Hispanic Community Perspectives on Clinical Trial Participation

Authors: Sophie Tahiri, MS, Director of Communication, TOTAL Diversity Clinical Trial Management, Diana Foster, PhD, CEO, TOTAL Diversity Clinical Trial Management, and Santiago Focil, MSc, Associate Director for Strategic Partnerships, FOMAT Medical Research

Abstract

Background

Hispanic individuals remain critically underrepresented in clinical trials, despite being one of the fastest-growing demographic groups in the United States. This underrepresentation exacerbates healthcare disparities and limits the generalizability of research findings. Key barriers include linguistic challenges, financial constraints, logistical difficulties, and historical mistrust in medical institutions. This study aims to assess Hispanic perspectives on clinical trial participation, identify obstacles to enrollment, and propose culturally responsive strategies to enhance engagement.

Methods

A bilingual survey was conducted among 94 Hispanic participants at two healthcare sites: *Clínicas Mi Salud FocilMed*, a general healthcare facility, and *Santa Maria Gastroenterology*, a specialty clinic. The survey assessed awareness of clinical trials, past participation, trust in research, and barriers to enrollment. Statistical analyses, including Fisher's exact tests and t-tests, were performed to compare differences between study sites.

Results

Clinical trial awareness was significantly higher at the general healthcare site (37%) than at the specialty clinic (4%) ($p < 0.01$). Participation rates were higher at *Clínicas Mi Salud FocilMed* (48%) compared to *Santa Maria Gastroenterology* (11%) ($p = 0.02$). The most reported barriers were language (61%, $p < 0.05$), financial constraints (38%), mistrust in institutions (42%), and logistical challenges such as transportation (25%) and time off work (22%). Trust in clinical trials varied by site, with participants at *Clínicas Mi Salud FocilMed* reporting higher confidence in research processes (53%) than those at *Santa Maria Gastroenterology* (29%). Community representation played a crucial role, as 89% of respondents stated they would be more likely to participate if researchers were from their own community.

Conclusion

Linguistic accessibility, financial assistance, and trust-building initiatives are critical to improving Hispanic participation in clinical trials. Culturally tailored recruitment strategies—such as hiring bilingual staff, engaging trusted community leaders, and providing financial incentives—are necessary to close the participation gap and ensure equitable representation in clinical research. Implementing these solutions will contribute to more inclusive and representative clinical trials, ultimately improving healthcare outcomes for Hispanic populations.

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Background

Diversity in clinical trials is essential to ensuring equitable healthcare outcomes and advancing scientific knowledge applicable to all populations. However, Hispanic individuals, despite being one of the fastest-growing demographics in the United States, remain critically underrepresented in clinical trials (Flores & Vega, 2020; Garcia & Duran, 2017). This underrepresentation results in significant disparities in the applicability of research findings to these populations, exacerbating existing health inequities (Moreno & Navarro, 2016). The barriers to participation among Hispanic individuals are multifaceted, spanning from linguistic and cultural differences to structural challenges such as lack of trust in medical institutions, limited outreach efforts, and logistical burdens (Heller et al., 2014; Martinez & Perreira, 2017).

Barriers to participation among Hispanic individuals are multifaceted, encompassing linguistic challenges, structural obstacles, and historical mistrust of medical institutions. Past unethical research practices, including the exploitation of marginalized populations in clinical trials, have contributed to skepticism and fear regarding medical studies (Smith & McCarthy, 2018). Misinformation and the absence of culturally relevant outreach further reinforce these concerns, emphasizing the need for researchers to build meaningful relationships within these communities. Effective engagement strategies include partnering with community leaders, implementing bilingual outreach, and integrating cultural competency into trial recruitment to foster trust and increase participation rates.

Additionally, many recruitment efforts fail to address the specific cultural and linguistic needs of this population, exacerbating disparities. Even when translated materials are available, complex medical terminology often remains a barrier, limiting comprehension and discouraging participation. Without effective communication strategies, potential participants may feel excluded or distrustful of the clinical trial process, perpetuating their underrepresentation in research. This study seeks to identify the primary challenges Hispanic individuals face in clinical trial participation and propose solutions to improve recruitment and retention efforts.

