

## CLINICAL TRIAL DIVERSITY AND ASIAN AMERICANS, NATIVE HAWAIIANS AND PACIFIC ISLANDERS

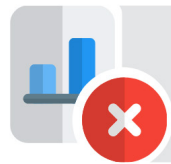
While the demographic diversity of the United States continues to grow, the inclusion of racial and ethnic minorities in clinical trials, including Asian Americans, Native Hawaiians and Pacific Islanders (AANHPI), lags at unacceptable rates. We as a nation cannot achieve health equity if we do not understand and have the supporting data and evidence to know how racial and ethnic minorities and other groups react to therapies through diverse clinical trials.



Since 1992, only 0.17% of the National Institutes of Health (NIH) budget included AANHPI participants. In 2018, only 0.38% of NIH clinical research expenses went to AANHPI research studies.<sup>1</sup>



AAs made up only 1.7% of patients for drugs for which at least 70% of a trial was conducted in the U.S., versus making up 6% of the U.S. population.<sup>2</sup>



FDA drug snapshots combine NHPI with American Indian and Alaska Native as "other", masking differences among the groups.<sup>3</sup>

**AANHPI**  
communities want to:  
"See ourselves in the  
research and the findings."  
"Make information  
more accessible..."<sup>4</sup>

**AANHPI**  
communities often find:  
"We get the crumbs  
of resources."  
"Our communities haven't  
been historically included."

### Why Does Clinical Trial Diversity Matter?

Clinical trials help to determine the benefits and risks of a particular medical treatment and are regulated by the Food and Drug Administration (FDA). The results of clinical trials provide data on whether a therapy is safe and effective for people. Clinical trial diversity matters because the people who participate in a clinical trial should be representative of the groups of people who will use the same therapy. This is particularly critical as AANHPIs, like other racial and ethnic minorities, disproportionately experience higher rates of many medical conditions, including diabetes, certain types of cancer and some types of infectious diseases.

**Failing to include racial and ethnic minorities, including AANHPIs, women and LGBTQIA+ persons, can create a false belief that a therapy that works for one group works just as effectively for all.<sup>5</sup>**

## Clinical Trial Diversity and COVID-19

Initial data shows that the AA community has been hit just as hard as Black and Latinx communities, facing at least a 30% increase in death in 2020.<sup>6</sup> In at least 8 states, the case fatality rate for NHPs is significantly higher than for Whites.<sup>7</sup> In Arkansas, Pacific Islanders make up just 0.3% of the population but account for 8% of COVID-19 cases.<sup>8</sup> An estimated 6 of the most promising COVID-19 vaccine candidates are part of the federally funded Operation Warp Speed, designed to rapidly produce a COVID-19 vaccine.<sup>9</sup> As of January 1, 2021, the FDA has granted emergency use authorization for two COVID-19 vaccines. Yet if recent history and data about COVID-19 clinical trial diversity<sup>10</sup> is any indication, AANHPIs stand to be left out, undermining health equity and an effective pandemic response.

## Why are AANHPIs and Communities of Color Missing from Clinical Trials?

Just as the United States population is incredibly diverse, the reasons why communities of color and other groups are underrepresented in clinical trials are equally diverse.<sup>11</sup> Some factors are cross-cutting and stem from systemic challenges, while others may be more specific to AANHPIs. It is important to also understand historical and current injustices that impact communities of color, including the Tuskegee study on African Americans<sup>12</sup>, lasting impacts of colonialism on Native Hawaiians and Pacific Islanders and continued racism and discrimination in health and health care. Together these experiences undermine trust amongst communities of color in the medical establishment.

### Common barriers that lock communities of color out of clinical trials<sup>13</sup>:

- ✓ Mistrust
- ✓ Lack of comfort in process
- ✓ Lack of information
- ✓ Time and resource constraints
- ✓ Lack of awareness

### Factors that impact AANHPI participation:

- ✓ AANHPIs trace their heritage to more than 50 different countries and speak more than 100 different languages. This rich diversity, can make culturally and linguistically accessible information about trials challenging, whether related to awareness about clinical trials and the opportunities to participate, or to strategies for participant recruitment and retention in a trial. Language access is cited as the *number one* barrier for AANHPIs to participating in clinical trials.
- ✓ Research data about AANHPIs is often lacking, either from not being collected at all or from having data that is collected and aggregated together. This lack of disaggregated data masks information about how these populations are impacted by certain medical conditions.
- ✓ Immigration-based restrictions on health insurance coverage often lock out AAPIs from coverage.
- ✓ AA subgroups may have different views about clinical trials, though research at the subgroup level is minimal.<sup>14</sup>
- ✓ Providers may not discuss clinical trials with their patients<sup>15</sup>, and/or have mistaken belief that AANHPIs are not impacted due to the lack of detailed data and cultural competency.

