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Transformational Strategies to Improve the Clinical Trial and Drug Development Process

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Abstract

Background: Clinical trial designs have historically been biased towards the Caucasian population, with limited representation of minorities due to factors such as financial barriers, inequity, and accessibility. This lack of diversity has resulted in the development of drugs that may not be effective or safe for underrepresented populations, thereby posing risks to minority health. This research aims to transform the clinical trial process by identifying innovative strategies to increase diversity, ensuring that clinical trials more accurately reflect the natural epidemiology of diseases, and ultimately driving improved drug development outcomes for all populations. **Method:** A three-stage study was conducted with distinct participant groups. Stage 1 (Group A) involved a 90-minute Zoom focus group with 19 biopharmaceutical professionals. Stage 2 (Group B) consisted of one-hour individual interviews with 10 patients or healthcare providers to explore their experiences and views on trial diversity. Stage 3 (Group C) used a survey of 305 diverse participants to validate and expand the findings. **Results:** Barriers to diversity in clinical trials that were identified include a lack of trust, limited access to trial facilities, socioeconomic challenges, ineffective recruitment strategies, and a shortage of culturally competent healthcare providers. Proposed solutions include transforming the trial process through regional trial hubs to enhance access, implementing culturally tailored recruitment strategies, and using telemedicine to reduce participant burden. Additionally, updating the DIVERSE Trials Act, implementing federal protections for clinical trial participants—similar to those provided for jury duty—and promoting transparency through community engagement can help rebuild trust and improve diversity in trial participation. **Conclusion:** This study demonstrates the significant impact of a lack of diversity in clinical trials on both drug development and health equity, emphasizing how disparities in patient access hinder the inclusivity of clinical research. By exploring how the clinical trial process can be transformed to increase diversity and access, the study offers practical, actionable solutions, including tar-

geted recruitment strategies, regional trial hubs, and culturally tailored outreach. Additionally, it illustrates how diversity in the patient population enhances the drug development process, ensuring clinical trials better reflect the natural epidemiology of the disease and improve the safety and efficacy of treatments. Through its interdisciplinary approach, grounded in complementary theories, this study provides valuable insights and significantly contributes to the literature, offering a roadmap for improving inclusivity in clinical trials and advancing health equity.

Keywords

Diversity, Health Equity, Clinical Trials, Drug Development, Clinical Trial Access

1. Introduction

Clinical trials have traditionally included 60% to 70% white males. Although African Americans make up 13.4% of the U.S. population, they only represent 5% of clinical trial participants. [1]

A 2020 FDA assessment revealed demographic disparities in clinical trial participants, with 76% white, 11% Asian, and 7% Black, despite global demographics showing 60% Asian, 16% African, 10% European, and 8% Latin American. [2] Clark *et al.* identified five critical barriers: mistrust, discomfort, lack of information, time/resource constraints, and lack of awareness. [3] Stronks *et al.* noted that minority participants are often too few for subgroup analysis and suggested considering multiple factors impacting healthcare efficacy. [4] Understanding environmental and genetic nuances among ethnic groups can improve knowledge of disease pathology and treatment options.

Examples of diversity's positive impact on research:

1) 75% of Pacific Islanders cannot convert an antiplatelet drug, increasing adverse outcomes post-angioplasty. [5]

2) Southeast and East Asians are at higher risk for carbamazepine-induced Stevens-Johnson Syndrome due to the HLA-B*1502 variant. [6]

3) A genetic variant protective against breast cancer was discovered in Latinas due to differences in Native American ancestry. [7]

4) Genetic differences among ethnic groups can lead to unexpected drug interactions. [8]

Gray *et al.* highlight that the lack of diversity in clinical trials hinders understanding the safety and effectiveness of therapies across various populations. [1] Excluding minorities can lead to dangerous generalizations about a drug's safety and efficacy. Clinical trials often prioritize quick enrollment by targeting large institutions with high patient populations, meeting targets, and reducing costs. However, this limits geographic and demographic diversity, potentially compromising the trial's effectiveness. True diversity in clinical trials is essential to ensure safe and effective

treatments for all groups. To ensure drugs being developed are both safe and efficacious, they should mirror the natural epidemiology of the disease being studied. This however is often not the case. For example, Asthma affects over 300 million people worldwide, with increasing prevalence. [9] A review of clinicaltrials.gov revealed most asthma studies are conducted in single countries, with few global studies. Current trials do not reflect the disease's true epidemiology. An example of the breakdown of a typical asthma study design can be seen in Table 1 below.

Table 1. Example of an actual asthma clinical trial demography (countries involved: Argentina & Brazil).

Race/Ethnicity, Customized Measure Type: Number | Unit of measure: participants				
Number Analyzed	120 participants	122 participants	125 participants	367 participants
Black or African American	6	5	4	15
White	113	115	114	342
Unknown or Not Reported	1	2	7	10

Note: Clinicaltrials.gov-Study ID # NCT01455194.

Table 1 provides a breakdown of a typical asthma clinical trial design, based on a study conducted at five investigative sites in Argentina, Brazil, Germany, Israel, and Russia, from 10 November 2011 to 15 August 2014. The intervention involved the drug Ciclesonide. This design represents standard inclusion/exclusion criteria and endpoint structures commonly used in Phase II–III asthma studies. The study was registered under the following identifiers: CL-9709-301-RD, 2011-000683-99 (EudraCT Number), U1111-1133-6333 (WHO Registry Identifier), and CL-9709-301-RDCTID (Israel Registry Identifier).

The data shows that white participants constitute the majority of the patient population, a trend commonly observed across most clinical trials, even when it does not align with the disease's epidemiology.

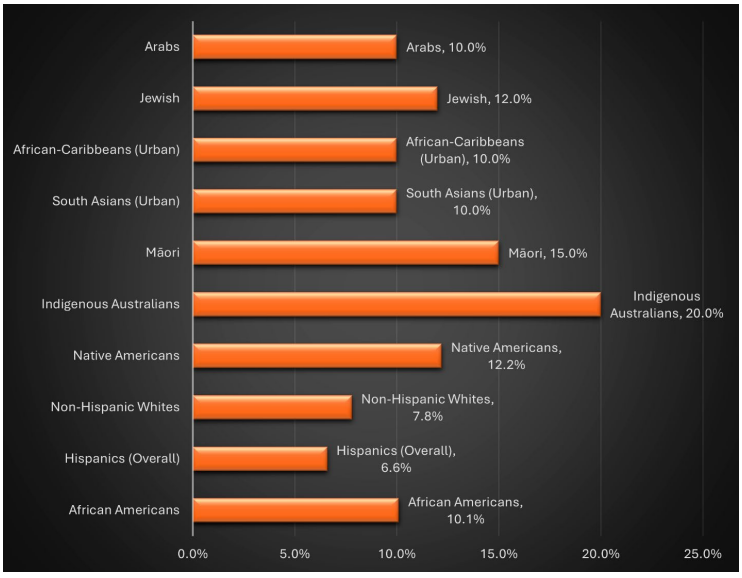


Figure 1. Actual ethnic prevalence of asthma.

Figure 1 illustrates the global distribution of asthma across various ethnic groups, highlighting a disproportionate impact on minority populations. The data reveals that these communities bear a significantly higher burden of the disease.