This study seeks to explore the perspectives of Hispanic individuals on clinical trial participation by analyzing data from two distinct healthcare settings: a general healthcare facility and a specialized gastroenterology clinic. By examining site-specific and demographic trends in knowledge, willingness to participate, and existing barriers, this paper aims to identify actionable strategies for improving Hispanic representation in clinical research.

Methods

Survey Design and Development

The survey was developed based on existing literature on barriers to clinical trial participation among minority populations. It was designed to capture key demographic information, knowledge levels, attitudes, and potential barriers affecting participation in clinical research. The survey consisted of multiple-choice questions, Likert-scale responses, and open-ended questions to allow for qualitative insights. A panel of clinical researchers, community health advocates, and a biostatistician reviewed the survey to ensure cultural and linguistic appropriateness for the Hispanic population. The final survey instrument was translated into Spanish and English to ensure accuracy.

Participant Recruitment

This study was conducted at two clinical sites with differing healthcare models to evaluate how general and specialty care settings influence clinical trial participation. Clínicas Mi Salud FocilMed (Site 1) is a general healthcare facility providing comprehensive medical services to Hispanic populations in Oxnard, California. Santa Maria Gastroenterology (Site 2) is a specialty clinic in Santa Maria, California, focused on gastrointestinal (GI) health within the Hispanic community. Importantly, the general healthcare site had more experience in recruiting for clinical trials compared to the gastroenterology site. While the Santa Maria Gastroenterology has conducted over 10 trials, its recruitment experience is less extensive than Clínicas Mi Salud FocilMed, which has conducted more than 40 trials. This difference in experience may have contributed to variations in awareness and participation rates. A total of 94 participants identifying as Hispanic from both sites were surveyed to assess their clinical trial knowledge, participation history, sources of information, barriers, and trust levels through direct outreach by clinic staff. Participants were informed of the study's purpose, and informed consent was obtained before completing the survey.

Data Collection and Analysis

Surveys were conducted remotely through a secure online survey platform, Google Forms, with options for responses in Spanish or English. The survey was fully anonymized, and bilingual staff were available to assist participants. Google Forms encrypts data both in transit and at rest, ensuring secure data collection. Responses were then exported to an encrypted, confidential database created using a Microsoft Excel platform for analysis. Data collection spanned eight weeks (October 2, 2024 – November 27, 2024), with weekly team meetings to ensure balanced representation from both sites.

Site-specific analyses were conducted in parallel, examining demographics, clinical trial awareness and participation, barriers to participation, trust in clinical trials, willingness to participate, and strategies to enhance participation. Scaled scores were created for these variables. Statistical analyses included Fisher’s exact tests for categorical comparisons (e.g., gender differences in participation) and t-tests for continuous variables (e.g., age differences between sites).

