Are You Concerned About Clinical Trial Enrollment and Representation?

SBIA Webinar
December 16, 2020
Presentation Outline

• Regulatory background on trial demographics
  
  Milena Lolic

• The status of trials diversity per Drug Trials Snapshots
  
  Melvyn Okeke

• Supporting future of diversity in clinical trials
  
  Kaveeta Vasisht
  Richardae Araojo
Disclaimer

• This presentation represents the personal opinions of the speakers and does not necessarily represent the views or policies of FDA

• No conflicts of interest to declare
Demographics in Clinical Trials
What’s in the Regs?

Milena M. Lolic, M.D., M.S.
Lead Medical Officer
PASE/CDER
What Does FDA Approve?

Ultimately, the indication garnered represents the population studied and for whom safety and effectiveness has been established.
Participants in the Trials

• Healthy volunteers
• Patients with the condition in various stages of disease
• Patients in various stages of treatment
• Patients with various comorbidities
• Patients of different sex, age, race, ethnicity background
FDA/CDER Requires Reporting
Final Demographic Rule 1998

• IND: tabulate the trial population by age, gender, and race in annual reports per 21 CFR § 312.33(a)(2) - IND annual report regulations

• NDA: tabulate and analyze safety and efficacy by age, gender, and race per 21 CFR § 314.50 (d)(5) - NDA content and format
FDA Encourages Diversity

- Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 1993
- Studies in Support of Special Populations: Geriatrics, 1994
- Collection of Race and Ethnicity Data in Clinical Trials, 2016
- Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies, 2017
- Pediatric Information Incorporated Into Human Prescription Drug and Biologic Product Labeling, 2019
- Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs, 2020
- Draft Guidance: Inclusion of Older Adults in Cancer Clinical Trials, 2020
- Development and Licensure of Vaccines to Prevent COVID-19, 2020
- On COVID-19: Developing Drugs and Biological Products for Treatment or Prevention, 2020
Gender Guideline
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs

• Lifts a restriction on participation by most women with childbearing potential from entering Phase 1 and early Phase 2 trials

• Requires sponsors to include a fair representation of both genders as participants in clinical trials so that clinically significant gender-related differences in response can be detected

• Identifies three specific pharmacokinetics issues to be considered when feasible
Race and Ethnicity Guideline
Collection of Race and Ethnicity Data in Clinical Trials

• Recommends the use of the standardized OMB race and ethnicity categories for data collection in clinical trials

• Recommends enrollment of participants who reflect the clinically relevant populations with regard to race, and ethnicity

• ICH-E5 describes how clinical data collected in one region can be used in the registration or approval in another region
Race and Ethnicity Categories

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

- Hispanic or Latino
- Not Hispanic or Latino
Age Guideline
Studies in Support of Special Populations: Geriatrics E7

• Protocols should not ordinarily include arbitrary upper age cutoffs

• Geriatric patients should be included in the Phase 3 in meaningful numbers

• Recognition of important pharmacokinetic differences between younger and older patients related to renal/hepatic function or to drug-drug interactions
Data Reporting-Age Categories

- Infants .................................... <2 years
- Children................................. 2-11 years
- Adolescents......................... 12-17 years
- Adults................................. ≥ 18 years
- Geriatrics ............................ ≥65, 65-74, ≥75 years
Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

• Broadening eligibility criteria in later stages of drug development for the phase 3 population
• Broader population through adaptive trial design, enrichment strategies
• Less burdensome trial participation
• Expanded access
• Inclusion of pregnant women
Demographics Matter

• Alosetron: approved for irritable bowel syndrome in women

• Isosorbide dinitrate/hydralazine hydrochloride: approved for heart failure in Blacks

• Carbamazepine: boxed warning for Asians

• PI sections for special populations
## Demographics Data Sharing

<table>
<thead>
<tr>
<th>Demographics in pivotal trials/subgroups</th>
<th>Reviews</th>
<th>PI</th>
<th>DTS</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Demographics in drug development program</th>
<th>Reviews</th>
<th>PI</th>
<th>DTS</th>
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<tr>
<th>Consumer friendly information</th>
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[www.fda.gov](http://www.fda.gov)
Challenge Question

True or False: Final Demographic Rule describes which demographic subgroups are expected to participate in the trials

TRUE

FALSE
You can observe a lot by just watching.

