The 2024 Sites and Patients Trends Report

A guide for biopharma and biotechnology organizations to maximize their site and patient recruitment efforts and capitalize on the latest trends to overcome patient recruitment and research site challenges to deliver superior patient recruitment performance.

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Introduction

The future for drug developers is defined by how effectively they adopt innovative strategies and new technologies, while navigating industry challenges and complexities. Sponsors must be able to stay abreast of emerging innovations, technologies and frameworks – and implement them appropriately – to facilitate successful development and delivery of therapeutics to market.

To enable drug developers to stay a step ahead, the PPD® clinical research business of Thermo Fisher Scientific Inc., the world leader in serving science, publishes The Pulse, our annual survey of 150 leaders at biotechnology and pharmaceutical organizations around the globe. *The Pulse* assesses trends in drug discovery and development, including challenges and approaches to patient recruitment, the ability to affect diverse patient enrollment and patient participation strategies.

Deriving from *The Pulse*, our 2024 Sites and Patients Trends Report serves as a roadmap for drug developers in a dynamic pharmaceutical landscape. Use this as a guide to:

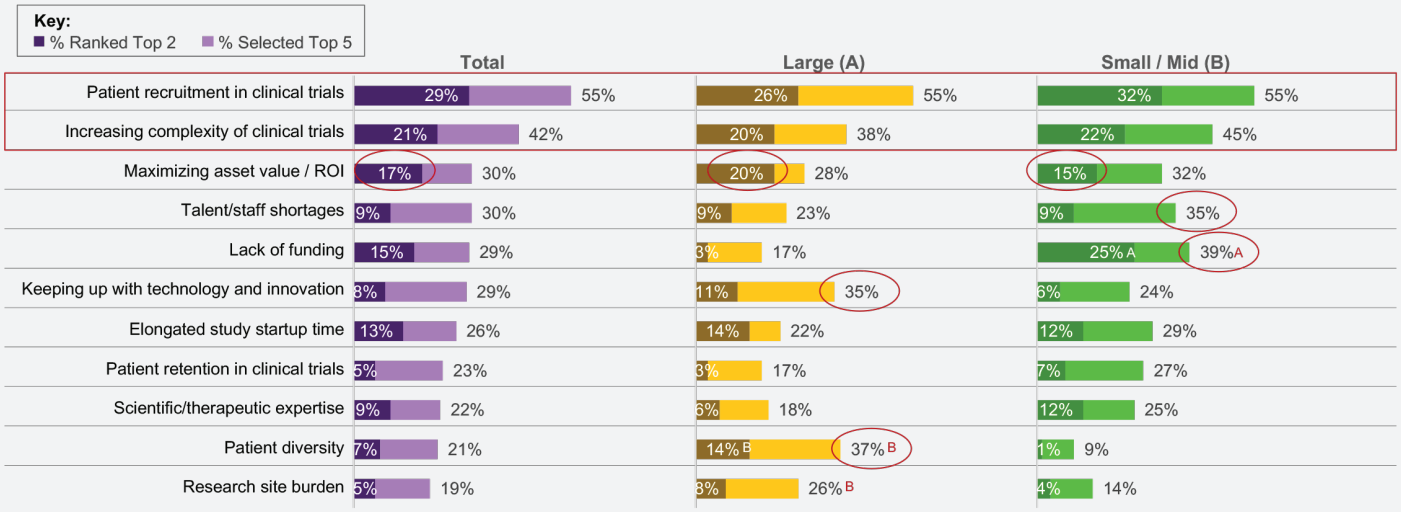
- **Understand the biggest challenges affecting site and patient recruitment and industry sentiments toward issues like patient diversity and participation strategies.**
- **Ensure you're maximizing your approach to site selection and patient recruitment with future-facing strategies and innovations.**
- **Leverage our keys to success to overcome challenges and drive superior patient recruitment performance.**

Patient Recruitment Remains the Greatest Challenge Facing Drug Developers

For two years in a row, patient recruitment and the increasing complexity of clinical trials have ranked as the top challenges facing drug developers of all sizes. More than half (55%) of survey respondents reported that patient recruitment in clinical trials is a primary hurdle facing their company.

