



How Germany can become a hotbed for pharmaceutical innovation once again

Executive summary

Collaboration among government agencies, the healthcare system, and pharma companies can cut the red tape and restore Germany as an attractive location for cutting-edge clinical trials.

International competition for investment in pharmaceutical research and development (R&D) has increased enormously, fueled largely by influences from the COVID-19 pandemic and geopolitical trends. As a result, pharma companies are in a heated race for market approval of innovative therapies and are evaluating local political conditions more closely than ever to optimize their investment and resource allocation.

While Germany, as a pharmaceutical market, is still attractive, it has been losing ground dramatically for several years—both globally and to other European countries. The mood among pharma companies' R&D executives reveals how serious the situation is: around two-thirds of such leaders confirm that Germany could become significantly less relevant for their companies in the next five years, according to a recent study conducted by Kearney and Verband Forschender Arzneimittelhersteller e.V. (vfa).

An ominous combination of events has led to this point. First, the regulations on market access, pricing, protection of intellectual property, and reimbursement have been tightened by the Statutory Health Insurance-Financial Stabilization Act (GKV-FinStG) and the upcoming EU pharmaceuticals package. Second, the attractiveness of conditions affecting Germany's research framework has declined.

If decisive action is not taken now, up to 40 percent of patients in Germany, who are currently participating in clinical trials, risk losing early access to innovative, not-yet-approved therapeutic options by 2030. Reversing this trend would have a positive impact on overall healthcare in the country: participating professionals in clinics and medical research would continue familiarizing themselves with the medicine of tomorrow, patients would have additional opportunities for effective treatment and the best care, and pharma companies would bring new medicines to the German market more quickly.

It is, therefore, in everyone's best interest to ensure the country regains its full strength as a location for pharmaceutical innovation.

The current picture: too much bureaucracy and overly long processes

The pace at which clinical research can be approved and conducted in Germany is slowing to a counterproductive level. It is impacted by inconsistent and overly bureaucratic approval procedures (such as having a separate authorization process for radiation protection). Complex contractual arrangements between clinics or medical practices (including trial centers) and pharmaceutical companies are also slowing clinical trials. This often leads to an excessively long delay before the first participants can be enrolled.

It is important to understand that big pharma companies cannot afford to delay completion of their clinical research programs because they are competing for first approval of medicines in a new class (known as first-in-class medicines) for large markets, including the United States and European Union. For young companies just developing their first product, a delay in clinical research could threaten their existence.

For these reasons, Germany risks losing the advantages of being a desirable country for trial participation conducted by pharmaceutical companies—with patients and medical centers in Germany already being left behind during international trial recruitment. Combined with increasingly unattractive market conditions, we fear Germany will be considered for even fewer trials or none at all as companies seek to place them and eventual product launches in countries with more attractive conditions.

Other countries can offer inspiration and great ideas

There are countries that have created pro-innovation research conditions leading to more health-related opportunities for their people. France and Spain have successfully improved their own research environments by adopting targeted measures that smooth contract negotiations and strengthen on-site resources. Other countries, such as Denmark, support innovative trial models and motivate patients to participate.

We believe Germany could learn from these approaches and benefit from similar measures.

Actions Germany can take to attract more pharmaceutical innovation

The Kearney-vfa study lays out how Germany can attract and retain more pharmaceutical innovation by addressing three key areas:

1. Allow medical research to again be carried out at a competitive pace.
2. Give pharma companies better access to research and patient data.
3. Strengthen the process for translating basic research findings into preventive and therapeutic options for maximum impact.

Within these areas, Kearney and vfa have identified seven fields of action where Germany can take steps to strengthen pharmaceutical innovation for its people:

1. Systematically reduce bureaucracy related to trial approvals.
2. Simplify contracting between medical institutions and trial sponsors.
3. Accelerate trial implementation by increasing the number of related specialists and improving patient recruitment.
4. Contribute to the collection of international medical research and patient data.
5. Enable and simplify data access for industrial research.
6. Promote excellence in science.
7. Strengthen networking and translational focus.

Using the power of collaboration

Kearney and vfa ultimately found that a collaborative roundtable or panel coordinated by the Federal Ministry of Health (Bundesministerium für Gesundheit) could be one of the most effective ways that Germany can regain and elevate its status as a prime location for pharmaceutical innovation in the world. This new body would define and drive the ambition, strategy, and a concrete implementation plan via joint dialog with relevant stakeholders to help the country reach its goal. The roundtable would enable regular exchange and consistently monitor whether measures are implemented and ambitions are achieved. This approach has already proven successful for Spain, which used it to become the top clinical research location in the EU.

Germany can determine its pharma-trial future

Change—positive or negative—usually happens in increments. For Germany, finding a way to reverse conditions that have, step by step, made it a less attractive place for pharma companies to conduct clinical trials would not only change the healthcare prospects for the country for the better, but more profoundly, open new windows to better health for its people now and in the future. Reversing the spiral from downward to the higher ideals reached through a collaborative approach could make Germany the next model for dynamic cooperation between pharma, a country, and its healthcare.