Yogi Berra
Backup Slide
Diversity in Clinical Trials from Drug Trials Snapshots Perspective

Melvyn Okeke, M.P.H., ORISE Fellow
Drug Trials Snapshot

• Web-based information about participation in clinical trials that supported the FDA approval of new drugs*

• Includes trial demographic, trial design, overall and subgroup assessments of safety and efficacy

*New Molecular Entities and original Biologic Licensing Applications
<table>
<thead>
<tr>
<th>Drug Trials Snapshot</th>
<th>Active Ingredient</th>
<th>Date of FDA Approval</th>
<th>What is it Approved For</th>
<th>Prescribing Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACOPRIFER</td>
<td>ferucarbotran</td>
<td>July 25, 2019</td>
<td>Treatment of low iron stores</td>
<td>Acufer</td>
</tr>
<tr>
<td>ADAKVEO</td>
<td>citizefotec-aq</td>
<td>November 5, 2019</td>
<td>Treatment of vasoocclusive crises in patients with sickle cell disease.</td>
<td>Addakeo</td>
</tr>
<tr>
<td>ADOXY</td>
<td>ribociclib</td>
<td>August 18, 2015</td>
<td>Treatment of acquired, generalized hypoxia sexual desire disorder (HSDD) in premenopausal women</td>
<td>Addy</td>
</tr>
<tr>
<td>ADLYXIN</td>
<td>linagliptin</td>
<td>July 27, 2016</td>
<td>Improvement of blood sugar control in adults with diabetes mellitus (DM) type 2 when used in addition to diet and exercise</td>
<td>Addyxin</td>
</tr>
<tr>
<td>AEAMCOLO</td>
<td>rifaximin</td>
<td>November 16, 2018</td>
<td>Treatment of traveler’s diarrhea in adults</td>
<td>Aeamcolo</td>
</tr>
<tr>
<td>AIMOVIG</td>
<td>ondansetron</td>
<td>May 17, 2018</td>
<td>Preventive treatment of migraine in adults</td>
<td>Aimovig</td>
</tr>
<tr>
<td>AJOVY</td>
<td>fimecprox</td>
<td>September 14, 2018</td>
<td>Preventive treatment of migraine in adults</td>
<td>Ajovy</td>
</tr>
<tr>
<td>AKLIEF</td>
<td>trifluridine</td>
<td>October 4, 2019</td>
<td>For the topical treatment of acne vulgaris in patients 9 years of age and older</td>
<td>Aklief</td>
</tr>
<tr>
<td>AKYANGEO</td>
<td>fosmatuzumab and palonosetron</td>
<td>April 10, 2018</td>
<td>Prevention of the nausea and vomiting that happens right away or later in adults receiving certain anticancer medicines (chemotherapy).</td>
<td>Akyangeo</td>
</tr>
<tr>
<td>AKLYMESA</td>
<td>alemtuzumab</td>
<td>December 11, 2015</td>
<td>Treatment of metastatic non-small cell lung cancer</td>
<td>Alkymesa</td>
</tr>
</tbody>
</table>

Showing 1 to 10 of 275 entries
**Drug Trials Snapshot Example**

**ADAKVEO (crizanlizumab-tmca)
ah dak vee oh
Novartis Pharmaceuticals Corporation
Approval date: November 15, 2019**

**DRUG TRIALS SNAPSHOT SUMMARY:**

**What is the drug for?**

ADAKVEO is used to reduce the frequency of certain crises episodes (called vaso-occlusive crises) in patients 16 years of age and older who have sickle cell disease.

Sickle cell is an inherited blood disorder in which the red blood cells are abnormally shaped (in a crescent or "sickle" shape). Vaso-occlusive crisis (VOC) is a common and painful complication of sickle cell disease that occurs when blood circulation is obstructed by sickled red blood cells leading to severe pain and organ damage.

