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Clinical Research in Germany:

What Still Needs to Be Done After the **Medical Research Act**

Opinion Paper

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Title
Clinical Research in Germany:
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Authors
Ann-Kathrin Klähn, Project Manager, inav GmbH, klaehn@inav-berlin.de
Dr. Christoph Bischoff-Everding, Senior Consultant
Dr. Malte Haring, Managing Director, inav GmbH

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inav – Private Institute for Applied Health Services Research GmbH
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Germany
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Executive Summary

Germany is among the world's leading locations for pharmaceutical research and development. Scientific excellence, a dense research landscape, and a strong industrial base provide excellent conditions for conducting clinical research at a premier level internationally. At the same time, developments in recent years have shown that adjustments are needed to make even more targeted and sustainable use of this potential.

The Medical Research Act (Medizinforschungsgesetz – MFG), adopted in July 2024, represents an important milestone in making clinical research in Germany more modern, efficient, and practice-oriented. Its aim is to simplify processes, advance digitalization, strengthen decentralized study structures, and thereby strengthen Germany's standing as a leading location for clinical research. Key measures include the introduction of binding standard contract clauses, the streamlining of radiation safety procedures, the authority of the Working Group of Medical Ethics Committees in the Federal Republic of Germany (AKEK) to issue binding guidelines, the option to label investigational medicinal products in English, the establishment of a specialized ethics committee for specific procedures, shortened approval timelines for mononational studies, and the implementation of electronic informed consent.

Whether the MFG can fully realize its potential depends largely on its implementation. This opinion paper provides an initial assessment of the clinical research landscape in Germany. It is based on a qualitative survey of experts from academia, industry, healthcare, and patient advocacy, and offers an evaluation of the new regulations as well as the development prospects for Germany as a research location.

The qualitative survey showed that the law is perceived as an essential basis for the future development of clinical research. Many of the approaches included are widely supported and viewed as good guidance for the future. At the same time, respondents emphasized that long-term success will largely depend on how consistently and practically the law is implemented. In addition, further political action is required, which must be promptly carried out by the legislator. The goal must be to achieve a comprehensive reform of the conditions for clinical research and to consistently strengthen the necessary framework.

Key Recommendations

From the experts' perspective, key recommendations to enhance the positive effects of the MFG include:

1. Strategically and sustainably embed research

The MFG should be understood as a building block of a coherent national research strategy. A binding roadmap with clear objectives, milestones, and evaluation mechanisms can help establish research as an integral part of healthcare provision. This also includes embedding research culturally in medical education and training, in order to foster a research-friendly mindset in clinical practice over the long term.

2. Enhance political coordination and supportive regulatory frameworks

Cross-departmental governance is necessary to address challenges such as data protection, drug pricing, approval procedures, and digitalization in an integrated manner. Contractual and approval processes should be further standardized and harmonized to enable studies to be conducted quickly and predictably. In addition to harmonizing processes at the federal and state levels, the targeted expansion of digital infrastructures (e.g., interoperable systems, improved use of electronic health records) is also a crucial component.

3. Embed outpatient care structurally and financially

General practitioners, specialists, and nursing staff should be more actively involved in study activities. This requires targeted funding programs, central coordination units, the deployment of qualified study personnel (e.g., study nurses), and transparent compensation models. Research practice networks and professional associations should provide training opportunities to strengthen research competencies and promote patient participation. The active involvement of patients and patient organizations, for example through transparent information and early communication, can increase acceptance and willingness to participate in studies.

Background

Germany is among the world's leading locations for pharmaceutical research and development. However, a growing gap has emerged between scientific potential and its concrete implementation in application-oriented development. While other countries are systematically and comprehensively reducing regulatory barriers (e.g., through one-stop shops that allow parallel reviews), providing investment incentives, and modernizing data infrastructures, Germany is falling behind as a research location on both the global and European stages. In particular, the field of translational research often lacks structural support and more productive transitions from idea to clinical testing. As a result, clinical trials are increasingly being relocated abroad, especially to countries with more efficient procedures and less stringent regulatory frameworks. The number of clinical trials initiated in Germany is declining, both in absolute terms and relative to the population. This poses the serious risk of losing innovative capacity, with consequences for healthcare, the economy, and the country's attractiveness as a research location (Bundesregierung, 2024). Germany's former role as the "pharmacy of the world" no longer exists.

To counter this development, the Federal Government has explicitly set the goal of consolidating the pharmaceutical industry as a leading industry and a key sector of Germany's knowledge and innovation economy (Bundesregierung, 2024). In terms of revenue, Germany is the fourth-largest pharmaceutical market in the world. Accordingly, Germany not only has an interest but also a responsibility to create conditions that support both basic and applied research.

Methodology

As part of the preparation of this opinion paper, 13 interviews were conducted. The discussions focused on clinical research in Germany in general, as well as the MFG and its resulting changes. Each interview lasted approximately 30 minutes.

The interviewees included experts from, among others, the Central Research Institute of Ambulatory Health Care in Germany (ZI), the German Pharmaceutical Industry Association (BPI), Charité Research Organisation, the BAG Selbsthilfe e.V. association, the Achse e.V. association, the German Association of Research-Based Pharmaceutical Companies (vfa), the GHSG Study Center at the University Hospital Cologne, the German Cancer Society (DKG), the Association of the Scientific Medical Societies (AWMF), the University Hospital Freiburg, and various pharmaceutical companies.

This opinion paper summarizes the experts' assessments of the situation of clinical research in Germany and the MFG. In addition, opportunities, barriers, and further development needs in the field of clinical research in Germany are identified. The experts' statements were supplemented by a literature review.

One key objective is to retain the value generated from research in Germany by creating supportive conditions for innovative manufacturers. Those who conduct research, produce, and run studies in Germany create jobs, strengthen the industrial base, and ensure early access to new therapies for patients in Germany.

Against the backdrop of a global and highly dynamic competitive environment, there is urgency to strengthen clinical research in Germany, combined with moderate deregulation and greater flexibility for research-active manufacturers in pricing. A strong and dynamic research landscape generates attractive and competitively necessary therapeutic innovations. Favorable conditions would enable research-based manufacturers to bring these innovations to patients quickly and without obstacles – supporting modern health-care and facilitating market access.

The prerequisites are excellent: Germany has a dense network of university and non-university research institutions, a high level of scientific and medical expertise, a strong industrial base, and a comparatively large population for study recruitment. However, practices and structures that translate this potential into concrete study activities still need to be developed. This particularly concerns more efficient processes, reliable conditions for market access, adequate pricing for innovations, funding, and strong collaboration between policymakers, researchers, industry, and healthcare practice.