Results

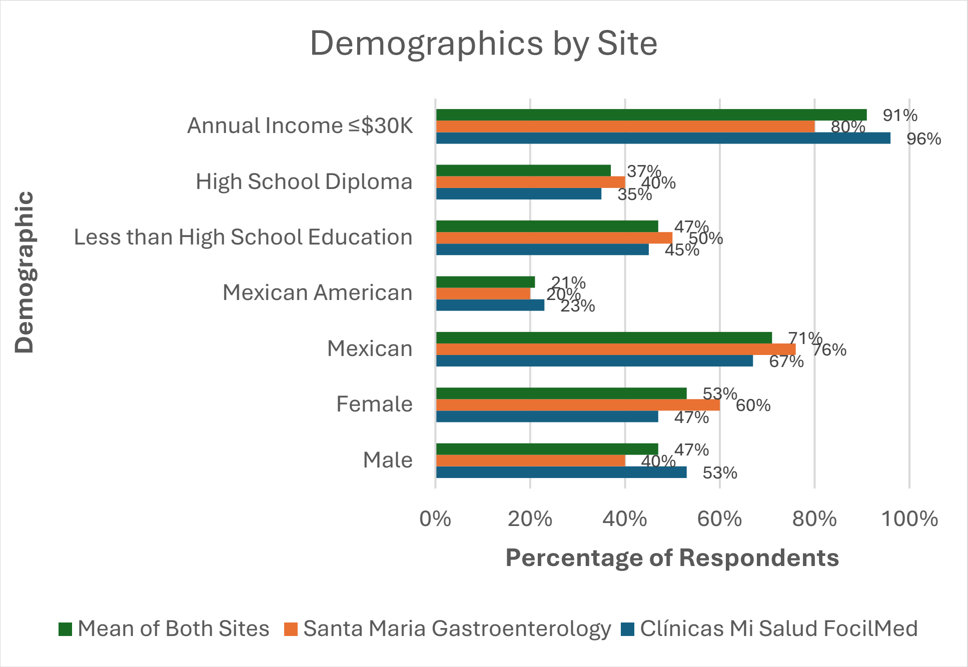
This study examined Hispanic perspectives on clinical trial participation by analyzing demographic characteristics, clinical trial awareness and participation, barriers to participation, trust in clinical trials, willingness to participate, and strategies to increase participation. The results demonstrated significant disparities in knowledge, engagement, and access between participants from Clínicas Mi Salud FocilMed (general healthcare facility) and Santa Maria Gastroenterology (specialty clinic). The statistical findings (*p*-values) highlight key differences across these two study sites.

Demographic Characteristics

Participants in this study were 47% male and 53% female, with a slightly higher proportion of males in Clínicas Mi Salud FocilMed (53%) compared to Santa Maria Gastroenterology (40%). The majority of respondents (71%) identified as Mexican, followed by Mexican American (21%), Central American (4%), South American (1%), other Hispanic/Spanish backgrounds (1%), and Filipino (1%).

Educational attainment varied significantly, with 47% of participants having less than a high school diploma, a factor that may influence comprehension of research materials (p = 0.04). Income disparities were evident, with 91% of participants reporting an annual income of $30,000 or less, and significantly lower incomes observed at Santa Maria Gastroenterology (p = 0.02). This may be attributed to the high proportion of retired participants, as employment status varied, with 23% working full-time, 14% part-time, and 37% retired.

Graph 1: Demographics by Site



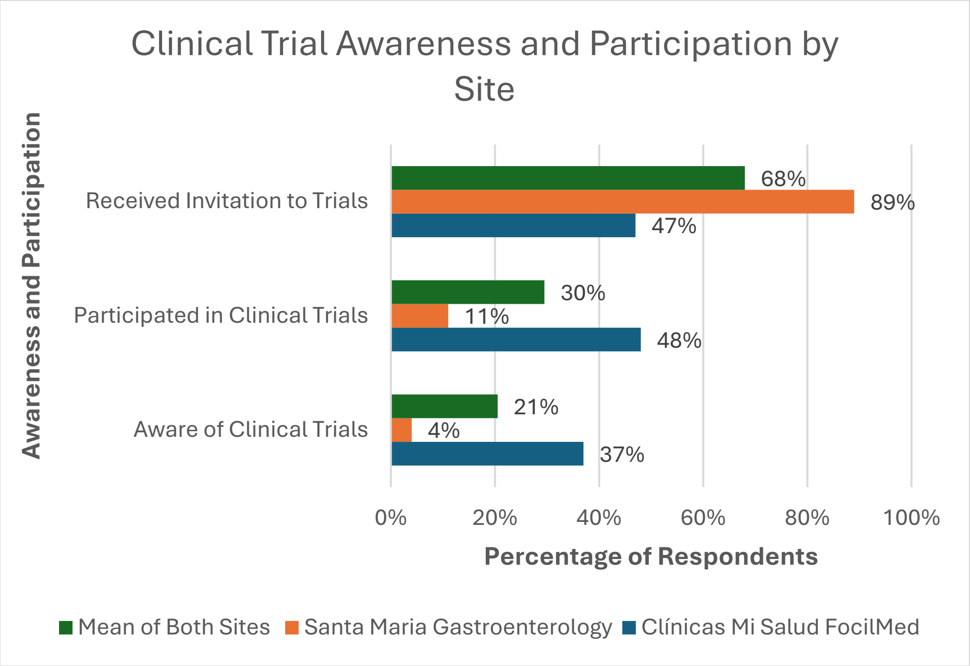
Clinical Trial Awareness and Participation