Pharmaceutical Companies' Biggest Challenges

(Challenges selected by 25% or more*)



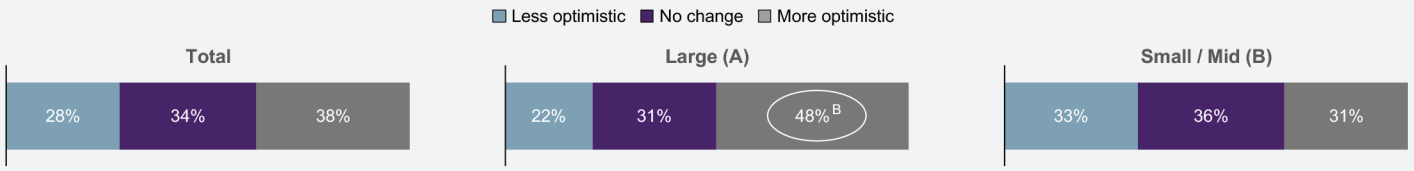
*See appendix for additional demographic detail

Optimism About Recruiting Qualified Patients is Increasing

In total, compared to how they felt two years ago, participants are slightly more optimistic than pessimistic about their ability to recruit qualified patients. This sentiment, however, is driven primarily by those at large firms; for those in small/mid-sized companies, it is approximately an even split.

- Optimism is up from the previous year's survey when only 26% of respondents indicated they were more optimistic.
- Optimism about patient recruitment in Asia exceeds levels in US/Canada & Europe, but they believe their ability to impact patient diversity has worsened.

Ability to Recruit Qualified Patients Compared to 2 Years Ago

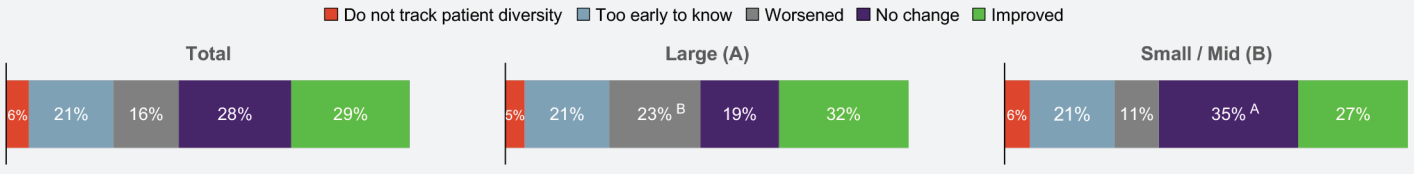


Improving Diverse Patient Enrollment is an Emerging Priority

Almost all participants are tracking patient diversity and there is more positivity than negativity about the progress being made in this area among those who have been monitoring long enough to see results. However, for about 1 in 5, it is still too early to tell.

- Large companies have a higher proportion than small/mid-sized companies who say their ability to affect patient diversity has worsened over the last two years.

Ability to Affect Diverse Patient Enrollment Compared to 2 Years Ago



Patient Participation Strategies Vary by Company Size

Multiple strategies are being employed by companies of all sizes to remove barriers to patient participation and meet diversity targets.

On average, companies are actively implementing 4.6 total strategies including:

- Establishing/improving relationships with patient advocacy organizations
- Building more inclusive criteria into protocol designs
- Offering patient assistance resources
- Remote monitoring
- Using patient-centric platforms/apps

+ Large Companies:

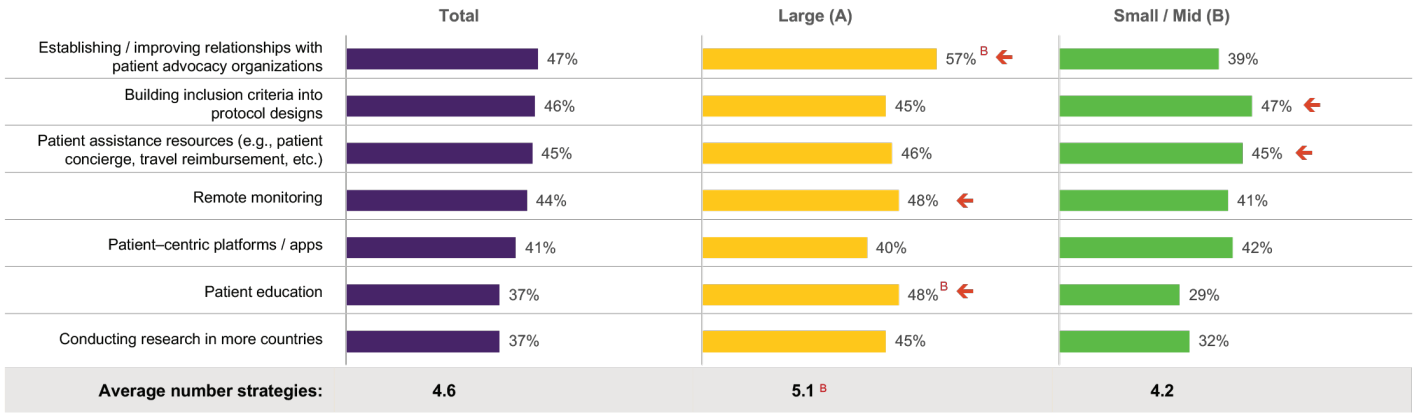
Building relationships with **patient advocacy groups** is the leading strategy, followed by remote monitoring and patient education.

