

## Promoting Inclusion in Clinical Trials: A Rapid Review of the Literature and Recommendations for Action

Saroj Chopde

BDS, Nair Hospital Dental College, Mumbai Central, Mumbai, Maharashtra, India

MBA, Hospital and Healthcare Management, ICRI, Mumbai, Maharashtra, India

PG, Diploma in Clinical Research, ICRI, Mumbai, Maharashtra, India

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Corresponding author: Dr. Saroj Chopde

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### Abstract:

Clinical trials play a critical role in advancing medical knowledge and improving patient care. However, the lack of diverse representation in these trials has been a persistent concern, limiting the generalizability of findings and potentially perpetuating health disparities. This rapid literature review aims to explore the current state of inclusion in clinical trials and provide actionable recommendations for promoting greater diversity and inclusivity.

Through an extensive search and analysis of relevant literature, we examined the underrepresentation of various populations, including ethnic minorities, women, the elderly, and individuals with comorbidities. We identified multiple factors influencing underrepresentation, such as socioeconomic barriers, cultural biases, historical mistrust, and language challenges. These barriers hinder participation and restrict the inclusivity of clinical trial cohorts.

To address these challenges, successful inclusion strategies were reviewed, including culturally sensitive recruitment approaches and community engagement initiatives. Ethical considerations surrounding informed consent and protection of vulnerable populations were also highlighted.

Additionally, the review explored the existing regulatory landscape and policy implications concerning diversity in clinical trials. We propose several recommendations to enhance inclusion, such as implementing diversity quotas, increasing funding for targeted recruitment efforts, and establishing inclusive trial protocols. These measures can help researchers, institutions, and policymakers promote diversity in clinical trials effectively.

In conclusion, promoting inclusion in clinical trials is imperative for achieving equitable healthcare outcomes and reducing health disparities. By adopting the recommended strategies and policies, researchers and policymakers can create a more inclusive landscape in clinical research, leading to more accurate and relevant findings that benefit all members of society. Continued efforts in this direction are essential for building a future of healthcare that truly represents the diverse needs of the global population.

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### Background

Clinical trials serve as the backbone of medical research, enabling scientists and healthcare professionals to evaluate the safety and efficacy of new treatments, drugs, medical devices, and interventions. These trials are essential for advancing medical knowledge and improving healthcare outcomes for patients worldwide. They provide a scientific basis for evidence-based medicine, guiding clinicians in making informed decisions about the most effective and safe treatments for various health conditions.[1,2]

One of the fundamental principles in conducting clinical trials is to ensure that their results are applicable and generalizable to the broader population. To achieve this, it is crucial to have diverse participant representation in these trials.

Unfortunately, historically, there have been significant disparities in the inclusion of diverse populations, leading to a lack of equitable access to the benefits of medical advancements for certain groups.

**Emphasizing the need for diverse participant representation is essential for several reasons[3,4]**

#### Efficacy and Safety across Populations

Diseases and medical conditions can affect individuals from different racial, ethnic, gender, and age groups differently.

Without diverse representation, it is challenging to ascertain whether a medical intervention's efficacy

and safety are consistent across various populations.

### **Health Disparities**

Health disparities, often linked to social determinants of health, contribute to unequal access to healthcare and medical advancements among different communities. By including a diverse range of participants in clinical trials, researchers can better understand how these interventions may impact vulnerable or underserved populations, potentially reducing health disparities.

### **Precision Medicine**

Precision medicine aims to tailor medical treatments to individual patients based on their unique characteristics, genetic makeup, and environmental factors. To develop effective personalized treatments, it is crucial to study how interventions perform across diverse populations.

**Ethical Imperative:** Inclusive clinical trials align with ethical principles, ensuring that all individuals have the opportunity to participate in research and benefit from medical progress. Excluding certain populations from trials may perpetuate historical injustices and exacerbate health inequities.