MFG: Modernizing Germany as a hub for research and pharmaceuticals

This is precisely where the pharmaceutical strategy adopted by the previous Federal Government in December 2023 comes into play. It aims to modernize Germany as a hub for research and pharmaceuticals and to provide impetus in areas where innovative capacity has so far been limited by regulatory, organizational, or financial constraints (Bundesregierung, 2024). The strategy sets out clear priorities to address deficiencies and regain international competitiveness. Within this framework, the Medical Research Act (MFG), adopted in summer 2024, was developed. The MFG offers numerous opportunities to structurally strengthen Germany as a research location and bring it closer to the international forefront. It is intended to provide key incentives for reducing bureaucracy, advancing digitalization and networking clinical trial processes, as well as to facilitate and accelerate clinical studies through improved framework conditions (Deutscher Bundestag, 2024).

Whether the MFG can fulfill this promise depends on its implementation and on whether it is possible to view the law not as a result or endpoint, but as the starting point of an evolving strategy process – aligned with the global competitive landscape – aimed at strengthening pharmaceutical research and innovative manufacturers in Germany, and to further develop it accordingly.

This opinion paper provides an assessment of the clinical research landscape in Germany, with a focus on an initial evaluation of the new regulations and the development prospects of Germany as a research location. It is based on a qualitative survey of experts from the German healthcare sector. Among those interviewed were representatives from medical societies, patient organizations, the pharmaceutical industry, clinical research, physician self-governance bodies, and university study centers.

Incentives for Medical Research

Despite a generally robust research infrastructure and political reforms such as EU Regulation 536/2014 (Clinical Trials Regulation – CTR) for clinical studies of the European Medicines Agency (EMA, 2025), Germany is increasingly losing its attractiveness as a location for clinical trials. In contrast, Spain demonstrates how successful location policy can work: it was the first EU country to implement the new regulation for clinical trials, thereby harmonizing national procedures. Through early and coordinated implementation of the CTR, investment-friendly structures, and close integration of commercial and non-commercial actors, Spain has risen to become the leading country in Europe for clinical trial initiations, with an average annual investment growth of 5.7 % between 2012 and 2022 (IQVIA, 2024).

In particular, compared with dynamically growing markets such as China and the USA, which benefit from liberal regulatory conditions, targeted support, and better access to data for patient recruitment, Germany risks falling behind not only in the European context but also on the global stage (IQVIA, 2024). Figure 1 below shows a comparison of the number of industry-sponsored studies in selected European countries between 2020 and 2024.

Germany has fallen considerably behind in the global research landscape. Although we remain one of the leading pharmaceutical markets, we conduct far fewer clinical trials than we are capable of. It is inconsistent to rely almost entirely on studies conducted in other countries.

Michael Fuchs, Head of the Study Center of the German Hodgkin Study Group (GHSG), University Hospital Cologne

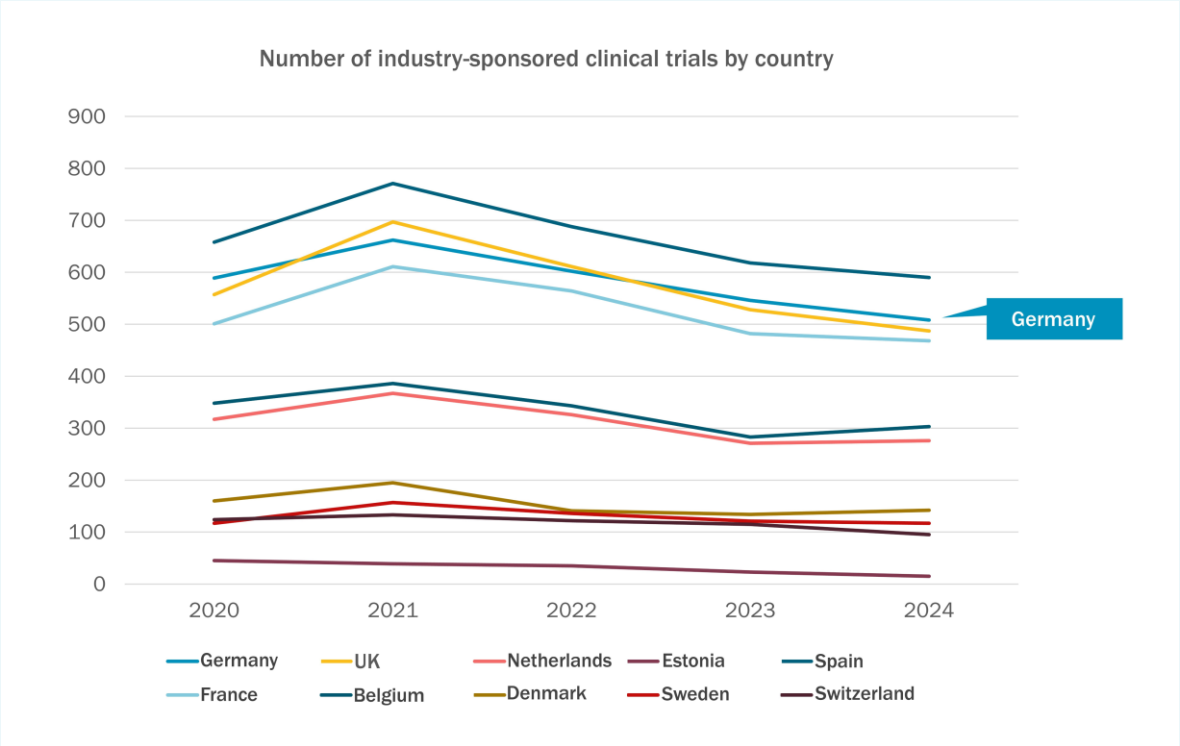


Fig. 1: Number of industry-sponsored clinical trials in selected European countries.
Source: inav, based on clinicaltrials.gov, as of 18 July 2025. The search on ClinicalTrials.gov was conducted using the following criteria: Study Type: Interventional Studies, Phase: Early Phase 1, Phase 1, Phase 2, Phase 3, Phase 4, Funder Type: Industry, Study Start from 01/01/[respective year] to 12/31/[respective year], and the respective country.

In Germany, it simply takes too long to complete all the start-up requirements and processes involved in preparing for studies. Compared to other countries that implement these requirements more quickly, it is clear that Germany is falling behind.

Jessica Brown, Global Study Manager, Pfizer Inc.

An international comparison shows that Germany can only catch up in the global competition for clinical trials with a strategically coordinated and practicable implementation of regulatory requirements – such as simplified, accelerated, and standardized ethics committee decisions, centralized contract design, and consistent digitalization of processes and documentation – together with a political prioritization of clinical research as a key driver of successful innovation. In the case of multinational studies, however, the possibilities of German ethics committees are limited by EU Regulation 536/2014; genuine acceleration is only possible for mononational studies.