+ Small/Mid-Sized Companies:

Protocol designs that incorporate **more inclusion criteria** and **patient assistance resources** are the top two strategies, perhaps because they are less resource-intensive than other strategies.

Top Strategies Used by Sponsors to Remove Barriers to Patient Participation and Meet Diversity Targets

(Strategies selected by 40% or more*)



= draws attention

*See Appendix for complete detail

Clinical Development Timelines are Returning to Pre-Pandemic Norms

Across the industry, somewhat more participants indicate that clinical development timelines are extending.

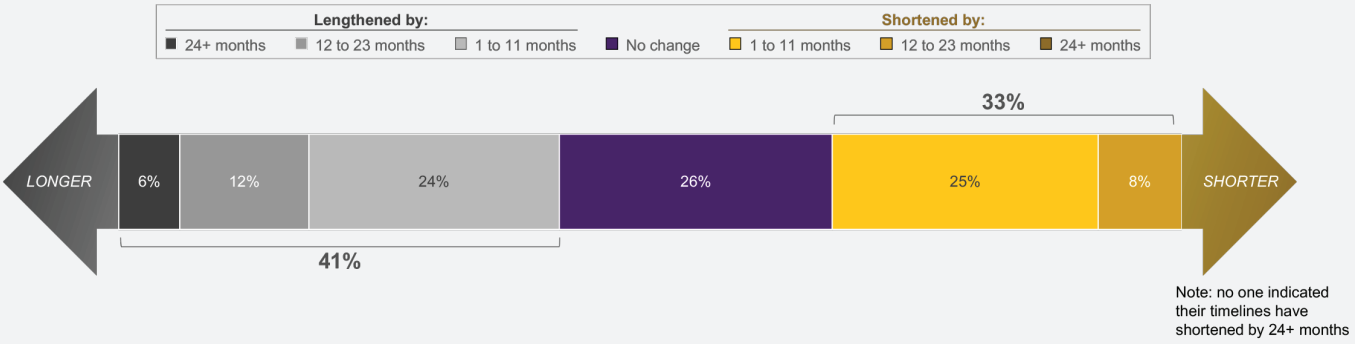
For those whose timelines have increased, most say they have lengthened by less than a year, but 2 out of 5 indicate their timelines have stretched out by more than 12 months.

Those who have experienced shorter development timelines say the reduction has primarily been in the range of 1 to 11 months.

The lengthening timeline trend may have plateaued; only 41% say timelines are longer vs. 52% in the previous year's survey.

Change in Timeline to Produce a Drug Compared to 2 Years Ago

(from first-in-human trials through regulatory submission)



Strategic Considerations for Selecting the Right Sites and Enrolling the Right Patients

Finding the right sites and patients for clinical trials is more challenging than ever. As more companies compete to recruit similar patient groups, it's paramount to efficiently reach qualified patients, reduce barriers to their participation and conduct studies at sites that are convenient and properly equipped.

Four pillars underlie a strategic approach to selecting the right sites and enrolling the right patients.

Strategic Feasibility

Strategic feasibility is a vital aspect of clinical trials that involves carefully assessing potential sites and patient populations for a study. Using various data sources, analytics and predictive modeling helps make informed recommendations on the best countries and sites to choose.

An important part of this process involves assessing the selected sites to ensure they have the necessary infrastructure and resources, reducing the likelihood of delays and maintaining high data quality standards. Sites should also be evaluated based on their access to patient populations, ensuring they can reach the specific demographics required for the study.

