



FDA'S COMMITMENT TO HEALTH EQUITY

FDA MISSION: The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation, and by regulating tobacco products.



FDA Defines Health Equity As

the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and other factors that affect access to care and health outcomes.

FDA Is Working to Advance Health Equity By

1. Advancing innovative equity initiatives
2. Implementing and operationalizing policies and guidance documents
3. Strengthening outreach, communication and engagement efforts
4. Funding health equity research
5. Advancing workforce initiatives



FDA HEALTH EQUITY LEGISLATION



Further Consolidated Appropriations Act, 2020

Section 3601 of Food and Drug Omnibus Reform Act (FDORA)

Signed into law as part of the Consolidated Appropriations Act, 2020, Congress requested the FDA's Office of Minority Health and Health Equity educate the public on the dangers of nonprescription drug products and cosmetics containing the ingredients hydroquinone and mercury, including partnering with community-based organizations with records of reaching out to communities.

Nonprescription (over-the-counter) skin lightening drug products and cosmetics containing hydroquinone and mercury have been marketed to Hispanic or Latino, Asian, Black or African American, or Middle Eastern and North African communities.

Signed into law as part of the Consolidated Appropriations Act, 2023. Advances clinical trial diversity by requiring sponsors of most drug

and device clinical studies to submit a diversity action plan when they submit key trial documents to the Food and Drug Administration (FDA).



FDA INNOVATIVE EQUITY INITIATIVES



OMHHE Reach Consortium

In 2023, OMHHE established the [Racial and Ethnic Minority Acceleration Consortium for Health Equity \(REACH\)](#).

REACH is a research consortium of organizations and institutions that aims to timely and efficiently help respond to OMHHE's health equity focused research needs.

OMHHE Enhance Equity Initiative

[OMHHE Enhance Equity initiative](#) highlights research projects and communication resources to enhance [EQUITY in clinical trials](#) by supporting efforts to advance diversity in clinical trials, [EQUITABLE data efforts](#) by increasing research studies about diverse groups including, but not limited to, ethnicity, race, age, disability and geography, and [EQUITY of voices](#) by amplifying FDA's communication with diverse groups and to ensure stakeholders, including

consumers, are informed about FDA's efforts and to understand diverse patient perspectives, preferences and unmet needs.

FDA OMHHE annual Health Equity Innovation Award: Enhance Equity Funding Opportunity supports collaborative scientific research projects with diverse organizations, to continuously advance the Enhance Equity Initiative.



OWH'S Diverse Women in Clinical Trials Initiative

OWH's [Diverse Women in Clinical Trials](#) Initiative was developed in collaboration with the NIH Office of Research on Women's Health to raise awareness about diverse women of different ages, races, ethnic backgrounds, and health conditions participating in clinical trials and to share best practices about clinical research design, recruitment, and subpopulation analyses. The initiative includes a consumer awareness campaign, as well as resources and workshops for health professionals and researchers.



FDA DEIA Strategic Plan

The overall vision for [DEIA at FDA](#) is to be a fair and united agency that leads the way on Diversity, Equity, Inclusion and Accessibility for HHS and the Federal government. The Objectives of the FDA Diversity, Equity, Inclusion and Accessibility Strategic Plan are:

- Increase inclusion of diverse groups by investing in community building and education
- Enhance equitable treatment of all employees
- Continue to promote a fair and protective workplace for all
- Enhance the collection, analysis, and reporting of demographic information
- Enhance outreach, recruitment, and retention efforts to increase representation of underrepresented groups

- Improve accessibility across the agency
- Leverage innovation and creativity to meet Center/Office-specific DEIA needs

CDRH Strategic Plan 2022-2025 Includes Advancing Health Equity

Multidisciplinary research efforts underway to foster improved evidence generation in underrepresented populations.

Focused efforts on bringing medical devices into patients homes to facilitate their realizing their greatest level of health.

For more information visit: <https://www.fda.gov/media/155888/download>

OCE Project Community

[Project Community](#) is a public health outreach initiative established by the FDA Oncology Center of Excellence for patients living with cancer, survivors, advocates, families, and people living in underserved urban and rural communities who are at greater cancer risk, especially minority populations, e.g., ethnic, urban, LGBTQ+, rural and those with limited access.

CTP Strategic Plan Advances Health Equity

Pursing the highest level of health for all people by integrating health equity into [CTP's programmatic, regulatory, policy and operational activities](#).

Impact: Through the projects and policies highlighted the FDA continues to support diversity efforts by encouraging research studies about diverse groups including, but not limited to, diverse ethnicities, races, ages, disabilities and geographic locations.