Patient Recruitment: Germany's Weakness

A key distinguishing feature of successful research locations is their ability to systematically recruit patients for clinical trials. Germany performs particularly poorly in patient recruitment by international comparison. In 2021, the number of industry-sponsored clinical trials per one million inhabitants with a study start was only 7.9 – far behind the leading European countries such as Belgium (33.3), Denmark (33.3), and Estonia (29.3), as well as the Netherlands (21) and Spain (16.3) (see Fig. 2).

In Germany, particularly for patient groups with rare diseases or hard-to-reach populations, restrictive data protection regulations continue to hinder efficient digital access to relevant health data, which would allow for the targeted and timely identification of potential study participants. Countries such as Israel, Estonia, and

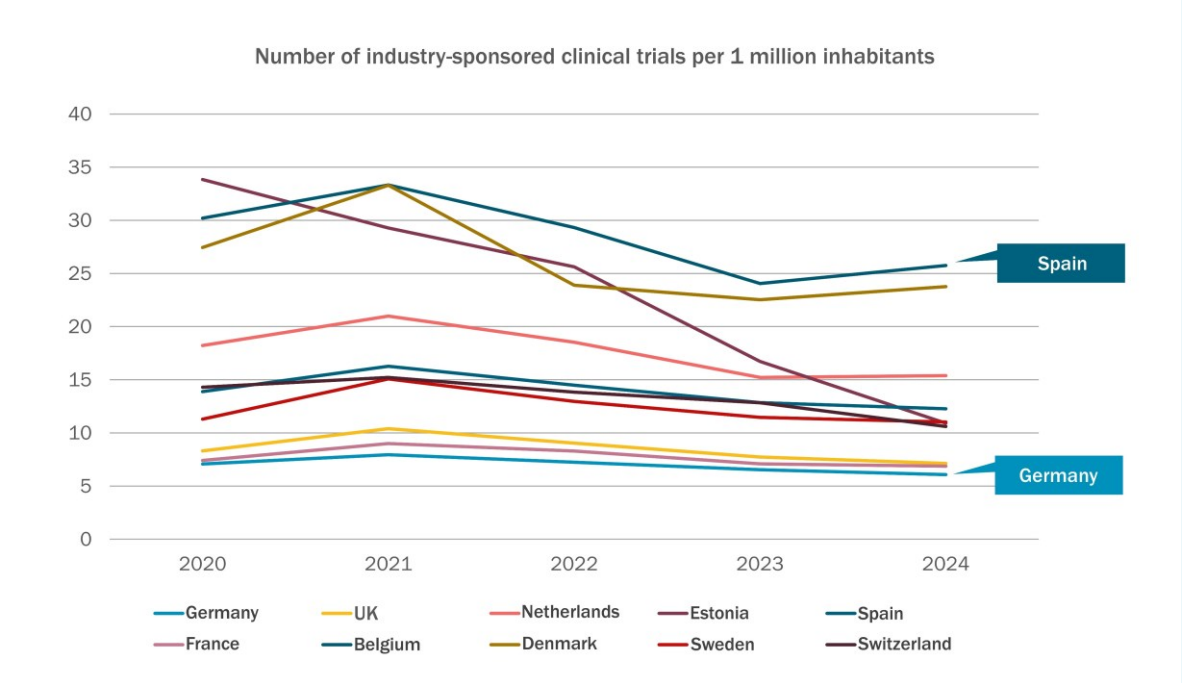


Fig. 2: Number of industry-sponsored clinical trials per one million inhabitants in a country comparison. Source: inav, calculation based on clinicaltrials.gov, as of 18 July 2025, and population data from the Federal Statistical Office of Germany (destatis), CEIC, tradingeconomics, and worldometers.

the Scandinavian states demonstrate how a digitally integrated healthcare system can strongly advance clinical research: potential study participants are systematically identified through electronic health records and contacted directly if eligible. Recruitment is fast, efficient, and data-driven (Digital Health Global, 2023; Laaksonen et al., 2022; Milani et al., 2025). In Germany, by contrast, recruitment is still unsystematic, often left to chance, and associated with high personnel costs.

Enhancing the Key Role of Physician Participation

Physicians play a key role in facilitating clinical trials. Greater involvement of outpatient care structures in clinical studies is considered a crucial lever to broaden recruitment and make it more patient-centered. General practitioners and specialists in outpatient care can act as key intermediaries, identifying suitable patients early, motivating them to participate, and referring them to study centers. The active engagement of research-oriented practices or entire research networks, whether regional or supra-regional, represents an important lever for achieving broader recruitment. A government-supported primary care system, combined with comprehensive use of electronic health records, can further enhance recruitment potential.

In our view, general practitioners also serve as important facilitators for clinical trials and participation in clinical studies. The involvement of physicians' practices can and must be improved to fully leverage this potential.

Prof. Dr. Jens Peters, Head of Clinical Research, German Pharmaceutical Industry Association (BPI)

However, in practice, time, resources, and motivation for participation in physicians' practices are often lacking. Given the limited time available in routine care, delegating tasks to non-physician staff, particularly study nurses, represents a meaningful relief for physicians. Non-physician staff can take on administrative, coordinating, and occasionally patient-facing tasks, such as documentation or scheduling. Interviews emphasize that support from study nurses is a central element in making physicians willing to integrate clinical studies into their daily practice. To enable the widespread deployment of study nurses beyond university centers, stronger institutional and financial support for such roles is necessary, for example through tax incentives, contribution-based grants, funding programs, centralized training opportunities, financial incentives, or integration into research networks. In the long term, new professional profiles could also emerge, specifically aimed at bridging healthcare delivery and research.

Over the long term, fundamental structural changes in both education and professional culture will be necessary. Several interviewees emphasized that research competence and interest must already be fostered during medical studies. A research-friendly mindset cannot be established overnight; it must be embedded early in medical curricula. Otherwise, there is a risk of a growing aversion to research within the German medical profession (Prof. Dr. Frederik Wenz, University Medical Center Freiburg). To achieve this, it is necessary to establish mandatory research components in medical education and training and to ensure the overall better integration of research-relevant content.

At present, there is also a lack of suitable information resources for treating physicians as well as for patients and their families — for example, a nationwide, standardized, digital, German-language, and user-friendly study registry. In addition, the various practice management systems (PMS) currently in use could be leveraged as continuously updated information platforms for planned and ongoing studies.