## How Can We Improve Clinical Trial Diversity?

Policy Makers	Industry, Researchers and Providers
<ul style="list-style-type: none"> <li>✓ National Institutes of Health (NIH) should work to increase diversity of clinical trial investigators.</li> <li>✓ NIH can conduct additional culturally and linguistically accessible public health messaging to encourage participation in clinical trials, particularly related to COVID-19 to build trust and awareness.</li> <li>✓ Commitments and mandates to increasing diversity must be backed by resources that are equitably distributed, including at the community level.</li> <li>✓ Build on successful community-engagement models, such as U.S. Department of Health and Human Services Regional Health Equity Councils.</li> <li>✓ Pass the Clinical Treatment Act to remove financial barriers for Medicaid enrollees participating in clinical trials.</li> <li>✓ Pass the comprehensive Health Equity and Accountability Act to address health equity.</li> <li>✓ Require that clinical trial data (including number of persons actually recruited) be collected, analyzed and reported consistent with Section 4302 data collection standards, at minimum, to ensure that subgroups are not aggregated together.<sup>16</sup></li> </ul>	<ul style="list-style-type: none"> <li>✓ All clinical trials and each clinical trial investigation site, should have protocols that provide a clear recruitment plan with specific race and ethnicity recruitment goals and present evidence of the degree to which racial and ethnic minority participants are being recruited and included.</li> <li>✓ All clinical trials and each clinical trial investigation site should build partnerships with trusted community leaders and organizations as part of their protocols for recruitment to build community trust.</li> <li>✓ Listen, understand and respect the voices of communities who have real concerns and questions. Work to address those concerns by including concrete partnerships with community representatives and organizations at trial sites.</li> <li>✓ Translate all public-facing clinical trial information into the most commonly spoken languages in the location and populations being targeted using plain language<sup>17</sup>. Language access is the number one barrier that prevents AAs and NHPs from learning about and joining trials.</li> <li>✓ Build in time for how public-facing clinical trial information will be adapted for different languages and cultural contexts and how translated resources and recruitment strategies will be <i>implemented</i> by culturally and linguistically competent research staff.</li> <li>✓ Engage community at multiple levels and mediums, such as ethnic media, role models, and community workshops. Talk about the value of participation from the viewpoint of community to community – not just the scientific basis.</li> <li>✓ Target education to diverse groups of physicians, including those at large health systems, health centers and small provider networks to encourage racial and ethnic minorities to join clinical trials.</li> </ul>

## Community and Advocates

- ✔ Continue to advocate for and share voices from your community about what it means to be a part of public health response and clinical research. Your voice matters.
- ✔ Consider sharing information about clinical trials with your community members and talking about the issue with your family and friends.

