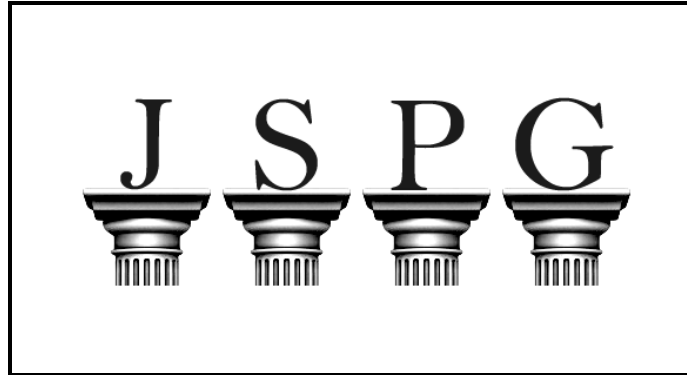


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OP-ED:

## **DIVERSITY IN CLINICAL TRAILS**

BY

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As a young African American woman interested in a clinical research career, my goal is to see clinical trials become as diverse as possible. For many years the “ideal” clinical participant was a white, middle-aged male. This person does not represent me in any way. It makes me question whether some of the drugs I might take will have more severe adverse effects simply because of human variation not represented in trials aimed at patient safety and efficacy.

With an operating budget of approximately \$32 billion, the National Institutes of Health (NIH) is the most influential biomedical research agency in the US. Because of this large investment, many people are demanding proof that the science being funded is translated into clinical interventions and improving health outcomes. Before promising therapies or treatments can be available in the United States, they must go through the clinical trial process. However, clinical trials face many problems that are not easily resolved. For example, lack of funding, eligible participants, as well as issues of privacy and conflict of interests are just a few of the many challenges placed on clinical trials. In addition, an often overlooked, but important, issue is the lack of diversity among participants, which could be addressed by implementation of new policies at the US Food and Drug Administration (FDA).

Logistics and time constraints make it challenging for many researchers to find participants for clinical trials as the pool of eligible participants is often small. Even after enrollment, there may be issues with participant retention, relocation, and mortality. Because of difficulties like these, many trials cannot sustain diversity even if it was selected for at the outset of the trial. However, diversity in clinical trials is not an option but a necessity. It should not be sacrificed because the results of the small pool represented in the trial can impact the health of thousands, even millions.

The NIH and the FDA regulate and oversee clinical trials. This includes requirements concerning informed consent and the protection of human subjects. Additionally, all clinical trials are monitored by an Institutional Review Board (IRB). In 1993, the NIH Revitalization Act was created and set guidelines that stated “women and minorities” should be included in NIH-sponsored clinical research, however, “inclusion” is loosely defined and often circumvented by scientists.<sup>i</sup> Although one might think that most clinical trials are mandated to have a diverse group of participants, before this act the government gave no guidelines on this subject and therefore it was not deemed as critical. Currently, there are still no significant FDA regulations about the actual composition of their experimental cohorts.<sup>ii</sup> For example, the pharmaceutical company Pfizer claims to seek diversity in both clinical investigators and staff but remains silent regarding the demographics of trial participants.<sup>iii</sup> Pfizer should be applauded in its efforts to diversify its workforce, but this diversification should also extend to clinical trial participants. Moreover when diversity is mentioned in the literature concerning clinical trials it is usually in the context of international clinical trials. In these instances, companies must follow not only FDA regulations--if they want to use the drug in the US-- but also the regulations in the foreign country that may or may not include a diverse group of participants.

One reason behind lack of information and regulation concerning clinical trials might be based on the fact that there is no standardized way to conduct a clinical trial. Different trials are looking at different medications, procedures and techniques and are focused on different diseases and conditions which often impact ethnic groups differently. Mandating diversity based on the

overall US population might be a difficult if not nearly impossible task. Trials that are looking at a very rare disease or one that disproportionately affects one ethnic group or population might have a hard time assembling a “diverse” experimental cohort. However, this does not mean that the FDA should overlook the importance of diversity, especially for diseases like diabetes which impact a broad population.