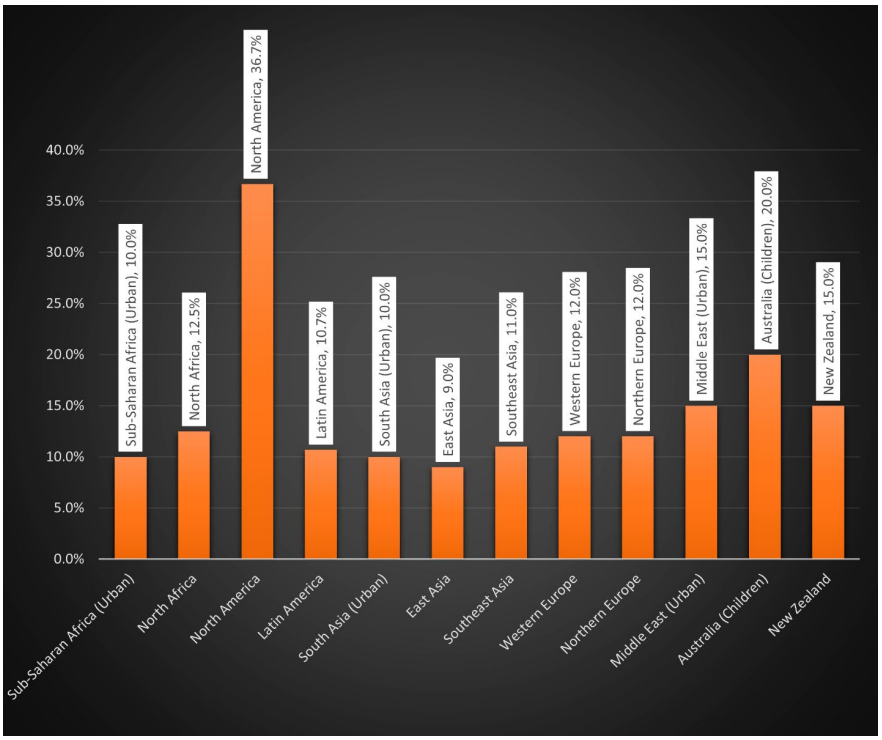


Figure 2. Actual geographical prevalence of asthma.

Finally, Figure 2 illustrates the global distribution of asthma patients across various regions. The data highlights that North America has the highest concentration of affected individuals, with 36.7% of the population impacted, significantly surpassing other regions. This visualization underscores the varying prevalence of asthma across different geographical areas. Data sources [10]-[17].

While diversity emphasizes inclusivity across ethnicity, gender, and age, equity ensures everyone has access to the same opportunities regardless of socioeconomic status. A diverse group can lack equity if some members have fewer opportunities. The American College of Physicians compared the healthcare systems of 12 industrialized countries with the U.S. and found the U.S. performed poorly in equity due to income-based disparities in access and quality. The Commonwealth Fund Commission highlighted a significant divide between low-income or uninsured individuals and those with higher incomes and insurance. Racial and ethnic disparities were also prominent. The key takeaway is that many countries have more efficient, lower-cost healthcare systems that outperform the U.S. in equity. [10]

2. Review of the Literature

The purpose of this literature review is twofold. The first is to discover and learn

more about some of the barriers impeding diversity in clinical trials and other interrelated factors; the second is to identify gaps in the literature for future research. The topic of diversity in clinical trials is frequently discussed in both academic and practitioner articles, but the main focus has been on ethnicity. This research will consider ethnicity but will cover two other facets of diversity namely health geography and socioeconomic status that also play a significant role in accessibility to clinical trials.

2.1. Diversity in Clinical Trials

Clinical trials should be representative of the epidemiology of the disease. This however is not always the case. Minority racial and ethnic groups make up roughly 40% of the population in the USA; however, of the 53 novel drugs approved in 2020, 75% of the 32,000 participants were white. [1] African American men are twice as likely to die from prostate cancer as white men, yet they make up less than 5% of participants in prostate cancer clinical trials. Other studies have indicated that differences in biology and genetics influence the efficacy of treatment, meaning that if a compound is not tested in a heterogeneous population, then these efficacy differences may be missed. [18] Despite efforts to enhance diversity in clinical trials, the enrollment of racial/ethnic minorities in the U.S. has declined over the past two decades. [19] All the literature reviewed was consistent regarding the lack of diversity in clinical trials, which can impact treatment response and overall survival. However, a recent study by Stewart *et al.*, concluded that remote clinical trials with online recruitment have shown an increase in diversity among study participants in terms of racial, ethnic, and geographic location. [20]

Most healthcare interventions designed to achieve health equity fail to achieve that goal due to gaps in knowledge and translation. As a result, racial/ethnic minority, rural, and low-income populations continue to experience suboptimal access to and quality of healthcare. The most effective approach involves implementing practical and scalable multilevel interventions, guided by transdisciplinary research collaborations and broad stakeholder engagement approaches to solving this problem. [21]

This paper approaches this concept by utilizing two different process-oriented theories, contextualism and dynamic capability theory, that have been previously applied to transform different areas of the healthcare industry.

2.2. The Theory of Contextualism

Contextualism as a theory of method was first described by the philosopher Stephen Pepper in 1942 and adapted by Pettigrew. This research is based on Pettigrew's Inquiry framework that advocates for longitudinal organizational transformation and asserts that change is varied and adaptable, involving incremental, political, cultural, environmental, and structural as well as rational dimensions. There are three components to Pettigrew's framework: content, context, and process. Pettigrew defined content as the area to be transformed, which may include

new personnel of a firm, or a new product or technology. Context refers to the environment in which organizations and stakeholders operate and is further divided into inner and outer contexts such that outer context refers to the socioeconomic, political, and competitive environment in which the firm operates, while inner context centers on the structure, corporate culture, and political context within the firm through which ideas for change have to proceed. Finally, the process of change refers to the actions, reactions, and interactions of the various interested parties as they seek to move the firm from its present to its future state. Processes are studied from two dimensions, the vertical and the horizontal. Vertical processes refer to the interdependences between the upper and lower units of analysis, for example, the impact of changing socioeconomic context on features of intra-organizational context. The horizontal dimension denotes the interconnectedness across sequential time, encompassing both present and future contexts. An approach that integrates multilevel or vertical analysis with processual or horizontal analysis is characterized as contextualist, as described by Pettigrew. [22] [23]

In Pettigrew's framework, contextualist inquiry is used to measure change over time. For this study, however, we will examine the impact of various variables on the outcome. To align my research with Pettigrew's terminology, the context refers to the environment in which the stakeholders operate, comprising both inner and outer environments. The inner environment is represented by biopharmaceutical companies, while the outer context includes two key variables: research diversity and equity. Additionally, regulatory and governing bodies, such as the FDA and Congress, indirectly influence this area of study. Factors impacting research diversity—such as socioeconomic status and health geography—are explored to understand how they affect a patient's ability to access clinical trials. The second variable, equity, addresses how disparities in healthcare access and treatment can significantly affect a patient's participation in clinical trials and overall healthcare outcomes.

The content in this framework refers to the areas targeted for transformation, specifically clinical trial design, to enhance equity and diversity. The third element of the framework process focuses on how this transformation occurs. As shown in **Figure 3** below, diversity, equity, and other stakeholders make up the outer context of the model, while the inner context is represented by biopharmaceutical companies. This inner context is the environment in which the stakeholders operate. The "content" to be transformed is the clinical trial design itself. The "process" involves the actions and interactions aimed at transforming clinical trials to increase diversity and improve access.

Figure 3 provides a visualization of Pettigrew's framework, which has been adapted to fit this research.

The contextual view was adopted to gain a deeper understanding of how transformation can be applied to improve clinical trial design. This theory was specifically chosen because it has previously been validated in supporting change within

the healthcare industry, as demonstrated by Romanow *et al.* Their study focused on transforming a paper-based system to an electronic record system, which opened new opportunities for stakeholders and enhanced the understanding of chronic care management for the underserved population in the community. [24]

