White paper

Patient recruitment

Humanizing patient recruitment in clinical research: A new paradigm in health care

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Executive summary

As the clinical trial landscape evolves, the role of patients is undergoing a significant transformation – and the patient recruitment process must adapt to keep pace. Key to this adaptation is bringing a patient-first approach to the process, offering a more personal touch to recruitment strategies.

This transformation is being driven by a variety of factors, including advancements in technology, changes in regulatory guidelines, and a growing emphasis on patient empowerment and awareness in health care. With the emergence of digital advancements, there are now more opportunities than ever to personalize the recruitment process and apply it with a patient first approach. Moreover, regulatory agencies and national health care bodies recognize the importance of patient engagement in clinical research and encourage patient involvement in the trial design and conduct.

These shifts lead us to today, where patients are increasingly being seen as partners rather than subjects in clinical research.

This white paper explores:

- the changing dynamics of patient recruitment and engagement,
- the rise of patient first approaches, and
- key strategies for humanizing patient recruitment in clinical research.

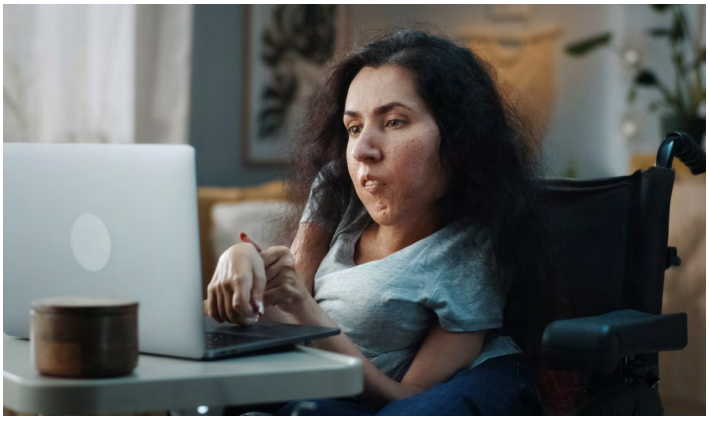
When harnessed successfully, these evolving trends and opportunities can improve the patient experience, showcasing the transformative power of humanizing the patient recruitment process in clinical research.

The changing landscape of patient recruitment

Clinical research plays a vital role in advancing medical knowledge and patient care. However, recruiting and retaining the right patients remains a significant challenge for sponsors. Current data suggests that up to 85% of clinical research fails to recruit or retain a sufficient sample size, resulting in a failure to meet accrual targets in four out of every five studies. This issue is further compounded by tight timelines, increasing competition, complex protocols, and stringent eligibility criteria, making the patient recruitment process more challenging than ever.

The way patients interact with clinical research is changing dramatically. Patients are increasingly taking control of their health care, using smart devices, wearables, and health trackers to monitor their health and make informed decisions about their care. Some are even considering clinical research as a first-line care option. This shift in sentiment demands a change in the way clinical research is conducted, with a greater focus on patient engagement and a move toward more digital and remote technologies.

Until recently, patient recruitment relied heavily on referrals from primary care physicians. However, with the advent of patient databases and the rise of patient involvement in care decisions, the recruitment process has become more diverse and dynamic. This new dynamic requires rethinking traditional recruitment strategies and adoption of innovative approaches that put the patient at the center of the process.



The health care and clinical research environments have also experienced considerable evolution, especially since 2020 when the industry increasingly began embracing digital and remote technologies to create greater access. This shift toward a more digital approach is humanizing the patient recruitment experience by making it more accessible and personalized.

When leveraged successfully, these industry and cultural shifts have the potential to improve the patient recruitment experience in clinical research.

It's all about engagement

The research industry is tasked with the dual responsibility of raising access to clinical research and ensuring that human connection is at the forefront of these initiatives. This is essential in the current landscape, where patients are increasingly discerning consumers of health care services.

In response, building trust with patients must be at the forefront of the recruitment process. The 2024 Edelman Trust Barometer revealed that while 73% of respondents trust the health care industry, only 50% trust innovations in the health care industry,

including gene-based medicines and artificial intelligence (AI)[1]. This trust gap underscores the importance of infusing human connection and engagement into the recruitment process.

