An FDA Perspective: The Need for Diverse Representation in Clinical Trials

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National Hispanic Health Conference, April 2019
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
Overview

• The Need for Diverse Representation in Clinical Trials

• FDA Policy Strategies to Support Diverse Participation in Clinical Trials

• Communication & Outreach Strategies to Improve 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.
The Continuing Conversation...

 Latinos Left Out Of Clinical Trials ... And Possible Cures

 Clinical Trials Have Far Too Little Racial and Ethnic Diversity
 It’s unethical and risky to ignore racial and ethnic minorities

 Lack of Diversity in Clinical Trials Hurts Patients and Drug Development
The Need for Diverse Participation

• 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

• Minorities may respond differently to medical products (ex: certain cancer treatments, heart failure medications)

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

- Mistrust and distrust of the medical system due to historical abuses
- Lack of awareness on the patient’s part
- 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/linguistically appropriate communication
- Perception that 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
FDA Safety and Innovation Act (FDASIA) Section 907
Action Plan Priorities & Strategies

Quality: Improve the completeness and quality of demographic subgroup data collection, reporting and analysis

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

Participation: Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation

- Public Meetings
- Tools to support diverse clinical trial participation

Transparency: Make demographic subgroup data more available and transparent

- Drug Trials Snapshots (CDER)
Clinically Relevant Enrollment

- FDA expectations are that sponsors enroll participants who reflect the demographics for clinically relevant populations with regard to age, gender, race, and ethnicity

- A plan to address inclusion of clinically relevant subpopulations should be submitted for discussion to the Agency at the earliest phase of development and, for drugs and biologics, no later than the end of the phase 2 meeting

- Inadequate participation and/or data analyses from clinically relevant subpopulations can lead to insufficient information in product labeling
Drug Trials Snapshots

WHAT IS THE PURPOSE OF DRUG TRIALS SNAPSHOT?

Drug Trials Snapshots provide consumers with information about who participated in clinical trials that supported the FDA approval of new drugs. The information provided in these Snapshots also highlights whether there were any differences in the benefits and side effects among sex, race and age groups. Drug Trials Snapshots is part of an overall FDA effort to make demographic data more available and transparent.

HOW TO USE SNAPSHOT:

Each Snapshot contains information about the drug in a question and answer format. At the end of each section of the Snapshot, there is a shaded bar with the words “MORE INFO.” Click the “MORE INFO” bar for more technical and detailed content. At the bottom of each Snapshot, there is a link to the drug’s Package insert as well as the medical review.

LIMITATIONS OF SNAPSHOT:

The Snapshot is intended as one tool for consumers to use when discussing a drug's risks and benefits with their physician. Do not rely on Snapshots alone to make decisions regarding medical care. Do not use Snapshots to substitute for advice from your healthcare professional. Conclusions regarding how effective and safe a drug is among different sex, race, and age groups cannot always be made, often because the numbers of patients in some groups are too limited to allow for meaningful comparisons to other groups and to the overall results.
### Drug Trials Snapshots: Summaries (2016-2018)

<table>
<thead>
<tr>
<th></th>
<th>WOMEN</th>
<th>BLACK or AFRICAN AMERICAN</th>
<th>ASIAN</th>
<th>WHITE</th>
<th>OTHER*</th>
<th>AGE 65 AND OLDER</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2016</strong></td>
<td>48%</td>
<td>7%</td>
<td>11%</td>
<td>76%</td>
<td>7%</td>
<td>21%</td>
</tr>
<tr>
<td><strong>2017</strong></td>
<td>55%</td>
<td>7%</td>
<td>11%</td>
<td>77%</td>
<td>14%</td>
<td>32%</td>
</tr>
<tr>
<td><strong>2018</strong></td>
<td>56%</td>
<td>11%</td>
<td>10%</td>
<td>69%</td>
<td>14%</td>
<td>15%</td>
</tr>
</tbody>
</table>

* The percentages of the categories “American Indian or Alaska Native (AI/AN),” “Native Hawaiian or Other Pacific Islander (NH/OP),” and “Unknown/Unreported” were small enough that we combined them into the “Other” category for the purposes of this review.

** These particular subgroups were calculated as part of a Geriatrics Report and are not a regular feature of the Drug Trial Snapshots.
Language Access Program

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

• FDASIA Section 1138

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

BE A #CLINICALTRIALSCHAMPION
Latinos Can Make a Difference in Clinical Trials
Minority Participation in Clinical Trials Videos

Videos highlighting the importance of minority participation in clinical trials.

Each video features a different theme and key message.
Diversity in Clinical Trials Resources

Minorities In Clinical Trials

FACT SHEET

Clinical trials are research studies that determine whether medical products like medicines, vaccines, or devices are safe and effective. These studies may show which medical approaches work best for certain illnesses or groups of people.

Office of Minority Health

4 Things you should know about the importance of minorities in clinical trials

4. You may help to test new medicines, vaccines, or devices.

hoja informativa

Las minas en los ensayos clínicos

La investigación necesita de USTED. Es SU decisión.

Participe en una investigación como voluntario(a)

For Consumers

Minorities in Clinical Trials

For Professionals

Minorities in Clinical Trials

Resource for you

- Clinical Trials: What Patients Need to Know
- Women in Clinical Trials
- Drug Trials Information
- ROSA Study: Reaching Out to Spanish-Speaking Women in Clinical Trials
- [Website or resource link]

If you think a clinical trial may be right for you, talk to your doctor. Additionally, you can learn more about clinical trials on the FDA’s website. Here are some resources:

- About Research Participation
- Fact Sheet: Minorities in Clinical Trials (Spanish)
- Brochure: Become a Research Volunteer (Spanish)
- Webinar: Get to Know Clinical Trials (Spanish)
- Clinical Trial Diversity Toolkit
- Collection of Race and Minority Data in Clinical Trials—Guidance for Industry and FDA Staff
- Women in Clinical Trials
- Inside Clinical Trials: Timing Medical Products in People
- Clinical Trials: Who Patients Need to Know
- Consumer Update: FDA Enhances Minor Participation, Diversity in Clinical Trials (Spanish)
- Consumer Update: Clinical Trial Sheds Light on Minority Health (Spanish)
- Consumer Update: It's Your Clinical Trial (Spanish)
- Consumer Update: What's Your Child Benefit from a Clinical Trial? (Spanish)
Building Partnerships and Collaborations

• Puerto Rico Clinical Research Summit (May 2018 & 2019)
  – Co-organized by FDA OMHHE, Yale University, Universidad de Puerto Rico, Universidad Central del Caribe, Ponce Health Sciences University, and the Puerto Rico Consortium for Clinical Investigation

• Yale and FDA OMHHE Memorandum of Understanding
  – To advance the Yale Cultural Ambassadors Program and engagement of community partners to increase diverse participation in clinical research
Opportunities

• Patient Engagement Activities
• Patient Focused Drug Development
• Evaluation of Inclusion/Exclusion Criteria
• Engaging Communities and Building Partnerships
Thank You!

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www.fda.gov/minorityhealth

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