Clinical trial awareness was significantly higher among participants from Clínicas Mi Salud FocilMed (Site 1), where 37% of respondents correctly identified the purpose and structure of clinical trials, compared to only 4% at Santa Maria Gastroenterology (p

< 0.01). Similarly, 48% of participants from general care settings had previously participated in a clinical trial, a stark contrast to the 11% participation rate at the specialty care clinic ($p = 0.02$). This difference suggests that patients receiving primary care may have greater exposure to clinical trial opportunities, potentially due to more frequent healthcare visits and broader provider networks.

Despite Santa Maria Gastroenterology reporting a higher proportion of participants who were invited to participate in a clinical trial (89%), actual participation remained lower than at Clínicas Mi Salud FocilMed (47% invited, 48% participation). This disparity indicates that invitation alone does not translate to enrollment, and that other systemic barriers—such as mistrust in specialty providers, medical complexity, or language barriers—may play a crucial role in decision-making.

Graph 2: Clinical Trial Awareness & Participation by Site

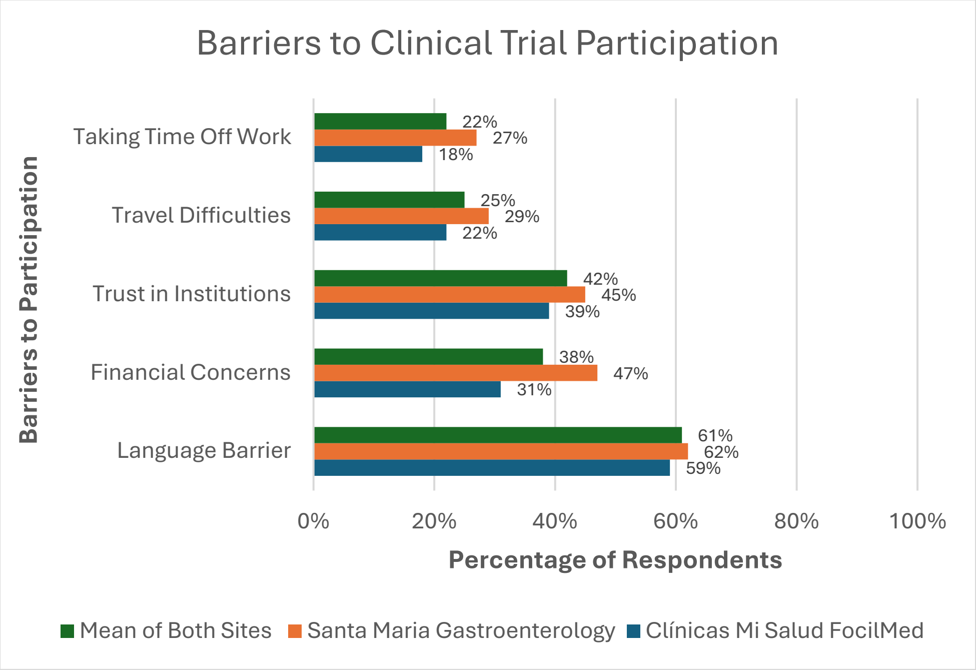


Barriers to Participation

Participants identified several key obstacles to participating in clinical trials. The most reported barriers were language (61%) ($p < 0.05$), financial constraints (38%), lack of trust in medical institutions (42%), travel difficulties (25%), and time off work constraints (22%). Language used by trial administrators hindered their willingness to enroll ($p < 0.05$). This challenge was slightly more pronounced at Santa Maria Gastroenterology (62%) compared to Clínicas Mi Salud FocilMed (59%). Gender differences were particularly pronounced, with women from Santa Maria reporting significantly more logistical barriers, including childcare responsibilities and transportation difficulties.