HIGHLIGHTS OF FDA GUIDANCES ADVANCING HEALTH EQUITY



The following documents are some of the draft and final FDA Guidance Documents focused on specific demographic groups and underserved populations, supporting overall FDA efforts to advance health equity. Draft guidances, when final, will represent FDA's current thinking on a topic.

Impact: These guidance documents are intended to foster participation in clinical research of underrepresented communities based on demographic characteristics such as but not limited to race and ethnicity, age, sex, gender other non- demographic characteristics.

Multiple Demographic and Non-Demographic Subgroups

Race/Ethnicity

[Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products \(2024, Draft\)](#)

This guidance provides FDA's recommendations on the use of a standardized approach for collecting and reporting race and ethnicity data in submissions from clinical studies and clinical trials for FDA-regulated medical products.

[Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial & Ethnic Populations in Clinical Trials \(2022, Draft\)](#)

The purpose of this guidance is to provide recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan to enroll an adequate number of participants in clinical trials from underrepresented racial and ethnic populations in the United States.

Pregnancy and Lactation

[Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials \(2018, Draft\)](#)

This guidance discusses how and when to include pregnant women in drug development clinical trials for drugs and biologics products based on FDA's current thinking.

[Pregnant, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products-Content and Format: Draft Guidance for Industry \(2020, Draft\)](#)

This guidance is intended to assist applicants with the content and format requirements for the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling for human prescription drug and biological products.

Age-Related

[General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products Guidance for Industry \(2022, Final\)](#)

This guidance provides recommendations for neonatal clinical pharmacology studies and is intended to assist sponsors of investigational new drug applications and applicants of new drug applications, biologics license applications and supplements of such applications who are planning to conduct clinical studies in neonatal populations.

[General Clinical Pharmacology Considerations for Pediatric Studies of Drugs, Including Biological Products \(2022, Draft\)](#)

This guidance assists sponsors, applicants, clinical investigators, and Institutional Review Boards in the design, planning, and assessment of clinical studies in pediatric populations.

[E11 Clinical Investigation of Medicinal Products in the Pediatric Population \(2020, Final\)](#)

This document is intended to encourage and facilitate timely pediatric medicinal product development internationally.



The following are some of the draft and final FDA Guidance Documents focused on addressing the multifactorial elements to increase clinical trial diversity. Draft guidances, when final, will represent FDA's current thinking on a topic.

Impact: These guidance documents provide recommendations that may reduce the burden of participating in clinical trials and promote participation in clinical research of underrepresented communities such as racial minorities, individuals with cognitive or movement disorders and communities with socio-economic challenges.



[Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry \(2020, Final\)](#)

This guidance provides recommendations for approaches that sponsors of clinical trials can take to increase enrollment of underrepresented populations in their clinical trials.

[Decentralized Clinical Trials for Drugs, Biological Products, Devices \(2023, Draft\)](#)

This guidance supports trial-related activities at other locations other than traditional clinical trials.

[Digital Health Technologies for Remote Data Acquisition in Clinical Investigation \(2023, Final\)](#)

This guidance supports the use of digital health technologies, such as wearable heart monitors, glucose monitors, and smartwatches to obtain information needed in clinical trials directly from trial participants. This can reduce the need for trial participants to report to clinical research sites.

[Considerations for the Conduct of Clinical Trials of Medical Products During Disruptions Due to Major Disasters and Public Health Emergencies \(2023, Final\)](#)

This guidance supports alternative approaches that sponsors of clinical trials can consider when there is a disaster or public health emergency.

[Application of Human Factor Engineering \(HFE\) Principles for Combination Products: Questions and Answers \(2023, Final\)](#)

This guidance focuses on considerations for the application of HFE principles to combination products comprised of a medical device combined with a drug or a biological product submitted for review in CBER, CDRH, or CDER. HFE is the application of knowledge about human behavior, abilities, limitations, and other characteristics of the users to the design of products to help ensure safe and effective use of the product.



FDA OUTREACH,
COMMUNICATIONS,
ENGAGEMENTS THAT ADVANCE
HEALTH EQUITY



Campaigns

Clinical Trial Campaign

OMHHE's [Clinical Trial Diversity Initiative](#) campaign includes an ongoing multi-media, public education and outreach campaign to help promote diverse participation in clinical trials; published clinical trial diversity resources in 11 languages (Spanish, Arabic, Cherokee, Simplified Chinese, Traditional Chinese, French, Hindi, Korean, Navajo, Tagalog, and Vietnamese). OMHHE also launched the bilingual multi-media Let's Take Charge campaign in partnership with the HHS Office of Minority Health to increase diverse participation in lupus clinical trials.

Impact: The campaign works to increase participation in clinical trials among diverse populations.