**How is this drug used?**

ADAKVEO is given by a healthcare provider directly into the vein (intravenous infusion) over 30 minutes. First two infusions are given 2 weeks apart followed by an infusion every 4 weeks thereafter.

**What are the benefits of this drug?**

Patients treated with ADAKVEO experienced fewer health care visits for VOC per year (about 1.63 visits), compared to patients who received a placebo (about 2.98 visits).

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**Who participated in the trials?**

Demographics of trial participants are presented below.

**Table 5. Baseline Demographics (Efficacy Population-ITT)**

<table>
<thead>
<tr>
<th>Demographic Parameters</th>
<th>ADAKVEO (N=67) n (%)</th>
<th>Placebo (N=65) n (%)</th>
<th>TOTAL (N=132) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>32 (47.8)</td>
<td>27 (41.5)</td>
<td>59 (44.7)</td>
</tr>
<tr>
<td>Female</td>
<td>35 (52.2)</td>
<td>38 (58.5)</td>
<td>73 (55.3)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>60 (89.5)</td>
<td>60 (92.3)</td>
<td>120 (91)</td>
</tr>
<tr>
<td>White</td>
<td>4 (6)</td>
<td>3 (4.6)</td>
<td>7 (5.3)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (4.5)</td>
<td>2 (3.1)</td>
<td>5 (3.7)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean years (SD)</td>
<td>30.9 (10.89)</td>
<td>29.3 (10.36)</td>
<td>30.1 (10.6)</td>
</tr>
<tr>
<td>Median (years)</td>
<td>29</td>
<td>26</td>
<td>28</td>
</tr>
<tr>
<td>Min, max (years)</td>
<td>16, 63</td>
<td>16, 56</td>
<td>16, 63</td>
</tr>
</tbody>
</table>
2019 Summary Statistics  
(Jan 1, 2019 - Dec 31, 2019)

In 2019, CDER approved 48 novel drugs*, either as New Molecular Entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologies License Applications (BLAs). Overall, 46,391 patients participated in these trials. Subpopulation demographics from these trials are presented below.

Table 1. Demographic Subgroups in 2019

<table>
<thead>
<tr>
<th>DEMOGRAPHIC SUBGROUPS</th>
<th>WOMEN</th>
<th>WHITE</th>
<th>BLACK or AFRICAN AMERICAN</th>
<th>ASIAN</th>
<th>HISPANIC</th>
<th>AGE 65 AND OLDER</th>
<th>UNITED STATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVERAGE</td>
<td>72%</td>
<td>72%</td>
<td>9%</td>
<td>9%</td>
<td>18%</td>
<td>36%</td>
<td>40%</td>
</tr>
</tbody>
</table>

*Data presented in this report are from 49 snapshots as one drug was approved for two indications.

More insight into demographics for all 49 CDER approved NMEs are provided below in Table 2.

Table 2. Percentage of Subpopulations* - All Approvals

<table>
<thead>
<tr>
<th>BRAND NAME</th>
<th>INDICATION</th>
<th>WOMEN</th>
<th>WHITE</th>
<th>BLACK or AFRICAN AMERICAN</th>
<th>ASIAN</th>
<th>HISPANIC</th>
<th>AGE 65 and OLDER</th>
<th>UNITED STATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCRUFER</td>
<td>Treatment of iron deficiency</td>
<td>68</td>
<td>83</td>
<td>12</td>
<td>2</td>
<td>14</td>
<td>41</td>
<td>57</td>
</tr>
<tr>
<td>ADAKVEO</td>
<td>Treatment of vasodilutive crisis in sickle cell disease</td>
<td>55</td>
<td>5</td>
<td>91</td>
<td>NR</td>
<td>24</td>
<td>0</td>
<td>75</td>
</tr>
<tr>
<td>AKLIEF</td>
<td>Treatment of acne vulgaris</td>
<td>55</td>
<td>87</td>
<td>7</td>
<td>3</td>
<td>17</td>
<td>0</td>
<td>45</td>
</tr>
</tbody>
</table>
Trial Participants by Sex

