AES Accelerated Enrollment Solutions

The *new standard* in clinical trial productivity.

WHITEPAPER

Navigating the complexities of patient recruitment and site selection in clinical trials

Executive Summary

Navigating the complexities of patient recruitment and site selection in clinical trials has become increasingly challenging for drug developers. The intertwined nature of these issues significantly impacts clinical trial timelines and costs, often delaying the introduction of potentially life-saving treatments to the market. Finding effective solutions to these challenges is crucial for the success of clinical research.

In this white paper, you will learn:

- Common challenges in site selection and patient recruitment
- Strategic considerations for selecting the right sites and enrolling the right patients
- Keys to success in sites and patients partnerships
- The strategic advantage of integrated site and patient recruitment solutions

By addressing these critical areas, drug developers can better navigate the complexities of clinical trials, ensuring successful outcomes and the timely introduction of new therapies to the market.

The high stakes of patient recruitment and site selection

Patient recruitment and site selection are critical components of clinical trials, yet they have become increasingly challenging for drug developers. Recent data highlights the growing complexity in identifying the right patients and sites, with nearly 40% of survey respondents indicating that patient recruitment remains a top challenge in clinical trials[1]. Similarly, about one in three global drug development leaders reported struggles with site feasibility and selection, underscoring the intertwined nature of these issues.

The stakes are high: up to 85% of clinical trials fail to recruit or retain a sufficient sample size, leading to unmet accrual targets in four out of five trials[2]. These shortfalls in recruitment and site selection prolong clinical trial timelines and escalate costs, delaying the introduction of potentially life-saving treatments to the market. Such inefficiencies hinder the overall progress of clinical research, making it imperative for drug developers to find partners who can effectively address both challenges.

Common challenges in site selection and patient recruitment

As clinical trials become more complex and ambitious, drug developers are encountering a range of challenges that can significantly hinder progress. From rising costs to the increasing intricacy of trial designs, the pressures on both patient recruitment and site selection are intensifying.

Rising costs of clinical trials

The escalating costs of clinical trials are a critical concern for drug developers, with nearly half of drug development leaders identifying this as their top challenge[1]. A significant factor contributing to these rising costs is the increasing difficulty in patient recruitment, which ranks as the second most influential driver of expenses in clinical research. As trials become more complex and targeted, finding suitable participants who meet specific criteria becomes increasingly challenging, leading to delays and additional expenses.

To mitigate these challenges and reduce costs, sponsors are increasingly adopting multiple patient-focused recruitment strategies. On average, sponsors are pursuing around five different approaches, including leveraging digital tools like AI-driven predictive analytics and social media campaigns, to identify and engage with potential participants more effectively. These strategies enhance recruitment efficiency and streamline trial timelines and optimize the overall budget.

Patient recruitment in clinical trials

Patient recruitment has remained one of the top challenges in clinical trials for three consecutive years, ranking second only to rising costs in 2024. Nearly 40% of global leaders identified patient recruitment as a significant obstacle facing their organization this year[1]. Unsurprisingly, struggles to recruit and retain qualified patients add to the growing cost of conducting clinical trials, exacerbating both of the top two challenges facing sponsors today.

Nearly one in three patients drop out of clinical trials[3], adding a heavy financial strain to the already high cost of clinical research. On average, it costs $6,533 to recruit a single patient to a clinical study, but the cost to replace a patient is more than three times as much, totaling around $19,533[4].

The primary patient recruitment challenges identified by global drug development leaders include identifying the right patients for specific studies and facing stiff competition with other trials or sites, particularly in cases involving rare diseases or where diversity in patient populations is required.

Large pharmaceutical companies often struggle with competition from other trials or sites, which can divert potential participants away. On the other hand, small to mid-sized companies face greater difficulties in finding the right patients who meet increasingly stringent eligibility criteria. These issues are exacerbated by the limited pool of patients for rare conditions and the need to ensure diversity in clinical trial populations, making patient recruitment an ongoing challenge across the industry.

Increasing complexity in clinical trials

The complexity of clinical trials has become a significant challenge for drug developers, with over a third (39%) reporting it as a major obstacle[1]. The rising complexity is largely driven by the need to enroll hard-to-find patient populations, particularly in trials that target rare diseases or highly specific subgroups[5]. This complexity is further compounded by the increasing number of endpoints and procedures required, as well as the global nature of many studies, which now span numerous countries and require the collection of vast amounts of data[6].