Figure

Seven fields of action to strengthen pharmaceutical innovation

Key area	Field of action	Measure
Increase the speed of clinical trials	I. Systematically reduce bureaucracy related to trial approvals	Clarify and simplify ethics committee requirements. Better guide applicants and present requirements for decisions in a transparent and comprehensible manner.
		Make data protection guidelines for clinical trials consistent nationwide. Create clear guidelines for applicants and ethics committees. Bundle responsibilities, grouping them, for example, with a federal agency to ensure the guidelines for clinical trials are interpreted and applied uniformly.
		Integrate the approval process for radiation protection at the Federal Office for Radiation Protection (BfS) with a federal authority, such as Federal Institute for Drugs and Medical Devices (BfArM) or Paul-Ehrlich-Institut (PEI), as part of the regular approval process. Equip federal authorities with additional personnel for this purpose. Alternatively, the BfS procedure for all trials could be integrated into the Clinical Trials Information System/EU Clinical Trials Register (CTIS/EU-CTR) procedure.
		Deadlines for approval of phase 1 trials, according to EU-CTR, must be shortened to days (cf. Belgium or Germany under the old AMG). PEI and BfArM, as well as ethics committees, must be equipped with additional staff for this purpose. More flexibility could be achieved by making the processes at the higher federal authorities and ethics committees more efficient.
		The approval process according to the Medicinal Products Act (AMG) and Medical Devices Act (MPG) for medicine and medical device combinations should, as far as possible for the German legislature, be standardized and brought together in a coordinated approval process. In addition, Germany should lobby for changes in this area at the EU level.
		Create a legal framework for conducting decentralized or hybrid clinical trials. Expand the use of digital technologies (such as wearables) and train relevant specialist personnel for clinics, universities, and industry.
	II. Simplify contracting between medical institutions and trial sponsors	Standardize model contracts and recommendations for trial sponsors and centers. If this is not successful, legal requirements, following the example of France, should set binding contractual standards.
		Make standards for trial compensation consistent. The basis for this should be transparent and regularly updated price catalogs based on the principle of "performance and compensation," which, following France's example, could be jointly developed by a commission of stakeholders under the coordination of the BMG or the BMBF.
		Standardize contracts between sponsors and centers, based on the principle "one trial, one center, one contract." Separate contracts, with radiology or pharmacy, for example, should be explicitly excluded by the participating physician practices or clinics. In addition, medical practices and clinics should be able to form a network and act as one trial center within the framework of clinical trials.
	III. Accelerate trial implementation by increasing the number of trial specialists and improving patient recruitment	Create additional dedicated positions at university hospitals for conducting clinical trials, financing them through the Federal Ministry of Education and Research (BMBF) or federal states.
		Address the shortage of skilled professionals through measures such as increased support for medical training or recruitment of more professionals. Offer attractive career options and education and training offers for scientific staff, with a required focus on clinical trials.
		Secure and expand the trial infrastructure in clinics and practices, and use a clear strategy for integrating trials into everyday clinical practice (by defining clear times for research participation, for example).
		Reconsider limitation of certain activities to the medical profession only and expand the competency profile of study nurses. At the same time, ensure the safety of trial participants and the quality of trial conduct.
		Have commercial and academic trial organizers establish a central trial registry that includes contact addresses. It should create transparency for the trial population and the medical profession about ongoing trials in Germany. In addition, trial participants must be provided with basic information about the benefits and risks of being in a trial by an oversight agency, such as the Federal Centre for Health Education (BZgA).
	Connect to modern standards for research data	IV. Contribute to the collection of international medical research and patient data
Establish a sustainable system for registry studies that supports the centralized preparation of health data for research purposes. To this end, existing registries should be made usable and linkable, for example through the use of a research pseudonym.		
V. Enable and simplify data access for industrial research		The exchange of standardized data, which was initiated as part of the medical informatics initiative through the creation of data platforms at university hospitals, must be further promoted, extending it to hospital groups or physicians in private practice, for example. Consider issues regarding international connectivity.
		Establish and secure a research data center, which should have effective governance and a sufficiently specialized staff. Industrial researchers should have equal access to health data and the research data center.
Strengthen R&D ecosystem for more translation	VI. Promote excellence in science	Allocate and target funding according to excellence and translation. Consistently monitor success. Decisions should be made by a broad, international panel of experts.
		Strengthen and promote cooperation between research institutions and clusters of excellence.
	VII. Strengthen networking and translational focus	Bolster science–industry cooperation, in particular by promoting innovation clusters, exchange of ideas (such as the permeability of training and employment systems between academia and industry), and networking among research, physicians, and science. Promote spin-offs more strongly (through simplified access to venture capital, for example).
		Bundle resources for tech transfer across non-university and university research, including the creation of a central point of contact (a one-stop store).
Pursue a holistic strategy	Form a panel to strengthen pharmaceutical R&D in Germany	Form a roundtable or panel that focuses on Germany as a trial location, coordinated by the BMG, and with involvement of all relevant stakeholders, to develop an overarching strategy for addressing existing problems. Then create and implement a plan to identify measures and consistently monitor success.

Sources: Verband Forschender Arzneimittelhersteller e.V.; Kearney analysis

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About Verband Forschender Arzneimittelhersteller e.V. (vfa)

The vfa is the association of research-based pharmaceutical companies in Germany. The association represents the interests of 48 of the world's leading research-based pharmaceutical companies and over 100 subsidiaries and affiliates in healthcare, research, and economic policy in Germany.

The member companies represent more than two-thirds of the entire German pharmaceutical market and employ approximately 94,000 highly qualified people in Germany. They ensure therapeutic progress in pharmaceuticals and safeguard the high standards of medicine therapy. Around 21,000 of their employees contribute to research and development of innovative medicines. In Germany alone, research-based pharmaceutical companies invest 8.7 billion euros annually in medicine research for new medicines to allow patients to lead a better life.

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