- **Global**
  - Total Participants: 292,937
  - Female: 52%
  - Male: 48%

- **United States**
  - Total Participants: 102,396
  - Female: 58%
  - Male: 42%

- **Rest of the World**
  - Total Participants: 189,541
  - Female: 49%
  - Male: 51%

- **Sex Distribution by Year**
  - Female
  - Male
Trial Participants by Race

- Race Distribution
- Race Distribution by Year

- Global
- United States
- World of the World
Participants by Age Group
Participants by Ethnicity

- Ethnicity Distribution
- United States
  - Total Participants: 1,307,500
- Rest of the World
  - Total Participants: 39,540

- Ethnicity Distribution by Year
  - Graph showing participation trends over years.
Rare Disease Population by Demographic Subgroups

- **Sex:**
  - Female: 49%
  - Male: 51%

- **Race:**
  - White: 70%
  - Asian: 9%
  - Black or African American: 11%
  - Other: 9%
  - American Indian or Alaska Native: 1%

- **Age:**
  - < 65 Years: 60%
  - >= 65 Years: 40%

- **Ethnicity:**
  - Hispanic or Latino: 34%
  - Not Hispanic or Latino: 6%
  - Missing: 6%
Distribution of Therapeutic Areas

- Cardiovascular Diseases
- Endocrinology and Metabolism
- Oncology and Hematology
- Infectious Diseases
- Neurology
- Gynecology
- Dermatology
- Pulmonology and Rheumatology
- Gastroenterology
- Psychiatry
- Ophthalmology
- Anesthesia and Analgesia
- Medical Imaging

Number of Participants:
- Cardiovascular Diseases: 58,998
- Endocrinology and Metabolism: 41,176
- Oncology and Hematology: 38,991
- Infectious Diseases: 37,782
- Neurology: 27,237
- Gynecology: 24,891
- Dermatology: 22,625
- Pulmonology and Rheumatology: 21,965
- Gastroenterology: 17,027
- Psychiatry: 15,812
- Ophthalmology: 12,306
- Anesthesia and Analgesia: 10,066
- Medical Imaging: 3,968
CE Question 1:
Which 3 states within US had the highest numbers of participants enrolled?

A. New York, Texas, Florida
B. California, NY, Texas
C. Texas, California, Florida
D. Texas, California, Georgia
Closing Remarks

• Participants are characterized with a predominantly younger white population.

• Need better reporting of race & ethnicity

• Observed therapeutic areas with equitable distribution

• Visit the Drug Trial Snapshot website to view the full Summary Report
Our Mission

- **Promote the inclusion of women in clinical trials** and the implementation of guidelines concerning the representation of women in clinical trials and the completion of sex/gender analysis.

- **Identify** and monitor the progress of **crosscutting** and multidisciplinary women's health initiatives including **changing needs, areas that require study, and new challenges** to the health of women as they relate to FDA's mission.

- **Serve** as the **principal advisor to the Commissioner** and other key Agency officials on **scientific, ethical, and policy** issues relating to women's health.
OWH achieves its mission through the foundational principle that Sex is a Biological Variable (SABV)
**Sex** is the classification of living things, generally as male or female according to their reproductive organs and functions assigned by the chromosomal complement.

**Gender** is defined as a person’s self-representation, or how that person is responded to by social institutions on the basis of the individual’s gender presentation.

Source: [Exploring the Biological Contributions to Human Health: Does Sex Matter](https://www.fda.gov) (2001)
OWH created the first FDA Women’s Health Research Roadmap

Priority Areas Outlined in OWH Women’s Health Research Roadmap

1. Advance Safety and Efficacy
2. Improve Clinical Study Design and Analysis
3. Evaluate New Modeling and Simulation Approaches
4. Advance Biomarker Science
5. Expand Data Sources and Analysis
6. Improve Health Communications
7. Identify Sex Differences via Emerging Technologies

Read the Women’s Health Research Roadmap

https://www.fda.gov/science-research/womens-health-research/womens-health-research-roadmap
Participation of Women in Clinical Trials Supporting FDA Approval of Cardiovascular Drugs, 2005-2015
Scott PE, Unger EF, Jenkins MR, et al. J Am Coll Cardiol; May 2018;
OWH Scientific Speaker Series