Diversity should not be seen as “one size fits all” solution, but the FDA could have regulations that require a significant and consistent effort towards diversity in clinical trials based on geography and the demographics of the populations affected. For example, a trial for a general pain relief drug performed in Texas should include a significant number of Hispanics compared to a trial taking place in South Dakota. Alternatively, a clinical trial on pre-menopausal breast cancer should include all types of women but be predominately African American due to the disproportionate share of African American women who suffer from the disease.<sup>iv</sup> If a region has a severe enough problem that a clinical trial is being performed there then it seems appropriate that a diverse group based on this sample would be representative.

The NIH grant award system presents a good model to follow when mandating diversity. Before every clinical trial, whether under the FDA or the NIH, each investigator should have to present an explanation regarding how the trial addresses diversity in both gender and race or ethnicity and how they are complying with consistent baseline criteria established by each department. If the study does not meet the criteria due to the experimental design or condition being studied, exceptions should be granted, but only on a case-by-case basis similar to what is done for grant exceptions. Under this model, including diversity in clinical trials would become routine.

The scientific literature has indicated for years that different populations can have different responses to drugs. One of the most controversial examples of this occurred in 2005, with the FDA approval of BiDil, a medication that increases nitric oxide, which can help patients with heart failure.<sup>v</sup> A study performed on African American men found that it reduced deaths by 43%.<sup>vi</sup> Nevertheless, a controversy has emerged as there is an implication that race is a biological variable that can be used to assess a drug’s efficacy. Although race is a sociological construct and an imperfect description of genomic characteristics, genetic variance based on different ancestry does exist and does play a role in health. Therefore, until we have a better way to identify these genetic differences, increasing the amount of individuals who self-identify as a racial or ethnic minority is our best option.

In the future, the FDA should take a more active role in ensuring that clinical trials have a heterogeneous composition. Differences in race, age, and sex are important factors in drug efficacy and if studies fail to take this heterogeneity into account, then study results will be biased. Furthermore, it is imperative that the US implement a new information system that allows scientists a way to categorize and assess diversity in their study cohorts based on ancestral characteristics and not social constructs. Additionally, more information and resources about clinical research and community partnerships should be made available to both scientists and the general public if we hope to increase minority enrollment in clinical trials. Fears about past research transgressions such as the Tuskegee syphilis study still plague communities, so we must provide adequate information to potential participants concerning the laws that prevent unethical research behavior. When principle investigators understand the attitudes of the community, and

participants understand the needs of the investigator, lasting research collaborations can be made. It is of the utmost importance that public health agencies create definitive policies that ensure that as the diversity of our country increases, this new composition is reflected in our biomedical research industry.

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<sup>i</sup> Lee, C. (2010). Race categorization and the regulation of business and science. *Law and Society Review*, 44(3), 617-649.

<sup>ii</sup> Lee, C. (2010). Race categorization and the regulation of business and science. *Law and Society Review*, 44(3), 617-649.

<sup>iii</sup> Pfizer. (2011 March). Diversity and inclusion. Retrieved from <http://www.pfizer.com/about/diversity/diversity.jsp>

<sup>iv</sup> Pinheiro, S. P. (2005). Racial differences in premenopausal endogenous hormones." *Cancer Epidemiology Biomarkers & Prevention*, 14(9), 2147-153.

<sup>v</sup> NitroMed. (2009) BiDil: patient: about BiDil. Retrieved from [http://www.nitromed.com/pnt/about\\_bidil.php](http://www.nitromed.com/pnt/about_bidil.php)

<sup>vi</sup> NitroMed. (2009) BiDil: patient: about BiDil. Retrieved from [http://www.nitromed.com/pnt/about\\_bidil.php](http://www.nitromed.com/pnt/about_bidil.php)

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## About the Author

Kara M. Calhoun is a Senior at Rice University in Houston, Texas majoring in Evolutionary Biology and Policy Studies with a minor in Anthropology. She is interested in health disparities, clinical research design and development as well as cancer prevention in high-risk populations. After graduation, Kara will be working at the National Cancer Institute and then attending medical school for a MD/MPH.