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Key Considerations Around Underrepresented Populations in Clinical Trials

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Increasing diversity and accessibility in clinical trials is critical to ensure that all populations can equitably benefit from clinical research and advancements in healthcare. Excluding specific population groups can compromise the validity and generalizability of research results, making it essential to address these disparities.

In our white paper, "Underrepresented Populations in Clinical Trials: Considerations, Diversity, Accessibility, and Patient Centricity," we describe the current landscape of diversity and accessibility in clinical research.

Here's a brief overview of key considerations for including underrepresented populations in clinical research, and regulatory guidance around the topic:

Minors and the elderly

Clinical research involving infants and older adults carries inherent risks due to age-related physiological differences, which need to be considered when designing such trials.[1]

Specific ethnic and racial groups

Marginalization of certain ethnic and racial groups in clinical trials continues to be a significant issue. Understanding the historical context of unethical research is essential for researchers to understand the mistrust that may exist towards trial participation within specific population groups.1 Additionally, recognizing genetic and disease predisposition differences among specific patient groups is an important consideration, with trial participation of such minority groups needed to be able to aid in uncovering population-specific health data.[1,2]

Rural communities

Rural communities face logistical, financial, and educational barriers to trial participation.[3] Efforts to address these barriers can make clinical trials more accessible and representative.

People with disabilities

Individuals with disabilities often experience more adverse health outcomes[4] yet are frequently excluded from the clinical research from which they could benefit. Providing appropriate accommodations and assistive technologies is essential for their inclusion.[5]

International participants

Drugs approved in one country may not be accessible in others where trials were initially conducted, raising ethical concerns. Researchers must consider the implications and strive for equitable access to treatments.[6]

Regulatory viewpoints

The FDA emphasizes the importance of avoiding unnecessary exclusions and broadening eligibility criteria to ensure trial participants reflect the intended drug users.[2] Recent guidance also promotes Diversity Action Plans to foster inclusion.[7] Furthermore, the FDA's patient-focused drug development (PFDD) guidances highlight the importance of incorporating patient perspectives into drug development.[8,9,10,11] These guidances provide strategies for collecting and using patient experience data and ensuring that clinical trials are designed with patient needs in mind.

Conclusion

Increasing diversity in clinical trials is paramount for advancing healthcare and providing equitable outcomes. Ensuring diversity and inclusion in clinical trials is essential to provide equitable healthcare and improve health outcomes for all.

Download the full white paper to read a more comprehensive exploration and learn how we can work together to promote diversity, accessibility, and patient- centricity in clinical trials.

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Authors

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Bill Byrom, PhD has over 30 years' experience as a clinical development specialist, an eClinical product strategy leader, and an industry expert in clinical outcome assessments. He has authored 80+ publications and two industry textbooks on electronic patient-reported outcomes (ePRO), and his recent research includes the use of wearables and bring-you-own-device (BYOD) eCOA in clinical trials. At Signant he provides eCOA science expertise into customer projects and company strategy.

Greta Marie de Waal, PhD provides scientific expertise and guidance relating to the implementation of electronic clinical outcome assessments (eCOAs) and has a special focus on eDiary design and accessibility of eCOA best practices. She completed her PhD in Physiological Sciences at Stellenbosch University, which focused on the bacterial and inflammatory involvement in colorectal carcinogenesis, and has 3+ years' experience in the clinical research industry. She has given scientific consultation for projects across a wide range of therapeutic areas, including oncology, infectious disease, dermatology, and gastroenterology.

Lauren Crooks, MSc has comprehensive cross-functional experience within the life sciences and information technology sectors. At Signant, she combines this experience to provide scientific consultation and support to clients on the implementation of eCOA to optimize patient care and outcomes in clinical trials. She has supported eCOA projects across multiple therapeutic areas, including dermatology and neurology, with a current focus on respiratory diseases.

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