

The Trial of the Future:

Fostering Diversity and Inclusion in Research

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- In compliance with ACCME Guidelines, I hereby declare:
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The Importance of Diversity in Research

- Enrolling diverse patient populations is key to developing new treatments
- Failing to test these treatments among a diverse population could significantly impact safety and efficacy



Why Do We Lack Diversity?

- Misconceptions of mistrust among minorities due to a long history of abuse and injustice
- In reality, minorities are just as likely to be willing to participate in clinical research
(<https://www.ncbi.nlm.nih.gov/pmc/articles/NIHMS35372/>)
- We need to do more to remove barriers and build opportunities for minorities to participate



COVID-19 and the State of Clinical Research

- COVID-19 has exposed the severity of our social and health disparities

| Rate ratios compared to White, Non-Hispanic Persons | Amer. Indian or AK Native, Non-Hispanic persons | Asian, Non-Hispanic persons | Black or African American, Non-Hispanic persons | Hispanic or Latino persons |
|-----------------------------------------------------|-------------------------------------------------|-----------------------------|-------------------------------------------------|----------------------------|
| CASES | 2.8x higher | 1.1x higher | 2.6x higher | 2.8x higher |
| HOSPITALIZATION | 5.3x higher | 1.3x higher | 4.7x higher | 4.6x higher |
| DEATH | 1.4x higher | No Increase | 2.1x higher | 1.1x higher |

Source: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>



#1: Connect with Patient Advocacy Groups

- Direct path to the patients and populations we need to reach
- Can help researchers connect with underserved populations



#2: Use Technology to Engage Patients

- Clinical research technologies can help expand research access to under-represented populations and regions
- Technology helps overcome hurdles such as cost, availability, and distance



#3: Expand Your Eligibility Criteria

- Small adjustments to how we recruit can lead to better predictability regarding things like disease onset
- To move the needle, diversity must be prioritized from the start



#4: Connect with Community Health Centers

- These centers often serve minority patients and other members of underserved populations
- Lots of trust built into these patient care relationships
 - Community health centers could help be "cheerleaders" for research



#5: Support Diversity in Public Policy

- Other countries' regulations currently mandate diversity in research...not yet in US
 - FDA could mandate diversity
- Instead of waiting for regulatory change, make diversity an internal mandate
 - Prioritize diversity from the top down
- Challenge existing processes and assumptions from end to end



What Can Sites Do?

- Cultural and linguistic access
 - Recognize the role of family and tradition—include the patient's family early on to support decision-making process
 - Easy to understand ICFs help build trust with patients and their families
 - Language equity—bilingual staff are critical
- Engage patients in trial decision making
 - Make sure study materials are appropriate and useful for diverse communities
- Community education
 - Bring research options to the patient in the clinical setting
 - Promote involvement with community leaders to build trust and promote awareness
- Safe participation
 - Make sure patients understand there are no legal repercussions to participating in research
- Technology
 - To reach broader patient population
 - To bridge language barriers



Characteristics of Sites Successful at Diverse Enrollment

- Successful sites have a higher commitment and make more efforts than less successful sites
- Commitments/efforts geared toward:
 - Developing more community connections
 - Providing incentives to staff and patients
 - Hiring providers and staff that can speak the language that the majority of patients speak
 - Providing training for staff to become culturally competent

Source: SCRS, [Diverse Enrollment In Clinical Trials: What Do Successful Research Sites Have In Common?](#)



Conclusion: What You Can Do Now

- Awareness and education
- Understand the gaps
- Deal with disparities (language, etc.)
- Once you have addressed these items, you can build a playbook of concrete action items
 - Things that can be addressed both in the long-term AND in the short-term

