies.

Strengths of Germany as a pharmaceutical innovation hub

Today, the German pharmaceutical research landscape has a wide variety of medical fields and technological expertise. The country has professional research institutes and pharma companies focused on chemically synthesized, biopharmaceutical or RNA-based active ingredients, vector viruses or cells (see figure 1). Germany also excels in the emerging field of RNA-based drugs, which have become particularly well known thanks to the first two mRNA-based coronavirus vaccines, one of which stemmed from Germany (see figure 2 on page 17).

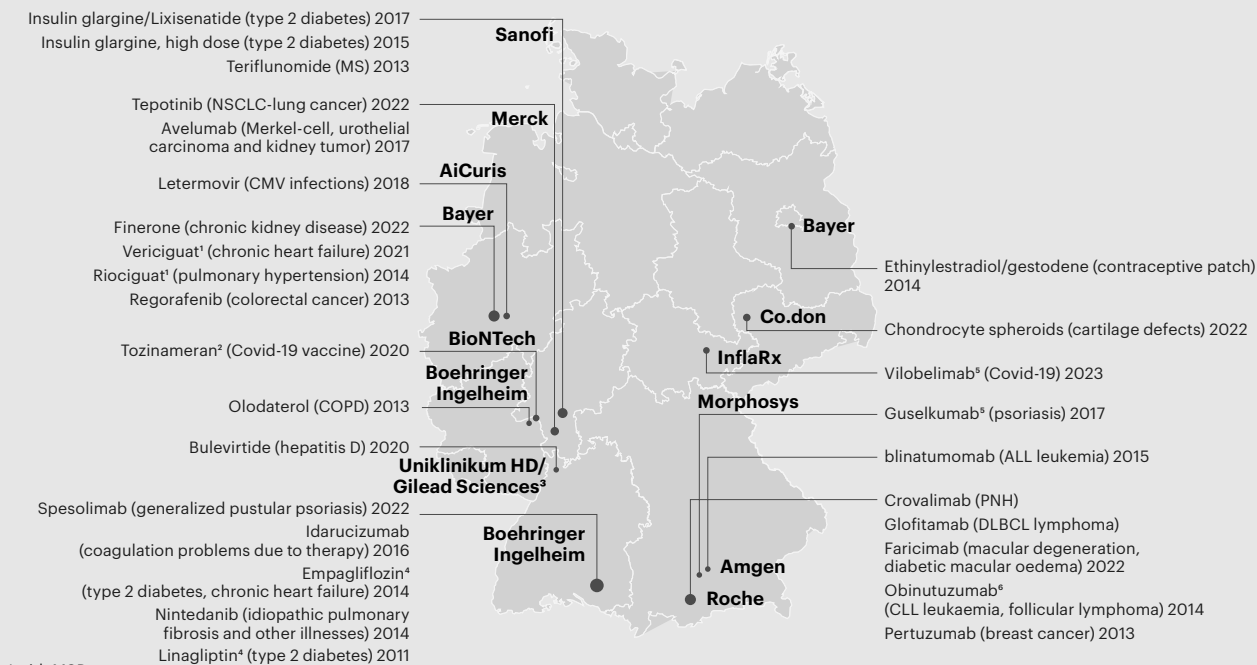
According to the Stifterverband, a German non-profit association, the annual R&D spend of pharmaceutical and biotech companies in Germany as of 2022 totaled €9.4 billion—€38 million per working day. European companies only spend similar amounts in Switzerland.

Many companies see their well-trained, dedicated employees as important assets of their German subsidiaries. In 2021, around 25,000 of them were in research and development; a roughly equal proportion of men and women worked in academic and technical professions.

Germany also stands apart for its vast network of excellent faculties at higher-ed colleges and universities of applied sciences. It also has a whole host of non-university research institutions such as the Max Planck, Leibniz and Fraunhofer Institutes, and Helmholtz Centers. In Germany, medical expertise is also bundled via the Competence Networks in Medicine, in which doctors research diseases such as sepsis or pediatric cancer across various organizations. Since 2009, six German centers for health research and a research network have been added, which aim to find new prevention and treatment options for common diseases.