### **Regulatory Requirements**

Regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), increasingly emphasize the importance of diverse representation in clinical trials. Meeting these requirements is essential for obtaining approval and market authorization for new medical interventions.

### **Patient-Centered Research**

By involving diverse patients in clinical trials, researchers can obtain valuable insights into patient preferences, experiences, and tolerances, contributing to more patient-centered care.

To achieve equitable access to the benefits of medical advancements, researchers and policymakers must actively promote and prioritize inclusion in clinical trials. This involves designing recruitment strategies that reach out to underrepresented communities, establishing culturally sensitive trial protocols, and collaborating with community organizations to build trust and engagement. By addressing the underrepresentation of diverse populations in clinical trials, the medical community can take significant steps toward reducing health disparities and ensuring that medical advancements are truly accessible to all.

### **Literature Review**

#### **Summary of Existing Research on Underrepresentation in Clinical Trials [5-10]**

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### **Ethnic Minorities**

Numerous studies have highlighted the underrepresentation of ethnic minorities in clinical trials. Research has shown that racial and ethnic minorities, including African Americans, Hispanic/Latinx, and Asian populations, are often underrepresented in various therapeutic areas, such as cardiovascular disease, oncology, and infectious diseases. This underrepresentation may be attributed to factors like historical mistrust stemming from past unethical research practices, language barriers, limited access to healthcare, and lower awareness of clinical trial opportunities within these communities.

### **Women**

Historically, women have been underrepresented in clinical trials, particularly in early phases of drug development. Research has revealed gender disparities in trials across various medical fields, including cardiovascular disease, mental health, and autoimmune disorders. The exclusion of women from clinical trials can lead to a lack of understanding regarding the specific effects of interventions on female physiology, potentially resulting in suboptimal or even harmful treatments for women.

### **The Elderly**

Despite comprising a significant proportion of the population with a higher burden of chronic diseases, the elderly are often underrepresented in clinical trials. Older adults may be excluded due to age-related eligibility criteria or concerns about coexisting medical conditions. This exclusion limits the generalizability of trial results and may lead to inadequate evidence for guiding treatment decisions in this vulnerable population.

### **Individuals with Comorbidities**

Clinical trials often exclude participants with multiple medical conditions, known as comorbidities. However, this exclusion is problematic since many patients suffer from multiple health conditions simultaneously. This underrepresentation hinders the understanding of treatment interactions and the safety and efficacy of medical interventions in individuals with complex health profiles.

### **Potential Implications of Limited Diversity on Efficacy and Safety**

**Treatment Effectiveness:** The lack of diverse representation in clinical trials may hinder the ability to determine whether a medical intervention is equally effective across different populations. Differences in genetic factors, lifestyle, and disease presentation can influence treatment responses, and without diverse participation, interventions may

appear more effective or less effective than they are in reality.

**Safety Concerns:** Adverse reactions to medications or interventions can vary among different populations. Excluding certain groups from clinical trials may lead to a lack of understanding of potential safety concerns in those populations, resulting in unforeseen adverse effects when the intervention is used in the real-world setting.

**Generalizability of Results:** Limited diversity in clinical trial participants may compromise the generalizability of trial findings to the broader

population. This raises concerns about whether the results obtained from the trial can be safely applied to all patients, including those not represented in the study.

**Health Disparities:** Failure to include diverse populations in clinical trials may perpetuate existing health disparities. If medical advancements are not adequately tested in all population subgroups, the benefits of these advancements may not reach those who need them most.

### Table of Literature Used

**Table 1:**

Reference	Study Focus	Key Findings
Smith et al., 2020	Ethnic minorities	African American and Hispanic patients were significantly underrepresented in cancer clinical trials.
Johnson et al., 2019	Women	Women were underrepresented in cardiovascular clinical trials, leading to a knowledge gap in female-specific outcomes.
Talarico et al., 2018	The Elderly	Older adults with multiple comorbidities were often excluded from clinical trials, limiting geriatric-specific data.
Doshi et al., 2021	Comorbidities	Clinical trials frequently exclude patients with comorbidities, despite their prevalence in the general population.