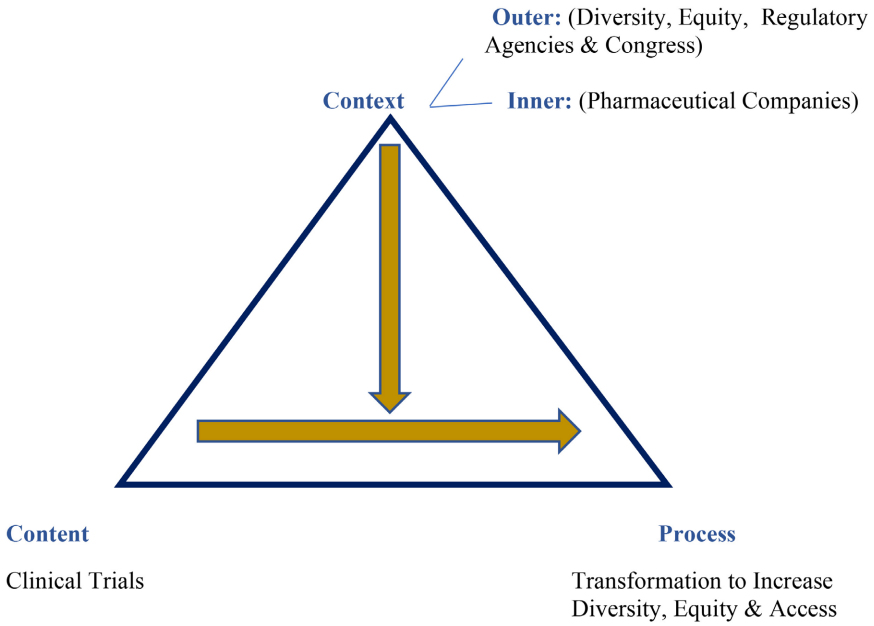
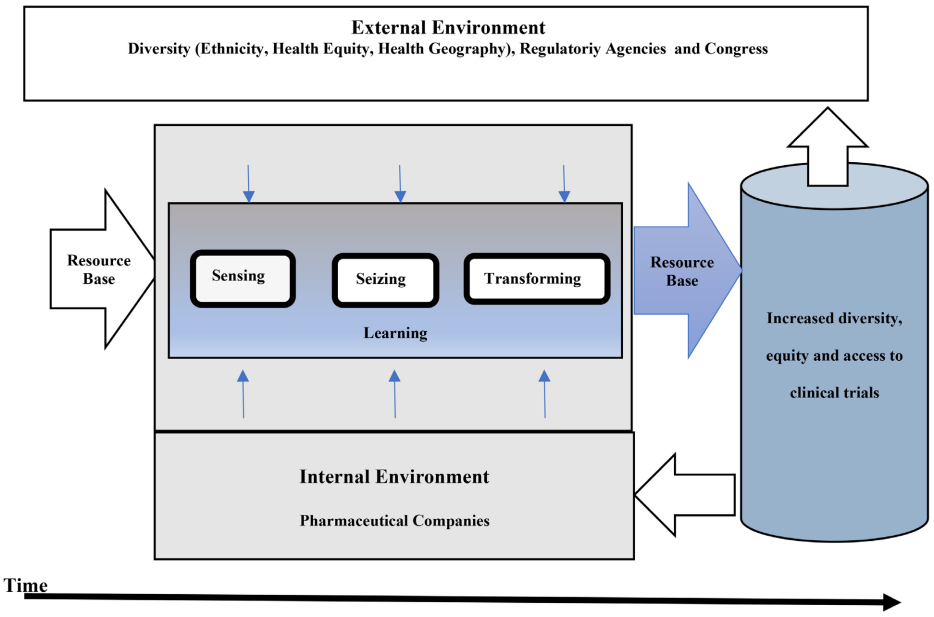


Figure 3. Adapted contextualist framework.

2.3. Dynamic Capability Theory

Like the theory of contextualism, dynamic capability theory also speaks to the transformation of processes. Dynamic capability (DC) theory emerged as both an extension to and a reaction against the inability of the resource-based view (RBV) to interpret the changing of resources and rapidly changing environments. [25] The RBV operates under the assumption that the resources needed to conceive, choose, and implement strategies are heterogeneously distributed across firms and that these differences remain stable over time. [26] The existing literature indicates that competitive advantages are hard to sustain in today's unstable markets, which feature fierce competition and disruptive technologies. This business reality has caused scholars to seek out new ways to more appropriately describe the processes that shape the relationship between business strategy and competition. That process has led to the idea that competitive advantage is transient and not sustainable. [27] As this study is more focused on the process rather than on resources, DC theory would be a better fit than RBV.

Figure 4 captures the various nuances involved in accomplishing change in the organization. Information comes in from the external environment and is processed and analyzed by the existing resources to determine if and how the information can be utilized. This is called "Learning". The resources release the newly modified output back into the external and internal environments, which is an iterative process.



Note: Figure adapted from The Fundamental Elements of Dynamic Capabilities Model (Nagel, Claudia 2017).

Figure 4. Adaptation of the Fundamental Elements of Dynamic Capabilities Model.

DC theory refers to intentionally changing the product or process, and the scale or market served by a firm. An organization is considered to have dynamic capabilities when it can integrate, build, and reconfigure its internal and external firm-specific capabilities in response to its changing environment. Dynamic capabilities refer to the efficient exploration and implementation of new opportunities. There are three main types of dynamic capabilities: sensing, seizing, and transforming. Sensing is finding and assessing opportunities outside the firm; essentially, it is simply gathering data. Seizing is deciding to act and mobilize the resources to acquire value from those chances. Finally, transformation occurs when steps are taken to implement changes based on the data gathered to either create a new product or adapt an existing product or process.

For this research, the production process refers to clinical trial design, while the market served is the population that will benefit from drugs developed through these trials. The theory of Dynamic Capabilities (DC) has been successfully applied in healthcare transformation, as demonstrated by researchers such as Evans *et al.*, and Andrew Agwunobi and Paul Osborne among others. This theory also complements the theory of contextualism, which is process-oriented and served as a key motivating factor behind its selection for this study. [28] [29]

2.4. Significance of This Research

Available literature underscores significant challenges in achieving diversity within clinical trials, highlighting barriers such as trust issues, socioeconomic constraints, geographic limitations, and cultural mismatches. For example, studies by Woods-Burnham *et al.* emphasize that the lack of representation among racial and ethnic

minorities in U.S. clinical trials compromises the generalizability of findings and leads to disparities in health outcomes. [22] Although legislation like the 17th Congress' DIVERSE Trials Act aims to promote inclusivity, these efforts often remain high-level without translating into actionable steps for addressing the specific needs of underrepresented populations. [30] Clark *et al.* further note that barriers such as geographic distance from trial sites and financial burdens prevent minority patients from participating in trials, underscoring the need for localized trial hubs and financial assistance programs to increase accessibility. [3]

In addition to these structural barriers, cultural competency among clinical trial staff is identified as a critical factor influencing patient participation. While the existing literature, such as the work by Hwang and Brawley, advocates for legislative incentives to promote diversity, it often lacks concrete recommendations for enhancing the cultural competence of clinical teams. [31] The current low participation rates among minorities—ranging from only 2% - 16% [1], demonstrate the inadequacy of traditional recruitment methods. This decline in minority participation highlights the need for innovative strategies that better engage underrepresented populations. The literature supports a shift towards more customized approaches, which take into account the cultural, social, and communication preferences of different ethnic groups. For example, Lai *et al.* found that traditional recruitment strategies have limited effectiveness in engaging minority populations for cancer prevention and treatment trials. [32] This emphasizes the need for recruitment methods specifically designed to address the unique barriers faced by minority groups. Similarly, UyBico *et al.* stress that community outreach alone may not be sufficient to enhance minority enrollment. Their findings suggest that combining outreach with more rigorous, evidence-based methods can lead to better outcomes. Further, a study on behavioral weight management among minority women showed that ethnically tailored messages in direct mail recruitment had a significantly positive impact on response rates, demonstrating the effectiveness of personalized outreach. [33]

While customized messaging can be effective, it is essential to recognize the potential pitfalls of culturally-targeted marketing. El Hazzouri and Hamilton found that minority participants responded negatively to ads featuring models from their ethnic backgrounds, particularly when they felt the ads reinforced negative stereotypes. However, when these messages were presented in community-based publications, the reaction was more positive. [34] This suggests that the context and medium of targeted messaging are just as important as the content itself.

Given the significant barriers to diversity in clinical trials, as highlighted by the literature, this study aims to propose a new approach for practitioners to ensure that clinical trial recruitment leads to a more diverse patient population, one that better reflects the natural epidemiology of the disease. The lack of minority representation compromises the generalizability of clinical trial findings and perpetuates health disparities. Previous efforts, such as the DIVERSE Trials Act, have not yet yielded actionable steps to overcome the structural and cultural barriers

that prevent underrepresented populations from participating.

This study will explore a multi-faceted strategy to increase diversity in clinical trials, incorporating localized trial hubs, financial assistance, and culturally competent recruitment techniques. It will address the socioeconomic and geographic barriers identified in previous research by Woods-Burnham *et al.*, Clark *et al.*, and Hwang and Brawley. In addition, the study will evaluate how culturally sensitive outreach methods, as advocated by Lai *et al.* and UyBico *et al.*, can be tailored to the needs of underrepresented populations to improve enrollment. This approach will also consider the lessons from El Hazzouri and Hamilton's findings on the importance of context and medium when using targeted messaging.