Sex Differences Impact Vaccine Efficacy: What You Need to Know
February 4, 2020
12:00 - 1:00 PM ET
CME/CPE/CNE Available

Sex Differences in COVID-19
October 20, 2020 | 12:00 - 1:00 PM ET | Adobe

COVID-19 and Pregnancy
What We Know
August 6, 2020 | 12:00 - 1:00 PM ET
Available via Adobe Connect

Office of Women’s Health
OWH Scientific Workshops and Public Meetings

Was held on September 27-28, 2018 at the US FDA White Oak Campus and via Webcast

Office of Women's Health
Integrating Sex and Gender to Improve Human Health Course

Available NOW: Free Online Courses Addressing Sex and Gender

Bench to Bedside: Integrating Sex and Gender to Improve Human Health
Explore sex- and gender-related differences in human health and disease.

Module 1: Immunology
Module 2: Cardiovascular Disease
Module 3: Pulmonary Disease
Module 4: Neurology
Module 5: Endocrinology
Module 6: Mental Health

Register at https://go.usa.gov/xvGwn.

https://orwh.od.nih.gov/career-development-education/e-learning/bench-bedside
Diverse Women in Clinical Trials

www.fda.gov/womeninclinicaltrials

WOMEN IN CLINICAL TRIALS = HOPE

Ask your healthcare provider if a clinical trial is right for you.

Office of Women’s Health

www.fda.gov/womeninclinicaltrials
Diverse Women in Clinical Trials

Print and Electronic Publications Available

15 Things You Should Know Before You Join a Clinical Trial

Being in a clinical trial is your choice. You should not feel pressured to join. You have the right to quit at any time. There are rules to protect people in clinical trials. Informed consent is the process of learning the key facts about the clinical trial before you join. This list is not everything you need to know, but it will help you start the conversation. Make sure that you have your questions answered before you agree to participate. Find out:

The Purpose and What Will Happen
1. The purpose of the study
2. The drugs, tests, and treatments you may receive
3. How long the study will last and how many times you will have to come
4. How they will keep your information private
5. What happens when the study ends

The Possible Risks and Benefits
The trial may provide treatments or screenings, but there is no promise that your health will get better. The medicine, test, or treatment may not work for you.
6. The benefits of the treatments
7. The risks and side effects of the treatments

What is FDA’s Role?
The U.S. Food and Drug Administration (FDA) makes sure medical treatments are safe and effective for people to use. FDA does not develop new treatments or conduct clinical trials.
The FDA Office of Women’s Health is partnering with the NIH Office of Research on Women’s Health on an initiative to promote the participation of diverse women in clinical trials. To learn more about these activities, go to: www.fda.gov/womeninclinicaltrials

Download the Fact Sheet

Download the Social Media Toolkit

Office of Women’s Health
Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

The 21st Century Cures Act P.L. 114-255

- Advise the Secretary of Health and Human Services (HHS) regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women
  - 15 recommendations
  - Implementation of recommendations report

Related Guidances

Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials Guidance for Industry

DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document, contact the Division of Pediatric and Maternal Health (CDER) at (301) 796-2290 or the Office of Communication, Outreach, and Development (CDER) at 800-835-4709 or 240-402-8810.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

April 2018
Clinical/Medical
Revision 1

Postapproval Pregnancy Safety Studies Guidance for Industry

DRAFT GUIDANCE
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For questions regarding this draft document, contact CDER Denise Johnson-Ulrich at 301-796-6409 or CBER the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8810.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2019
Clinical/Medical

Clinical Lactation Studies: Considerations for Study Design Guidance for Industry

DRAFT GUIDANCE
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2019
Clinical/Medical
• **Guidance for Industry: COVID-19: Developing Drugs and Biological Products for Treatment or Prevention (May 2020)**
  – FDA encourages the enrollment of pregnant and lactating individuals in the phase 3 (efficacy) clinical trials if appropriate.

