ODC Life Sciences

WHY LATAM IS THE FUTURE OF PATIENT RECRUITMENT

White Paper

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EXECUTIVE SUMMARY

Clinical research faces a critical challenge: the difficulty of recruiting patients efficiently. Many studies fail to meet enrollment timelines, resulting in delays, increased costs, and significant financial impact for sponsors. Traditional markets such as the United States and Europe are saturated, while regulatory demands for diversity in clinical data continue to grow. In this context, Latin America emerges as a strategic alternative, offering faster recruitment, diverse populations, and competitive costs, while maintaining global standards of quality and compliance.

THE CURRENT PARADIGM: THE GLOBAL RECRUITMENT BOTTLENECK

Clinical development has entered a critical bottleneck period as many trials are stalling or failing due to one persistent challenge: patient recruitment. Data from major academic cancer centers demonstrate that more than 50% of initiated clinical trials failed to enroll a single patient over the study period.[1] This uneven distribution of patient enrollment across active trials underscores a systemic recruitment challenge within the current clinical research model. For small and mid-sized biotech companies, prolonged recruitment delays can erode investor confidence, create funding gaps, and, in some cases, threaten the financial viability of the organizations conducting these trials.[2]

Countries that are traditionally recruitment powerhouses—such as the United States, Western Europe, and parts of East Asia—are no longer delivering at scale. Sites are saturated, patients are overburdened with competing trial options, and the cost of recruitment continues to rise. The estimated direct daily cost to conduct a Phase II or Phase III clinical trial is approximately $40,000 per day. With those in respiratory, rheumatology, and dermatology having the highest relative daily direct costs.[3] At the same time, the number of trials has almost tripled globally in the past decade,[4] creating intense competition for a limited pool of eligible patients. Even with aggressive site activation and digital recruitment tools, many sponsors face months of delays, escalating budgets and protocol amendments driven by under-enrollment.

Adding to the dilemma of general recruitment inefficiency is the rising scrutiny from regulators around population diversity. The FDA's Diversity Action Plan framework, new ICH guidelines and global demands for inclusive data are forcing sponsors to rethink traditional site selection strategies.[5,6] Yet in legacy markets, diversity goals are often aspirational, hampered by systemic barriers to minority enrollment. *"Patient recruitment is the single greatest threat to clinical development today — but it's also the biggest opportunity. As traditional markets become*

saturated and stagnant, Latin America offers a fresh path forward: faster enrollment, broader access, and real diversity. The sponsors that are willing to bring trials to LATAM are facing low to no competition to recruit patients for their clinical trials. Our clients have had great success in expediting clinical enrollment, leveraging the large population of Latin America. We are at the epicenter of a vast shift in development strategy, and we strongly believe that the new paradigm of global recruitment will include LATAM." Daniel Zequeto, ODC Life Sciences CEO.

SITE SATURATION

As more companies and biotech hubs gain influence, the speed and efficiency of clinical enrollment become vital. A growing number of players are competing with similar modalities and technologies for a finite pool of patients.

According to ClinicalTrials.gov, the number of interventional clinical trials increased from 1,873 in early 2000 to 22,131 in early 2020—an increase of approximately 1,082%.[7] This rising statistic showcases the need for companies to rethink their core strategies regarding patient enrollment.

Despite being home to the most advanced healthcare infrastructure, traditional clinical trial geographies are constrained by systemic inefficiencies that hinder patient recruitment. One of the most pressing issues is site saturation which leads to high patient competition.

For example, at Memorial Sloan Kettering Cancer Center (MSK) in New York City — one of the leading U.S. research institutions — 531 trials are actively recruiting as of August 27, 2025.[8] Although outpatient visits do not represent unique patients and participation rates may vary at high-volume sites, MSK reports roughly 1.05 million outpatient visits annually.[9] Estimating that only 4% of cancer patients nationwide enroll in clinical trials,[10] this equates to approximately 42,000 potential patients, approximately 79 per active trial — underscoring the intense competition for enrollment. This problem is seen throughout the leading cancer institutions in the country, showcasing the highly competitive nature of patient recruitment at hospitals and sites within the United States.

Leading research sites often host dozens of concurrent clinical trials, many of which target overlapping patient populations. As a result, patients are over-screened, screen failure rates rise, and enrollment slows. Sites, driven by enrollment incentives, may overcommit and underdeliver, stretching timelines and increasing costs.[3,11]

Compounding this is the lack of physician engagement and referral support.[12] Busy community physicians are rarely incentivized or equipped to identify and refer patients to clinical trials,[13,14] and even dedicated investigators often operate at capacity. This bottleneck limits trial access to a narrow pool of patients, concentrated in large academic sites, excluding broader populations who may be eligible but remain unreachable through traditional recruitment channels.[15]

LACK OF DIVERSITY

One of the most persistent challenges in clinical research is the low level of diversity. Despite growing attention from regulators, patient advocates, and industry leaders, clinical trials continue to significantly underrepresent marginalized racial and ethnic groups, women, and other historically underserved populations.