By addressing the gaps and challenges outlined in existing research, this study aims to develop actionable solutions that enable clinical trials to include a patient population that mirrors the epidemiology of the disease being studied. The research questions guiding this study are thus twofold:

RQ1: How can the clinical trial process be transformed to enhance patient access and retention?

RQ2: How can a more varied patient population enhance the drug development process?

Through these questions, the study will explore strategies for engaging a broader range of participants, and examine the influence of diverse representation on the efficacy and safety of new treatments across racial and ethnic groups.

3. Research Methodology

Qualitative research is a popular research method that is particularly appealing for applied disciplines since processes, problems, and/or programs can be studied to engender understanding that can improve practice. [35] As stated by Stevens and Wrenn exploratory research is needed whenever the decision-maker has the following objectives:

1) More precisely defining an ambiguous problem or opportunity;

2) Increasing the decision-maker's understanding of an issue;

3) Developing hypotheses that could explain the occurrence of certain phenomena;

4) Generating ideas;

5) Providing insights;

6) Establishing the priorities for future research or determining the practicality of conducting some research;

7) Identifying the variables or levels of variables for descriptive or causal research. [36]

This global study seeks to explore how transforming the clinical trial and drug development process can enhance diversity, access, and the quality of drug products. By identifying barriers and challenges, the study aims to generate innovative solutions for improving the drug development process, ultimately advancing health equity and treatment efficacy.

Creswell's (1994) definition of quantitative research involves the exploration of phenomena through the collection of numerical data, which are then analyzed using mathematically based methods, primarily statistics. This type of research is generally used to establish generalized facts about a particular topic. This type of research is usually done using surveys, experiments, and so on. [37] For this research, a survey will be utilized. It is therefore beneficial to utilize both qualitative and quantitative research methods in this research.

A mixed-methods approach was utilized, as recommended by Yin, because it enables researchers to address more complex research questions and gather a richer, more comprehensive set of evidence than any single method alone. [38] The literature review highlighted that most studies employed a singular approach, which is why a holistic methodology was selected for this research to analyze the various key variables that significantly impact access to clinical trials. The study was approved by an Institutional Review Board (IRB), Reference Number 374115. The study was determined by the IRB to be exempt from federal regulations as defined in 45 CFR 46 and was evaluated for the following:

1) Determination that it falls within one or more of the eight exempt categories allowed by the institution.

2) Determination that the research meets the organization's ethical standards.

All participants voluntarily provided consent to participate in the study and for the publication of the final data. This global mixed-method study aims to enhance diversity and access to clinical trials by identifying barriers and exploring strategies to improve health equity.

3.1. Data Collection

Semi-structured Zoom interviews were conducted, and the recordings were transcribed. Data was collected from three groups:

Group A: Participants for Group A (focus group) were recruited via professional and academic networks, targeting individuals without direct ties to rare diseases. This focus group was conducted in two sessions due to time zone differences (May 30 and June 5, 2023). The 90-minute session included 19 experts from various sectors, such as Contract Research Organizations (CROs), regulatory leaders, Diversity, Equity, and Inclusion (DE&I) leaders, Subject Matter Experts (SMEs), and policy advisors. They offered valuable insights into the observed barriers and proposed actionable solutions.

Group B: Group B participants included rare disease patients and caregivers, identified through advocacy groups, known investigators, and professional networks within the clinical research community. Interviews were conducted from June 14 to August 14, 2023. These one-hour interviews involved 10 individuals directly affected by rare diseases, including patients, caregivers, and advocates, with a focus on their clinical trial experiences and potential improvements in equity.

Group C: Survey tools for Group C were developed from the qualitative find-

ings and administered via Qualtrics. Group C (survey) participants were recruited using an online survey platform and community outreach, ensuring demographic and ethnic diversity through targeted sampling. A total of 305 participants from multiple countries were surveyed to expand upon the findings from Groups A and B.

3.2. Data Analysis

Yin outlined a method for analyzing qualitative data to identify patterns, and relationships, and formulate theoretical propositions. [39] Building on this work, along with Janesick's contributions, the following steps were applied in the data analysis for this research. [40] The transcribed interview data was first coded by thoroughly reviewing the interview notes to identify emerging themes. These codes were then grouped into conceptual themes, which were examined to uncover interrelationships. The themes were organized to create a coherent structure for the paper. Hypotheses were developed based on the data and prior research, leading to recommendations for improving diversity in clinical trials. Additionally, quantitative survey data was analyzed descriptively by demographic categories, providing further validation of the interview findings.

4. Results

The results of this study identified several critical barriers to increasing diversity in clinical trials, including lack of trust, limited access to local trial facilities, socioeconomic challenges, ineffective recruitment strategies, burdensome protocol designs, and a lack of culturally competent healthcare providers. Health equity, as discussed by participants, varied across regions. In countries with national healthcare systems, like Canada and Argentina, there were fewer disparities in access to treatment and trial participation. Participants emphasized that historical mistrust and perceived bias continue to discourage minority populations from participating in clinical research, a challenge further exacerbated by the geographic concentration of trial sites in urban areas that are inaccessible to many. Financial barriers, such as travel costs, time off work, and out-of-pocket expenses, deter participation, particularly among lower-income groups.

Moreover, traditional recruitment methods often fail to effectively engage diverse communities, while complex and time-consuming protocol designs place undue burdens on participants, especially those with employment or caregiving responsibilities. The shortage of culturally competent healthcare providers also hampers effective communication and reduces comfort for minority patients, making them less likely to engage in clinical trials.

These findings underline the need for targeted, culturally sensitive solutions that directly address these barriers. Transforming the clinical trial process through localized recruitment strategies, financial support, simplified protocols, and enhanced cultural competency can ensure that clinical trials better represent the patient population, aligning with the natural epidemiology of the disease and ulti-

mately improving drug safety, efficacy, and health equity.

Table 2 and Table 3 provide a demographic breakdown of all the participants which consists of a wide array of individuals with a connection to the healthcare industry, ranging from policy experts to IRB, patients, caregivers, etc.

Table 2. Composition of Group A participants.

Participant ID #	Gender	Race/Ethnicity	Location	Industry Affiliation
CROIV015	Female	White	Harlange, LU	CRO
DEIJS016	Female	White	SRY, UK	DE&I
DEIRM017	Female	Hispanic	FL, USA	DE&I
DEIDH018	Female	Black	NC, USA	DE&I
DMPLD001	Female	White	CA, USA	Health Sector
PELK002	Female	White	CA, USA	Public Policy Affairs Expert
PEBSR005	Female	White	OR, USA	Public Policy Affairs Expert
SLNM003	Female	White	CA, USA	Specialty Vendor (Genetic Testing SME)
CRODA004	Male	White	CA, USA	CRO
CROAK005	Female	Indian	BC, CAN	CRO
IRBSC006	Female	White	MO, USA	IRB
CROAR007	Female	White	AZ, USA	CRO
DEIKP008	Male	Black	CA, USA	CRO
RLSW009	Male	White	AZ, USA	Regulatory Expert (FDA)
HSCM010	Male	Black	OH, USA	Health Sector (Physician)
ILJS011	Male	White	CA, USA	Insurance (Advocate)
ILNC012	Female	White	IN, USA	Insurance (Advocate)
ILCB013	Female	White	PA, USA	Insurance (Access Manage Care)
CLEL014	Male	White	CA, USA	Public Policy Expert (Mayor)

A diverse group of experts from various countries, representing a wide range of roles within the biopharmaceutical industry.

Table 3. Composition of Group B participants.

Participant ID #	Gender	Ethnicity	Location	Role
CGMH001	Male	Black	NC, USA	Caregiver
CGLD002	Female	White	CA, USA	Caregiver
PTLH001	Female	White	CA, USA	Patient
ESAS001	Female	White	CA, USA	Endpoint Specialist
PHSJ001	Female	White	MD, USA	Physician
PHLM002	Male	White	WA, USA	Physician
PHMZ004	Female	Hispanic	BUE, ARG	Physician
PHLW003	Female	White	ONT, CAN	Physician
PAJM001	Female	White	WA, USA	Patient Advocate
PTIB002	Female	Hispanic	Guatemala City, GTM	Patient

Table 4. Data analysis of Group A & B findings.