Figure 1

Medicines with active ingredients that were largely developed in Germany, from 2011 onward



¹ with MSD

² with Pfizer

³ previously Myr Pharmaceuticas

⁴ with Lilly

⁵ with Janssen

⁶ Development started in Switzerland

Note: The names of the active ingredients, the indications, and the year of the first international market launch are listed for all medicines, as of June 2024.

Sources: Association of Research-based Pharmaceutical Industry in Germany (VFA); Kearney analysis

Roadblocks and how they are tackled

Despite so much in its favor and all the success stories, it's impossible to ignore that Germany's still not reaching its potential as a pharmaceutical R&D hub.

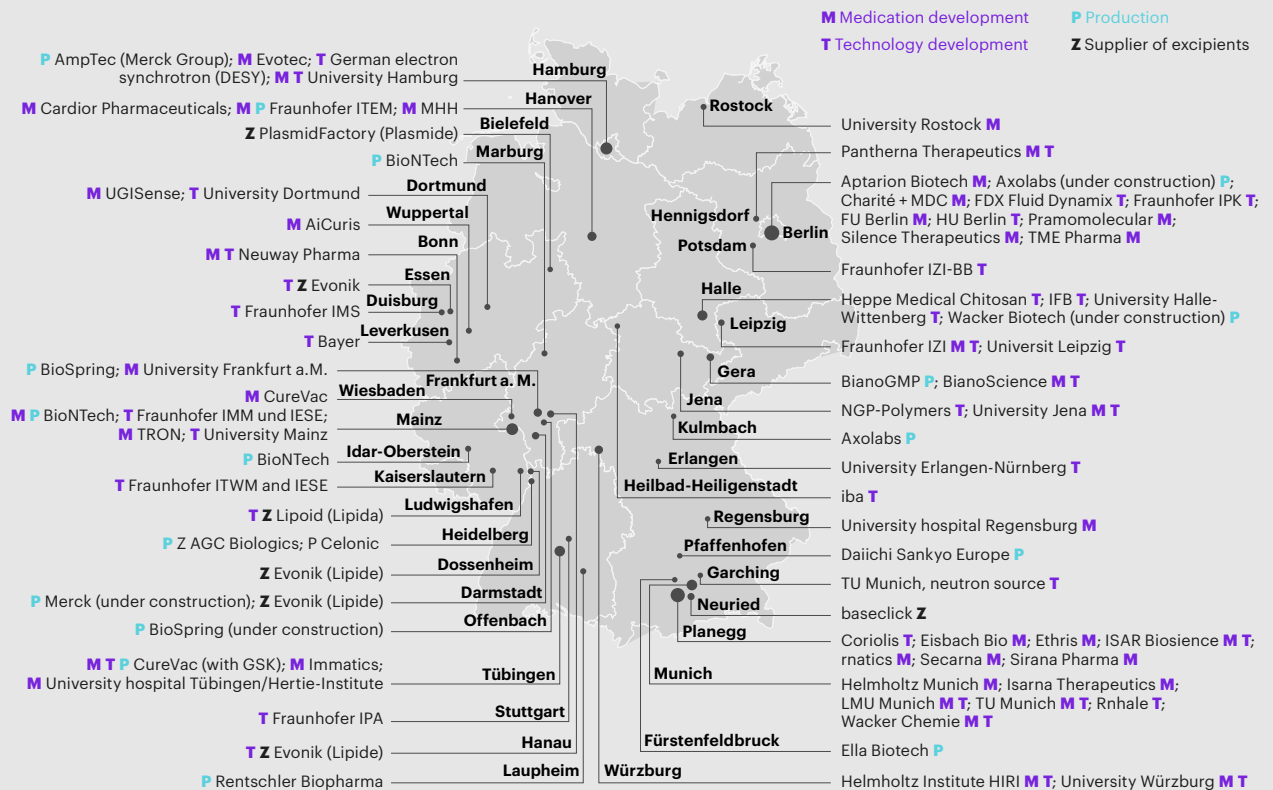
Start-ups are all too rarely founded in the wake of groundbreaking basic research that subsequently spawns the development of approved and marketable medication. Several studies, most recently Pharma-Innovationsstandort Deutschland (2023)¹ by the VFA and Kearney have shown that poor access to venture capital and excessive bureaucracy are the main roadblocks. Nevertheless, the success of the German-American mRNA vaccine against COVID-19 appears to have renewed investors' confidence in German pharmaceutical research.