Provide Financial Incentives

To secure and actively promote physician engagement, financial recognition for the time invested in practice plays a central role. Beyond structural and organizational hurdles, practices must consider whether participating in clinical research is worthwhile at all. While fees for study investigators are generally considered attractive, there is a lack of clear incentives for general practitioners to engage with studies or actively inform patients, as the effort required for individual assessment, patient consultation, and referral is not compensated.

A simple, transparent, and standardized remuneration system could help integrate clinical research more broadly into routine care. At the same time, such a flat-rate approach carries risks, as cost structures differ significantly between regions – for example, due to variations in collective wage agreements, living costs, or staff availability.

In studies on rare diseases, where only a few patients per practice are eligible, the additional attention required in daily practice is particularly high. Interviewees considered a targeted flat-rate compensation for this extra effort to be especially helpful.

In Spain, regional cost catalogues are available, and in the UK, an interactive digital cost tool is used to calculate study site services in full in advance. Germany needs a similar system.

Dr. Thorsten Ruppert, Senior Manager for Research, Development and Innovation, German Association of Research-Based Pharmaceutical Companies (vfa)

Of course, additional study-related workload in physicians' practices would need to be compensated within the treatment process. However, remuneration for such study services should not be so high that it displaces other healthcare services. Instead, it should be aligned with the time required to perform them.

Dr. Dominik von Stillfried, Chairman of the Board, Central Research Institute of Ambulatory Health Care in Germany (ZI)

Digitalization and Infrastructure: Great Potential, Significant Gaps

Another key barrier to conducting clinical studies in outpatient care is the additional documentation workload, which prevents many practices from participating. The goal must therefore be to minimize the documentation burden for practicing physicians and to create synergies with routine documentation. The use of electronic health records (EHRs), integration with practice management systems (PMS), and structured data systems could significantly simplify the inclusion of suitable patients through a unified data portal function. This requires a standardized, nationwide infrastructure with clear legal guidelines, investments in IT infrastructure, and interoperability standards.

The use of existing real-world data (RWD) should also be increasingly considered in clinical studies, for example to fully or partially replace control groups. This could allow recruitment to be limited to the experimental study arm.

Nevertheless, according to the interviewees, data protection must remain the highest priority when using health data, both in terms of data security and patient trust. A lack of legal clarity, fragmented data infrastructures, and the tension between data minimization requirements and research needs currently hinder the use of existing data. Consequently, binding and transparent regulations for data use and high security standards are required to safeguard patient data sovereignty while promoting research. Successful models, such as in Estonia, demonstrate that data protection and research are not mutually exclusive – provided there are clear governance rules, transparency mechanisms, and a high level of patient involvement (Open Access Government, 2025).

> *The MFG is intended to accelerate everything, but in practice, we are still doing some tasks with pen and paper just as we did 20 years ago.*
>
> *We need to reach a point where duplicate documentation is avoided, for example by automatically extracting data from clinical records. In addition, it should consistently be possible in studies for patients to take on part of the documentation themselves—either by wearing a sensor or by entering data directly.*
>
> **Prof. Dr. Frederik Wenz**, Chief Medical Director and Chairman of the Board, University Medical Center Freiburg

Promote Decentralized Clinical Trials

The clinical trial landscape remains concentrated in large university centers, while patients in rural areas remain comparatively hard to reach. Although many affected individuals are willing to travel longer distances to participate, lack of public transportation, insufficient infrastructure, and time constraints make this difficult. To ensure equal opportunities in healthcare, a structural shift toward decentralized clinical trials (DCTs) with research networks involving suitable physician practices is needed. This approach was considered beneficial in several interviews.

Denmark is considered a European pioneer in the field of decentralized clinical trials (DCTs) and demonstrates how targeted political prioritization, regulatory willingness to innovate, and a fully digitalized healthcare system can modernize research. In 2021, the Danish Medicines Agency published comprehensive DCT guidelines and established the DCT Dialogue Forum, an institutionalized platform that fosters structured exchange between authorities, industry, research, and patients. Early study results from research-based pharmaceutical companies indicate that DCTs lead to better patient retention, increased diversity in recruitment, and greater efficiency in study conduct. They therefore have the potential to sustainably strengthen Europe's competitiveness in clinical research. (Healthcare DENMARK, 2022)

From the perspective of the interviewed experts, the MFG offers an opportunity to advance decentralized clinical research in Germany, notably by redefining the traditional concept of study sites. In the future, not only fully equipped study centers should be considered, but also local healthcare settings such as physician practices or mobile services. In rural regions, where study offerings have so far been limited, digital solutions can help reduce existing disparities. Importantly, the law also creates new opportunities for participation in clinical research for chronically ill patients and those with rare diseases who are often not linked to university centers. This brings research closer to routine care and the daily lives of many patients. A reliable digital infrastructure, combined with clear legal frameworks and data security, is a prerequisite. Digital solutions such as telemedicine, e-consent, or remote monitoring are considered key drivers for decentralized study models and can play a central role in sustainably lowering bureaucratic and access barriers.

Education, Information, and Awareness for Greater Patient Participation

Furthermore, a fundamental cultural shift regarding patient participation is required, complementing individual measures and based on three central pillars: education, empowerment, and information. A representative survey shows that nearly half of Germans have insufficient knowledge about clinical studies (see Fig. 3).

Patients should be regarded not merely as a target group but as active partners in research. To increase their willingness to participate in studies, greater awareness of the societal value of clinical research is necessary. The population's affinity for and interest in pharmacological research – and thus their willingness to participate in studies – should be raised and strengthened through publicly available information that is clear, accessible, and engaging across various channels (TV, social media, print media).

According to the interviewees, a key barrier to patient participation is currently the lack of clear and easily accessible information. Patients with chronic or rare diseases, in particular, show strong interest in participating when studies are communicated clearly, transparently, and convincingly. Therefore, permanently established, layperson-friendly information platforms are needed to educate about the benefits, risks, and rights in the context of clinical studies. Long-term awareness campaigns – for example, by

We could treat significantly more patients in clinical studies if awareness were higher.

Dr. Michael Busse, Head Clinical Development & Operations Germany, Boehringer Ingelheim

We primarily recruit study participants through direct outreach on social media. This works very well.