In addition to its impact on site selection and patient recruitment, strategic feasibility also plays a crucial role in optimizing study outcomes and reducing startup cycle times. By suggesting the ideal mix of sites and countries, generating enrollment projections and streamlining the site selection and setup process, strategic feasibility contributes to successful study execution, improved efficiency, and the generation of meaningful results.

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

Leveraging advancements in technology, data analytics and patient-centric approaches can improve recruitment outcomes and accelerate the development of new therapies.

Advanced analytics, predictive modeling and machine learning streamline the site selection process, allowing for more informed decision-making, while innovative strategies for patient recruitment improve enrollment and better attract eligible participants.

Embracing innovation improves study efficiency and expedites recruitment, increasing speed to market. These advancements help pave the way for successful and impactful clinical trials. By harnessing the power of big data, workflow management and artificial intelligence, complex and multi-layered clinical trials can be simplified, mitigating risks and setting the stage for commercial success.

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
- 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 Centricity

Patient centricity is a key factor in the success of today's clinical trials. By actively involving patients in decision-making and prioritizing their needs, preferences and experiences, drug developers can improve participant engagement, retention and compliance, leading to better overall trial success.

This, in turn, improves data quality and reduces the risk of dropout, ultimately strengthening the validity and reliability of study findings. Moreover, patient centricity fosters trust and transparency between researchers and participants, creating a collaborative environment that promotes open communication and mutual respect.

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

Site intelligence and activation are crucial for successful clinical trials. Site intelligence involves analyzing data on potential research sites, considering factors like capabilities, patient populations and performance history. This information helps make informed decisions when selecting sites, improving recruitment, data quality and study timelines.

Site activation is the process of preparing selected sites for a trial. This includes establishing contracts, obtaining regulatory approvals, training staff and ensuring necessary resources are in place. Effective activation enables prompt study initiation and smooth conduct, ensuring seamless enrollment, data collection and adherence to protocols.

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

The 2024 trends show that patient recruitment remains a notable challenge and a pressing priority, which makes having the right sites and patients partner a critical decision point.

A strong sites and patients partner enables pharmaceutical developers to navigate the evolving landscape of the biotechnology and pharmaceutical industry; 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-centric sites that live where your patients do

A global portfolio of our own 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 Digital and decentralized solutions that are right-sized for you

A robust digital and decentralized clinical trial ecosystem delivers solutions for all types of studies – using technology and support services for easier trial participation, better retention and high engagement.

We Forecast What's Next, So You Stay Ahead

Our 2024 Sites and Patients Trends Report illuminates the pharmaceutical landscape's shifting dynamics, emphasizing the pivotal role of patient recruitment and site selection. Key trends reveal that patient recruitment remains a significant hurdle facing global companies of all sizes. While optimism about patient recruitment is increasing, affecting diverse patient enrollment is emerging as a top priority.

The current and future state of patient recruitment and site selection highlights the industry's response to keep up with regulatory change and industry shifts and an increasingly customer-centric landscape. To keep pace in 2024 and beyond, drug developers must prioritize strategic relationships with a sites and patients partner that is ready for all phases of development, delivers a wide range of solutions and brings innovation to maximize efficiency, engagement and speed to market.

The PPD clinical research business of Thermo Fisher Scientific is the leading provider of site and patient recruitment solutions with a reputation for keeping patients at the forefront. With more than 30 years of proven experience in the industry and nearly 5,000 recruited studies, **our teams know what it takes to bring the right patients to the right sites**.

Our unique combination of global site locations, patient-centric and digital solutions and forward-thinking services take patient engagement, enrollment and retention to the next level. And when your studies are ready to recruit, you'll have access to a database of 100 million households of fully identified patients – about 20 million of whom self-identify as coming from diverse backgrounds.

PPD is your single partner delivering innovative site and recruitment solutions that center on patients so you can be centered on success.

Work with a sites and patients provider that sets the trends.
We're closer to patients, faster to recruit.
Tap into the expertise of PPD sites and patients solutions today.

Methodology: The Pulse is an annual survey conducted by the PPD clinical research business of Thermo Fisher Scientific. We surveyed 150 participants, director-level or higher, at pharmaceutical, biopharmaceutical or biotechnology companies in March/April 2023. Participants worked in roles related to drug development at companies with at least one compound in development. Geographies surveyed were Asia, Europe and US/Canada. Large organizations, with annual R&D spend of $1 billion or more, comprised 43% of respondents, while small/mid organizations with an annual R&D spend of less than $1 billion comprised 57% of respondents.

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