As an example, the FDA report "Drug Trial Snapshots" shows that among 32,000 individuals who participated in new drug trials in the U.S. in 2020, only 8% were Black, 6% Asian, 11% Hispanic, demonstrating significant underrepresentation of these demographic groups. These rates fall well below the U.S. Census data, which found 14.2% of the population was Black, 7.2% Asian, and 18.7% Hispanic.[16,17]

Similarly, a recent analysis that examined data from 341 Phase III clinical trials supporting drug approvals in the US between 2017 and 2023 found that only 6% of pivotal studies achieved enrollment that aligned with the distribution of the four largest racial and ethnic groups in the US population.[18]

Several factors contribute to this persistent lack of diversity in clinical research. Historical mistreatment, unconscious biases among healthcare providers, limited cultural awareness, and language barriers can undermine communication, reduce trust, and hinder recruitment into trials.[19,20]

Structural barriers also play a significant role: minority communities often face limited access to healthcare, economic constraints, and practical challenges such as inflexible work schedules and reliance on public transportation, all of which reduce their chances of learning about and participating in clinical studies.[19,20]

As trial recruitment tends to draw from narrow, less diverse segments of the population, broader patient groups remain excluded, limiting both enrollment diversity and overall enrollment volume.[21] As a result, many studies fail to capture how treatments may perform across different patient populations, reinforcing the need for more inclusive research strategies.[16]

Former FDA Commissioner Robert Califf emphasized this point in an interview with Applied Clinical Trials, stating that "Participants in clinical trials should be representative of the patients who will use the medical products."[22] This focus on understanding not only the patients within the clinical trial but also the broader commercial opportunity, places additional pressure on companies to recruit efficiently, and to understand the populations their products are intended to serve.

The FDA's Diversity Action Plan Draft Guideline from 2024, further underscores this need, stating: "Improving access to clinical trials, such as by initiating the study in geographical sites with diverse populations, could help drugmakers achieve enrollment goals."[5] This explicit recommendation encourages sponsors to think more broadly – beyond traditional recruitment geographies – to meet diversity and enrollment targets.

FINANCIAL IMPLICATIONS FOR SPONSORS

Missing recruitment timelines has direct and compounding financial consequences for sponsors.

The estimated direct daily cost to conduct a clinical trial is approximately $40,000 per day for phase II and III clinical trials and a single day of delay can represent approximately $500,000 in lost prescription drug or biologic sales, or even more depending on the phase and therapeutic area,[3] due to extended operational costs, missed market opportunities, and delayed milestone payments or regulatory filings.

For small- and mid-sized biotech companies, such delays can erode investor confidence, trigger down rounds, and compromise licensing and merger and acquisition negotiations. For large pharma, prolonged timelines reduce effective patent life and undercut revenue projections. In both cases, sluggish recruitment directly impacts a company's valuation, resource allocation, and strategic momentum.

In an interview with Pharmacy Times, Harsha Rajasimha, Founder and CEO of Jeeva Informatics, stated that "The number one challenge we heard firsthand from various biopharmaceutical sponsors and medical device sponsors is patient recruitment... 30% of clinical trials terminate because they're unable to enroll the target number of patients in that clinical trial. Of the 70% of trials that progress beyond recruitment barrier, the majority of them are still delayed... These drugs and devices have a very finite patient life, during which that return on investment must be recovered of all the R&D costs."[23]

WHY LATIN AMERICA IS A STRATEGIC REGION FOR CLINICAL TRIAL SPONSORS

Latin America delivers an ideal mix of recruitment speed, patient access, and operational efficiency at a time when global sponsors are increasingly constrained by saturated sites, rising costs, and diversity mandates – yet the region remains underrepresented in clinical trials.

This imbalance is reflected in the WHO trial registry dataset (1999 to June 2025): the United States recorded 197,090 trials, while the combined total across key LATAM countries (Brazil, Mexico, Argentina, Chile, Colombia, Cuba, Uruguay, Peru, and Venezuela) was 52,615.[4] In practical terms, fewer trials per capita means less competition for eligible patients, creating the conditions for faster recruitment in LATAM.