Participant Type	RQ1 Diversity	RQ 2 Impact of Diversity on Drug Development
Caregiver	1. Lack of easy access to hospitals that have specialists in the disease 2. Lack of trust 3. No healthcare providers that look like them 4. Study-related costs not covered by the study 5. Study design too burdensome *Health Equity*: 1. Access to good healthcare is only available in wealthy zip codes 2. Equity might take some unsafe drugs off the market, some drugs that weren't properly studied	Increases drug safety and efficacy
Endpoint Specialist	*Health Equity*: 1. Lack of access 2. No access to translators or documents in multiple languages	A drug more aligned with the "intent to treat population"
Patient	1. Geographic location 2. A lot of the study-related costs are not covered 3. Information is needed in multiple languages 4. Lack of patient involvement in design *Health Equity*: 1. Not everyone has the same level of support or access to healthcare	1. A drug more aligned with the "intent to treat population" 2. Increased transparency

Continued

Patient Advocate	1. Lack of trust 2. Lack of awareness 3. Lack of information 4. Inefficient recruitment measures 5. Bias towards larger institutions for speedier enrollment which are not diverse *Health Equity*: 1. All patients have access to the same information on the website, but not all patients have access to a computer or the Internet.	Builds trust.
Physician	1. Protocol design (keep it simple, not too burdensome) 2. Family, work, and time restraints 3. Inefficient recruitment measures *Health Equity*: 1. Patients must travel hundreds of miles because it's the only way to receive good healthcare. 2. Lack of equity in the cost of drugs for third-world countries participating in clinical trials. Prices do not match the economic status of the country.	1. Creates a sense of partnership, builds trust, and increases compliance in clinical trials. 2. It increases their understanding of the science of the disease.
Focus Group (Health Sector, Policy maker, Insurance advocates, DE&I Leaders, CRO, Specialty Vendors)	1. Lack of diversity in research providers. 2. Mistrust 3. Geographic Location 4. Inefficient recruitment measures. 5. Inadequate regulation by the government.	Rebuild trust in the drug development process. Create partnerships between drug sponsors and the community.

Table 4 provides a thematic analysis of the data from both groups to identify recurring themes and potential solutions to address both research questions.

Table 5. Consensus on barriers on RQ1 & RQ2.

Participant Type	RQ1 Enhancing Diversity	No. Participants	RQ2 Impact on Drug Development	No. Participants
Caregiver	1. Lack of easy access	2	1. True safety and efficacy of drugs unknown.	1
	2. Lack of trust	2		
	3. Lack of diversity in healthcare providers	1	2. Drugs do not always address the patient's needs.	2
	4. Geographic location	2		
	5. Full coverage of study-related costs	2	3. Increases understanding of the disease	1
	6. Study design is too burdensome	2		

Continued

Endpoint Specialist	1. Lack of access	1	1. True safety and efficacy of drugs unknown.	1
	2. Information is needed in multiple languages	1	2. Drugs do not always address the patient's needs.	1
	3. Lack of health equity	1	3. Increases understanding of the disease.	1
Patient	1. Geographic location	2	1. True safety and efficacy of drugs unknown.	2
	2. Full coverage of study-related costs	2		
	3. Information is needed in multiple languages	1	2. Drugs do not always address the patient's needs.	
	4. Lack of access	2	3. Increases understanding of the disease.	1
	5. Study design is too burdensome	2		
Patient Advocate	1. Lack of trust	2	1. True safety and efficacy of drugs unknown.	2
	2. Lack of awareness	2		
	3. Lack of information	2		
	4. Lack of access	2	2. Drugs do not always address the patient's needs.	2
	5. Bias towards larger institutions for speedier enrollment which are not diverse	2		
			3. Increases understanding of the disease.	2
Physician	1. Study design is too burdensome	3	1. True safety and efficacy of drugs unknown.	3
	2. Family, work, and time restraints	3	2. Drugs do not always address the patient's needs.	3
	3. Identify local facilities that can serve remote patients	3		
	4. Geographic Location.	3	3. Increases understanding of the disease.	3
	5. Lack of equity in the cost of drugs for third-world countries	1		

Continued

Focus Group (Health Sector, Policy maker, Insurance advocates, DE&I Leaders, CRO, Specialty Vendors)	1. Lack of diversity in healthcare providers	13	1. True safety and efficacy of drugs unknown.	15
	2. Expand the hospital network to include local facilities	12	2. Drugs do not always address the patient's needs.	14
	3. Mistrust	19	3. Increases understanding of the disease.	13
	4. Lack of access	17		
	5. Lack of health equity	19		

Based on the results in Table 5, there was clear consensus across all participant groups regarding the key barriers to diversity in clinical trials and how diversity impacts drug development. While not all participants responded to every topic, the alignment on each barrier and its implications for clinical trial diversity is robust, indicating strong agreement on the issues discussed.

4.1. Group C Survey Results

A convenient sample was chosen to determine if their opinions would align with existing research regarding barriers to clinical trial participation. The sample was skewed towards minorities. Group C concluded with a total of 305 participants, with the data displayed in various formats, as seen in Figures 5-8. Figure 5 captures the geographic distribution of Group C participants, showing the highest concentration in the USA (212 participants) followed by Jamaica (15 participants) and smaller numbers across 8 other countries. Figure 6 depicts the ethnicity distribution of participants, showing the largest group as Black or African American (134 participants), followed by White (83), and other ethnicities in smaller numbers such as Multiracial (16), Asian (10), and others.

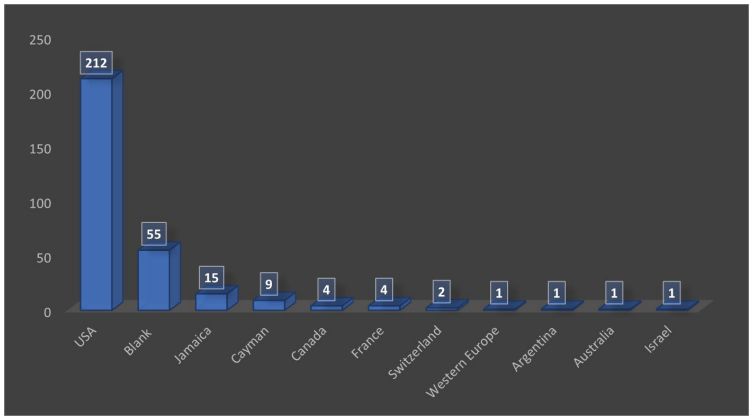


Figure 5. Group C participants by geographic distribution.

As seen above, most of the participants are from the U.S., with a very small number from several other countries.

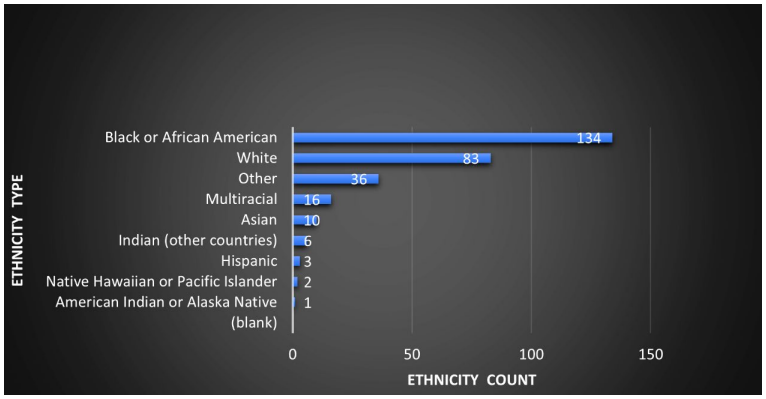


Figure 6. Group C participants per ethnicity.

Black or African Americans appear most often. Twenty participants did not identify their race. Roughly 80% of the participants have a tertiary-level degree.