1. Examining clinical research projects funded by the National Institutes of Health, a cross-sectional study found 529 research projects focused on Asian American, Native Hawaiian and Pacific Islander participants between 1992 and 2018, **composing only 0.17% of the total NIH budget**. According to the same analysis, this proportion of budget has only increased from 0.12% before 2000 to 0.18% after 2000. Doãn LN, Takata Y, Sakuma KK, Irvin VL. Trends in Clinical Research Including Asian American, Native Hawaiian, and Pacific Islander Participants Funded by the US National Institutes of Health, 1992 to 2018. *JAMA Netw Open*. 2019;2(7):e197432. doi:10.1001/jamanetworkopen.2019.7432.
2. Caroline Chen and Wiley Wong, "Black Patients Miss out on Promising Cancer Drugs," *ProPublica* (Sept. 19, 2018). Available at: <https://www.propublica.org/article/black-patients-miss-out-on-promising-cancer-drugs>.
3. 2019 Drug Trials Snapshot Report, *Food and Drug Administration* (January 2020). Available at: <https://www.fda.gov/media/135337/download>.
4. For example, research has shown that persons of Asian descent may be more sensitive to the statin drug Rosuvastatin D, prompting the FDA to suggest a lower dosage while research continues on the subject. See "Crestor, Prescribing Information," *Food and Drug Administration* (January 2005). Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2005/213666s1r0051b1.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/213666s1r0051b1.pdf). See also analysis of differences in pharmacokinetics that can affect drug therapies between East Asians and Caucasians. Kim, Kiman & Johnson, Julie & Derendorf, Hartmut. (2004). Differences in Drug Pharmacokinetics Between East Asians and Caucasians and the Role of Genetic Polymorphisms. *Journal of clinical pharmacology*. 44. 1083-105. 10.1177/0091270004268128. See also research finding that certain asthma medication does not work as well for African American and Puerto Rican children as it does for those of European ancestry. Nicholas Weiler, "Genomic Evidence Reveals Why Asthma Inhalers Fail Minority Children," *University of California San Francisco* (March 14, 2018). Available at: <https://www.ucsf.edu/news/2018/03/410041/genomic-analysis-reveals-why-asthma-inhalers-fail-minority-children>.
5. Flagg A, Sharma D, Fenn L, Stobbe M. COVID-19's Toll on People of Color Is Worse Than We Knew. *The Marshall Project*. (August 21, 2020).
6. Testimony from the *National Council of Asian Pacific Islander Physicians* to the Committee on Ways and Means (June 9, 2020). Available at: [https://mcusercontent.com/d7f02dd24377959c916d14de6/files/5e9e9b24-21f8-4d67-93d2-4f218db2e323/NCAPIP\\_Statement\\_to\\_House\\_Ways\\_and\\_Means\\_Committee\\_on\\_COVID\\_19\\_Disparities.pdf](https://mcusercontent.com/d7f02dd24377959c916d14de6/files/5e9e9b24-21f8-4d67-93d2-4f218db2e323/NCAPIP_Statement_to_House_Ways_and_Means_Committee_on_COVID_19_Disparities.pdf).
7. Jackson, Lagipoiva, "Pacific Islanders in US Hospitalized with COVID-19 at up to 10 Times the Rate of Other Groups," *The Guardian*. (July 26, 2020). Available at: [https://www.theguardian.com/world/2020/jul/27/system-is-so-brokencovid-19-devastates-pacific-islander-communities-in-us?CMP=share\\_btn\\_link](https://www.theguardian.com/world/2020/jul/27/system-is-so-brokencovid-19-devastates-pacific-islander-communities-in-us?CMP=share_btn_link). See also *UCLA Center for Health Policy Research*. NHPICDPL COVID-19 Data Policy Lab Dashboard. Accessed August 31, 2020. [https://public.tableau.com/views/NHPICDPL\\_Dashboard\\_with\\_extract/NHPICDPLDashboard?:embed=y&:showVizHome=no&:host\\_url=https%3A%2F%2Fpublic.tableau.com%2F&:embed\\_code\\_version=3&:tabs=no&:toolbar=yes&:animate\\_transition=yes&:display\\_static\\_image=no&:display\\_spinner=no&:display\\_overlay=yes&:display\\_count=yes&:language=en&:publish=yes&:loadOrderID=0](https://public.tableau.com/views/NHPICDPL_Dashboard_with_extract/NHPICDPLDashboard?:embed=y&:showVizHome=no&:host_url=https%3A%2F%2Fpublic.tableau.com%2F&:embed_code_version=3&:tabs=no&:toolbar=yes&:animate_transition=yes&:display_static_image=no&:display_spinner=no&:display_overlay=yes&:display_count=yes&:language=en&:publish=yes&:loadOrderID=0).
8. "Explaining Operation Warp Speed," *U.S. Department of Health and Human Services* (Accessed December 14, 2020). Available at <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html>.
9. A review of all COVID-19 treatment-related clinical research studies with study participants in the United States published up to July 10, 2020 found that out of 6 studies (including 3 randomized clinical trials), 4 included race and ethnicity data, finding that race and ethnicity is not uniformly reported in COVID-19 research studies. For example, Black patients were consistently unrepresented compared to their disease burden. In a study conducted in New York City (NYC), 11% of the study population were Black and 51% were Hispanic. According to the NY Department of Public Health, 30% of NYC's cases were Black. As a result, Black patients were underrepresented in this study and Hispanic patients were overrepresented. Asians made up 8% of NYC cases, but 0% of the study population. Borno, Hala T et al. "COVID-19 disparities: An urgent call for race reporting and representation in clinical research." *Contemporary clinical trials communications* vol. 19 100630. 30 Jul. 2020. doi:10.1016/j.conctc.2020.100630
10. See Sheba George, Nelida Duran, and Keith Norris, "A Systematic Review of Barriers and Facilitators to Minority Research Participation Among African Americans, Latinos, Asian Americans, and Pacific Islanders," *American Journal of Public Health* 2004, 104, e16\_e31, <https://doi.org/10.2105/AJPH.2013.301706>
11. Scharff, Darcell P et al. "More than Tuskegee: understanding mistrust about research participation." *Journal of health care for the poor and underserved* vol. 21,3 (2010): 879-97. doi:10.1353/hpu.0.0323
12. Luther T. Clark, Laurence Watkins, Ileana L. Piña, Mary Elmer, Ola Akinbooye, Millicent Gorham, Brenda Jamerson, Cassandra McCullough, Christine Pierre, Adam B. Polis, Gary Puckrein, Jeanne M. Regnante Corrigendum to "Increasing Diversity in Clinical Trials: Overcoming Critical Barriers". [Current Problems in Cardiology, Volume 44, Issue 5 (2019) 148–172] *Current Problems in Cardiology*, Available online 25 July 2020, Pages 100647. Available at: <https://www.sciencedirect.com/science/article/pii/S0146280618301889>.
13. Ma, Grace X et al. "Increasing Asian American participation in clinical trials by addressing community concerns." *Clinical trials (London, England)* vol. 11,3 (2014): 328-335. doi:10.1177/1740774514522561
14. *Id*
15. Information provided by participants at an event convened by the *Asian & Pacific Islander American Health Forum* as part of the Precision Medicine Initiative.
16. NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, *National Institutes of Health*. (Nov. 28, 2017). Available at: <https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm> NIH updated Policy and Guidelines requires that all NIH funded phase III clinical trials occurring after Jan. 25, 2019 report on sex/gender and race/ethnicity of participants when publishing on Clinicaltrials.gov. However, data at the subpopulation level is not required, but only encouraged.
17. Federal Plain Language Guidelines. Available at: <https://www.plainlanguage.gov/guidelines/>.