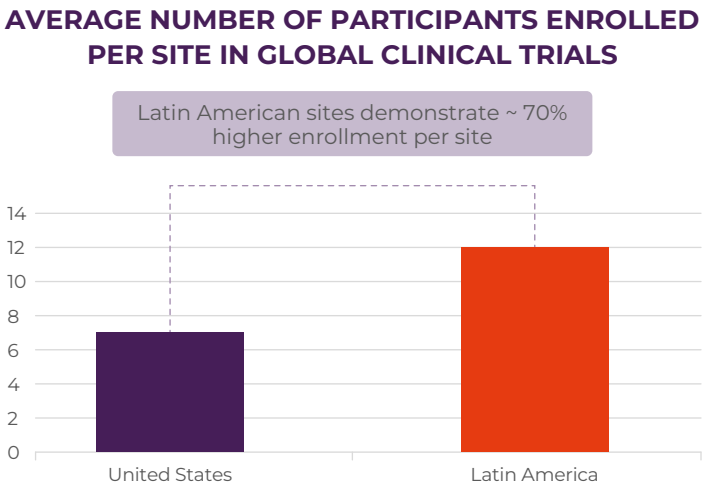
In countries like Brazil, Argentina, Colombia, and Mexico, collaborative healthcare systems combined with strong physician-patient relationships foster a referral culture that drives rapid enrollment.[24,25]

Sites in LATAM have demonstrated strong performance in recruitment, meeting or exceeding enrollment targets, in contrast to the lower rates frequently reported in the U.S. and Europe.[24,25]

On average, clinical trial sites in the United States enroll approximately 7 participants per trial, whereas sites in Latin America enroll about 12

participants per trial. This higher per-site recruitment productivity reflects larger available patient pools and strong investigator engagement, contributing to shorter enrollment timelines and more efficient trial execution.[24]

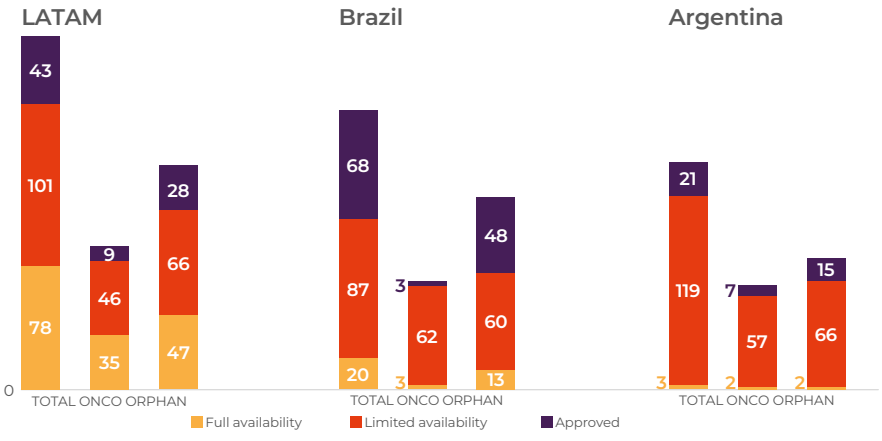
Figure 1: Average number of participants enrolled per site in global clinical trials



Source: Adapted from Clinical research in Latin America: – The New Frontier Journal for Clinical Studies, 2019.[24]

The region also offers large, treatment-naïve patient populations, many of whom are eager to participate in trials due to limited access to cutting-edge therapies through public health systems.[24] For them, clinical trials may represent the only access to innovative therapies in Latin America. According to the FIFARMA W.A.I.T. Indicator it takes, on average, 4.75 years for new medicines to become publicly available in Latin America after FDA or EMA approval.[26] During this extended access gap, there is a larger pool of treatment-naïve or minimally treated patients, especially in earlier lines of therapy.

Figure 2: Average number of participants enrolled per site in global clinical trials



Source: Adapted from IQVIA; FIFARMA. Patient W.A.I.T. Indicator 2023: Latin America. Final Report, 2024[26]

An assessment of the effective availability of these therapies (Figure 02), demonstrates that a substantial proportion of oncology and orphan disease treatments are concentrated within the private healthcare sector, with limited penetration into public health systems, particularly in Brazil and Argentina. This underscores that, in addition to delaying drugs to become publicity available, access to innovative therapies is characterized by significant inequities in distribution, resulting in a large unmet medical need within public institutions and underserved regions. This reality not only reinforces the humanitarian value of research participation but also translates into faster and more highly motivated patient enrollment for sponsors.[26]

Daniel Zequeto SME, CEO of ODC Life Sciences, a São Paulo–based, Patient Recruitment–focused CRO, states *"The global clinical trial model is broken, not because of science, but because sponsors keep looking for patients in the same places, creating a high competition across programs. In Brazil and Argentina, we're enrolling faster, with greater diversity,*

and at a fraction of the cost — without compromising data integrity. Sponsors that integrate LATAM into their strategy aren't just accelerating trials, they're unlocking a new standard for global clinical development."