SkinFacts! Campaign

OMHHE launched the [SkinFacts! campaign](#) in 2022 as part of an effort to educate consumers about the potential dangers of skin-lightening nonprescription drug and cosmetic products containing hydroquinone and mercury. The multi-media campaign featured television, radio, online and Google Ads and presents information and health education resources in English, Spanish and 13 additional languages. OMHHE also developed a partner toolkit and a dedicated web page, "What You Need to Know about Skin Lightening Products." Over two years, the SkinFacts! campaign earned more than 37 million impressions, reaching audiences with information in Somali, Arabic, Haitian Creole, Traditional and Simplified Chinese and Hindi.

Impact: The campaign helps consumers avoid potentially dangerous over-the-counter skin lightening products containing hydroquinone or mercury.

Next Legends Campaign

In 2022, the FDA Center for Tobacco Products launched "[Next Legends](#)" which advances CTP's mission to promote health equity by acknowledging and addressing disparities in tobacco use, especially among at-risk American Indian and Alaska Native (AI /AN) youth. The campaign features tailored messaging that reflects an understanding of key cultural aspects and community norms. The "Next Legends" e-cigarette prevention campaign delivered more than 100 million impressions across various media and digital channels.

Impact: The campaign is helping reduce tobacco use among AI/AN youth.

Project ASIATICA

FDA's Oncology Center of Excellence launched Project ASIATICA in 2023. The project includes a [webpage](#) with translations into the ten mostly commonly spoken Asian languages in the US that is accessible to patients and the public. Project ASIATICA features culturally and linguistically tailored oncology toolkits for Asian American, Native Hawaiian, and Other Pacific Islander patients with cancer with general resources on cancer, cancer prevention and screening, and participation in cancer clinical trials.

Impact: The project is helping provide consumers with important in-language information.

Select Outreach & Engagement Activities

OCE National Black Family Cancer Awareness Week

Annually, since July 2021, OCE Project Community has led the inclusion of African American people for cancer-related public health outreach, directed communication and social media engagement via #BlackFamCan, various community forums and a dedicated public panel discussion. The annual dedicated "Conversation on Cancer" public panel discussion, series of community forums and the weeklong social media engagement refer people with cancer, advocates, families and external stakeholders invested in equity to refer them to general resources on cancer, cancer prevention and screening, and participation in cancer clinical trials often tied to Cancer Moonshot goals.

Impact: The conversations deliver important and potentially life-saving information.

Public availability of National Black Family Cancer Awareness initiative and social media toolkit. [Webpage](#), consistently updated since 2021, features culturally relevant and Cancer Moonshot goal-tailored toolkits for Black audiences, specifically HBCUs, Faith Based organizations and service-focused sororities and fraternities known as the Divine Nine. Webpage links to other OCE Project Community resources for patients with cancer, advocates, families and communities providing general resources on cancer, cancer prevention and screening, and participation in cancer clinical trials.

Impact: The effort is increasing the availability of lifesaving resources.

OCE Conversation on Cancer

is a US-based public panel discussion series ([webpage](#)) since 2018, collaborating with European Medicines Agency on some events since October 2023. Conversations on Cancer series topics have included discussions of racial/ethnic cancer disparities, gender issues and fertility challenges, awareness and participation in oncology clinical trials and health care access for many underserved populations: Native American, LGBTQ+, Latinx, Asian and Pacific Islander, and African American communities.

Impact: The series works to advance equity in oncology.

Public Education Program: The Real Cost

[The Real Cost](#) currently focuses on the prevention of tobacco use in youth. Latest evaluation results of “The Real Cost” are promising, indicating that increased ad exposure increases youth’s negative beliefs about e-cigarettes and cigarettes.

Impact: The effort works to decrease tobacco use among youth.

FDA Pregnancy Exposure Registries Webpages

Pregnancy exposure registries are studies that collect health information on exposure to medical products such as drugs and vaccines during pregnancy. OWH maintains a list of studies that are actively enrolling to help increase awareness of opportunities to participate in this research. In 2023, OWH promoted pregnancy exposure registry participation with a new [video](#), [blog](#), and an updated [website](#). Currently, there are 150 registries [listed](#) on the webpage.

Impact: The registries are helping health care professionals learn more about the safety of medicines and vaccines used during pregnancy.

FDA HEALTH EQUITY RESEARCH



Research Hubs

OMHHE Enhance Equity Research Hub

The FDA Office of Minority Health and Health Equity (OMHHE) [Enhance Equity Research Hub](#) provides information about OMHHE-funded research projects that are a vital part of achieving the OMHHE mission to promote and protect the health of diverse populations through research and communication of science that addresses health disparities.