Additionally, financial constraints were a notable obstacle for 38% of participants, with those from the specialty clinic reporting a higher concern (47%) than those from the general care site (31%). These findings suggest the need for culturally responsive solutions such as bilingual study materials, financial incentives, and flexible scheduling.

Graph 3: Barriers to Clinical Trial Participation

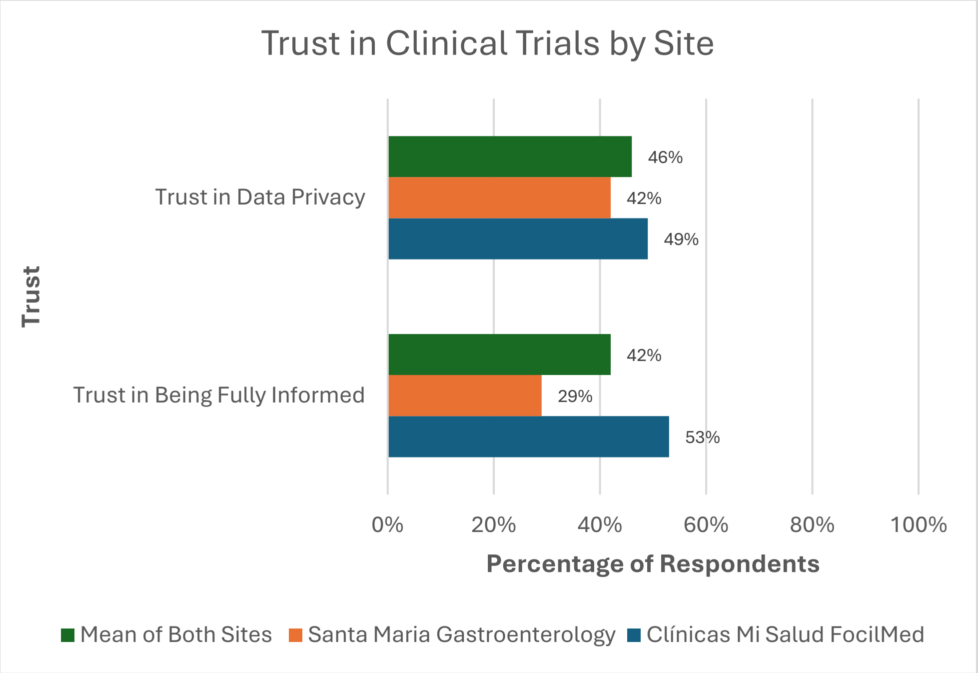


Trust in Clinical Trials

Trust in the research process emerged as a key determinant of willingness to participate. Overall, 42% of participants had high trust in being fully informed about their rights, with higher trust levels among FocilMed participants (53%) compared to Santa Maria participants (29%). Similarly, trust in data privacy was slightly higher among FocilMed respondents (49%) than Santa Maria respondents (42%).

These findings align with prior research (Al et al., 2023), which suggests that strong patient-provider relationships, as frequently seen with individuals receiving care in general healthcare settings, can enhance patients' trust and willingness to participate in clinical trials.