Dr. Robert Schultz-Heienbrok, Director Scientific Services, Charité Research Organisation

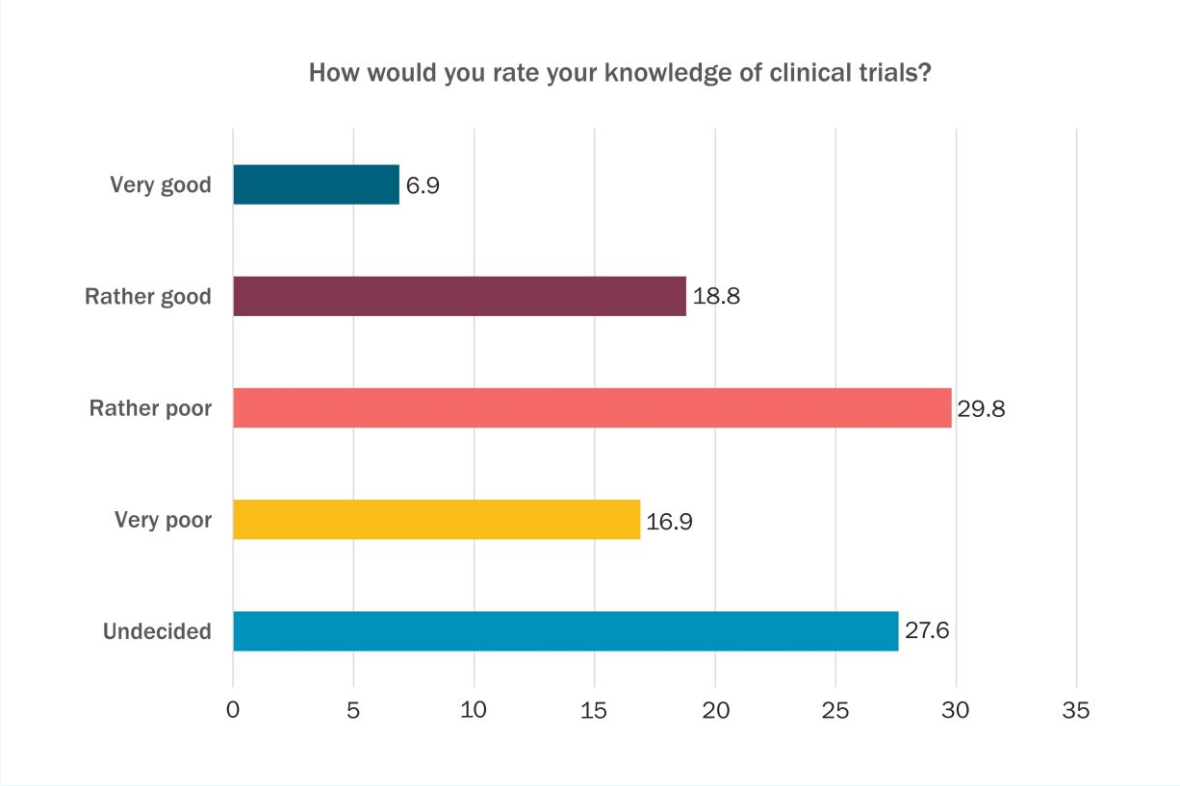
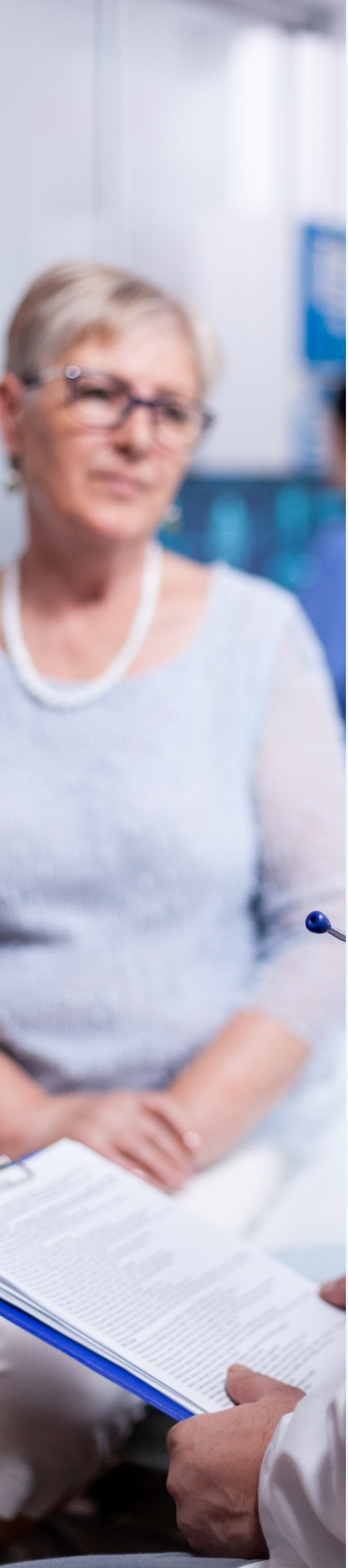


Fig. 3: Knowledge about clinical studies. Source: Survey by vfa and BPI, based on Civey survey, September 2024 (Die forschenden Pharma-Unternehmen – vfa, 2024b)



the Federal Institute for Public Health (BIÖG) – would also be recommended to help strengthen the population's willingness to participate in research. Such information initiatives should not be driven solely by industry.

Clinical studies should be presented not as a burden, but as an opportunity – for example, as access to innovative, not yet approved medicines, more intensive medical care, better treatment outcomes, or the chance to contribute to the development of medical innovations. In the interviews, there was unanimous agreement that there is substantial potential regarding study participants, which has so far not been fully realized in Germany.

We must not pressure people too strongly to participate in studies, as this often provokes resistance—even leading to conspiracy theories related to clinical research. Our recommendation is rather to approach the topic of study participation in a factual and scientifically reasonable manner.

Dr. Siiri Doka, Head of Health and Nursing Policy Department, BAG Selbsthilfe e.V.

Regarding information initiatives, I would like to see political support. If such efforts come solely from companies, they always carry a corporate connotation. Yet, for these companies, the focus is far more than economic. It is about scientific research.

Dr. Michael Busse, Head Clinical Development & Operations Germany, Boehringer Ingelheim

Efforts are needed to foster a more positive perception of clinical studies among the general public, which would also increase the overall willingness to participate. At the same time, the existing need for information about currently recruiting studies must be better addressed.

Dr. Thorsten Ruppert, Senior Manager for Research, Development and Innovation, German Association of Research-Based Pharmaceutical Companies (vfa)

It can indeed be useful for public organizations to provide information about clinical studies. What are the requirements for participation? What is important to know? A checklist could be helpful to allow patients to assess whether participating in a study is relevant or appropriate for them.

Dr. Siiri Doka, Head of Health and Nursing Policy Department, BAG Selbsthilfe e.V.

Make Patient Benefits Transparent

Last but not least, the perceived benefits also influence acceptance of and participation in clinical studies. Studies are primarily relevant for patients when they provide tangible advantages in daily treatment and are not solely conducted for research purposes. Compensation should play a minor or no role in this context. While it should reimburse effort, it must not, with respect to protecting vulnerable groups, lead to participation solely for financial reasons (see Art. 28(1)(h) EU Regulation 536/2014). This aspect is also reviewed by the responsible ethics committees as part of the approval process.