• **Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19 (June 2020)**
  – FDA encourages vaccine developers to consider early in their development programs data that might support inclusion of pregnant women and women of childbearing potential who are not actively avoiding pregnancy in pre-licensure clinical trials.
Pregnancy Registries

Many women need to take medicine while they are pregnant. Some women take medicines for health problems, like diabetes or high blood pressure, that can start or get worse when a woman is pregnant. Some women use medicines before they find out they are pregnant.

A pregnancy exposure registry is a study that collects health information from women who take prescription medicines or vaccines when they are pregnant. Information is also collected on the newborn baby. This information is compared with women who have not taken medicine during pregnancy.

Enrolling in a pregnancy exposure registry can help improve safety information for medicines used during pregnancy and can be used to update drug labeling. Learn more about how you can help.

Resources For You

- List of Pregnancy Exposure Registries
- COVID-19 Pregnancy Registries

Office of Women’s Health
www.fda.gov/pregnancyregistries
Dynamic Social Media Content on Twitter, Facebook & Pinterest
OWH Strategic Priorities

Office of Women's Health Strategic Priorities; Establishment of a Public Docket; Request for Comments

A Notice by the Food and Drug Administration on 07/10/2020

This document has a comment period that ends in 28 days. (09/08/2020)

Docket Number FDA-2020-N-1391
Heart Health for Women

Getting a Beat on What Women Know about Heart Health

Heart disease is the leading cause of death for women in the United States. Find out what other women like you know about heart health and get tips on how to keep your heart healthy!

Getting a Beat On What Women Know About Heart Health

FDA Office of Women’s Health: Getting a Beat on What Women Know About Heart Health

En Español
Consumer Resources

www.fda.gov/womenshealthpubs
Stay Connected With OWH

twitter.com/FDAWomen

facebook.com/FDA/

dfa.gov/consumers/consumer-information-audience/women
Challenge Question

Which of the following statements about sex and gender is correct?

a) Sex is a biological variable
b) The terms *male* and *female* are used to characterize gender
c) Gender is a binary variable
d) Sex and gender are synonymous terms
Thank you

www.fda.gov/womens
www.fda.gov/womenshealthresearch
@FDAWomen on Twitter
The FDA Office of Minority Health and Health Equity:

Efforts to Diversify Clinical Trials

www.fda.gov/healthequity
Speaker

RADM Richardae Araojo

Associate Commissioner for Minority Health
Director, Office of Minority Health and Health Equity
Disclaimer

• This presentation represents the personal opinions of the speaker and does not necessarily represent the views or policies of FDA

• No conflicts of interest to declare
Objectives

• Provide an overview of the U.S. Food and Drug Administration’s Office of Minority Health and Health Equity (OMHHE)

• Describe FDA OMHHE’s Diversity in Clinical Trials Initiative

• Provide an overview of communication and outreach strategies to advance diverse participation in clinical trials
FDA Office of Minority Health and Health Equity (OMHHE)

**Mission**
To promote and protect the health of diverse populations through research and communication that addresses health disparities.

**Vision**
To create a world where health equity is a reality for all.
FDA OMHHE Goals

Goal 1: Improve regulatory science by increasing clinical trial data available on racial and ethnic minorities; improve data quality to determine how minorities react to medical products; and increase transparency and access to available data.

Goal 2: Strengthen FDA’s ability to respond to minority health concerns.

Goal 3: Promote health and safety communication to minority populations who often experience low health literacy and/or speak English as a second language.
### Research and Collaboration
- Intramural Research
- Extramural Research
- FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) Projects
- Broad Agency Announcement (BAA)
- Other research opportunities
- Internships and Fellowships
- Academic Collaborations
- FDA & HHS Working Groups & Collaborations
- Stakeholder Input into Research Agenda

### Outreach and Communication
- Programs/Initiatives/Campaigns
  - Diversity in Clinical Trials Initiative
  - Language Access Program
- Health Education Materials
- Social Media
- Newsletter & E-alerts
- Website
- Health Equity Lecture Series & Webinars
- FDA & HHS Working Groups & Collaborations
- Stakeholder Meetings/Symposiums/Exhibits
- Foster collaboration between FDA & stakeholders
Language Access Program