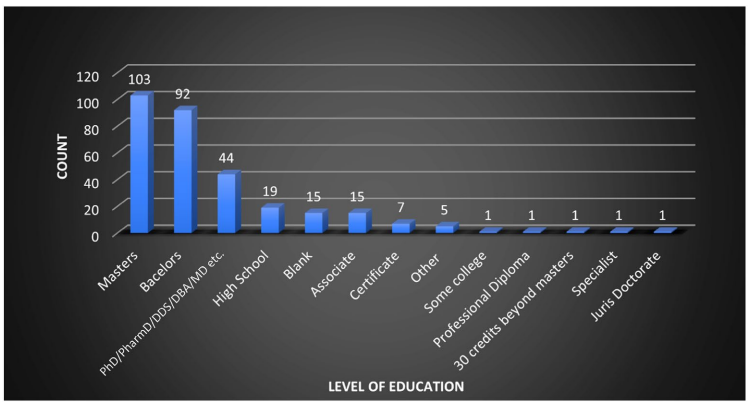


Figure 7. Group C participants per education attainment.

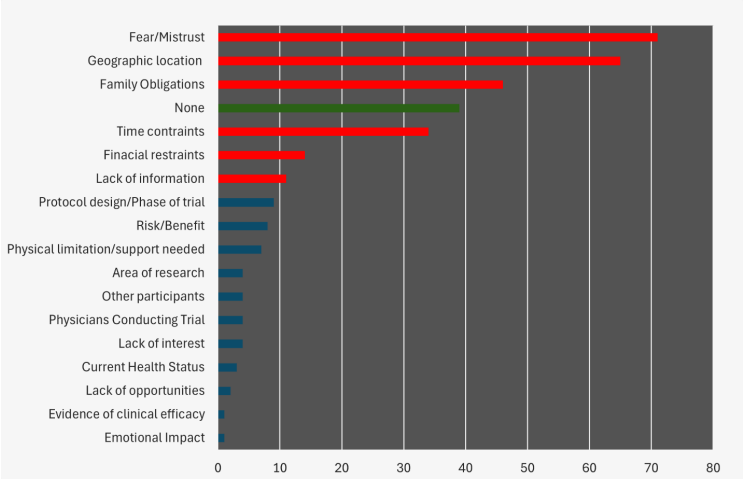


Figure 8. Group C survey responses to barriers to clinical drug trial participation.

The results corroborate the views of Group A and B participants and align with the literature cited throughout this study. Clark *et al.* [3] identified barriers such as mistrust, lack of time and resources, lack of awareness, and time constraints. Of the 305 participants, 239 responded. As shown in **Figure 8**, mistrust was one of the most common barriers (−29%), followed by geographic location (−27%). This supports the statements and beliefs of Group A and B interviewees.

Drawing from the insights shared by all participants, a distinct set of barriers to achieving diversity in clinical trials has been identified. These barriers, along with proposed solutions and actionable implementation strategies, are outlined below.

4.2. Lack of Trust

Many minority groups have historical and cultural mistrust of clinical trials due to past exploitation and perceived biases in the healthcare system. This mistrust is exacerbated by the lack of representation within clinical trial teams, leading to a reluctance among these populations to participate in medical research.

Solutions and Implementation Plan

1) Engage Community Leaders and Patient Advocates:

Solution: Partner with trusted community leaders, such as faith-based leaders, social activists, and patient advocates, to build credibility and encourage participation.

Implementation Plan: Establish ***Community Advisory Boards*** **(*CABs*)** composed of local leaders and patient advocates. These boards can help create culturally relevant trial materials, provide feedback on recruitment strategies, and lead ***Community Information Sessions*** that educate and engage local populations. This approach can help bridge the trust gap by showing potential participants that trusted figures support the trial.

2) Increase Transparency and Provide Education:

Solution: Transparently communicate the purpose, risks, and benefits of clinical trials to potential participants. Providing clear, accessible information can help demystify the process and build trust.

Implementation Plan: Develop ***Educational Campaigns*** that explain clinical trials in simple terms, emphasizing the protections in place for participants. These campaigns can be distributed via local media, social media, and in-person at community events. Consider offering ***Pre-Trial Information Sessions*** where potential participants can ask questions and address concerns about the trial process, privacy, and data security.

4.3. Limited Access to Local Trial Facilities

Clinical trials are often conducted at large urban centers, which are inaccessible to patients in rural or underserved areas. This geographical limitation disproportionately impacts minority populations, who may not have the resources or time to travel long distances for participation.

Solutions and Implementation Plan

Establish Regional Clinical Trial Hubs:

Solution: Set up clinical **Trial Satellite Sites** in community hospitals, clinics, and federally qualified health centers (FQHCs) located in diverse and rural areas. This would make it easier for patients to participate without traveling to urban centers.

Implementation Plan: Partner with local healthcare facilities to create Regional Clinical Trial Hubs equipped with the necessary technology and personnel to conduct trial assessments. Utilize ***Mobile Health Units*** that can travel to participants' communities for assessments, reducing the need for patient travel. Implement Telemedicine Options for remote consultations and follow-ups to further minimize the burden on participants. To ensure sustainability, these hubs could be funded through public-private partnerships, incorporating NIH grants, biopharmaceutical industry contributions, and community-based healthcare funding models. Additionally, establishing cost-sharing agreements among stakeholders could support infrastructure and ongoing operations, especially in underserved regions.

4.4. Utilize Virtual Recruitment and Participation

Solution: Implement digital platforms to allow for virtual recruitment, pre-screening, and even data collection where possible. This approach can improve accessibility for participants who may not be able to visit trial sites regularly.

Implementation Plan: Develop a ***User-Friendly Online Platform*** where potential participants can learn about the trial, complete pre-screening assessments, and engage with trial coordinators. Use ***Video Consultations*** for participants to conduct interviews and certain assessments, where applicable.

4.5. Socioeconomic Barriers

These include financial costs associated with trial participation, such as travel, time off work, childcare, and other out-of-pocket expenses. These barriers can prevent individuals from lower-income backgrounds from participating, further limiting diversity in clinical trials. Addressing these barriers is crucial for equitable representation.

Solutions and Implementation Plan

Provide Financial Assistance for Participants:

Solution: Offer financial support programs to cover expenses related to participation, including travel, lodging, and compensation for lost wages, making trials more accessible for those with economic constraints.

Implementation Plan: Establish a **Participant Assistance Fund** dedicated to reimbursing out-of-pocket expenses. Create **Flexible Compensation Models** for time spent in trials, allowing participants to be compensated for their time and travel. Publicize the availability of this support to potential participants to ensure they know these resources exist.

Partner with Employers and Community Organizations:

Solution: Collaborate with local employers and community organizations to provide additional support for participants, such as flexible work schedules or subsidized childcare.

Implementation Plan: Establish **Employer Partnerships** with local businesses willing to provide paid time off or flexible scheduling for employees participating in clinical trials. Partner with **Community Organizations** that can offer subsidized childcare services during trial appointments, helping to alleviate a key barrier for participants with caregiving responsibilities.

4.6. Lack of Culturally Competent Healthcare Providers

This can alienate minority patients, who may feel misunderstood or undervalued if providers are not trained to communicate effectively with diverse populations. Culturally competent care is essential to create a welcoming environment and encourage minority participation in clinical trials.

Solutions and Implementation Plan

1) Implement Cultural Competency Training for Trial Staff

Solution: Conduct mandatory cultural competency workshops for all clinical trial staff to ensure they are equipped to engage with patients from various cultural backgrounds sensitively and respectfully.

Implementation Plan: Develop ***Cultural Competency Workshops*** in collaboration with diversity and inclusion experts. Make this training part of the onboarding process for all trial staff, including researchers, coordinators, and healthcare providers. Conduct ***Ongoing Training Sessions*** to reinforce and update skills, incorporating feedback from trial participants to tailor the curriculum.

2) Recruit Diverse Healthcare Providers and Trial Staff

Solution: Focus on hiring and training a diverse clinical trial staff that better reflects the populations being studied, which can increase comfort and trust among minority participants.

Implementation Plan: Establish a ***Diversity Hiring Initiative*** for clinical trial positions, prioritizing applicants with backgrounds and experiences that align with the trial's target population. Partner with ***Minority Medical Associations*** to recruit diverse healthcare providers and ensure they have access to resources for participating in clinical research. Additionally, provide ***Mentorship Programs*** for diverse staff to ensure they feel supported and can bring their unique perspectives to trial operations. Mentorship programs aimed at increasing diversity in clinical research staff can lead to more culturally competent trial environments, fostering trust and communication with participants from underrepresented communities. Diverse staff often serve as relatable advocates, improving recruitment and retention of minority participants.

