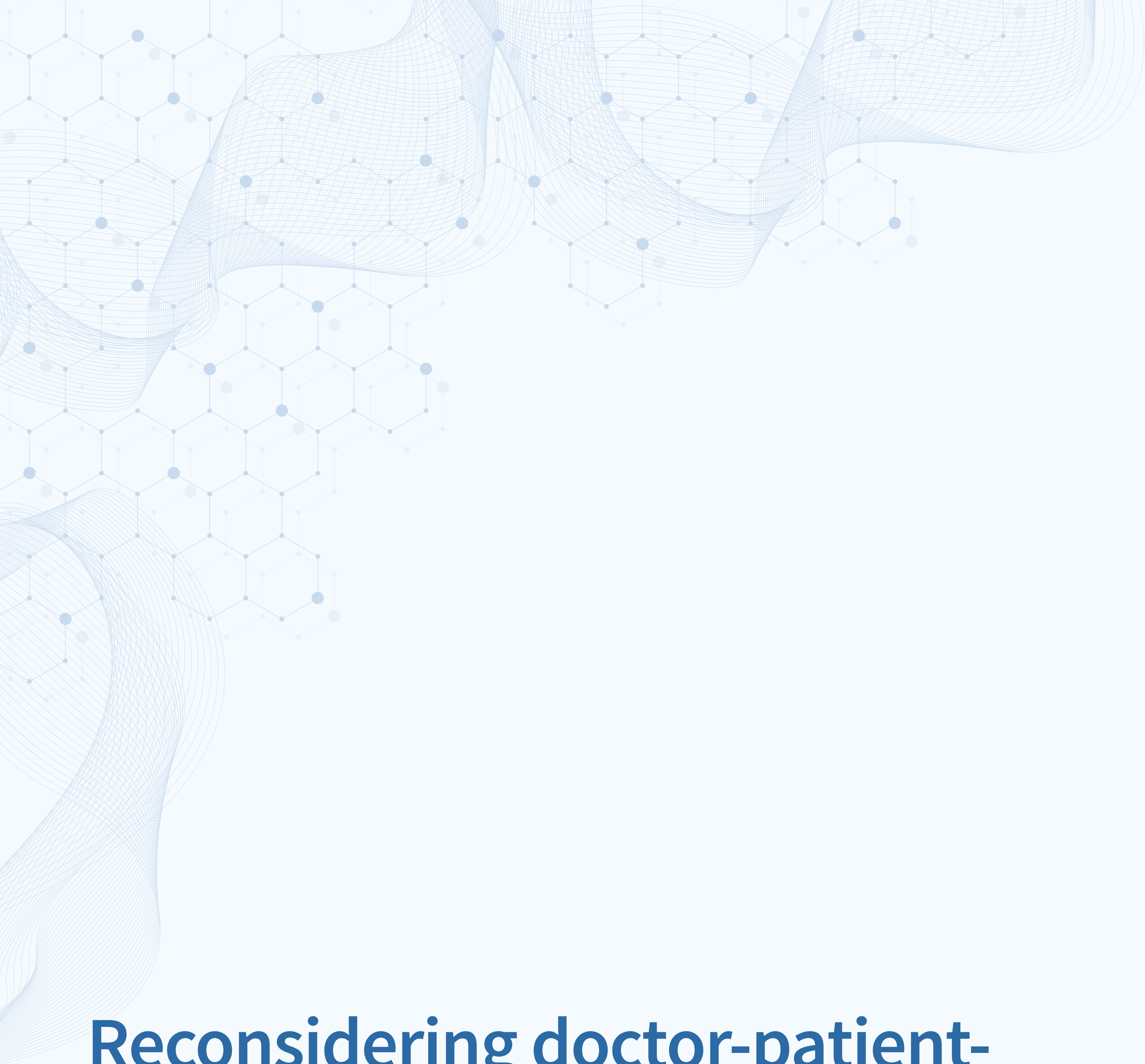

Reconsidering doctor-patient-communication to enhance participation in clinical trials

Artificial intelligence as a tool: raising awareness of clinical trials, enabling access, strengthening participation

Theses and recommendations from experts in patient advocacy, healthcare providers, and cross-industry collaboration

ACCESS TO CLINICAL TRIALS AND THE USE OF ARTIFICIAL INTELLIGENCE

Qualitative interviews with healthcare experts

In 2023, we conducted a series of interviews on personalized doctor-patient-communication with 21 representatives from the healthcare sector. The goal was to explore the topic from three perspectives: patients, medical and scientific practice, and innovation-driven industry. This interdisciplinary dialogue provided valuable insights into opportunities and challenges, particularly regarding communication, trust, and transparency in everyday medical practice.

