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Welcome

The success of a clinical trial highly depends on finding and keeping qualified participants. Yet, this crucial phase continues to pose significant challenges. \underline{A} recent study found that more than 80% of clinical trials fail to meet their enrollment targets, resulting in longer timelines, budget issues, and, in some cases, early termination.

In the U.S., roughly 30% of participants drop out before trials conclude, further compromising data outcomes. Financial barriers, complex enrollment procedures, and inconsistent communication from study teams are among the leading causes. These issues don't just slow progress—they drain valuable resources. According to Market.us, delays in clinical trials can cost sponsors between \$600,000 and \$8 million per day in lost development and launch opportunities.

To overcome these hurdles, many sponsors are now turning to specialized outsourcing partners. By delegating patient recruitment, pre-screening, communication, and follow-up to expert teams, you can achieve better results while controlling costs.

This white paper is tailored for sponsors and stakeholders seeking to reduce operational costs without compromising trial integrity. It explores the most common enrollment challenges and demonstrates how strategic outsourcing, when paired with the right tools and processes, can help clinical trials run faster, smarter, and more cost-effectively.

The High Stakes of Clinical Trial Enrollment



Patient enrollment is a significant, yet often challenging, aspect of clinical trials in the pharmaceutical and biopharmaceutical sectors. The process of identifying, recruiting, screening, and randomizing participants is essential not just for advancing research but also for managing costs effectively.

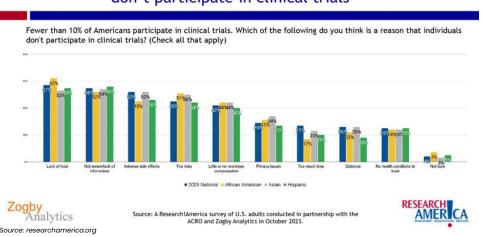
Without sufficient qualified patients, trials stall. Delays in enrollment not only extend timelines and increase operational costs but also delay patient access to potentially life-saving therapies. In some cases, they can even jeopardize the viability of the entire study.

Enrollment also influences the scientific integrity of trials. Inadequate sample sizes or lack of diversity can compromise data quality, making it more challenging to draw valid conclusions or gain regulatory approval.

As pressure increases to reduce trial costs while accelerating results, efficient and cost-effective enrollment strategies have become a top priority. Many sponsors are turning to specialized third-party providers to streamline this process without sacrificing quality.

An <u>online survey</u> conducted by Zogby Analytics on behalf of Research!America and ACRO, in October 2023, found that lack of trust and information are top reasons people do not participate in clinical trials.

Lack of trust and information are top reasons people don't participate in clinical trials



Understanding Clinical Trials

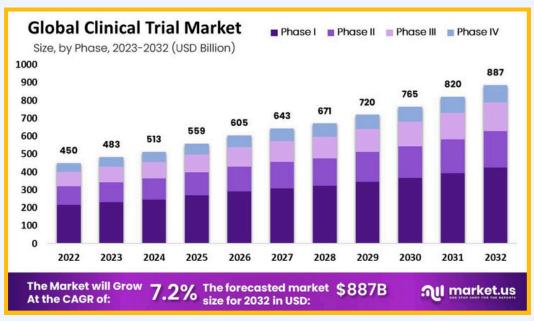
What Are Clinical Trials?

<u>Clinical trials</u> are research studies that evaluate the safety and effectiveness of new medical treatments, devices, drugs, or interventions in human participants. These trials adhere to strict regulatory standards and are crucial for obtaining market approval and enhancing patient care.

Clinical Trials versus Clinical Studies

While both involve research with human participants, *clinical studies* is a broader term. *Clinical trials* specifically test new treatments through controlled protocols, while observational studies monitor outcomes without intervention.

The global clinical trial market is on a strong growth trajectory, projected to reach \$887 billion by 2032, up from \$450 billion in 2022, with a compound annual growth rate (CAGR) of 7.2%. This rapid expansion reflects increasing investment in all trial phases, especially as demand rises for faster and more efficient drug development.



Source: media.market.us

Key Stakeholders Involved

Clinical trials rely on coordination between multiple parties, each playing a distinct role in ensuring the study runs smoothly and meets its objectives. From funding and oversight to execution and participation, here are the key stakeholders who move the process forward.



- **Sponsors:** Fund and oversee the trial (e.g., pharmaceutical and biotech companies).
- Contract Research Organizations: Manage operational aspects.
- Investigators and Sites: Execute study protocols.
- **Regulatory Bodies:** Ensure safety and compliance (e.g., FDA).
- Patients: Volunteer their time and trust.