4.7. Protocol Design

This often poses a significant barrier to diversity in clinical trials, as the complexity and intensity of trial requirements can deter participation, particularly among

minority and low-income populations. Many clinical trial protocols include frequent visits, extensive assessments, and long durations, which can be overwhelming for participants with full-time jobs, family responsibilities, or limited access to transportation. This barrier disproportionately impacts those who may already face economic and logistical challenges, ultimately limiting the representation of diverse populations in clinical research.

Solutions and Implementation Plan

1) Simplify Protocol Requirements

Solution: Streamline trial protocols to reduce the number of required visits and assessments, focusing only on essential data points. This could involve using remote monitoring for some assessments, reducing the need for in-person visits.

Implementation Plan: Conduct a ***Protocol Review*** to identify non-essential procedures and explore remote data collection options. Implementing ***Telehealth Visits*** for assessments that don't require direct physical examination can reduce the time burden on participants. Furthermore, collaborate with clinical trial design experts to create patient-friendly protocols that maintain scientific rigor while considering participant convenience.

2) Incorporate Flexible Visit Schedules

Solution: Offer flexible visit scheduling, including evening and weekend appointments, to accommodate participants' work and family obligations.

Implementation Plan: Partner with clinical trial sites to establish ***Extended Hours*** during high-demand periods, such as evenings and weekends. For larger trials, implement ***Mobile Units*** that travel to participants' homes or community centers to perform assessments and collect data, further reducing transportation barriers.

3) Provide Alternative Data Collection Methods

Solution: Utilize wearable technology and mobile health (mHealth) applications to collect data remotely. These technologies can track health metrics, medication adherence, and other critical data points without requiring frequent site visits.

Implementation Plan: Integrate ***Wearable Devices*** and ***Mobile Health Apps*** into the protocol design, allowing participants to record data at home. Implement a **Training Program** for participants to familiarize them with these devices, ensuring ease of use. Additionally, offer ***Technical Support*** to troubleshoot any device-related issues, making remote data collection as accessible as possible.

4) Implement Adaptive Trial Designs

Solution: Use adaptive trial designs that allow for modifications based on interim data. This can enable adjustments to the protocol to reduce participant burden and increase retention rates.

Implementation Plan: Engage in ***Pre-Trial Simulations*** to anticipate how adjustments might be made during the trial based on interim results. Establish a ***Data Monitoring Committee*** that regularly reviews participant feedback and trial data to make real-time adjustments as needed. This adaptive approach can help maintain participant engagement by addressing concerns or barriers as they arise.

4.8. Recruitment Strategies

This is a crucial aspect of achieving diversity in clinical trials, yet traditional methods have proven ineffective in engaging minority and underrepresented populations. Many recruitment efforts rely heavily on large academic centers and urban hospitals, which often lack access to diverse patient populations due to their geographic locations. This can lead to a homogeneous participant pool that does not adequately represent the broader population. Addressing recruitment challenges through targeted and culturally sensitive approaches is essential to enhance diversity in clinical trial participation.

Solutions and Implementation Plan

1) Expand Recruitment Beyond Traditional Academic Centers:

Solution: Partner with community hospitals, clinics, and federally qualified health centers (FQHCs) in diverse and underserved areas to create additional recruitment sites. These locations often serve populations that are more representative of the wider patient community.

2) Implementation Plan:

a) Partner with Community Healthcare Facilities: Establish partnerships with local hospitals, community health centers, and FQHCs in underserved areas. These facilities often serve more diverse patient populations, including those from various ethnic backgrounds and lower SES groups.

b) Conduct Outreach Programs: Collaborate with community organizations, local health departments, and advocacy groups to raise awareness about clinical trial opportunities. Organize informational sessions and recruitment drives in these communities to build trust and educate potential participants on the benefits and process of trial participation.

c) Leverage Telehealth for Remote Recruitment: For trials that require travel to larger facilities, use telehealth platforms to conduct initial consultations and pre-screening interviews. This approach reduces the need for patients to travel unnecessarily and makes it easier for those in remote locations to participate.

4.9. Culturally Tailored Recruitment Materials

Solution: Create recruitment materials that are linguistically and culturally appropriate for the target populations. This includes using multiple languages, culturally relevant imagery, and messaging that resonates with the community's values and concerns.

Implementation Plan: Collaborate with ***Community Leaders and Cultural Consultants*** to develop and review recruitment materials. These materials should be available in languages commonly spoken within the community and distributed through ***Trusted Community Channels***, such as local radio, newspapers, and community centers. Consider using ***Social Media Targeting*** to reach specific demographics and tailoring content to reflect the cultural and linguistic nuances of the target audience.

4.10. Leverage Social Networks and Community Ambassadors

Solution: Utilize the influence of social networks and trusted community members to spread information about clinical trials. Community ambassadors, such as religious leaders, social workers, and local healthcare providers, can play a key role in encouraging participation.

Implementation Plan: Recruit and train ***Community Ambassadors*** who can advocate for the clinical trial within their social circles. Provide these ambassadors with ***Educational Materials*** about the study, so they are well-equipped to answer questions and address concerns. Organize

Community Information Sessions led by ambassadors to discuss the trial, its goals, and the importance of participation. This strategy can be particularly effective in building trust and overcoming cultural barriers.

4.11. Implement Direct and Personalized Outreach Methods

Solution: Use direct mail, text messages, and phone calls with personalized content to reach potential participants. This approach can increase engagement by making individuals feel personally invited and valued.

Implementation Plan: Develop ***Ethnically Tailored Outreach Campaigns*** using direct mail and digital communications targeted at specific demographics. Use ***Personalized Messaging*** to highlight the relevance of the trial to the recipient's background or community health concerns. Follow up with ***Telephone Outreach*** conducted by culturally competent staff who can answer questions and provide additional information, ensuring the interaction feels approachable and personal.

A single, one-size-fits-all approach is unlikely to succeed in engaging diverse populations. By employing a mix of strategies tailored to each group's unique cultural context and communication preferences, pharmaceutical companies can better align their clinical trials with the natural epidemiology of the diseases they study. A commitment to diverse recruitment strategies not only enhances the representativeness of trial results but also ensures that the safety and efficacy of new treatments are validated across the full spectrum of the patient population.

5. Congress & Regulatory Bodies

The recommendations to improve diversity in clinical trials must take into account the policy and regulatory frameworks that govern the industry. While the proposed amendments to the DIVERSE Trials Act and the enhanced role of regulatory bodies like the FDA provide essential structural support, additional actionable strategies are needed to address the operational and cultural barriers that still hinder clinical trial inclusivity. The following recommendations focus on practical steps that stakeholders across the clinical trial ecosystem can take to further promote diversity, equity, and access.

5.1. Amendments to the DIVERSE Trials Act

Suggested amendments to the DIVERSE Trials Act include mandating annual trans-

parency reports from sponsors detailing participant demographics, offering tax incentives for enrolling underrepresented populations, and expanding grant funding to trial sites in medically underserved areas.

5.2. Congressional Support for Equitable Trial Access

In the interest of advancing health equity, Congress could extend similar employment protections to clinical trial participants as it currently provides to individuals fulfilling jury duty. Just as civic participation in the legal system is considered a societal obligation, contributing to the development of safe and effective medical treatments through clinical research should be recognized as a public good. This is especially relevant for increasing minority participation, as many individuals from underserved communities may hesitate to enroll in trials due to fears of job loss or workplace penalties. Ensuring that clinical trial participation is protected by federal law would affirm its societal value and enable more inclusive representation in research. After all, a healthy population is fundamental to the exercise of all civic duties, including those enshrined in the judicial process.

5.3. Role of Regulatory Bodies

Beyond issuing guidance documents, regulatory bodies such as the FDA should incentivize inclusive trial design by incorporating diversity metrics into the approval process, offering fast-track or priority review for sponsors demonstrating strong diversity frameworks, and partnering with trial sponsors to develop culturally appropriate enrollment strategies.