The discussions made one thing clear: doctor-patient-communication consistently emerges as a pivotal factor for trust, participation, and informed decision-making. Access to clinical trials and the availability of relevant information remain key challenges that all stakeholders are committed to addressing together. Both patients and healthcare providers expressed a need for improved, easily accessible, and quality-assured information about ongoing studies.

Representatives from cross-industry sectors emphasized that progress requires interdisciplinary and cross-sector collaboration, projects, and partnerships to advance and shape the digital transformation, and with it, the future of doctor-patient-communication. All stakeholders highlighted the potential of artificial intelligence (AI) to effectively support both information dissemination and communication between physicians and patients. There was not only a shared awareness of existing challenges but also a strong desire to translate this awareness into tangible progress.

Following our initial findings, we conducted a second series of interviews to address existing gaps and explore emerging key themes. In recent months, we have observed notable progress in the integration and application of AI within the fields of health data and clinical research. To capture these developments, we carried out twelve qualitative expert interviews to collect current experiences, professional assessments, and proposed solutions.

This paper explores how the responsible use of technology can advance doctor-patient-communication and, in the medium term, facilitate patient access to clinical trials, while examining the specific role that AI may play in this process.

We aim to achieve the following with this position paper:

Raise awareness

of the structural, communicative, and digital barriers currently separating patients from clinical trials.

Highlight the potential

of AI to identify relevant studies at an early stage and communicate them in a patient-centered way.

Develop actionable solutions

that assign shared responsibility to all stakeholders - from policymakers and industry to the medical profession and healthcare governance bodies.

Reconsidering doctor-patient-communication to enhance participation in clinical trials

Artificial intelligence as a tool: raising awareness of clinical trials, enabling access, strengthening participation

Although clinical trials are essential for medical progress, they often remain invisible to many patients. Only a small proportion of eligible individuals are informed about participation opportunities. Physicians frequently lack the time, technical support, or systemic incentives to actively recommend clinical studies. To address this issue, targeted access to clinical trials would not only offer patients additional therapeutic options but also accelerate knowledge acquisition.

Start-ups, research institutions, and technology-driven companies have developed a wide range of AI-based digital solutions. These tools, for example, can automatically evaluate patient data and compare inclusion and exclusion criteria for clinical studies. However, despite technological advances, these solutions have had little large-scale impact. Their implementation is frequently hindered by outdated IT infrastructures, a lack of interoperability, unclear responsibilities, and high regulatory barriers.

Patients demonstrate a growing interest in actively participating in research processes when they receive clear information, are involved transparently, and offered continuous support. Many would appreciate it if their doctors informed them about suitable clinical studies and offered assistance in accessing them. However, physicians report that they often lack sufficient information and the necessary digital tools. In addition, informing patients about clinical studies and referring them to nearby study centers requires time that is not reimbursed. There are no incentives for doing so - on the contrary, it creates additional work for which physicians receive no compensation at all.

PATIENT REPRESENTATIVES

Ludwig Hammel
Patient Representative, German Ankylosing Spondylitis Association

"It won't work without patient data – and certainly not without patients."

It is repeatedly evident that information about studies is either too complicated or simply not accessible. We need a platform where studies are explained clearly, in plain language, well-structured, and ideally digital.

Dr. Barbara Keck
Managing Director of the German National Association of Senior Citizens' Organisations

"Transparency is the key for me. I want to know who is responsible for a study and how likely it is to succeed."

Older people and those with multiple chronic conditions are often not even approached about clinical trials, although their considerable interest. We need study designs that are truly inclusive.

Bernd Rosenbichler
Social Entrepreneur, Branewo gUG

"AI can help, but it must not become a black box. Trust is created through clear communication, not through technology alone."

Patients today are willing to engage actively, if given the opportunity. We do not just want to provide data; we want to contribute our ideas, participate in decision-making and understand the impact of our participation.

Information gaps, trust, and the role of AI

Many patients encounter clinical trials only by chance. What is needed is medically supervised, digital, and comprehensible communication that builds trust and facilitates access to trials.