Graph 4: Trust in Clinical Trials by Site



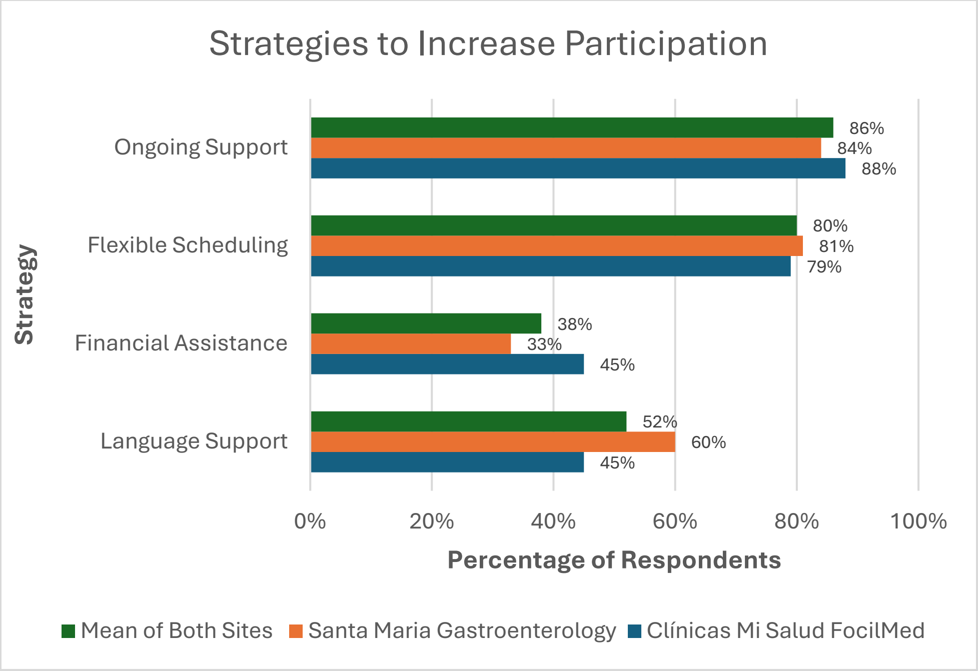
Willingness to Participate and Strategies for Inclusion

The willingness to participate in clinical trials was notably influenced by community representation. 89% of participants stated they would be more likely to enroll in a study if researchers were members of their own community, highlighting the importance of recruiting diverse research teams and engaging trusted local organizations in recruitment efforts.

Additionally, bilingual assistance was a key determinant, with 52% of respondents indicating that access to Spanish-speaking research staff would increase their likelihood of participation. Site-specific differences were observed, as 60% of Santa Maria Gastroenterology participants prioritized bilingual support compared to 45% at Clínicas Mi Salud FocilMed.

Furthermore, 51% of participants expressed high willingness to use wearable health monitors for research purposes, with a significant difference between general care patients (61%) and specialty care patients (38%). This suggests that incorporating digital health solutions may be more effective in primary care settings where patients are already accustomed to broad health monitoring.

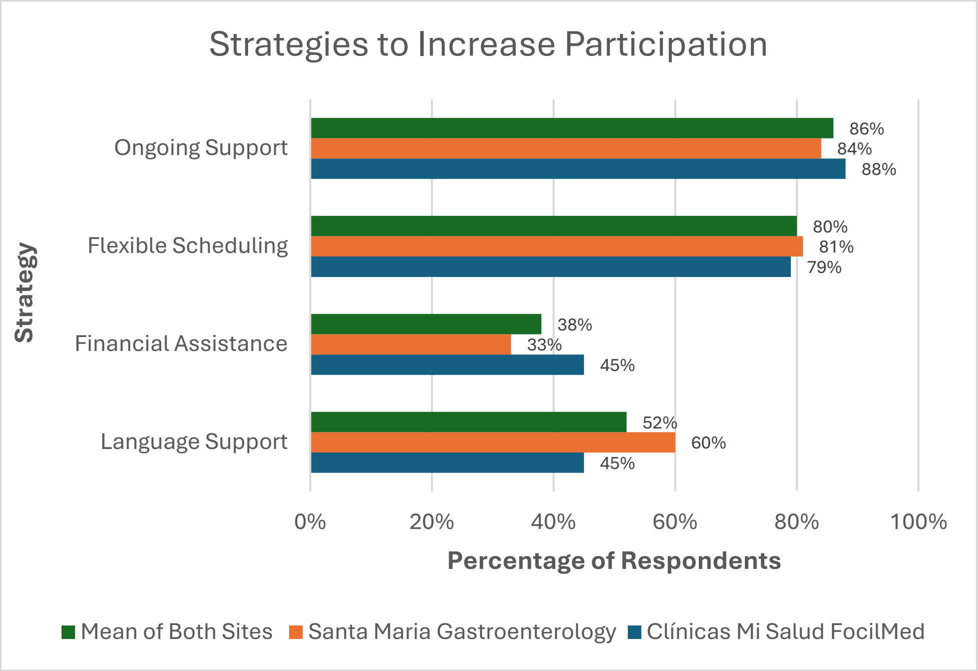
Graph 5: Willingness to Participate by Research Activity