Why Timely and Effective Enrollment Matters

Timely enrollment isn't just about staying on schedule, it's about avoiding the rising financial burden of delays, which can cost sponsors millions in development hold-ups and lost market opportunities.

Moreover, from a commercial perspective, delays in enrollment can extend timelines and inflate costs, diminishing potential returns on investment. Ultimately, ensuring timely enrollment is vital not only for the successful execution of research but also for fostering innovation and maintaining competitiveness in the market.

By prioritizing effective enrollment strategies, researchers can protect the integrity of their findings and ensure that valuable scientific inquiries are not hindered.

The Enrollment Crisis: What's Slowing Down Trials Today

Most trials struggle to meet their recruitment targets on time, and some never reach them at all. These delays have a ripple effect, driving up costs, weakening data quality, and slowing down the delivery of new therapies to market. Below are the most common issues that continue to challenge trial teams:

Slow Recruitment

Traditional methods (flyers, ads, referrals) are ineffective for enrolling patients quickly.
Without digital tools or improved recruitment methods, many sites struggle to enroll enough patients.

Complex Protocols

Stricter eligibility requirements disqualify willing patients, reducing the number of eligible participants and extending the recruitment time.

High Dropouts Rates

Engaging patients post-enrollment is challenging; long wait times and poor communication can lead to dropouts.

Operational Costs

Delays in enrollment increase trial costs, which in turn impact the resources allocated to site management and staffing.

Limited Reach

Trials often target a narrow participant pool near research centers, limiting access for rural and underserved communities and thereby reducing the diversity of the data.

Smarter, Leaner, Faster: Outsourcing as a Strategic Advantage

As clinical trials become increasingly complex, efficient operations are crucial, especially for patient enrollment. By outsourcing, you can access effective recruitment strategies without the high costs of developing them in-house.

What Is Clinical Trial Outsourcing?

Clinical trial outsourcing involves delegating trial-related tasks like patient recruitment, data management, and monitoring to CROs and specialized third-party providers.

The market for clinical trial outsourcing is rapidly growing, valued at USD 50.7 billion in 2024 and projected to reach <u>USD 70 billion by 2029</u>. These figures reflect the growing reliance on outsourcing as a strategic solution for companies seeking to reduce costs, accelerate development, and leverage specialized expertise, particularly in high-volume markets such as the U.S.

The Advantages of Clinical Trial Outsourcing

Flexibility: Adapt quickly to changing trial needs, timelines, or protocol adjustments without overextending internal teams.

Scalability: Quickly expand or reduce resources based on enrollment pace, trial phase, or site performance, ensuring optimal support at every stage.

Access to expert resources: Tap into advanced tech designed for today's clinical trial challenges, from digital recruitment tools to compliance tracking.

Trained teams with domain expertise: Access experienced agents who understand patient engagement, regulatory protocols, and trial-specific requirements.

Faster execution: Established workflows and systems reduce setup time and accelerate recruitment activities from day one.

Cost efficiency: Reduce fixed overhead and avoid long-term staffing costs by leveraging a strategic partner in a region offering lower wages without sacrificing quality.

The right outsourcing partner reduces friction, enhances quality, and delivers a return on investment (ROI), helping trials stay on track, on budget, and fully enrolled. By choosing the right outsourcing model, sponsors can reduce costs without compromising data quality, patient experience, or regulatory compliance.

Choosing the Right Outsourcing Model

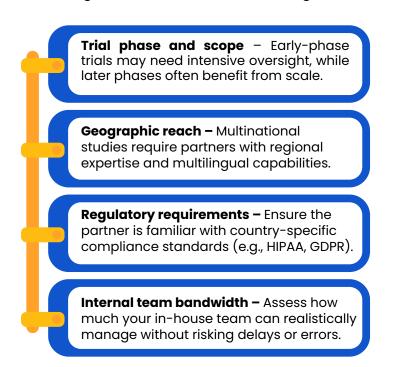
The best model depends on the specific needs of your research. Selecting the right structure can significantly impact the outcome of your enrollment strategy. Some trials require full operational support, while others only need assistance in specific areas, such as patient recruitment or data management. Understanding the differences between available models helps ensure you're not overcommitting or under-resourcing essential functions.

Full-Service Outsourcing, Full-Service Provider, or Hybrid?