Opportunities and expectations regarding AI

Navigation through complex information, such as medical reports or study documents

Structured presentation of personalized patient information, including opportunities for feedback and follow-up questions

Identification of suitable studies based on individual data as well as personal life circumstances

At the same time, it is emphasized that AI must not operate in isolation from medical communication. Trust does not emerge from technology alone, but from its responsible integration into human interaction and professional dialogue.

Structural expectations for the system

Transparent study platforms and websites with plain-language content

Greater promotion of health literacy, e.g., via patient organizations, apps, or media initiatives

Continuous and understandable feedback during and after study participation

Mandatory publication of all study results also to strengthen trust in research

Moreover, there is a strong call for study communication to be understood not as an obligation but as a genuine dialogue - honest, empathetic, and transparent.

Findings across both interview series

Interviews with patients and their representatives reveal a clear picture: access to information about clinical trials remains insufficient. Information is often overly complex or not available at all. Many patients learn about studies only by coincidence or through their own research, while physicians rarely, if ever, raise the topic during consultations. Older individuals and those with multiple conditions are particularly affected, despite their often high level of interest.

There is a strong demand for a clear, digital, and easily accessible platform that explains studies transparently and in plain language, including information on study sponsors, expected outcomes, and potential risks. Physician involvement is considered crucial: patients want to be informed early and individually about possible study participation, ideally by the physicians they trust.

In this regard, many interviewees emphasize the need for a new form of communication, one that is not a one-way flow of information but an honest and empathetic dialogue. Study communication should not merely inform but also build trust, enable participation, and incorporate feedback both during and after the study. Patients do not wish to be mere data providers; they want to be involved in study processes from the outset, to contribute ideas, participate in decision-making, and understand the impact of their involvement.

This requires not only comprehensible information materials but also targeted measures to strengthen health literacy, for example through patient organizations, apps, or media. The pharmaceutical industry is regarded as a key player in providing validated information, although it is equally emphasized that medical judgment must remain independent.

Most patients regard AI as a supportive tool that helps them navigate complex information, prepare personalized materials, and identify suitable studies. Particularly valuable is its potential to organize content more effectively, facilitate feedback and interaction, and tailor study opportunities to individual life contexts.

In this context, however, patients stress that AI must not function in isolation. Trust can only develop if AI systems are transparent and embedded within human, physician-guided communication. The pandemic has served both as a catalyst for digital innovation and as a magnifying glass for existing gaps, particularly regarding digital infrastructure and patient-centered system design. Consequently, patients express a clear desire to be actively involved in the further development of new digital and AI-driven solutions.

HEALTHCARE PROVIDERS

Dr. med. Hans-Jürgen Häfele

Board-certified General Practitioner

“Medical specialists are crucial for study referrals.“

Platforms for searching clinical studies are, in principle, known - but in practice, they are hardly usable. They are too confusing, and it takes far too long to find a suitable study.

Prof. Dr. Irit Nachtigall

Director of the Institute for Hygiene and Environmental Medicine at Vivantes Hospitals and Professor of Hygiene and Infectiology at Medical School Berlin (MSB)

“Many patients are unaware of the possibility of participating in a study due to a lack of targeted and proactive information.“

There is great potential in AI, particularly when it comes to automatically identifying whether a patient might qualify for a clinical trial.

Prof. Dr. Eckhard Nagel

Physician, Professor of Medical Management and Health Sciences at the University of Bayreuth, and Chairman of the Board of the Medical University of Lusatia – Carl Thiem

“For me, clinical studies are an extended care option - but only if quality and structures are in place.“

Trust is the most essential prerequisite. Those who want to engage patients in studies must show them that they are part of an important process and that their participation creates value for the community.

Dr. med. Torsten Schröder

Head of the Berlin Simulation and Training Centre, Charité

“The national medical register act marks an important first step; now we urgently need its practical and effective implementation.“

We need uniform standards for data collection to ensure high data quality, straightforward access, interoperability with other platforms, and an appropriate legal framework. This is an opportunity we should seize without delay.

Patient journey, everyday practice, and usability

The patient journey through the healthcare system remains too fragmented, and existing digital solutions still do too little to support the transition into clinical studies. To improve guidance, interconnected systems are needed that ease the burden on physicians and make study information more accessible.

Opportunities arising from AI and digital solutions

Automated recommendation systems operating in the background that alert physicians when a patient may be eligible for a clinical study.