To build this trust and embed a sense of human connection into the recruitment process, it is essential to engage and empower patient communities, both online and in-person. These communities serve as a platform for recruiting qualified patients, increasing trust in the medical community and supplying a valuable source of real-world data[2]. By providing a platform for open dialogue, information sharing, and support, patient advocacy and community groups alleviate fears and misconceptions about clinical research.

In doing so, they have become a source of trusted information for patients and their caregivers. These groups often bring in underrepresented populations, which is essential for understanding the safety and efficacy of therapeutics and meeting regulatory guidelines, like those established by the U.S. Food and Drug Administration (FDA)[3]. Recent data suggests that community outreach and patient engagement efforts led to an 11% increase in the representation of Black patients in clinical research over the past decade[4]. This is a significant increase, but there is still much work to be done to ensure that all populations are adequately represented in clinical research.

To keep pace with these changes, the industry is shifting from a transactional conversation with patients to a continuous dialogue about health care – an approach that offers mutual benefits for patients, providers and sponsors. By engaging patients in ongoing conversations about their health, providers gain a better understanding of their needs and concerns, which helps inform the design and implementation of clinical research. This approach not only enhances patient trust and satisfaction but also improves the quality of data collected during research, leading to more reliable and actionable insights.

Industry leaders ranked patient centricity as the key trend that will shape the clinical trial industry over the next five years[5]. This reflects a growing recognition of the importance of putting patients at the center of the clinical trial process, from design to implementation. In fact, evidence suggests that involving patients as early as the trial-design phase leads to faster enrollment, higher retention and better compliance with study procedures[6]. The result is better quality data to support drug or device approval, underscoring the importance of patient engagement for improving the patient experience and ensuring the success of clinical research[7].

The future is collaborative

The future of patient recruitment lies in collaboration across parties and in areas like education and awareness, technology, and collaboration with national health care bodies.

Empowering participation: Enhancing education and awareness through collaboration

Enhancing patient education and awareness is a fundamental strategy in encouraging broader participation in clinical research. Crafting clear, simple and easily shareable messages about this research is a crucial part of the process. A collaborative effort is needed to achieve this, with health professionals, patient support groups, research institutions, drug sponsors and even the media working together.

This collaborative endeavor can demystify clinical research for the public. Going beyond the basics of what clinical research is, the objective is to illustrate how clinical research advances medical science and improves patient care, thereby fostering a deeper understanding that can encourage greater participation. Ultimately, this leads to more successful patient recruitment efforts.

Highlighting the benefits of participating in clinical research – like potential access to new treatments and the opportunity to contribute to medical research – is equally important. Understanding the process and recognizing the benefits can motivate more people to get involved. This increased participation benefits both individual patients by providing access to new treatments and enhances the health care industry at large. Greater involvement in clinical research leads to more diverse results, which enriches the overall quality of the research.

Unifying tech: A collaborative approach to streamlining clinical trial technologies

In today's digital age, technology has become an indispensable part of modern clinical research. It has revolutionized the process, from patient recruitment and data collection to trial

management and follow-up. However, with the multitude of tools and products available, there is a growing need for collaboration to streamline these technologies.

Collaboration between tech companies, research institutions, drug developers and health care providers – combined with input from the end user – is key to harnessing its full potential. By pooling their resources, expertise and insights, these entities can work toward a common goal – simplifying and enhancing the technological aspect of clinical research. This joint effort can significantly reduce the burden on trial sites and patients by minimizing the number of tech platforms needed for each study.

Leading with a patient-first mindset is essential to increase patient satisfaction and make it easier for patients to navigate the trial process, which can, in turn, boost recruitment and retention rates. By working together to consolidate tools and products, we can enhance the efficiency and effectiveness of clinical research, improve the patient experience, and most importantly, drive better health outcomes.

United for progress: The power of collaboration with national health care bodies

Collaboration with national health care bodies is a crucial cornerstone for the future of patient recruitment. These bodies, with their extensive reach and influence, can significantly impact the way patient recruitment is approached and implemented.