- **Full-Service Outsourcing (FSO):** Provides end-to-end trial support across the entire trial lifecycle, from planning and recruitment to monitoring and reporting. This approach is beneficial for sponsors who lack the expertise or resources to handle and manage the whole project independently.
- **Functional Service Provider (FSP):** Focuses on specific functions such as patient outreach, pre-screening, data handling, or contact center support. This is a cost-effective option when you want to retain in-house control of core operations while filling skill or capacity gaps.
- **Hybrid Studies:** Combines elements of FSO and FSP, offering flexibility to outsource selected tasks while keeping others internal. This is well-suited for mid-sized trials or teams with uneven resource distribution.

Decision Criteria

When selecting an outsourcing model, consider the following:



Step-by-Step Framework

1

Define your goals and timeline

What are your enrollment targets, and how quickly do you need to achieve them?

Identify resource and expertise gaps Identify where you lack capacity or specialized expertise.

2

3

Match the model to your trial needs Align the structure with what your study actually requires.

Evaluate vendor experience

Look for proven results in your therapeutic area and population type.

4

5

Ensure compliance, scalability, and cultural alignment
Ensure compliance and team compatibility.

Best Practices to Optimize Enrollment Through Outsourcing

When executed well, outsourcing enrollment can deliver strong results. To get the most out of your outsourcing strategy, consider the following best practices:



Use multilingual agents for a broader reach.

Supporting multiple languages helps engage diverse and global patient populations, improving inclusivity and enrollment rates.



Align KPIs with enrollment milestones.

Define clear performance benchmarks such as response rates, screening completions, and conversion timelines to ensure progress is measurable and on track.



Implement SLAs to maintain quality and responsiveness.

Service level agreements (SLAs) help maintain consistent performance, set expectations for turnaround times, and ensure accountability across functions.



Provide ongoing training on protocol-specific needs.

Equip vendor teams with up-to-date information about trial protocols, eligibility criteria, and compliance requirements to ensure accuracy and minimize rework.



Maintain open, consistent communication with the vendor.

Regular check-ins, real-time updates, and clear escalation paths foster transparency, helping to resolve issues quickly and keeping the partnership aligned.

Tech Tools Powering Faster, Smarter Enrollment

Technology plays a bigger role in improving clinical trial enrollment. It speeds up the recruitment process while enhancing accuracy and compliance at every stage. A good outsourcing partner uses advanced technology to ensure trial success.

Here are some key tools that leading outsourcing companies use today:

Al and machine learning for patient targeting

Predictive algorithms help identify eligible patients more quickly by analyzing health records, demographics, and online behavior, thereby reducing manual workload and increasing match accuracy.

Digital pre-screening and eligibility tools

Automated questionnaires and online eligibility forms quickly filter out ineligible candidates, allowing agents to focus only on high-potential participants.

eConsent platforms for easier, faster onboarding

Secure, user-friendly digital consent tools make it simpler for patients to understand and agree to participate, streamlining enrollment and improving compliance.

CRM-powered contact centers for ongoing engagement

Integrated CRM (customer relationship management) systems track every patient interaction, support follow-up scheduling, and send automated reminders, helping maintain strong engagement and reduce drop-off.

Centralized dashboards for sponsor oversight

Sponsors can monitor performance, track key performance indicators (KPIs), and identify bottlenecks in real-time through centralized platforms that consolidate data across multiple sites and vendors.

Managing the Risks: Outsourcing Without Losing Control

Outsourcing offers speed and efficiency, but it also introduces potential risks that can impact trial results. Without the supervision, even the best partnerships can face setbacks. That's why it's essential to build safeguards into the outsourcing process from the start.

Understanding the most common pitfalls—and how to manage them—helps sponsors retain control while still reaping the benefits of outsourced support.

Common Pitfalls



Misaligned Goals

A lack of clarity between sponsors and vendors can lead to conflicting priorities or unmet expectations.

Quality Inconsistencies

Quality inconsistencies can affect patient experience and data reliability if effective management of training, processes, and communication is not in place.

Data privacy or compliance issues

Improper handling of sensitive information or failure to follow regulations (e.g., HIPAA, GDPR) can lead to legal risks and reputational damage.

Set clear SLAs and accountability metrics.

Define service level agreements (SLAs) that outline performance standards, timelines, and responsibilities to keep both parties aligned.

Provide regular training and quality assurance for agents

Ensure all outsourced agents stay current on study requirements and compliance protocols, reducing the risk of error or misinformation.

Ensure all communications are HIPAA and GDPR compliant.

Utilize secure platforms and auditready systems to safeguard patient data and ensure compliance with regional data protection laws.

Your Next Step: Outsourcing for Faster Enrollment

Clinical trial success begins at the enrollment desk. A slow or inefficient recruitment process can derail timelines, inflate costs, and delay patient access to therapies. That's why strategic outsourcing has become an essential part of modern trial management, enabling trials to move faster, reach further, and accomplish more with less.