• Over 65 million Americans speak a language other than English at home

• Program goals:
  – provide access to translation services
  – offer easy to read materials in other languages
  – oversee volunteer’s program

• Language Access Services
  – provide flexible means for FDA centers and offices to acquire language services
A Decade of FDA Advancing Health Equity

By: RADM Richard A. Arvizu, Pharm. D., M.S., Associate Commissioner for Minority Health

The U.S. Food and Drug Administration is working around the clock with our U.S. government partners, medical product manufacturers and international partners to address the coronavirus disease 2019 (COVID-19) pandemic. As the FDA remains steadfast in our urgent response efforts to the pandemic for all Americans, including the nation’s most vulnerable communities, I would be remiss not to pause for a moment to mark the importance of National Minority Health Month, observed every April. The commemoration highlights advancements that have been made, and steps we can continue to take, to increase health equity and reduce health disparities among diverse populations. This year, the occasion is especially significant because it marks the 10-year anniversary of the FDA’s Office of Minority Health and Health Equity (OMHHE), an office committed to reducing the health inequities minorities face that often contribute to reduced quality of life and premature death (watch the OMHHE video below to learn more).
Office of Minority Health and Health Equity Strategic Priorities; Establishment of a Public Docket; Request for Comments

A Notice by the Food and Drug Administration on 01/03/2020

AGENCY:
Food and Drug Administration, HHS.

ACTION:
Notice; establishment of a public docket; request for comments.

SUMMARY:
The Food and Drug Administration (FDA or the Agency) is opening a public docket to solicit input and comments from interested stakeholders, including racial and ethnic minority, underrepresented, and underserved populations in establishing strategic priorities for the Office of Minority Health and Health Equity (OMHHE). This will help the Agency ensure that important health concerns are carefully considered in establishing priorities.
Clinical Trial Diversity: Why it matters?

• Racial and ethnic minorities have been historically under-represented in clinical trials

• Need representation to study the effects of medical products in the people who will ultimately use them

• Persons of different ages, races, and ethnicities could react differently to certain medical products

• To understand health disparities - diseases that occur more frequently or appear differently in diverse populations
Barriers to Clinical Trial Participation

- Mistrust and distrust of the medical system due to historical abuses
- Lack of awareness of what a clinical trial is and what it means to participate
- Inadequate recruitment and retention efforts
- Lack of minority physicians, researchers, and clinical investigators
- Misunderstanding of racial/ethnic minorities’ beliefs and values that contribute to their decision making process
- Lack of culturally and linguistically appropriate communication
- Perception that racial/ethnic minorities do not want to participate
- Physicians/providers may not talk to their patients about clinical trials
- Enrollment criteria
- Return of Results
- Privacy concerns
- Lack of access
- Time and resource constraints for patients
2012 FDA Safety and Innovation Act (FDASIA) Section 907
Action Plan Priorities & Strategies

**Priority One**
Improve the completeness and quality of demographic subgroup data collection, reporting and analysis (Quality)

**Priority Two**
Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation (Participation)

**Priority Three**
Make demographic subgroup data more available and transparent (Transparency)

**FDA Guidance Documents**
- Collection of Race and Ethnicity Data in Clinical Trials
- Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies

**Public Meetings**
Tools to support diverse clinical trial participation

**Drug Trials Snapshots**
(Center for Drug Evaluation and Research)
COVID-19
Inclusion of Diverse Populations

• FDA Guidance for Industry on Development and Licensure of Vaccines to Prevent COVID-19; June 2020

  ▪ “FDA encourages the inclusion of diverse populations in all phases of vaccine clinical development. This inclusion helps to ensure that vaccines are safe and effective for everyone in the indicated populations.”

  ▪ “FDA strongly encourages the enrollment of populations most affected by COVID-19, specifically racial and ethnic minorities.”

