



Association of Black Cardiologists, Inc.
Saving the Hearts and Minds of a Diverse America

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ABC MISSION:

To promote the prevention and treatment of cardiovascular disease, including stroke, in Blacks and other minorities and to achieve health equity for all through the elimination of disparities.

July 19, 2021

The Honorable Anna Eshoo
272 Cannon House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Congresswoman Eshoo:

The Association of Black Cardiologists (ABC) appreciates the opportunity to provide feedback on the discussion draft of the Diverse and Equitable Participation in Clinical Trials (DEPICT) Act. Attaining diversity in clinical trials is a long-standing issue of importance to ABC members. We therefore applaud your leadership in this regard.

There are a number of factors that can influence the efficacy and safety of new medicines and medical products, including sex, age, race, ethnicity, lifestyle, and genetic background. Yet, racial and ethnic minorities continue to be underrepresented in cardiovascular and other clinical trials.

The lack of diversity in clinical trials also contributes to racial bias in clinical decision making, and it can skew decision making about the cost-benefit of therapeutics. Indeed, the failure to achieve diversity in clinical trials has far reaching effects, including the perpetuation of disparities in health care.

We hope the following responses to your questions, as well as other comments and suggestions, will be useful as you finalize the DEPICT Act for introduction. We thank you for recognizing the contributions ABC can bring to this discussion, and we look forward to working with you to achieve passage of the DEPICT Act this year.

How can we best ensure sponsors are held accountable for enrolling participants that reflect the diversity of the intended patient population without inadvertently slowing research?

We support Section 2 of the draft legislation that would require premarket reporting of diversity plans for clinical trials and studies and the explicit requirement those diversity plans include the estimated prevalence in the United States of the disease or condition for which the drug is being developed or investigated,

disaggregated by demographic subgroup, including age group, sex, race, and ethnicity. We also strongly support a requirement that the sponsor's targets for enrollment in the clinical trial or trials involved be similarly disaggregated by age group, sex, race, and ethnicity.

To meet these targets, we also support, as called for in your draft legislation, a diversity action plan for how the sponsor will meet such targets, including demographic-specific outreach and enrollment strategies, study-site selection, clinical trial inclusion and exclusion practices, and any diversity training for trial personnel.

The ABC was involved with a collaborative study¹ that involved ABC physician members, individuals from a large research-intensive biopharmaceutical company, clinical trial experts, and other key stakeholders to investigate barriers to minority participation in U.S. clinical trials and to identify potential solutions. The study specifically focused on minority patients, referring physicians, investigators who were minority-serving physicians, and trial coordinators. The overall goal was to develop potentially sustainable solutions that would benefit all key stakeholders and lead to making diversity in clinical trials a standard part of the clinical research model.

Study findings emphasized that effective communication, across key stakeholders, is a solution to address critical barriers to clinical trial participation. As part of a diversity action plan for demographic-specific outreach and enrollment strategies, sponsors should include plans for collaboration and partnership with key stakeholders, community and civic organizations and leaders, and the faith-based community. These partnerships will help to improve participant trust, and, consequently, trial enrollment and retention. Sponsors should be required to provide training among all trial personnel about the importance of diversity and the corresponding scientific and educational rationales, and should be required to provide appropriate culturally sensitive and health-literate educational materials for recruitment, enrollment, and retention activities.

To make sure these actions are taken, we recommend it be the responsibility of sponsors to ensure that investigators and all stakeholders involved in the clinical trial process incorporate an "Inclusive Clinical Trials Implementation Checklist" (Appendix A) to address the barriers to minority participation in clinical trials. Compliance with this or a similar checklist could be part of the annual assessment of whether a sponsor is meeting or continuing to strive toward diversity targets.

Further, we recommend federal funding for clinical trials should be tied to recruitment of diverse populations for the trials, as well as to the development of or partnership with an existing community engagement infrastructure, including partnerships with minority-serving research institutions and community health centers.

¹ Clark LT, Watkins L, Piña IL, Elmer M, Akinboboye O, Gorham M, Jamerson B, McCullough C, Pierre C, Polis AB, Puckrein G, Regnante JM. Increasing Diversity in Clinical Trials: Overcoming Critical Barriers. *Curr Probl Cardiol.* 2019 May;44(5):148-172. doi: 10.1016/j.cpcardiol.2018.11.002. Epub 2018 Nov 9. Erratum in: *Curr Probl Cardiol.* 2021 Mar;46(3):100647. PMID: 30545650.

How should diversity enrollment targets be determined? Should the targets be based on disease prevalence in the U.S.? How should international clinical trial data be considered?

As detailed in your draft legislation, we agree the representation of study subjects in a clinical trial should be reflective of the estimated prevalence in the United States of the disease or condition which a drug is approved to treat, disaggregated by demographic subgroup, including age group, sex, race, and ethnicity. Or, in the case of a medical device, the patient population in the United States expected to use the device, disaggregated in the same manner.