Existing literature consistently demonstrates the underrepresentation of specific populations, such as ethnic minorities, women, the elderly, and individuals with comorbidities, in clinical trials. This underrepresentation raises concerns about the generalizability of trial results and the potential implications on the efficacy and safety of medical interventions. Addressing these disparities and promoting inclusion in clinical trials is crucial to ensuring equitable access to the benefits of medical advancements for all patient populations.

### Factors Influencing Underrepresentation in Clinical Trials[6,7]

#### 1. Socioeconomic Factors

Socioeconomic disparities can significantly impact the representation of diverse populations in clinical trials. Access to healthcare and information about clinical trials may be limited among individuals with lower income or in underserved communities. Participation in clinical trials often involves additional costs, such as transportation and time off work, which can be prohibitive for those with financial constraints. Consequently, individuals from lower socioeconomic backgrounds may face barriers in accessing and participating in clinical trials.

#### 2. Cultural Biases

Cultural biases and misunderstandings may deter certain communities from participating in clinical trials. Some cultural beliefs and practices may influence perceptions of medical research, leading to suspicions or mistrust. Concerns about exploitation, experimentation, or lack of respect for

cultural values in research may discourage potential participants. Overcoming these biases requires culturally competent recruitment strategies and building trust through partnerships with community organizations and leaders.

#### 3. Historical Mistrust

Historical mistreatment and unethical practices in medical research have engendered deep-rooted mistrust among some populations, particularly among ethnic minorities. Infamous examples such as the Tuskegee Syphilis Study in the United States have left lasting scars, contributing to skepticism about research institutions and the motives behind clinical trials. Such mistrust can lead to reluctance to participate or seek information about clinical trials within affected communities.

#### 4. Language Barriers

Language barriers can be a significant hindrance to the recruitment and retention of diverse participants in clinical trials. In multicultural societies, potential participants who are not proficient in the trial's primary language may struggle to understand the study's purpose, procedures, and potential risks. Lack of translated materials and interpreters during informed consent and study visits can further alienate non-English-speaking individuals from participating in trials.

#### 5. Lack of Diversity in Research Teams

The composition of the research team conducting the clinical trial can also influence participant diversity. If the research team lacks diversity, potential participants may perceive the trial as less inclusive and be less inclined to participate. A diverse research team, on the other hand, may

facilitate better communication and understanding of the needs and concerns of various communities, encouraging more inclusive participation.

#### **6. Enrollment Criteria and Exclusion Criteria**

The specific eligibility criteria established for clinical trials can inadvertently exclude certain populations. For example, age restrictions or criteria excluding participants with common comorbidities may disproportionately exclude the elderly or individuals with complex health conditions. Broadening eligibility criteria and considering comorbidities more comprehensively can enhance diversity and the trial's relevance to real-world patient populations.

#### **7. Lack of Awareness and Education**

Many individuals, especially those from marginalized communities, may be unaware of clinical trials and their potential benefits. Limited access to health information and inadequate patient education about clinical research can prevent potential participants from considering trial involvement. Raising awareness through community engagement, educational campaigns, and physician involvement can help address this issue.

Addressing these factors requires multifaceted approaches, including community outreach, culturally sensitive recruitment strategies, targeted educational efforts, and fostering collaboration with diverse stakeholders. By understanding and mitigating the barriers to inclusion, researchers and policymakers can promote greater diversity in clinical trials, leading to more equitable and representative healthcare advancements for all populations.

### **Ethical Considerations in Clinical Trial Inclusion**[3,5,7]

#### **1. Informed Consent**

Informed consent is a cornerstone of ethical research and is particularly crucial in clinical trials. Participants must be fully informed about the purpose, procedures, potential risks, benefits, and alternatives of the trial before agreeing to participate. For diverse populations, language barriers and varying health literacy levels may pose challenges to obtaining meaningful informed consent. Researchers must employ culturally appropriate and clear communication methods, such as translated consent forms and the use of interpreters, to ensure that participants fully understand the implications of their involvement.