• FDA Guidance for Industry on COVID-19: Developing Drugs and Biological Products for Treatment or Prevention; May 2020

  ▪ “Racial and ethnic minority persons should be represented in clinical trials. Sponsors should ensure that clinical trial sites include geographic locations with a higher concentration of racial and ethnic minorities to recruit a diverse study population.”
Diversity in Clinical Trials Initiative

Developed an ongoing multi-media public education and outreach campaign to raise awareness around the importance of diverse participation in clinical trials.
Motivators for Campaign

• Reinforce the importance of diverse participation

• Educate consumers about key issues

• Help stimulate dialogue among peers and patient-provider
Diversity in Clinical Trials Campaign

BE A #CLINICALTRIALSCHAMPION

Videos
Newsletters & E-alerts
Webpage
Stakeholder Collaboration
Podcasts
Social Media
Communications Toolkit
Culturally & Linguistically Tailored
Diverse Participation in Clinical Trials
Videos and Podcast
Shirley’s Story: Diversity is Critical to Making Better Medical Products
Veterans in Clinical Trials

Quinyardo McClain
Staff Sergeant (US Army Res.)

Zulma Santiago
Closed Circuit (US Army Res.)

Javier Chávez
First Sergeant (US Army Reserve)
Diversity in Medical Device Clinical Trials Video

U.S. FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE CLINICAL TRIALS
Examples of Stakeholder Engagement Activities

• The Alliance of Multicultural Physicians and FDA OMHHE Memorandum of Understanding
  • Collective of the Association of American Indian Physicians (AAIP), Association of Black Cardiologists (ABC), National Council of Asian Pacific Islander Physicians (NCAPIP), National Hispanic Medical Association (NHMA), and National Medical Association (NMA). Opportunities to collaborate on developing educational, outreach, and training initiatives for physicians and the patients they serve to advance health equity.

• Yale and FDA OMHHE Memorandum of Understanding
  • To advance the Yale Cultural Ambassadors Program, an engagement of community partners to increase diverse participation in clinical research
Examples of Stakeholder Engagement Activities

• The Multi-Regional Clinical Trials Center and Harvard, “Achieving Diversity, Inclusion, and Equity in Clinical Research” Workgroup and Diversity Framework
  – Heterogeneity of Treatment Effects in Clinical Trials: Methods and Innovations; November 30 - December 1, 2020.

• Clinical Trials Transformation Initiative (CTTI) Diversity Project
  • CTTI is a Public-Private Partnership Co-founded by Duke University and FDA

• Society for Clinical Research Sites (SCRS) Diversity Awareness Program
Research Collaborations

- Broad Agency Announcement (BAA)
- CERSIs
  - University of Maryland
  - UCSF-Stanford
  - Johns Hopkins University
  - Yale-Mayo Clinic
- Intramural Research
Strategies to Support Diverse Participation

- There is not a one size fits all approach
- All actions should begin and end with the patient in mind
- A plan to address inclusion should be developed early on
- Consistent and continued community engagement
- Engage patients in trial design, logistics, and recruitment and retention practices
- Site locations where there are more racial and ethnic minorities
- Workforce diversity
- Engage providers
- Cultural sensitivity, competency, and awareness
- Eliminate language barriers
- Organizational goals that support diversity
Health Education

Brochures | Fact Sheets | Infographics | Podcast

Sickle Cell Disease

FAC SHEET
Sickle cell disease is an inherited blood cell disorder. Red blood cells become rigid and clump together, which can block blood flow. When this happens, oxygen cannot get to parts of the body.

Key Facts
- When the blood flow is blocked, the affected area can become very painful.
- Sickle cell crisis is a medical emergency that requires immediate medical attention.

Asthma

FAC SHEET
Asthma is a chronic inflammatory disease that affects the airways. It can cause Bronchial asthma, which can lead to asthma attacks. Asthma can be managed with medication and lifestyle changes.

Key Facts
- Asthma attacks can be triggered by several factors, including dust, pollen, smoke, and exercise.
- Medications can help control asthma attacks.

Steps to Control Your Asthma

FDA Office of Minority Health and Health Equity
One strategy to raise awareness on clinical trial diversity is to develop culturally and linguistically tailored health education materials.

a) True  
b) False
Thank You!

Follow us at: @FDATHealthEquity

Email us at: OMHHE@fda.hhs.gov

Visit us at: FDA.gov/HealthEquity

Join webinars and stakeholder calls