



HEADACHE ON THE HILL

CO-SPONSOR THE NIH CLINICAL TRIAL DIVERSITY ACT

(S. 1701/H.R. 3503)

Ensure Equitable Research for All

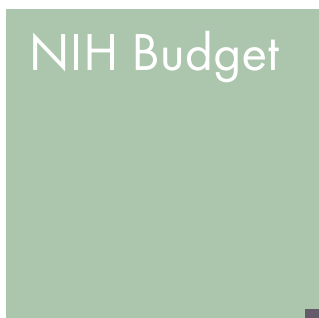
The NIH Clinical Trial Diversity Act seeks to address critical gaps in clinical research by promoting inclusivity and diversity in clinical trials. Recognizing that diseases affect people differently based on a variety of factors including race, ethnicity, age, sex, and sexual orientation, the Act underscores the necessity of including a broad spectrum of participants to ensure that scientific advancements benefit all communities equally.

THE IMPERATIVE FOR DIVERSITY IN RESEARCH

Historically, clinical trials have predominantly recruited White male participants, leading to significant knowledge gaps in understanding how diseases, treatments, and preventive measures perform across different populations.¹ This limitation is particularly concerning given the diverse ways individuals experience diseases and respond to treatments, thereby impacting the quality of healthcare decision-making and treatment effectiveness.


HEADACHE DISORDERS:

Under-researched
Underfunded
Stigmatized



Just 0.2%
of NIH budget goes to headache and migraine research, despite the drastic impact of headache disorders

IMPACT OF HEADACHE DISORDERS

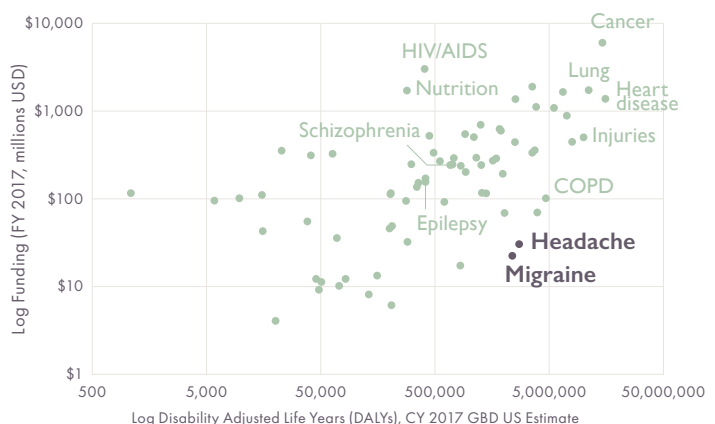
<p>INDIGENOUS COMMUNITIES have the highest prevalence of disabling headache.</p>	<p>Migraine is 3 to 4× more prevalent in </p> <p>WOMEN</p>
<p>BLACK AND HISPANIC patients are respectively 25% and 50% less likely to be diagnosed with migraine compared to white patients, even though their prevalence of migraine is roughly equivalent.</p>	

HEADACHE DISORDERS ARE AN ECONOMIC ISSUE

3.5 MILLION 
Emergency department visits per year in the US.

\$78B Annual direct and indirect cost of migraine to US companies

NIH FUNDING VS. US DALYS



HEADACHE DISORDERS RESEARCH

Headache disorders are under-researched, underfunded, and stigmatized, and impact diverse populations in different ways.² Despite the drastic impact of headache disorders, the NIH has provided only \$104 million in funding for migraine and headache disorders, roughly 0.2% of its total budget.³ Migraine research consistently receives some of the lowest levels of funding relative to burden amongst all the nation's highest-burden diseases.⁴

- Headache disorders affect roughly one out of five women in the U.S. and account for roughly three percent of all emergency department visits annually.²
- Migraine is the second leading cause of global disability. For young women it is the leading cause of disability, accounting for almost five percent of total lost healthy life years.⁵
- Despite the similar prevalence of severe headaches and migraines across racial and ethnic groups, significant disparities in diagnosis, treatment, and outcomes persist, with Black, Hispanic, and Native/Indigenous populations facing underdiagnosis and inadequate treatment.⁶
- Native/Indigenous people in America have the highest prevalence of migraine and severe headache in the United States at 19.2%.⁶
- The LGBTQ community encounters unique challenges, including biases in healthcare and gaps in research, especially concerning the effects of hormonal therapy on migraine disorders.⁶
- The majority of participants in migraine research trials are White, female and of higher socioeconomic status. Studies are needed that include diverse patients in all stages of life, including during pregnancy and lactation and the peri- and post-menopausal period. Pediatric studies that include children and adolescents are also needed to determine safety and efficacy of treatment for this patient population.

Notes

1. <https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html>
2. Rebecca Burch et al., *The Prevalence and Impact of Migraine and Severe Headache in the United States: Figures and Trends From Government Health Studies*.
3. NIH REPORT, *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, (Mar. 31, 2023), <https://report.nih.gov/funding/categorical-spending#/>.
4. Robert E. Shapiro, *What Will it Take to Move the Needle for Headache Disorders*, 60, *Headache*, 2059, 2068 (2020).
5. T.J. Steiner et al., *Migraine Remains Second Among the World's Causes of Global Disability, and First Among Young Women*, 21, *The J. of Headache and Pain*, 137 (2020)
6. Kiarashi J, VanderPluym J, Szperka CL, Turner S, Minen MT, Broner S, Ross AC, Wagstaff AE, Anto M, Marzouk M, Monteith TS, Rosen N, Manriquez SL, Seng E, Finkel A, Charleston L 4th. *Factors Associated With, and Mitigation Strategies for, Health Care Disparities Faced by Patients With Headache Disorders*. *Neurology*. 2021 Aug 10;97(6):280-289. doi: 10.1212/WNL.00000000000012261. Epub 2021 Jun 9. PMID: 34108270; PMCID: PMC8424498.

THE NIH CLINICAL TRIAL DIVERSITY ACT WOULD:

- Require NIH to work with clinical trial sponsors to develop clear and measurable **recruitment and retention goals** based on disease/condition prevalence as well as a rationale for specified goals and a recruitment plan.
- Ensure the availability of less burdensome follow-ups during clinical trials (e.g., fewer follow-ups, phone participation, weekend hours) to increase participation of **underrepresented populations**.
- Launch a **public awareness campaign** across federal agencies related to research participation opportunities.

AHDA ASK:

Co-sponsor the NIH Clinical Trial Diversity Act (S. 1701/H.R. 3503).



ALLIANCE FOR HEADACHE
DISORDERS ADVOCACY

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