On the other hand, a 2023 study by the Fraunhofer Institute ISI confirmed Germany's broad expertise in drug development. However, it also emphasized that the country's competing with other nations in key fields of technology, each of which has achieved a higher degree of sovereignty in these fields.

Over the past few years, Germany has also fallen behind when it comes to hospitals and medical practices participating in clinical trials of drugs. This area is just as crucial to companies as it is to patients. But, at 641 trials, Germany was still number two worldwide behind the United States until 2016. In 2022, the country was only involved in 524 trials. In 2023, there were probably even fewer, and Germany was overtaken by at least four other countries. A comparison of countries in the VFA/Kearney study¹ shows just how far behind Germany is. In Denmark, 29,300 people per million take part in drug trials, but in Germany, the figure is a paltry 1,500. The two nations are worlds apart in this respect.

¹ Philipp et al. (2023). Pharma-Innovationsstandort Deutschland. Kearney/VFA, www.de.kearney.com

Figure 2
German sites for RNA-based vaccines and therapeutic drugs



Sources: Association of Research-based Pharmaceutical Industry in Germany (VFA); Kearney analysis

This may seem surprising at first glance, as Germany has efficient hospitals with medical expertise and high levels of care in data collation that pharmaceutical companies frequently praise. However, the speed at which it can obtain approvals, clarify data protection issues, and sign contracts with hospitals is just as important to pharma. The option of using anonymized health data from the population for trial planning also plays a role. Many other countries are far better positioned to do so.

Fortunately, in 2023, the German government realized that it had to legislate to improve the situation. For example, the recently passed Health Data Utilization Act makes it easier for companies to access anonymized health data. And the purpose of the upcoming Medical Research Act (MFG) is to remove some of the barriers to approval procedures and contract negotiations for clinical drug trials. The bill is a step in the right direction but will not suffice to return Germany to the international top group. To do so requires a fundamental turnaround supported by many stakeholders. A good example is Spain, which has been the European champion in the industry's clinical trials league for several years. The 2022 austerity act impaired marketing conditions for medications in Germany. It's another roadblock that needs to be eliminated. Companies were used to being the first to supply newly approved drugs in Germany. They will now have to reevaluate their position, at least for some new products anyway. Because undervaluing the medication's benefits and risking inappropriately low reimbursement from German healthcare insurers will attract attention beyond Germany's borders. This will also cause ripples when German hospitals decide in favor of, or against, participating in clinical trials.

Pharma's counting on Germany because Germany's counting on pharma

Despite the difficult market conditions in some areas, research-based pharmaceutical companies are again increasingly focusing on Germany as a location for major investments. Several corporations in Germany are planning to set up state-of-the-art production capacities for cancer and obesity drugs, for instance. Others are freeing up new lab capacities for research into biopharmaceuticals as well as chemically synthesized and RNA-based drugs and gene therapies. Consequently, companies are showing faith in the German government's apparent intention to recognize the pharmaceutical industry as a leading industry in the country's future. After all, this industry is made for the job because it creates exceptional value, sought-after export goods, and highly qualified jobs without guzzling huge quantities of energy.

Research-based pharma companies focusing on Germany as a location for major investments.

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