Clinical studies provide access to innovative therapies, particularly in areas with insufficient care. In the case of rare diseases, research often represents the only way to develop and provide evidence-based treatment options.

According to a survey, the chance of a cure or of symptom relief and access to new treatments are the two most frequently cited reasons for participating in a study (see Fig. 4). It is not only access to studies that matters, but also the accompanying support and the trust of patients.

It is generally welcome that companies conduct research projects in consultation with patient organizations. Ideally, the involvement of patient representatives should take place already during study planning, particularly when defining endpoints and determining whether the research questions can be operationalized as intended.

Florian Innig, Board Member, Achse e. V.

In oncology, the motivation to participate in a study often stems from a sense of desperation. For many patients, when no therapeutic alternatives remain, a clinical trial represents the only option left.

Dr. Johannes Bruns, Secretary General, German Cancer Society (DKG)

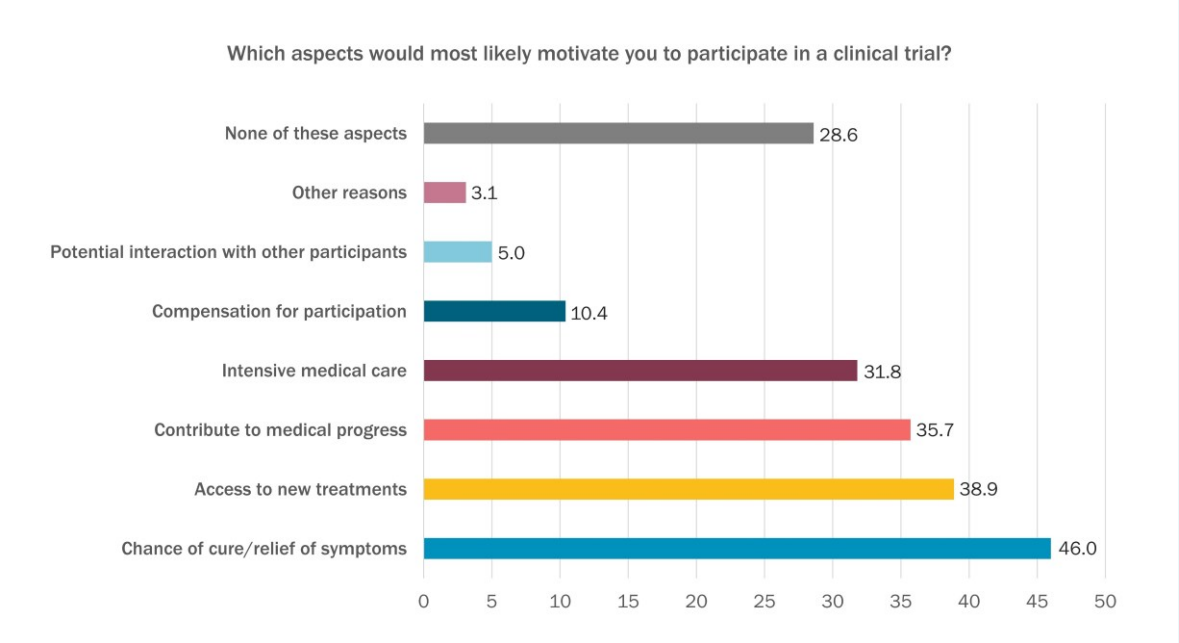


Fig. 4: Factors influencing participation in a clinical study. Source: Survey by vfa and BPI, based on Civey survey, September 2024 (Die forschenden Pharma-Unternehmen – vfa, 2024b)

I am critical of situations where compensation for participating in a study is excessively high. When participants have a certain intrinsic motivation, this supports the quality of the data. Therefore, reimbursement and personal motivation should be balanced appropriately.

Prof. Dr. Rolf-Detlef Treede, President, Association of the Scientific Medical Societies (AWMF)

When we or our organizations recommend studies, the central question is always whether they offer a genuine benefit for patients. We also assess whether the company is transparent with existing study results and, for example, whether the study protocol is provided. All of these factors speak to the trustworthiness of the study.

Dr. Siiri Doka, Head of Health and Nursing Policy Department, BAG Selbsthilfe e.V

With personalized, genome-based medicine, our cohorts have become so small that competition for study participants is already intense. The five-percent requirement will increase this competition even further. However, it could also serve as a wake-up call for many sites to invest more in professional structures, enabling them to offer studies and manage them effectively.

Dr. Britta Lang, Head of the Clinical Trials Center, University Hospital Freiburg

Civil society actors, such as patient organizations, play a key role. It is important not to view these organizations merely as recruitment aids, but as credible intermediaries who can critically assess the value of clinical studies and build trust. Early and structured involvement of these organizations in clinical studies is therefore essential to enable patient-centered, real-world research approaches. In addition, many organizations have targeted communication channels with broad reach, which provide a significant advantage when engaging potential participants.

Leveraging the Competition for Study Participants

Under the Statutory Health Insurance Financial Stabilization Act (GKV-Finanzstabilisierungsgesetz) of November 7, 2022, the so-called “AMNOG guardrails” were introduced. These rules stipulate that a new drug may not be priced higher than the appropriate comparator therapy, even if its added benefit has been proven. If no additional benefit is demonstrated, the cost must be lower. With the MFG, the guardrails no longer apply to drugs with a relevant share of clinical trials conducted in Germany. A “relevant share” is defined as at least five percent of trial participants being recruited from German study sites. According to interviewees, this provision increases pressure on patient recruitment. Study centers increasingly compete for patients, particularly when multiple studies on similar compounds run concurrently. However, this regulation is not seen as a decisive driver for study investments; it is primarily perceived as an additional regulatory burden. Some respondents noted that this competition could also serve as an incentive to invest in professional infrastructures.

The requirement that five percent of study participants come from sites in Germany represents a fairly high hurdle. Currently, this target is often not met. The effort for companies increases significantly due to the five-percent requirement. It can also lead to intensified competition for patient groups when multiple studies are conducted simultaneously for the same indication.

Prof. Dr. Jens Peters, Head of Clinical Research, German Pharmaceutical Industry Association (BPI)

Strengthen and Professionally Expand Specialized Ethics Committees

Multinational study consortia today primarily prioritize countries with reliable study infrastructure, good organization, rapid approvals, digital data availability, and predictable processes. In Spain, a coordinated study landscape has developed in recent years: national and regional ethics committees work closely with the Ministry of Health and the Agency of Medicines and Medical Devices (AEMPS). The result is significantly shortened study start times, close collaboration with sponsors, and a high number of multinational studies. (Sofpromed, 2022)

Although EU Regulation 536/2014 (EU-CTR) now provides a uniform procedure with fixed timelines, these are often fully utilized. To sustainably improve the quality and speed of clinical studies, ethics committees need better resources, and Germany must engage more actively in the further development of the EU-CTR. The establishment of a Specialized Ethics Committee for particular procedures is regarded by most experts as a significant advancement, although it represents only a compromise.