The FDA's Patient Engagement Collaborative and Clinical Trials Transformation Initiative are prime examples of collaborative efforts that place patients at the heart of the process. These initiatives underscore the FDA's recognition of the invaluable insights that patients and their caregivers offer. Their understanding of patient needs, preferences and potential barriers to trial participation provides a unique perspective that is indispensable for shaping effective clinical research[8]. Rather than simply involving patients as participants, these initiatives strive to make them central to the entire end-to-end clinical trial process.

Building on this patient-first approach, these collaborative initiatives work to enhance the design of research. They aim for designs rooted in a deep understanding of the patient population, and are also ethical, efficient, and respectful of patient rights and dignity.

Promoting transparency is another cornerstone of these FDA-led initiatives. The goal is to foster trust and instill confidence by providing clear, accessible information about every aspect of the trial, from its purpose and procedures to its potential risks and benefits. In line with this commitment to transparency, the FDA ensures that patients are kept abreast of the progress and results of the trial, further enhancing their engagement and trust in the process.

By making research more patient-focused, transparent and respectful of patients, participation becomes a more attractive and feasible option for prospective participants.

Looking ahead, it is clear that the future of patient recruitment is not an isolated endeavor. Rather, it is a collaborative effort that requires the active participation and cooperation of various stakeholders, including health care providers, researchers, sponsors, patients, sites, caregivers, advocacy groups and national health care bodies.

Unlocking success: Three key strategies for humanizing patient recruitment in clinical research

In the evolving landscape of clinical research, the effective recruitment and retention of study participants is paramount. Successful organizations will humanize this critical process by focusing on three essential areas: education and awareness, which ensures patients are well-informed about research; AI, which streamlines the recruitment process; and adopting a patient-first mindset, which emphasizes increasing access and removing barriers. By integrating these areas, organizations can create a more patient-friendly and efficient clinical trial process.

Patient-centered education: Empowering participants through knowledge and awareness

Fundamental to the success of clinical research is the improvement of patient education and awareness, emphasizing meaningful partnership with participants rather than transactional interactions that are solely protocol driven. Organizations that succeed in recruiting patients for clinical research will invest more time in sharing the value of clinical research and educating about indications. This involves not only explaining the purpose and potential benefits of clinical research but also demystifying

the trial process, addressing common misconceptions, and alleviating fears.

Creating accessible educational materials is an essential step in this process. The materials should be designed with the ideal patient population in mind, meaning they should be relevant, informative and culturally sensitive. In other words, the materials should respect and acknowledge the cultural norms, beliefs and values of the population for which they are intended. This cultural sensitivity can build trust and rapport with potential participants, making them more likely to consider participating in clinical research.

In addition to being culturally sensitive, educational materials should be tailored to various literacy levels. Using plain language, avoiding jargon, and explaining complex concepts in a clear and simple way are easy-to-implement tactics that have a significant impact on the end user. Visual aids, such as diagrams and infographics, can also be used to make dense information more digestible and engaging.

Language accessibility is another key factor to consider. Making educational materials available in the patient's native language can significantly increase their accessibility. This can be particularly important for populations with limited proficiency in English, who may otherwise be excluded from participating in clinical research due to language barriers.

The goal of these efforts is to create a well-informed patient population that is more likely to participate in clinical research. According to a study by the National Institutes of Health, patient understanding and knowledge of clinical research are key determinants of their willingness to participate[9]. By improving patient education and awareness about clinical research, sponsors can increase participation rates and ensure that trial participants are more representative of the broader population, leading to reduced study timelines and bolstering compliance with regulatory mandates.

AI unleashed: Harnessing technology to humanize patient recruitment in clinical research

It's no surprise that AI is positioned to play a pivotal role in the future of clinical research. In the sites and patients world, it is expected to become an integral part of identifying and onboarding the right patients and sites for clinical research, revolutionizing the way we approach patient recruitment and trial management.