These challenges can lead to extended timelines and increased costs, making it difficult for trials to meet their objectives efficiently. However, leveraging an extensive patient database and a global network of sites can help mitigate these issues by providing access to rare patient populations, thereby reducing both timelines and costs. This approach streamlines the recruitment process and ensures that trials are more likely to succeed by reaching the necessary patient groups more effectively.

Feasibility and site selection

Feasibility and site selection have become critical challenges for nearly one in three drug developers, according to recent surveys[1]. As clinical trials become more complex, identifying and selecting the right sites is increasingly difficult, especially when faced with the pressure to meet tight timelines and maintain budget constraints.

To mitigate these challenges, almost half of the surveyed drug developers are now using more sites for each study to increase patient access and enrollment[1]. Access to a robust, global site network is crucial, offering drug developers the ability to tap into a wide array of pre-qualified, experienced sites, ensuring that trials are faster to start and more likely to meet patient recruitment targets. This strategic approach enhances speed to market and significantly improves the likelihood of reaching the right patient populations, ultimately contributing to the success of clinical trials.

Finding vendors with scientific and therapeutic expertise

Over 25% of drug developers struggle to find vendors with the necessary scientific or therapeutic expertise[1]. This gap can impede clinical trial success, as vendors lacking specialized knowledge may fail to provide the high-quality support required. Vendors with dedicated clinical research staff trained in specific therapeutic

areas offer superior study support, addressing complex scientific and clinical challenges more effectively.

Specialized expertise is crucial for enhancing trial efficiency and accuracy. Vendors with targeted knowledge can navigate therapeutic nuances more effectively, leading to improved data quality, quicker problem resolution and a faster path to market. Their tailored support and innovative solutions help reduce trial time and costs, ultimately accelerating the development of new therapies.

Elongated study startup times

Nearly a third (27%) of drug developers report significant challenges due to elongated study startup times[1]. This issue has become more pronounced across the industry, with an increasing number of sponsors noting extensions in total clinical development timelines. These delays can have substantial impacts, from escalating costs to extended time-to-market for new therapies.

To address these challenges, it's crucial to focus on efficiently identifying the right sites—those with experience in both clinical research and the specific therapeutic area of interest. Effective site selection, combined with swift patient enrollment and retention strategies, plays a key role in reducing startup times. By streamlining these processes, drug developers can minimize delays, adhere to budgets and ultimately lower study costs. Ensuring a smooth and timely start-up is essential for maintaining budget adherence and driving down overall study expenses, thus enhancing the overall efficiency of clinical trials.

Strategic considerations for selecting the right sites and enrolling the right patients

As the demand for similar patient populations rises, efficiently reaching qualified patients and minimizing barriers to participation become crucial. Conducting studies at convenient and properly equipped sites can significantly enhance recruitment and retention. To address these challenges effectively, it is important to focus on four key pillars that guide the selection of suitable sites and the enrollment of the right patients. These pillars ensure that clinical trials are conducted smoothly and successfully.

Strategic feasibility

Strategic feasibility plays a critical role in the successful execution of clinical studies by suggesting the ideal mix of sites and countries, generating precise enrollment projections, and streamlining the site selection and setup process. These measures collectively contribute to improved efficiency and the generation of meaningful results. By focusing on strategic feasibility, organizations can better navigate the complexities of patient recruitment and site selection, ensuring that trials are both effective and timely.

Look for a sites and patients partner that:

- Leverages multiple sources of data to inform country and site recommendations, ensuring access to the sites and patient populations most conducive to your protocol parameters.
- Performs analytics and predictive modeling to recommend the optimal site-country mix.
- Generates enrollment and timeline projections

based on extensive data and experience.

- Incorporates cloud-based solutions that streamline and automate the selection and setup of the top-performing clinical research sites.

Clinical innovation

Advancements in technology, data analytics and patient-first approaches are revolutionizing clinical research, significantly improving recruitment outcomes and site performance. These innovations are instrumental in accelerating the development of new therapies. By harnessing the power of big data, workflow management and artificial intelligence, the complexities of multi-layered clinical trials can be simplified. This not only mitigates risks but also sets the stage for commercial success, ensuring that new treatments reach the market more efficiently and effectively.

Look for a sites and patients partner that:

- Leverages technology to streamline repetitive, scripted tasks, like reviewing documents for critical errors to increase speed, efficiency and accuracy.
- Invests in real-time monitoring to enhance quality assurance and enable quick pivots that save time and money.
- Embraces and implements advancements in digital and decentralized trial elements to reach ideal patients and improve study retention.
- Offers full transparency on your study's progress by consolidating and standardizing data from multiple sources.
- Presents study data real-time via a client-facing dashboard for instant access to enrollment numbers, site performance and other critical parameters of study progress.