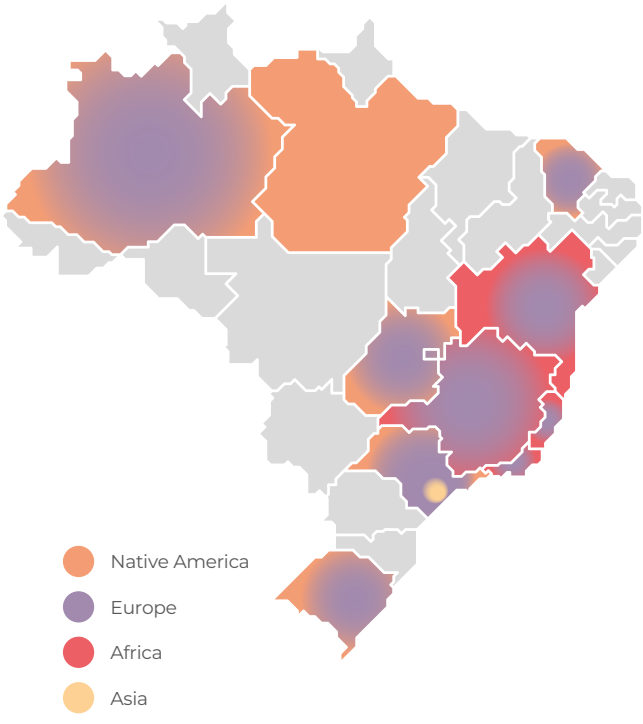
Operationally, LATAM offers meaningful cost advantages without compromising quality. In a 2019 market report, Hernandez noted that clinical trial and standard-of-care costs across the region are significantly lower when converted to major currencies such as USD and EUR, which materially contributes to overall cost-effectiveness.[24] Other published industry perspectives similarly describe Latin America as providing access to strong, virtually untapped patient pools while also delivering cost savings compared with higher-cost regions, such as North America and Europe.[27]

However, despite Latin America's competitive cost advantage, it is important to consider that the regional landscape presents relevant particularities, especially regarding regulatory convergence across Latin America, which remains uneven. While agencies such as ANVISA (Brazil) and COFEPRIS (Mexico) have adopted ICH-aligned Common Technical Document formats, priority review mechanisms and reliance pathways, implementation practices and review timelines still vary across those countries. Independent assessments highlight ongoing improvements in transparency and regulatory framework across LATAM, while also noting persistent gaps in predictability. These dynamics underscore the need for strong regulatory expertise and strategic site selection to mitigate risk and enable more predictable trial start-up and execution. [28,29]

Beyond operational considerations, these same structural advancements have positioned the region as a strategic contributor to broader regulatory and scientific priorities. There is a growing acceptance of LATAM trial data by both the FDA and EMA.[24]

Finally, LATAM contributes significantly to the growing emphasis on racial and ethnic diversity in clinical data. The population's unique genetic admixture — spanning Indigenous, African, European, and Asian ancestry — offers a robust and globally relevant dataset that strengthens regulatory submissions and aligns with evolving diversity requirements.[30]

Figure 3: Geographic Distribution of Genetic Ancestry and Diversity in Brazil



Source: Adapted from Nunes K, Araújo Castro e Silva M, Rodrigues MR, et al. Science. 2025.[31]

CONCLUSION BY ODC LIFE SCIENCES

The clinical development landscape is evolving — and so must the strategies that underpin it. With persistent recruitment delays, rising demands for diverse data, and increasing cost pressures, traditional geographies are no longer sufficient to meet the operational and regulatory expectations of modern clinical trials. Latin America offers a proven, scalable, and underutilized solution. The region delivers accelerated enrollment, high-quality data, and access to large, diverse, treatment-naïve populations — all within globally accepted regulatory frameworks. As global sponsors seek to derisk development timelines and optimize trial execution, strategically integrating Latin America into the recruitment model is no longer an opportunity — it's a competitive necessity.

ABOUT ODC LIFE SCIENCES

ODC Life Sciences is a Latin America-based clinical research organization (CRO) specializing in patient recruitment and site engagement across Brazil and Argentina. We partner with global biopharmaceutical companies and CROs to accelerate enrollment timelines, increase participant diversity, and deliver high-quality data that support global regulatory submissions.

With deep regional expertise, a robust site network, and a technology-enabled approach to patient identification and engagement, ODC helps sponsors overcome recruitment bottlenecks and execute high-performance trials across multiple therapeutic areas. Our mission is to unlock Latin America's full potential as a strategic engine for global clinical development.

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