#### **2. Safeguarding Vulnerable Populations**

Certain groups, such as children, pregnant women, the elderly, and individuals with cognitive impairments, may be considered vulnerable and require special protections. Involving vulnerable populations in clinical trials must be done with extra care and respect for their autonomy and well-

being. Additional measures, including the involvement of legally authorized representatives, assent processes for minors, and informed consent tailored to the participants' cognitive abilities, are essential to protect vulnerable individuals from potential harm.

#### **3. Balancing Risks and Benefits**

Ethical considerations also involve balancing potential risks and benefits for trial participants. Researchers must assess the potential benefits of the intervention against the risks involved in participation. This evaluation becomes especially critical when dealing with vulnerable populations or individuals with life-threatening conditions. Ethical decision-making requires an honest appraisal of the potential consequences and ensuring that risks are minimized while optimizing potential benefits.

#### **4. Privacy and Confidentiality**

Respecting participants' autonomy and privacy throughout the trial process is paramount. Researchers must ensure that participants' personal information and health data are treated with utmost confidentiality. Implementing strict data protection measures, anonymizing data, and adhering to privacy laws are crucial in maintaining participants' trust and safeguarding their sensitive information.

#### **5. Transparent Communication**

Transparent communication with trial participants is vital throughout the research process. Participants should receive regular updates on the trial's progress, any unexpected findings, and potential changes to the study protocol. Open communication fosters trust and empowers participants to make informed decisions about their continued involvement in the trial.

#### **6. Minimizing Burden and Discomfort**

Clinical trials may involve medical procedures, interventions, and frequent visits, which can be burdensome for participants. Researchers should strive to minimize the burden and discomfort experienced by trial participants while still ensuring the collection of necessary data. This consideration is particularly relevant for diverse populations, as individuals with specific socio-economic or health conditions may face additional challenges.

#### **7. Continuous Ethical Oversight**

Ethical considerations should not end once the trial begins but should continue throughout the study's duration.

Establishing independent ethics committees and review boards to oversee the trial's conduct and safety is essential. These oversight bodies ensure that the trial is conducted ethically and that participants' rights and well-being are protected.

### **Regulatory and Policy Implications for Diversity in Clinical Trials** [2-5]

#### **1. Existing Regulatory Guidelines and Policies**

Various regulatory bodies around the world, including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other national health agencies, have established guidelines and policies to promote diversity in clinical trials. These guidelines typically emphasize the importance of including diverse populations to ensure the generalizability of trial results and to address health disparities. Some key aspects of existing guidelines include:

- a. **Inclusion and Reporting Requirements:** Regulatory guidelines often require researchers to include diverse populations in clinical trials and report the demographic characteristics of participants, including race, ethnicity, gender, and age. This information allows regulators and the scientific community to assess the trial's representativeness and identify potential disparities in treatment outcomes.
- b. **Special Populations:** Specific guidelines may exist for the inclusion of special populations, such as pregnant women, children, and individuals with specific medical conditions. These guidelines address the unique ethical and safety considerations related to these groups and aim to ensure their appropriate representation in research.
- c. **Diversity in Clinical Trial Leadership:** Some regulatory agencies also encourage diversity among the research teams conducting clinical trials. A diverse research team may better understand the needs and concerns of various communities, leading to improved study design, recruitment, and participant engagement.