The key is choosing partners who understand the stakes, deliver measurable results, and align with the unique needs of each trial. Ultimately, enrollment success isn't just about volume. It's about reaching the right patients at the right time and in the right way.



How Select VoiceCom Enhances Clinical Trial Outcomes

Select VoiceCom (SVC) delivers industry-compliant contact center solutions for clinical trials. With experience supporting global studies across a wide range of medical fields, we help CROs and sponsors overcome common recruitment challenges and meet enrollment goals.

Our approach combines trained agents who offer HIPAA-compliant communications and real-time enrollment updates. Whether you're managing a local study or coordinating a global Phase III trial, SVC has a proven track record of helping CROs and sponsors achieve trial success without compromising quality.

Glossary

Clinical Trial

A research study that tests new medical treatments or interventions to evaluate their safety and effectiveness in humans.

Patient Enrollment

The process of identifying, recruiting, screening, and registering qualified participants for a clinical trial.

Dropout Rate

The percentage of participants who leave a clinical trial before it is completed, often affecting data quality and outcomes.

Contract Research Organization (CRO)

A company hired by a sponsor to manage clinical trial operations such as recruitment, data collection, and regulatory compliance.

Sponsor

The organization, typically a pharmaceutical or biotech company, that funds and oversees the clinical trial.

Functional Service Provider (FSP)

An outsourcing model where specific trial functions, like patient outreach or data handling, are handled by external experts while the sponsor keeps core control.

Hybrid Model

An outsourcing approach that combines in-house trial management with selected outsourced functions, offering flexibility and control.

eConsent

An electronic method for obtaining patient consent, making it easier and faster for participants to review and sign consent forms digitally.

Pre-Screening

A step in recruitment where patients are assessed for basic eligibility before undergoing full screening for trial participation.



Scalability

The ability to increase or reduce resources, such as staff or support, based on the needs of the trial.

Service Level Agreement (SLA)

A formal agreement between sponsors and vendors that defines expected performance standards, timelines, and accountability.

HIPAA (Health Insurance Portability and Accountability Act)

A U.S. federal law that sets standards for protecting sensitive patient health information, ensuring confidentiality, security, and access control during medical research and clinical trials.

GDPR (General Data Protection Regulation)

A regulation enforced by the European Union to protect personal data and privacy. It governs how clinical trial data is collected and used, especially for participants within the EU.

Resources

Welcome

Source: https://media.market.us/clinical-trials-statistics/

Choosing the Right Outsourcing Model

Source: https://www.ppd.com/blog/outsourcing-clinical-trials-models-overview/

Your Next Step: Outsourcing for Faster Enrollment

Source: https://www.appliedclinicaltrialsonline.com/view/future-proofing-outsourcing-strategy-agile-fast-moving-clinical-trial-ecosystem/

Understanding Clinical Trials

Source: https://media.market.us/clinical-trials-statistics/, https://fightfungus.org/what-is-a-clinical-trial/

The Enrollment Crisis: What's Slowing Down Trials Today

Source: https://www.scirp.org/journal/paperinformation?paperid=128354

Smarter, Leaner, Faster: Outsourcing as a Strategic Advantage

Source: https://www.globenewswire.com/news-release/2024/12/31/3003065/28124/en/, https://www.transparencymarketresearch.com/clinical-trials-outsourcing-market.html

Enabling Success Through Technology: Tools That Deliver Result Source:

https://www2.deloitte.com/content/dam/insights/us/articles/22934_intelligent-clinical-trials/DI_Intelligent-clinical-trials.pdf

CONTACT US







At Select VoiceCom, we assist CROs and sponsors in addressing challenges related to clinical trial enrollment. Our contact center operations are onsite and compliant with HIPAA and GDPR, providing support from trained agents with real-time recruitment assistance.

We understand the urgency and complexity of your trial demands. That's why our solutions are structured to facilitate faster participant engagement while ensuring compliance throughout the process.

Accelerate Trial Enrollment with Expert-Driven Support

Clinical trial enrollment is too important to leave to chance. Select VoiceCom provides the right support for your trial needs. From lead generation to screening and appointment setting, our trained teams work in a secure, performance-focused environment built for speed and accuracy.

Let's Connect

Discover how Select VoiceCom enables CROs and sponsors to enroll participants faster, stay compliant, and maintain trial momentum without compromising quality.

Contact our Sales Team at



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www.selectvoicecom.com

Connect with us today, and let's soar to new heights together.