Data protection–compliant AI systems that run locally and operate without external connections to ensure security.

AI-supported conversation guides or personalized phrasing modules to help communicate study information clearly, empathetically, and efficiently.

It is highlighted that AI must never replace medical reasoning. Clinical judgment and communication must remain central; technology should relieve physicians, not disempower them.

Structural preconditions for change

A central, functional study platform with intuitive user guidance.

Binding interface standards for practice and hospital IT systems.

Incentives for study referral, e.g., through time budgets or billable services.

More training and continuing education on the role of clinical studies in everyday care.

Moreover, a socially supported culture of study participation should be fostered, focusing on patient benefit, not merely research efficiency.

Findings across both interview series

The perspectives of physicians and research-active healthcare professionals demonstrate that clinical studies are generally regarded as a valuable extension of medical care but often fail due to structural and communication barriers. Many patients never learn that they might qualify for a study, either because information does not reach them or because physicians, constrained by time, motivation, or integration into practice workflows, do not actively inform them. Office-based physicians in particular face a multitude of demands and often feel left without adequate support when it comes to facilitating study participation. While study registries are recognized as potentially useful tools, they are, in their current form, perceived as confusing, impractical, and poorly integrated into existing practice systems.

In light of this, there is a strong demand for technical support, particularly in the form of intelligent yet data-secure systems that alleviate rather than add to physicians’ workload in daily practice. AI is considered a promising tool, for instance, through automated recommendation mechanisms that discreetly identify potentially eligible patients in the background. AI-supported communication aids and individualized information modules are also viewed as effective means of improving patient engagement and clarity.

Physicians emphasize, however, that AI must never replace medical judgment or personal dialogue. Technology should support rather than override; medical autonomy and individual communication must remain at the core of professional practice.

Beyond technological solutions, healthcare providers highlight the need for structural reform: functional and user-friendly study platforms, clear interface standards for IT systems in practices and hospitals, and tangible incentives to integrate study referrals into routine care, such as billable services or dedicated time allocations. They also call for greater inclusion of clinical research topics in medical education and training.

Ultimately, a broader cultural shift is required. Participation in clinical studies should be understood as a contribution to the common good, with a clear focus on patient benefit rather than research efficiency alone.

Daniel Kompe
Microsoft Digital Health Evangelist /
Healthcare Technology Strategist

"Patients expect to be in control of their own data and to also manage and use their data by themselves. Suitable possibilities and AI tools already exist and are ready to be used."

AI is no longer just an opportunity but an absolute necessity. The demand, particularly in diagnostics, is immense. We must finally move forward with consistent implementation.

Johannes Maes
CEO and Co-Founder of MediTech

"Rather than additional paperwork, doctors need support in the form of a software that can determine whether someone is suitable for a study during the initial consultation."

Technology itself is not the problem. What is missing is implementation, clear responsibilities, and the courage to take the first steps.

Dr. Matthieu-P. Schapranow
Sc. Manager of Digital Health Innovations at the Hasso Plattner Institute,
University of Potsdam

"AI can help but only if we finally create suitable infrastructure for it. Currently, we are even lacking the basics."

In Germany, we are still far too slow when it comes to clinical research and digitalization. Other countries are moving at a completely different pace, even though we, too, have the necessary expertise.

Dr. Bertram Weiss
V.P. Health of Merantix Momentum

"We talk constantly about interoperability, but more attention should be paid to the basics. Legacy systems, missing APIs, insufficient budgets."

AI is coming. The question is no longer whether we will use it, but how. It's about developing practical solutions.

Infrastructure, AI potential, and implementation barriers

The digital infrastructure in healthcare is widely regarded as outdated and insufficiently supportive of innovation. To enable progress, interconnected data, clearly defined responsibilities, and structures are required that not only avoid hindering innovation but actively promote it.

Opportunities enabled by AI and digital solutions

Patient matching, site selection and study design can be significantly improved through AI-based 'research agents' and semantic data analysis.

Overcoming language barriers with AI, present study content in lay-friendly terms, and reduce dropout rates through continuous communication.

Automated feedback after study completion can help build trust and create learning loops within the system, for example through personalized result reports.

AI-supported tools hold particular potential to improve the efficiency of identifying suitable clinical studies, support clinical decision-making, and enhance communication between physicians and patients. This potential lies especially in their integration into general practitioner and specialist systems, for example through structured data collection and algorithmic recommendations during initial consultations.