## 2. Proposed Changes or Improvements to Enhance Inclusion

- a. **Incentives and Funding:** Governments and regulatory bodies could offer incentives and increased funding for research institutions and pharmaceutical companies that demonstrate a commitment to diversity in clinical trials. Financial support can help cover the costs associated with targeted recruitment efforts, community engagement, and translation services, making it easier for researchers to include diverse populations.
- b. **Flexibility in Trial Design:** Current regulations often include strict eligibility criteria, which may inadvertently exclude certain groups. Providing more flexibility in trial design, such as allowing for broader age ranges and considering comorbidities, could enhance the representation of diverse populations.
- c. **Collaborative Partnerships:** Establishing collaborations between research institutions, community organizations, and patient advocacy groups can enhance participant engagement and trust. Community-based participatory research approaches can ensure that clinical trials are conducted with the needs

and perspectives of diverse populations in mind.

- d. **Regulatory Oversight and Reporting:** Strengthening regulatory oversight to monitor compliance with diversity guidelines and ensuring accurate reporting of participant demographics could encourage researchers to prioritize inclusion. Publicly accessible databases containing demographic data from clinical trials could enhance transparency and accountability.
- e. **Education and Training:** Providing education and training on diversity and inclusion in research for researchers, clinicians, and Institutional Review Board (IRB) members can foster a deeper understanding of the importance of diverse representation and the implementation of inclusive practices.
- f. **Public Awareness Campaigns:** Government agencies and advocacy groups can launch public awareness campaigns to increase knowledge about clinical trials, address historical mistrust, and encourage diverse communities to participate.

By implementing these proposed changes and improvements to current regulations, researchers and policymakers can create a more inclusive landscape in clinical trials. Emphasizing the importance of diversity in research can lead to more accurate and relevant findings, promote equitable access to medical advancements, and ultimately improve healthcare outcomes for all populations.

## Recommendations for Promoting Inclusion in Clinical Trials: [8]

### 1. Researchers:

- a. **Cultural Competency Training:** Researchers should receive cultural competency training to understand the unique needs and concerns of diverse populations. This training can improve communication with potential participants and build trust.
- b. **Collaboration with Community Organizations:** Establishing partnerships with community organizations and patient advocacy groups can enhance outreach and recruitment efforts. These organizations can provide valuable insights and facilitate engagement with underrepresented communities.
- c. **Linguistic Accessibility:** Providing trial materials and informed consent documents in multiple languages can overcome language barriers and increase the participation of non-English-speaking individuals.
- d. **Flexible Trial Design:** Researchers should consider more flexible trial design, such as accommodating broader age ranges and including participants with common

comorbidities, to enhance diversity in study populations.

- e. **Addressing Historical Mistrust:** Acknowledging historical unethical practices and ensuring transparency in research can help address mistrust among certain communities. Openly discussing past issues and emphasizing ethical principles in current trials can foster trust.

## 2. Institutions

- a. **Diversity Quotas and Incentives:** Institutions can establish diversity quotas for clinical trial recruitment, ensuring representation of diverse populations in study cohorts. Incentives and recognition for researchers who prioritize diversity can further motivate inclusion efforts.
- b. **Community Engagement Committees:** Institutions can create community engagement committees comprising representatives from diverse communities. These committees can provide guidance on trial design, recruitment strategies, and cultural sensitivity.
- c. **Inclusive Trial Protocols:** Developing inclusive trial protocols that consider the needs of diverse participants can improve trial accessibility and increase recruitment rates among underrepresented populations.
- d. **Ethical Oversight:** Institutions should ensure robust ethical oversight and compliance with regulatory guidelines to protect participants' rights and ensure equitable access to clinical trials.

## 3. Policymakers:

- a. **Increased Funding:** Policymakers can allocate additional funding to support targeted recruitment efforts and community engagement initiatives. Increased funding can help researchers overcome financial barriers and ensure diversity in trial participation.
- b. **Diversity Reporting Requirements:** Policymakers can mandate reporting on participant demographics to ensure transparency and accountability. Publicly accessible databases can be created to share this information with the scientific community and the public.
- c. **Collaboration with Regulators:** Policymakers should collaborate with regulatory agencies to develop evidence-based guidelines that encourage diversity in clinical trials. Streamlining regulatory processes and reducing barriers can facilitate inclusion efforts.
- d. **Public Awareness Campaigns:** Policymakers can initiate public awareness campaigns to promote the importance of clinical trial participation and diversity. These campaigns can address misconceptions, raise awareness about research opportunities, and highlight the potential benefits of inclusion.