Research Roadmaps

OWH Women’s Health Research Roadmap

The FDA Office of Women’s Health developed the Women’s Health Research Roadmap outlining priority areas in which new or further research is needed and serves as a catalyst for research collaborations both internal and external to FDA. OWH is currently in the process of updating the

Roadmap. This Roadmap provides a science-based framework to support and fund research activities in areas that are essential to OWH’s and FDA’s mission. All research projects funded by OWH (including all projects since 2021) are aligned with one or more of the Roadmap priority areas.

Intramural Research Programs

OMHHE Intramural Research Program

The Office of Minority Health and Health Equity (OMHHE) [Intramural Research Program](#) works with FDA centers to support research studies about minority health and health disparities. The OMHHE Challenge Grants support intramural research in collaboration with FDA scientists.

Research under this program provides insight into the scientific basis for individual therapies. Studies also provide future directions for research and aid regulatory decision-making.



OWH Intramural Research Program

OWH welcomes intramural research proposals focused on promoting and protecting women’s health. This program supports research advancing the health of diverse populations of women, including women with a diverse array of co-morbidities as well as those from diverse backgrounds, diverse racial and ethnic populations, diverse ages, and diverse life stages [e.g., those of reproductive potential, those who are pregnant or lactating (including maternal health topics), and those who are menopausal or post-menopausal].

OWH also supports women’s health research through FDA’s Special Funding Initiative, which is part of the FDA Intramural Research Program.

Continued on page 8



Continued from page 7

Extramural Research Programs

OMHHE Extramural Research Program

OMHHE funds collaborative scientific research projects with diverse organizations through OMHHE's annual Health Equity Innovation Award: [Enhance Equity Funding](#) Opportunity. The purpose of this funding opportunity announcement (FOA) is to fund innovative research that will strengthen and advance minority health and health equity objectives. Areas of interest include proposals that focus on advancing equity in clinical trials by supporting efforts to advance diversity in clinical trials, equitable data efforts by increasing data available on diverse groups including, but not limited to, ethnicity, race, age, disability and geography, and equity of voices by increasing understanding of diverse patient perspectives, preferences, and unmet needs.

OWH Extramural Research Program

Scientists outside of FDA may respond to an annual call for proposals to compete for grant funding through FDA's Broad Agency Announcement (BAA) and FDA's Centers of Excellence in Regulatory Science and Innovation (CERSI) program. OWH welcomes research proposals focused on promoting and protecting women's health. This program supports research advancing the health of diverse populations of women, including women with a diverse array of co-morbidities as well as those from diverse backgrounds, diverse racial and ethnic populations, diverse ages, and diverse life stages (e.g., those of reproductive potential, those who are pregnant or lactating (including maternal health topics), and those who are menopausal or post-menopausal).

ADVANCING WORKFORCE INITIATIVES

FDA

FDA OMHHE and NHGRI Fellowship in Genomic Science and Health Equity

OMHHE advances scientific workforce diversity by supporting post-doctoral fellowship programs such as the [Genomic Science and Health Equity \(GSHE\) Fellowship](#), a joint program with the FDA OMHHE and the National Human Genome Research Institute (NHGRI) at the National Institutes of Health (NIH). The fellowship program is designed to prepare fellows to use genetic, genomic and pharmacogenomic approaches to advance minority health and health equity and train them in the research methodology and medical product development processes that facilitate the delivery of drugs, biologics and devices from bench to bedside.

The fellow gains unique experiences by working closely with mentors at both FDA OMHHE, Centers and NIH, including the opportunity to advance their knowledge of health disparity and regulatory sciences.





OWH Research Fellowship

The OWH Research Fellowship Program is designed to promote innovative research and collaboration between FDA Center investigators and OWH within FDA's intramural research environment to facilitate the progress of women's health studies. This program supports research advancing

the health of diverse populations of women, including women with a diverse array of co-morbidities as well as those from diverse backgrounds, diverse racial and ethnic populations, diverse ages, and diverse life stages [e.g., those of reproductive potential, those who are pregnant or lactating (including maternal health topics), and those who are menopausal or post-menopausal]. OWH has supported 2 research fellows and their projects. One OWH-funded Center Staff Fellow explored knowledge gaps in the use of cannabis-derived products (CDP) and dietary supplements among women. The project included an assessment of patient and healthcare provider perspectives on CBD and other cannabinoid use, sex differences in the effects of CBD and other cannabinoids, use of CBD and other cannabinoids in pregnancy, and government agency perspectives on CBD research and evaluation.

CFSAN & U.S. Department of Education Minority Science and Engineering Improvement Program (MSEIP)

This program assists predominantly minority institutions in effecting long-range improvement in science and engineering education programs and increasing the flow of underrepresented ethnic minorities, particularly minority women, into science and engineering careers.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.