Systemic preconditions for change

Low-threshold certification paths, e.g. for platform providers in the C5 context (C5 defines minimum requirements for secure cloud computing).

Binding technical standards and API requirements for hospitals and IT systems.

State-supported incubators to help start-ups develop early pilot applications.

Responsibilities and clear accountabilities, e.g. for data access and interoperability.

Several participants expressed concern that Germany and Europe may fall behind internationally if processes are not simplified, competencies consolidated, and practical models actively supported.

Findings across both interview series

The perspective of innovation-driven industry and technology-oriented stakeholders in healthcare reveals a consistent picture. AI is no longer an optional topic for the future but a necessary technology to improve clinical study processes and doctor-patient-communication. Interviewees emphasized that patients must be empowered to understand and use their own data, which requires accessible and well-designed digital tools. Physicians should likewise be supported, for instance through intelligent software capable of indicating during the initial consultation whether a patient qualifies for a study.

From the cross-industry perspective, the main challenges lie not in the technology itself but in its practical implementation. Undefined responsibilities, limited budgets, and outdated IT systems slow progress, while other countries are advancing at a considerably faster pace.

A key obstacle is Germany's insufficient digital infrastructure. Hospitals and medical practices frequently rely on outdated software, incompatible systems, and lack binding technical standards. Clinical data are often stored in inaccessible silos, insufficiently standardized, and difficult to retrieve. This affects structured care data, real-world data, and results from previous studies alike. Regulatory frameworks such as the Medical Device Regulation (MDR), the EU AI Act, and C5 certification create significant barriers, particularly for smaller providers. Moreover, the lack of pilot projects, feedback mechanisms, and clearly defined contact points impedes innovation and complicates the development and integration of practical digital solutions.

Nonetheless, interviewees identified substantial potential in the use of AI throughout the entire study process. AI can support the matching of patients to suitable studies, the selection of appropriate sites, and the optimization of study design. It can also help overcome language barriers, make study content more comprehensible, and strengthen trust in research through automated, personalized feedback after study completion. Particularly promising is the integration of AI-supported tools into general and specialist care systems, facilitating structured data collection and intelligent decision support during patient consultations.

To realize this potential, simplified certification procedures, binding interface standards, clearly defined responsibilities, and government-backed support for start-ups in early development stages are essential. Without such measures, Germany and Europe risk losing their international competitiveness.

Strategies for a future-oriented approach to clinical trials

Contributing to more visibility and understanding of study information

There is a need for a publicly accessible and easy-to-understand platform featuring search and filter functions as well as concise summaries, ideally linked to existing health applications or patient portals. Such a platform could be curated by established institutions such as the Federal Institute for Drugs and Medical Devices (BfArM) or gematik, but it should be developed collaboratively with patients, physicians, and industry representatives.

Strengthening study referral through digital systems

Practice software, hospital information systems (HIS), and electronic health record (EHR) modules should incorporate interfaces that automatically suggest suitable studies to physicians, for example based on diagnosis codes or treatment histories. These systems must be easily accessible, compliant with data protection regulations, and practical for everyday use, ideally through automated, AI-driven recommendation mechanisms. Funding programs or regulatory frameworks could establish targeted incentives for providers and operators. Above all, physicians need clearly defined processes rather than additional barriers.

Promoting digital solutions with real interoperability

Clear and binding interface standards are needed for applications that enable study matching and communication, similar to what gematik is planning in the German personal health record (ePA) context. In addition, funding programs should specifically promote interoperability and market access for start-ups and specialized technology providers, for example through sandbox environments, fast-track certification, and low-threshold integration with ePA or systems operated by the National Association of Statutory Health Insurance Physicians (NASHIP).

The legislator has already created important incentives through the Medical Research Act and the Health Data Use Act. These initiatives should be expanded to support public pilot platforms, such as “Digital Study Guides,” that systematically integrate clinical studies into medical practice. Furthermore, a substantial investment initiative is required to modernize the often outdated IT infrastructure within the healthcare system.

Institutionalizing feedback and participation

Patients, in particular, expressed the wish that clinical studies should routinely include patient-oriented result reporting, either directly through treating physicians or via digital channels such as applications, online portals, or follow-up letters. Such feedback mechanisms can strengthen trust, transparency, and motivation, thereby contributing to a sustainable improvement of the study culture in Germany.