6. Findings as they Relate to the Theories

An interdisciplinary approach was employed in reviewing the data, using two theories to support this study: Dynamic Capabilities and Contextualism. The transformation or reconfiguration observed involves shifting the clinical trial process to one that is more diverse and patient-centric. The ethnic composition of clinical trials should reflect the disease population for which the drug is being developed. In June 2022, Congress passed a bill urging biopharmaceutical companies to increase diversity in clinical trials, marking a significant push for industry-wide change. Similarly, drug development must be reflective of diverse populations. The lack of diversity in clinical trials has resulted in drugs being developed with testing limited to small ethnic subgroups, leaving their safety and efficacy uncertain across all populations. Table 6 integrates the key concepts of each theory—sense, seize, and transform for DC theory, and context, content, and process for Contextualism—and demonstrates how these concepts relate to the research findings.

Pettigrew used contextualism to analyze organizational change over time. In this study, contextualism is combined with Dynamic Capabilities (DC) theory to analyze the findings in Table 6, to drive change in clinical trials and the drug development process. This interdisciplinary approach serves as a novel theoretical contribution to the field.

Table 6. Summary of research findings in light of the DCT and contextualist theories.

DCT	Sense	Seize	Transform
Context	1. Lack of diversity 2. Lack of easy 3. No healthcare providers that look like them. 4. Lack of trust 5. Lack of awareness 6. Lack of information 7. Geographic location 8. Lack of equity in healthcare	1. Update the Diversity Act to ensure diversity is a requirement, not an option. 2. Identify Liaisons from Biopharma for community outreach. 3. Identify liaisons within communities to support diversity both in the patients and practitioners.	
Content	1. Too burdensome 2. Lacks transparency 3. Lack of patient involvement in the drug development process.	1. Use focus groups and surveys to identify the specific needs of the patients to develop drugs that address the issue that is of most importance to the patient. 2. Involve patients as early as possible throughout the life of the study. 3. Provide infrastructure to develop local. 4. Use feedback from patients to improve protocol design.	
Process	The need for a redesign of the process	Analysis of pros and cons of increasing transparency and diversity in clinical trial design.	Increased diversity and access to clinical trials through the transformation of dynamic capabilities.

Reviewing Table 5, the first dynamic capability in DC theory, sensing, involves assessing opportunities and gathering data. Several key issues are highlighted in the data, which identify the challenges at hand. From the perspective of contextualism, the context refers to the inner and outer environments within which stakeholders operate. All factors related to sensing can be found within these contextual environments.

The second dynamic capability, seizing, involves making decisions and allocating resources to act on the opportunity. Focus groups and individual interviews provided valuable recommendations, such as expanding the clinical trial network by leveraging local facilities. Seizing aligns with the content element of contextualism, which focuses on the area to be transformed—in this case, the clinical trial process.

Finally, the last dynamic capability, transformation, involves implementing changes based on collected data to either create a new product or adapt an existing process. This study aims to explore ways to transform the clinical trial process to enhance diversity and access. Given the strong interconnection between health equity and diversity—particularly for minority populations—improving diversity in clinical trials requires addressing health equity simultaneously. By tackling health equity, we can increase access to clinical trials, thereby fostering greater diversity

and more inclusive research.

7. Discussion

The findings from this study provide a comprehensive view of the barriers hindering diversity in clinical trials and propose targeted, transformative solutions to address them. Key barriers identified include lack of trust, limited access to trial facilities, socioeconomic challenges, ineffective recruitment strategies, burdensome protocol designs, and a lack of culturally competent healthcare providers. These factors disproportionately affect minority populations, limiting their representation in clinical trials and potentially skewing trial outcomes. Such barriers not only reduce the generalizability of trial results but also restrict access to potentially life-saving treatments for underrepresented groups.

To address these challenges, this study proposes several actionable solutions: Community Advisory Boards to build trust, Regional Clinical Trial Hubs to improve access, Participant Assistance Funds to alleviate financial burdens, and Culturally Tailored Recruitment Materials to enhance engagement. In addition, integrating Telemedicine and Remote Monitoring options into protocol designs can significantly reduce participant burden, making trial participation more feasible for those with complex schedules or limited mobility. These solutions aim to transform the clinical trial process to better reflect the diversity of the populations trials intend to serve.

A critical insight from this study is the importance of culturally competent healthcare providers and diverse clinical research teams. Previous studies, such as those by Saha *et al.*, have shown that diverse healthcare providers improve patient comfort and reduce miscommunication. This study extends these findings by recommending mandatory cultural competency training for clinical trial staff and diversity hiring initiatives, ensuring that trial teams are more representative and better equipped to engage minority populations.

This research also addresses the geographic barrier, which has often been acknowledged but rarely tackled with practical solutions. By proposing the creation of Regional Clinical Trial Hubs and telemedicine for remote participation, the study offers a practical blueprint for increasing accessibility, particularly for rural and economically disadvantaged populations. This focus on accessibility is critical for bridging the gap between the ideal of inclusive trials and the realities of participation, an issue also emphasized by organizations like the FDA in their Patient-Focused Drug Development (PFDD) guidelines but under-addressed in most trial frameworks.

Furthermore, while existing literature highlights the need for trust-building, this study offers specific, actionable initiatives, such as Community Information Sessions led by trusted local figures, to effectively close the trust gap. These initiatives, when implemented, could transform the recruitment and retention of minority participants, fostering a more inclusive clinical trial environment.

This study fills key gaps in the existing literature by providing not only an un-

derstanding of the barriers but also concrete, evidence-based strategies for overcoming them. Previous research has often identified these challenges but lacked comprehensive solutions tailored to minority populations. By combining community outreach, social network engagement, and ethnically tailored messaging, this study offers a structured approach that has shown promise in improving participation rates among underrepresented groups. In doing so, it contributes novel, actionable solutions for making clinical trials more inclusive and reflective of the population they seek to serve.

8. Conclusions

The barriers to diversity in clinical trials are multifaceted, stemming from historical, social, and logistical challenges. This study has identified these barriers and proposed solutions that not only address practical concerns but also promote a more inclusive approach to clinical research. By expanding recruitment sites, simplifying protocol designs, providing financial assistance, and ensuring cultural competence among trial staff, the clinical trial industry can make significant strides toward increasing diversity and improving access.

This research directly answers the study's guiding research questions. First, it outlines how the clinical trial process can be transformed to enhance diversity by proposing targeted strategies such as culturally tailored recruitment methods and regional trial hubs. Second, it explores how greater diversity in the patient population can improve the drug development process by ensuring that clinical trials better reflect the natural epidemiology of the disease, ultimately enhancing drug safety, efficacy, and access.

By offering actionable solutions that address gaps in existing literature, this study provides a roadmap for pharmaceutical companies, clinical research organizations (CROs), and policymakers to make clinical trials more inclusive. Implementing these strategies will not only improve the generalizability of research findings but also ensure equitable access to treatments for underserved populations. To achieve these goals, clinical trial designers, CROs, and policymakers must prioritize diversity through targeted recruitment, regional hubs, and telemedicine. Funding and regulatory bodies should incentivize the creation of Participant Assistance Funds and Cultural Competency Training for trial staff. Prioritizing diversity is essential for both scientific rigor and ethical responsibility in healthcare, ensuring trials are more representative and better aligned with the populations they aim to serve.

Moreover, the role of Congress and regulatory bodies, such as the FDA, is crucial to supporting these operational changes. Legislative amendments, like those proposed for the DIVERSE Trials Act, alongside regulatory incentives, will provide the structural support necessary to drive the widespread adoption of these practices. Additionally, implementing federal protections for clinical trial participants—similar to those granted for jury duty—could remove employment-related barriers and promote broader participation. By fostering an environment that encourages diversity through inclusive policies, clinical trials can achieve more eq-

uitable outcomes that benefit all populations.

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Ethics Approval

The study was approved by Georgia State University, Institutional Review Board (IRB), Reference Number 374115. The study was determined by the IRB to be exempt from federal regulations as defined in 45 CFR 46 and was evaluated for the following:

1) Determination that it falls within one or more of the eight exempt categories allowed by the institution.

2) Determination that the research meets the organization's ethical standards.

Author's Contribution

Allison Bowen: Concept, data collection, and writing—draft/revisions; Satish Nargundkar: Methodology and review.

Consent to Participate

All participants voluntarily provided consent to participate in the study.

Consent for Publication

All participants voluntarily provided consent for the final data to be published.

Conflicts of Interest

The authors declared no potential conflicts of interest concerning the research, authorship, and/or publication of this article.

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