Strategies to Increase Participation

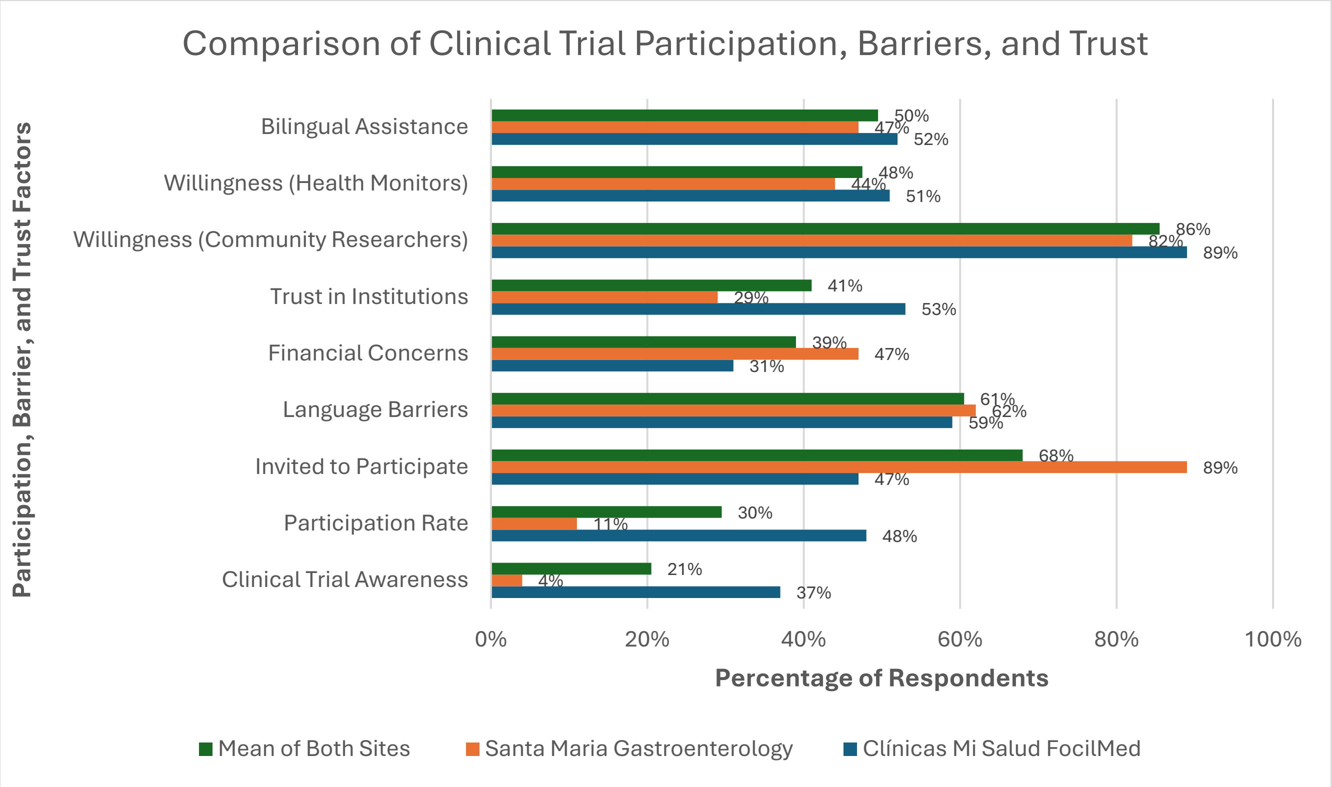
Participants identified several interventions that would improve their likelihood of enrolling in a clinical trial including language support (52%), financial assistance (38%), flexible scheduling (80%), and ongoing support during and after participation (86%).These findings highlight the importance of patient-centered approaches in research, particularly for underrepresented populations.