The Specialized Ethics Committee not only simplifies procedures but also contributes to accelerating the overall approval process without compromising the substantive quality of evaluations. In fact, the concentrated professional expertise ensures well-founded assessments and reduces the need for follow-up queries.

However, the newly established Specialized Ethics Committee for particular procedures was staffed significantly smaller than originally planned. Some respondents expressed the expectation of continuous professional development and interdisciplinary expansion.

In my view, the establishment of the Specialized Ethics Committee is well-intentioned but poorly executed. It is true that a standardized and harmonized approach and equal treatment are expected from ethics committees. The creation of a federal ethics committee has not succeeded for various, partly justified reasons. While we now have a new committee for particularly complex studies, the existing problem of decentralized ethics committees has not been resolved.

Dr. Britta Lang, Head of the Clinical Trials Center, University Hospital Freiburg

These specialists are, of course, able to review a protocol or study plan in the ATMP field much more quickly and effectively than members of a regular ethics committee, which typically evaluates less complex studies. This allows issues or questions to be resolved more rapidly, saving a significant amount of time.

Prof. Dr. Jens Peters, Head of Clinical Research, German Pharmaceutical Industry Association (BPI)

Accelerate Standardized Contract Processes

Through shortened approval timelines for mononational studies, binding standard contract clauses, enhanced predictability via central coordination offices, and the introduction of digital processes, the Medical Research Act (MFG) provides a significant opportunity to re-establish Germany's competitiveness in clinical research within Europe. However, this requires that these measures are also practically effective and implementable.

According to the experts, new opportunities for collaboration are also emerging, for example with research practice networks featuring decentralized recruitment as well as with non-university care facilities (such as hospital groups or supraregional medical centers) that have previously been scarcely involved. The targeted expansion of regional networks, the qualification of contracted physicians, and appropriate remuneration models for study-related services can help decentralize and better connect the study landscape.

The legislator has recognized that certain study questions require special expertise and experience. To my understanding, the Medical Research Act is the result of this insight.

Michael Fuchs, Head of the Study Center of the German Hodgkin Study Group (GHSG), University Hospital Cologne

The reduced processing time for mononational studies is a positive signal, helping Germany regain competitiveness in this area, particularly within Europe.

Dr. Thorsten Ruppert, Senior Manager for Research, Development and Innovation, German Association of Research-Based Pharmaceutical Companies (vfa)

The issue with the standard contract clauses is that when both parties agree, they might not actually follow them. As a result, the regulation's full potential is not being realized.

Dr. Britta Lang, Head of the Clinical Trials Center, University Hospital Freiburg

Clinics have different cost structures, and, for example, a study nurse in Munich is more expensive than one in Berlin. Using the same cost rate in different locations may therefore no longer cover the actual costs.

Dr. Michael Busse, Head Clinical Development & Operations Germany, Boehringer Ingelheim

Several respondents noted that in multicenter studies, especially in later phases, contract coordination remains a recurring hurdle. Lengthy coordination processes, inconsistent requirements, and lack of standardization regularly lead to significant delays in study initiation. This is especially problematic for cross-site projects that require parallel negotiations with multiple clinics. Institutions operating as corporate entities (e.g., GmbH or AG) with contractual independence, on the other hand, report significantly faster processes and decisions. Their greater flexibility makes them more efficient in implementation and attractive partners for sponsors.

Although the MFG (implemented in Section 42d(1) of the German Medicinal Products Act (AMG)) provides for the first time the development of binding standard contract clauses intended to simplify processes, central challenges remain in the eyes of the experts. The current version of the clauses under the Standard Contract Clause Regulation (StandVKlV) is considered impractical and unrealistic. If it remains in this form, the goal of harmonization may not be achieved. While the new legal ordinance under the MFG represents a good approach, it remains incomplete.

Furthermore, the highly variable cost structures between institutions continue to impede rapid agreement. The previously mentioned proposal for a nationwide standardized cost catalog is discussed controversially by the interviewees. On the one hand, standardization would be desirable. On the other hand, given the federal structures and the resulting regional cost differences, implementation would be difficult.

The regulation on standard contract clauses is fundamentally important and positive. However, it only addresses part of the contractual negotiation problem. The issue of costs remains unresolved. During the legislative process for the Medical Research Act, the Federal Council had called for a standardized cost catalog, but this has not yet been adopted by the Federal Government. Recommendations developed by the associations for comprehensive service accounting are only advisory and address basic principles. We would therefore welcome binding legal requirements, as is the case in France, for example.

Dr. Thorsten Ruppert, Senior Manager for Research, Development and Innovation, German Association of Research-Based Pharmaceutical Companies (vfa)

Reduce Regulatory Uncertainties

Despite numerous reforms and increased European harmonization, national specificities remain a systemic weakness for Germany as a location for clinical studies. In particular, deviations from EU standards in radiation protection continue to create uncertainties for applicants, according to the interviewees. Varying deadlines and procedures complicate planning and undermine the reliability of the approval process. Although integrating radiation protection notifications into the EU-CTR procedure and having them reviewed by ethics committees makes applications less complex, the MFG provision allowing a 50-day extension for extensive radiation safety reviews is seen as particularly critical. If this exception is applied too often, it could act as a brake on clinical studies in Germany.

Beyond radiation protection, the interviewees also reported opaque procedures, differing interpretations by authorities, restrictive data protection interpretations, and an overall high coordination effort. This complexity particularly deters international sponsors, who expect predictable and legally secure processes. Some experts see this as a competitive disadvantage compared to countries with clear role definitions, consistent application practices, and comprehensive digitalization.

Furthermore, many regulatory frameworks are now defined at the EU level, which limits the national scope for implementing independent regulations. With persistently high regulatory density and insufficient adaptability, Germany risks losing ground internationally. According to the interviewees, it is therefore particularly important to make targeted use of the remaining leeway, harmonize national procedures, and provide applicants with clear guidance through transparent guidelines and early consultation. Overall, Germany needs to adopt a more pragmatic approach, finding a middle ground between necessary bureaucracy and unnecessary overregulation. Only a deliberate political course correction can strengthen trust in Germany as a study location and secure its long-term attractiveness for clinical research.

Outlook

The Medical Research Act (MFG) provides a solid foundation for strengthening clinical research in Germany. It addresses long-standing weaknesses, such as those related to digitalization, procedural clarity, and patient involvement. In addition, it sends important signals to enhance Germany's competitiveness on the international stage.