Patient-first approaches

Actively involving patients in decision-making and prioritizing their needs, preferences and experiences are pivotal strategies in modern clinical research. By adopting patient-first approaches, drug developers can significantly enhance participant engagement, retention and compliance. This focus on the patient fosters a more positive trial experience and contributes to better overall trial success, ensuring that studies are conducted more effectively and efficiently.

Look for a sites and patients partner that:

- Gauges the patient and caregiver voices through protocol-specific surveys that identify potential issues with protocol design, patient recruitment and retention.
- Customizes patient concierge services to ease the burden of travel, scheduling, clinic visits and other logistical barriers to study participation.
- Engages with patient advocacy groups and patient advisers to guide study design, planning and execution based on unique patient populations and protocol parameters.
- Designs patient-friendly outreach campaigns that validate their experiences and reduce fear and uncertainty surrounding clinical trials.
- Partners with disease-specific patient communities to enhance awareness and improve access to clinical trials as possible treatment options.

Site intelligence and activation

Effective site intelligence and activation are crucial for the prompt initiation and smooth conduct of clinical studies. By optimizing these processes, organizations can ensure seamless enrollment, efficient data collection and adherence to protocols. This streamlined approach accelerates study timelines and enhances the overall quality and reliability of clinical trial outcomes.

Look for a sites and patients partner that:

- Secures country-level approvals.
- Drives document collection for ethics committee

and regulatory submissions.

- Negotiates global site contracts and budgets.
- Leverages tools to enhance site selection and facilitate secure document workflow.
- Utilizes master agreements with sites and investigators to expedite startup process.

Keys to success in sites and patients partnerships

A strong sites and patients partner enables sponsors to navigate the evolving drug development landscape; leverage new, future-focused strategies and innovations; and ensure successful clinical development programs. Together, these capabilities, insights and expertise will keep drug developers ahead of the curve.

1. **Patient-first sites that live where your patients do.**
   A global portfolio of dedicated research sites and strategic site partnerships, from commercial to community-based – specialized, virtual, or mobile -- means you can engage with patients in any trial phase more effectively and efficiently.

2. **Recruitment and retention services that put the patient first.**
   Global, regional, and community-based flexible recruitment models ensure that diverse patients are represented, and enrollment goals are hit on time, while patient support services resolve patient barriers and reduce site burden.

3. **Home trial services that bring key trial components to the patient.**
   A critical facet of the digital and decentralized clinical trial ecosystem aimed at reducing barriers to patient participation. Study-specific analyses gauge patient burden and the impact of in-home trial protocol on participation, retention and engagement.

The strategic advantage of integrated site and patient recruitment solutions

Partnering with experts who offer integrated sites and patient recruitment solutions is essential for successfully navigating the challenges faced by today's sponsors. The complexity of patient recruitment and site selection requires a strategic approach that leverages innovation to maximize flexibility and efficiency.

Forming strategic partnerships with established site networks offers drug developers significant benefits, including enhanced efficiency, faster patient recruitment and improved data reliability. These networks leverage extensive therapeutic area experience and well-established infrastructures, resulting in reduced costs and shorter trial timelines. By collaborating with site networks, sponsors increase their chances of bringing effective therapies to market more swiftly.

Accelerated Enrollment Solutions (AES) exemplifies these qualities with its comprehensive range of solutions tailored to meet diverse needs. Our extensive network of 150+ high-enrolling research sites throughout the world ensures increased access and improved patient diversity, while a robust patient database supports a patient-first approach to recruitment. Flexible home trial services, therapeutic area expertise and purpose-built sites staffed to handle large patient volumes address major challenges facing today's clinical trials.

The advantages of working with a single vendor are significant, including closer control over sites,

standardized processes, operational efficiencies, streamlined startup and enhanced quality control. AES's capacity to support all phases of clinical trials—from Phase I to Phase IV—and a variety of therapeutic areas underscores our capability to adapt to sponsor needs and budgets.

By providing scalable, best-in-class site and patient recruitment solutions, AES ensures that sponsors are well-equipped to achieve successful outcomes throughout the clinical research process.

AES Clinical Research Network and Patient First Recruitment solutions - streamlining patient recruitment, humanizing the patient experience.

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