Graph 6: Strategies to Increase Participation



The comparative analysis of clinical trial participation, barriers, and trust across the two study sites highlights distinct trends in engagement and willingness to participate. Graph 7 presents a visual representation of key factors influencing participation, including awareness, invitation rates, financial concerns, and trust in institutions.

Graph 7: Comparison of Clinical Trial Participation, Barriers, and Trust



Discussion

This study highlights critical disparities in Hispanic clinical trial participation, emphasizing the need for culturally congruent recruitment strategies. Differences in awareness and participation between general healthcare and specialty care settings indicate that recruitment efforts must be tailored to specific patient populations. While access to research opportunities is essential, structural challenges such as communication barriers, financial constraints, and medical mistrust significantly impact participation rates.

Linguistic accessibility emerged as a major obstacle, with 61% of participants citing language as a barrier. Although bilingual resources exist, complex medical terminology remains a deterrent, particularly for individuals with limited health literacy. Similar challenges have been observed in other underrepresented populations, where medical mistrust and language barriers hinder engagement (Flores & Vega, 2020;

Wright & Brown, 2021). Ensuring that research teams reflect the language, culture, and lived experiences of participants can improve trust and participation.

Financial concerns, including out-of-pocket costs, lost wages, and transportation, were significant deterrents, particularly among specialty clinic participants with higher financial insecurity. With a majority of participants reporting annual household incomes under $30,000, clinical trial participation may pose an economic burden. Providing stipends, transportation assistance, and childcare support could mitigate these barriers, aligning with previous research indicating financial constraints as a key deterrent to enrollment (Garcia & Duran, 2017).

Trust in clinical research was another determining factor. Participants in the general healthcare setting demonstrated higher trust in clinical trials than those in specialty clinics, reinforcing the importance of strong patient-provider relationships. Historical unethical research practices targeting marginalized populations have contributed to skepticism toward clinical studies. Nearly 90% of participants indicated they would be more likely to participate in a trial if the research team reflected their own community. Increasing representation of Hispanic investigators and study coordinators is a critical step toward closing this trust gap.

An often-overlooked factor in recruitment success is site experience. While both study sites had prior research involvement, the general healthcare site had a longer history with a greater number of trials. This difference may have contributed to higher awareness and trust levels. Future studies should consider site experience when evaluating recruitment challenges and outcomes.

Conclusion

To achieve equitable Hispanic representation in clinical trials, researchers must implement culturally congruent, community-driven strategies. Addressing linguistic accessibility, financial support, trust-building, and site experience are critical to increasing participation. Embedding bilingual researchers from the community, providing financial incentives, and strengthening community partnerships can enhance engagement.

Additionally, leveraging digital health tools in primary care settings presents opportunities for broader participation, but accessibility must remain a priority. Future research should assess the long-term impact of these interventions, particularly regarding participant retention.

Ensuring the inclusion of Hispanic individuals in clinical research is not just a matter of scientific integrity but a necessary step toward reducing health disparities. Without intentional efforts to close the participation gap, research findings will continue to lack the diversity needed for effective medical advancements. By implementing culturally responsive, community-centered recruitment strategies, clinical trials can become more inclusive, ultimately improving healthcare outcomes for all populations.

Contributors: Bupendra Shah, PhD, Brisq Consulting and Luis Castillo, MD, Remote Study Coordinator, FOMAT Medical Research

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