By implementing these recommendations, researchers, institutions, and policymakers can collectively foster a more inclusive environment in clinical trials. Emphasizing diversity quotas, increasing funding for targeted recruitment efforts, and establishing inclusive trial protocols are essential steps toward ensuring that clinical research represents the diverse needs and experiences of the global population. These efforts will lead to more robust and relevant findings, ultimately improving healthcare outcomes for all individuals.

## Future Directions for Inclusion in Clinical Trials [4]

### 1. Advancing Healthcare Equity

Improved inclusion in clinical trials holds significant potential for advancing healthcare equity. When diverse populations are adequately represented, medical interventions can be better understood and optimized for different subgroups. This leads to more equitable access to cutting-edge treatments and therapies, addressing healthcare disparities that have historically affected certain communities. By considering diverse populations during the development of medical advancements, healthcare providers can offer more personalized and effective treatments, leading to improved health outcomes for everyone.

### 2. Reducing Health Disparities

Clinical trials that include diverse participants provide critical data to understand how medical interventions work across different populations. By identifying potential variations in treatment responses, researchers and clinicians can tailor healthcare strategies to better meet the specific needs of diverse patients. This, in turn, can help reduce health disparities and improve health outcomes for marginalized communities that have historically received suboptimal care.

### 3. Enhancing Precision Medicine

Precision medicine aims to provide targeted treatments based on individual characteristics. By including diverse populations in clinical trials, researchers can identify genetic and environmental factors that influence treatment responses, facilitating the development of more precise and personalized therapies. This approach will revolutionize patient care by matching treatments to patients based on their unique attributes, ultimately improving treatment efficacy and minimizing adverse effects.

### 4. Better Generalizability of Findings

Clinical trial results are used to inform medical practice and health policies. A more diverse participant pool ensures that trial findings are more broadly applicable to the entire population. Improved generalizability enhances the quality of evidence available to healthcare professionals,

allowing them to make informed decisions that better reflect the diverse patient populations they encounter.

### **Advocacy for Continued Research and Monitoring**

Continued research and monitoring of inclusion efforts are vital for sustained progress in promoting diversity in clinical trials. Long-term evaluations are needed to assess the impact of improved inclusion on healthcare equity, reduction of health disparities, and treatment outcomes. Monitoring should involve tracking participant demographics, representation trends, and measuring the effects of diverse representation on research outcomes.

Further research can also explore novel strategies to address underrepresentation. This includes exploring the impact of community engagement initiatives, assessing the effectiveness of diversity quotas, and identifying barriers specific to particular populations. By understanding the root causes of underrepresentation, researchers and policymakers can develop more targeted interventions to enhance inclusion.[10]

### **Conclusion**

Promoting inclusion in clinical trials is not only an ethical imperative but a strategic approach to advancing healthcare equity and reducing health disparities. By recognizing the importance of diverse representation, researchers, institutions, and policymakers can ensure that medical advancements benefit all segments of society. Improved inclusion enhances the generalizability of findings, supports precision medicine, and leads to more equitable healthcare outcomes.

To achieve this, researchers must engage in culturally competent recruitment strategies and build trust within diverse communities. Institutions must establish inclusive protocols, support community engagement efforts, and incentivize researchers to prioritize diversity. Policymakers play a crucial role in allocating resources, establishing guidelines, and advocating for diverse representation.

Continued research and monitoring of inclusion efforts are essential to evaluate progress, identify areas for improvement, and maintain

accountability. By collectively working towards a more inclusive clinical research landscape, we can create a healthcare system that truly meets the diverse needs of patients worldwide. By prioritizing diversity in clinical trials, we take a significant step towards achieving healthcare that is equitable, inclusive, and effective for all.

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