Expert assessments also indicate that the MFG can only be effective if its implementation and further development are consistently aligned with the actual needs of patients, healthcare providers, and industry. In this sense, the MFG does not mark an endpoint but rather the beginning of a longer-term development process aimed at realizing the full potential of Germany as a research location.

Many of the law's effects will only become apparent over time. Nevertheless, key weaknesses remain that must be addressed in the ongoing legislative process and during implementation:

- Clinical trials are still conducted too rarely in outpatient settings. Structural incentives and support programs are lacking, as are decentralized studies that would motivate physician practices to participate.
- The use of health data for research purposes remains highly restricted due to data protection regulations, as well as a lack of standardization and interoperability.
- Bureaucratic hurdles, such as in contract management or study documentation, significantly hinder participation in clinical trials.
- Research-relevant content has so far not been systematically integrated into medical education and training.
- There is a lack of long-term strategies for the promotion and training of study personnel, particularly outside of large centers.

Recommendations for Sustainable Implementation

1. Approach Research Strategically and with a Long-Term Perspective

The MFG should be regarded as the first building block of a coherent research promotion strategy. Experts advocate not stopping at individual measures but developing a comprehensive vision with clear objectives and coordinated funding instruments. The Federal Ministry of Health (BMG) and the Federal Ministry of Education and Research (BMBF) should work together with professional societies, industry, and patient representatives to create a binding national roadmap for clinical research. This roadmap must include clear milestones, target indicators, and evaluation mechanisms to make progress measurable. Research must be recognized as an integral part of healthcare and politically prioritized accordingly. The Federal Government should secure multi-year funding for strategic innovation projects, while the Federal Joint Committee (G-BA) and the federal states systematically integrate research aspects into regional healthcare planning to sustainably promote and structurally embed innovative projects.

2. Strengthen Political Coordination across Sectoral Boundaries

Clinical research cannot be considered in isolation. Many challenges span across systems, such as interfaces with data protection regulations, drug pricing, digitalization, health services research, and innovation promotion. A cross-departmental governance approach is therefore required, which can identify regulatory hurdles early, develop practical solutions, and actively represent national interests at the EU level. For this purpose, the Federal Chancellery should establish a permanent interministerial steering committee on clinical research, which meets regularly to review topics such as data protection, drug pricing, and infrastructure, and to develop coordinated solutions. The BMG should actively represent Germany's positions in relevant EU bodies and advocate for practical adaptations of European regulations, such as the Clinical Trials Regulation and data protection requirements. Parallel federal-state working groups should harmonize responsibilities and procedures to ensure uniform approval processes across all federal states and enhance predictability for research institutions and sponsors.

3. Structural and Financial Integration of Outpatient Care Settings

General practitioners, specialists, and nursing staff must be actively integrated into the clinical trial landscape. This is essential to establish decentralized structures and make studies more accessible locally. Research practice networks can play a key role in this, but they require targeted support, including dedicated training programs, central coordination offices, and financial incentives for patient recruitment. BMG and G-BA should establish a nationwide funding program for outpatient study practices, offering financial incentives, setting up central coordination offices, and supporting the deployment of qualified study personnel, such as study nurses. Associations of Statutory Health Insurance Physicians (KVen) should implement transparent compensation models that fairly reflect the additional time needed for patient assessment, information provision, and study referrals. Complementing these measures, research practice networks and professional medical societies should provide structured training programs for general practitioners, specialists, and nursing staff to strengthen research competencies in outpatient care and increase participation in clinical studies.

Annex: Scope of the Medical Research Act in Relation to Clinical Trials

The Medical Research Act (MFG), enacted in July 2024, is a central component of the previous federal government's National Pharmaceutical Strategy, which was presented in December 2023. The law aims to improve the framework conditions for medical research in Germany, accelerate patient access to innovative therapies, and enhance Germany's competitiveness as an international hub for clinical trials. At the same time, the MFG addresses various structural barriers that have previously hindered or slowed down the conduct of clinical studies. (Bundesregierung, 2024; Deutscher Bundestag, 2024)

A key objective of the MFG is to reduce bureaucracy and accelerate clinical trial processes. For example, the processing time for so-called "mono-national studies," i.e., studies conducted exclusively in Germany, is to be reduced to a maximum of 26 days. Central measures also include the legal approval of electronic consent, the promotion of decentralized studies, and the introduction of binding standard contract clauses to avoid lengthy contract negotiations.

Another key focus of the law is the improvement of regulatory procedures. This includes, among other things, the consolidation of approval and notification processes as well as the integration with radiation protection regulations. In addition, a central coordination office is being established at the Federal Institute for Drugs and Medical Devices (BfArM), complemented by specialized ethics committees at the federal level, for example for studies involving children or the use of radiation.

Criticism of the Current Framework of the MFG

The current framework of the MFG is particularly criticized for the newly introduced possibility of agreeing on confidential reimbursement rates for patented pharmaceuticals, the partial revision of the so-called AMNOG framework, and the establishment of a specialized ethics committee at the BfArM (AOK-Bundesverband, 2024; Arbeitskreises Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland e. V. [AKEK], 2024; BAG Selbsthilfe, 2024; BKK Dachverband e. V., 2024; Bundesverband des pharmazeutischen Großhandels e. V. [PHAGRO], 2024; Die Arzneimittelimporteure e. V., 2024; Die forschenden Pharma-Unternehmen [vfa], 2024a; Gemeinsamer Bundes-ausschuss [G-BA], 2024; GKV-Spitzenverband, 2024; IKK e.V., 2024; IQWiG, 2024; Kassenärztliche Bundesvereinigung [KBV], 2024; Netzwerk Evidenzbasierte Medizin e. V., 2024; Pharma Deutschland e. V., 2024; PKV, 2024; Verband der Ersatzkassen e. V. [vdek], 2024). This underlines the need to further develop the framework for medical research in Germany, including greater involvement of general practitioners, the delegation of medical tasks to study nurses, and clearer rules on data protection (AOK-Bundesverband, 2024; Bundesverband Medizintechnologie e.V. [BVMed], 2024; Deutsche Hochschulmedizin [DHM], 2024; Die forschenden Pharma-Unternehmen [vfa], 2024a; Kassenärztliche Bundesvereinigung [KBV], 2024; Nationale Akademie der Wissenschaften Leopoldina, 2024).

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inav | Institute for Applied Health Services Research

inav – Private Institute for Applied Health Services Research GmbH
Schiffbauerdamm 12
D-10117 Berlin
Phone +49 30 24 63 12 22
E-Mail info@inav-berlin.de
Web www.inav-berlin.de