In the context of patient recruitment, AI can perform automated eligibility analysis, matching potential participants to research based on a range of factors, including their medical history, current health status and genetic profile. This ensures that the right patients are selected for each trial, improving the efficiency and speed of the recruitment process, and potentially increasing the trial's success rate.

AI can also simplify trial searching capabilities, making it easier for patients to find and participate in relevant research. This can involve using natural language processing to understand patient queries, machine learning algorithms to match patients with suitable research, and predictive analytics to forecast patient enrollment and retention rates.

Furthermore, AI can be harnessed to identify trends and patterns in data, potentially leading to more effective and efficient research. For example, machine learning algorithms can analyze vast amounts of data to identify factors that influence patient enrollment and retention, predict trial outcomes, and suggest improvements to trial design and execution.

In the future, we can expect AI to become even more integrated into the clinical research process, with advancements in technology leading to more sophisticated and accurate tools for patient recruitment and trial management[10]. These advancements will enhance the efficiency and effectiveness of the clinical research process and reduce patient and site burden. By leveraging AI, researchers can identify and target better qualified patients, which will result in fewer pre-screening visits for patients. This reduction in patient and site burden is expected to streamline processes and improve resource allocation, ultimately benefiting patients and researchers.

Breaking down barriers: A patient-first approach to increase access in clinical research

Despite a growing appreciation for the importance of clinical research, there is a significant gap between the number of people who support trials and the number who participate. More than 70% of the population believes patients need more access to clinical research and opportunities to participate[11]. However,

studies show that fewer than 5% of adult cancer patients enroll in clinical research[12] and only 6% of the general population participates in clinical research each year[13].

These statistics underscore the need for a concerted effort to overcome the numerous barriers that limit patient participation in clinical research. Barriers such as limited access to trial information, geographical distance to trial sites, distrust of the medical system, and insufficient clinical trial awareness or health literacy can all deter potential participants.

Access to clinical research can be limited by a variety of factors, including extensive time commitments, high travel costs, child care responsibilities and potential loss of wages due to time away from work. These barriers can be particularly daunting for individuals from lower socioeconomic backgrounds, who may not have the resources or flexibility to overcome them.

To effectively address these barriers and increase patient recruitment and enrollment, sponsors must adopt a patient-first approach that focuses on increasing access to research and removing barriers to participation. Solutions could involve offering remote participation options for patients who are unable to travel, providing transportation assistance for those who can or even offering child care assistance.

Building trust with patient groups and increasing awareness around clinical research is also essential for overcoming barriers to participation. Working closely with community organizations, patient advocacy groups, and health care providers to deliver accurate and accessible information about clinical research moves sponsors closer to that end. By demystifying the trial process and highlighting the potential benefits of participation, fears and misconceptions about clinical research fade and more patients consider participating.

Charting the path forward: The power of partnership in advancing patient recruitment

As we navigate significant changes in the health care environment, the role of patients has evolved. Because today's patients are more proactive and are increasingly involved in their own care, sponsors must evolve their approach to patient recruitment.

The key to solving the patient recruitment puzzle lies in its humanization. This transformative shift necessitates a patient-first approach in which the needs, experiences and preferences of patients drive decision-making. Sponsors with the greatest success will prioritize education and awareness, leverage AI and emerging technologies to increase efficiencies, and focus on the patient to increase access and remove barriers to trial participation.

At the forefront of this evolution is the PPD™ clinical research business of Thermo Fisher Scientific, a leading provider of global clinical research solutions. We offer flexible recruitment options and patient-centered protocols to match the right patients with the right research. Our data-driven, human-centered approach focuses on locating, matching, and delivering patients to trials, addressing one of the industry's biggest challenges. We provide a broad range of capabilities to support unique protocols, alongside creative solutions and patient advocacy relationships to ensure patients are matched to the right trials.

As we look toward the future of patient recruitment in clinical research, we see a horizon marked by collaboration, patient-first approaches, and technological advancement. The focus will be on amplifying education efforts, harnessing the power of AI and eradicating barriers. With these strategies and an experienced clinical research solutions partner leading the way, sponsors can enhance the patient recruitment process and contribute to improved health outcomes for all.

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