In response, digital feedback channels should be established throughout the entire patient journey, enabling both physicians and patients to provide input on study design, communication, and accessibility, for example through survey tools or continuous evaluation processes. Participation should not conclude with the signing of the consent form.

Improving the visibility of study culture in society

Germany needs an actively developed and broadly supported communication strategy to promote a culture of clinical research, comparable to national campaigns on organ donation, prevention, or digitalization. This is not about advertising, but about the strengthening of trust, transparency, and understanding. Communication should be accessible, multilingual, and co-created by patients themselves. Health insurance funds, medical associations, professional federations, and industry should also be involved as key actors in a system that once again makes research visible as a public good.

Defining responsibilities and taking accountability

The continued development of study infrastructure, particularly with respect to AI and patient-centered referral, requires clear political responsibility and operational accountability. Within the framework of the Medical Research Act, governance structures should be established to ensure the sustainable implementation of platform operations, AI authorization, and system integration.

Looking ahead, collaborative formats involving policymakers, healthcare governance bodies, industry, and civil society are essential to jointly advance implementation capacity, not by shifting responsibilities, but through shared accountability.

Conclusion

The analysis of interviews with patients and their representatives, physicians, and cross-industry experts reveals a clear overall picture. Access to clinical studies and communication surrounding them are regarded by all stakeholders as highly important, yet widely perceived as inadequate. Patients seek personalized, comprehensible, and transparent information about studies, as well as stronger involvement in decision-making processes. Physicians likewise view clinical studies as a valuable extension of patient care but report practical barriers to referral, a lack of technological support, and excessive workload in everyday practice. Representatives from the cross-industry sector emphasize Germany's insufficient digital infrastructure, missing standards, and slow pace of implementation, while at the same time underscoring the considerable potential of digital technologies, particularly AI.

All three perspectives highlight that AI already holds significant relevance today and will play a central role in the future, not as a replacement, but as a supportive instrument. The technology can assist in processing complex information, identifying suitable studies, and enhancing communication between physicians and patients. To realize this potential, essential structural prerequisites must be established: interoperable IT systems, binding interface standards, user-friendly platforms, and reliable data protection frameworks. Physicians also require targeted training to use AI safely and effectively in the best interests of their patients. Both industry and patient representatives regard interdisciplinary collaboration between research, technology providers, and healthcare practice as a key driver for establishing a patient-centered, efficient, and trustworthy study culture.

The interviews with representatives from patient advocacy, clinical practice, and industry clearly show that access to clinical studies can only be improved when information, communication, and infrastructure are addressed in an integrated manner. Clinical studies must become visible where people seek guidance, whether in medical consultations, digital applications, or reliable public platforms.

Accordingly, specific structural and technical foundations are required. Physicians need integrated systems for study referral, patients require comprehensible feedback and accessible information tools, and technology-oriented providers must be granted fair access to healthcare systems. Clear roles and responsibilities must be defined for all stakeholders. The use of AI can effectively support these processes, provided it is implemented responsibly.

Common ground across all perspectives

Desire for greater **transparency, clarity, and access** to information regarding clinical studies

Emphasis on **patient autonomy** and the right to informed participation

Consensus on the **potential of AI** to improve information processing, diagnostics, and communication

Call for enhanced digital infrastructure and interoperable IT systems

Need for interdisciplinary collaboration to develop patient-centered solutions

Focus areas of the individual perspectives

Patients: Emphasis on personal communication, trust, and easily understandable information.

Healthcare Providers: Key obstacles include impractical systems, limited time, and insufficient incentives. AI is expected to provide support but must not replace medical judgment.

Industry: Criticism of slow implementation, regulatory barriers, and inadequate infrastructure, accompanied by a call for clear responsibilities and binding technical standards.

The results of this project are intended as an invitation to collaboration. The recommendations underline that access to clinical studies is not the responsibility of individual stakeholders but a shared concern of the healthcare system as a whole. Enabling participation requires collective solutions supported equally by policymakers, healthcare providers, industry, and patients.

We extend our sincere gratitude to all participants in our interview series for their valuable contributions and insights.

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Patient Representative, German Ankylosing Spondylitis Association

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Board-certified General Practitioner

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Publisher of the memorandum:
SNPC GmbH, Knesebeckstr. 59 – 61, 10719 Berlin

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Editorial deadline:
October 2025

The editorial creation and design were financially supported by Pfizer Pharma GmbH.