Enrolling subjects in ratios reflective of the population, which can be difficult to achieve, can create significance for the total study population; however, it may not be informative for a particular sub-population. For example, if prevalence of a disease or condition is higher in one subgroup, there may be value in enrolling disproportionate numbers from that subgroup since the subgroup will likely be the primary target of marketing and use efforts. It is not unreasonable, though perhaps impractical, to perform adequately-powered controlled post approval studies in each subgroup to prove efficacy and safety. It may be that with the development of reliable Real World Evidence data collection and analysis, post-marketing experience can be used to assess efficacy and safety in subgroups inadequately studied in the registrational trials.

The overwhelming majority of therapeutic products approved for use in the United States will also be used in regions outside the United States. The data derived from clinical studies should be representative of the demographic composition anticipated to receive the treatments, just as they should in the United States. However, use of data obtained from groups that are markedly dissimilar to the demographics present in the United States can broaden the gap of clinical data available to advance health care in America. It is well known that dissimilarities based on race/ethnicity, social positioning/determinants of health, access to health care, as well as cultural factors such as diet, health literacy and therapeutic expectations can markedly vary clinical outcomes of patients undergoing treatment for a specific illness. Data obtained from international sources should be matched to specific U.S. demographic groups for consideration of U.S. approval. For instance, data from Black South Africans may not be generalizable to outcomes in African Americans.

How should we structure grant programs within the Department of Health and Human Services to (1) enhance community engagement and outreach to underserved communities and (2) increase the capacity of Community Health Centers to participate in clinical trials and research?

ABC suggests the development and dissemination of best practices and tools to enhance community engagement and outreach to underserved communities should include input from investigators who: 1) have longstanding experience in community engagement and outreach; 2) are representative of populations underrepresented in biomedical research; or 3) are representatives of institutions with a longstanding history of working with underserved populations, such as research centers within minority institutions. As such, we recommend the activities delineated in Section 6 of your draft legislation be modified to require consultation with investigators who possess the aforementioned background and expertise.

Historically, diverse clinical trial enrollment has been perceived to add expense due to lengthened study timelines and diminished data quality due to patient non-compliance and site study conduct. A recent study² found cardiovascular research subject diversity may be predicted from site characteristics and enhanced without compromising key study performance metrics.

ABC supports grants to community health centers, including rural health clinics, federally qualified health centers, and Indian Health Service facilities, for the purpose of increasing their capacity to participate in clinical trials and research. As called for in your legislation, we agree grants should be used to hire necessary personnel, including research nurses and study coordinators, and to develop community engagement strategies and build community partnerships.

Ultimately, a ‘culture of research’ should be developed and supported throughout the medical community to continuously and consistently collect clinical data to guide efforts to advance health care. Potential data sources should include industry sponsored research, federally sponsored research, as well as health (provider) system, insurance (payor), medical society and patient reported data and information.

Treating physicians are often the gateway to participation in clinical trials. The results of the study published in *Current Problems in Cardiology*³ reinforce the findings of others and of national surveys that physicians are consistently rated as the most trusted source of information for patients. However, physicians, who are often already under significant time constraints, that are worsened by regulatory and administrative burdens like prior authorization, may lack the time required to explain clinical trials to their patients. They may also be concerned that clinical trial participation may interfere with the physician-patient relationship, and they may lack comfort with obtaining informed consent and/or explaining clinical trials.⁴ Nationally, Medicaid rates are about 70 percent of Medicare rates on average, with variation by type of service. A good starting point to help create incentives for treating physicians to direct patients to clinical trials and to ensure that all patients have the same access to potentially cutting edge treatments offered through clinical trials is to improve Medicaid rates, including by setting them on par with Medicare rates.

Additionally, educational efforts must include providing information to Medicaid beneficiaries about coverage of routine patient costs for items and services furnished in connection with a qualifying clinical trial.

² Batchelor WB, Damluji AA, Yong C, Fiuzat M, Barnett SD, Kandzari DE, Sherwood MW, Epps KC, Tehrani BN, Allocco DJ, Meredith IT, Lindenfeld J, O'Connor CM, Mehran R. Does study subject diversity influence cardiology research site performance?: Insights from 2 U.S. National Coronary Stent Registries. *Am Heart J*. 2021 Jun;236:37-48. doi: 10.1016/j.ahj.2021.02.003. Epub 2021 Feb 24.

³ Clark LT, Watkins L, Piña IL, Elmer M, Akinboboye O, Gorham M, Jamerson B, McCullough C, Pierre C, Polis AB, Puckrein G, Regnante JM. Increasing Diversity in Clinical Trials: Overcoming Critical Barriers. *Curr Probl Cardiol*. 2019 May;44(5):148-172. doi: 10.1016/j.cpcardiol.2018.11.002. Epub 2018 Nov 9. Erratum in: *Curr Probl Cardiol*. 2021 Mar;46(3):100647. PMID: 30545650.

⁴ *ibid*.

The ABC thanks you for this opportunity to share its views and suggestions. We look forward to ongoing collaboration with you on this important topic and on other ways to improve health equity. Should you desire additional information or wish to speak with any of ABC's member experts, please contact Camille Bonta, ABC policy consultant, at (202) 320-3658 or cbonta@summithealthconsulting.com.

Sincerely,



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