An FDA Perspective on Clinical Trial Inclusion & Demographics: Challenges and Opportunities

Martin Mendoza, PhD
Director, Extramural Research Program
FDA Office of Minority Health

September 21, 2017
Disclosure Information

- We have no financial relationships to disclose
- We will not discuss off label use and/or investigational use in this presentation
- The views expressed here are ours and not FDA
FDA’s Mission

FDA is responsible for **protecting the public health** by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.

• Oversee products worth over $2 trillion a year that account for approximately 20 percent of consumer spending

• Help the public get accurate, science-based information they need to use medicines and foods to maintain and improve their health.

• Regulate the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

• Ensure the security of the food supply

• Fostering development of medical products to respond to deliberate and naturally emerging public health threats (Ebola, Zika)
Globalization and Regulated Products

Food
• 10-15% of all food consumed by U.S. households is imported
• ~ 50% of fresh fruits and 20% of fresh vegetables imported
• 80% of seafood eaten domestically is from outside the U.S.
• Food imports increased 10% per year from 2005-2011

Devices
• At least 50% of all medical devices used in the U.S. are imported
• Medical device imports grew at over 10% per year from 2005-2011

Drugs
• At least 40% of drugs on U.S. shelves come from overseas
• 80% of API manufacturers are located outside the U.S.
• Estimates are that 60% or more of clinical data submitted is ex-US
Minorities and clinical trials: Building a case for increased participation
## Minorities and Clinical Trials

<table>
<thead>
<tr>
<th></th>
<th>US Population</th>
<th>Industry Trials</th>
<th>NIH Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>African-Americans</td>
<td>12%</td>
<td>5%</td>
<td>15%</td>
</tr>
<tr>
<td>Hispanics</td>
<td>17%</td>
<td>3%</td>
<td>7.6%</td>
</tr>
</tbody>
</table>

Note: NIH clinical trials have 30% minority representation overall
# Overview of Demographic Inclusion

<table>
<thead>
<tr>
<th></th>
<th>WOMEN</th>
<th>AFRICAN AMERICAN</th>
<th>ASIAN</th>
<th>WHITE</th>
<th>AGE 65 AND OLDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVERAGES</td>
<td>46%</td>
<td>8%</td>
<td>12%</td>
<td>76%</td>
<td>26%</td>
</tr>
</tbody>
</table>
## Percentage of Patients Enrolled in Prostate Cancer Clinical Trials

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>47.7</td>
<td>29.2</td>
</tr>
<tr>
<td>Canada</td>
<td>10.1</td>
<td>7.1</td>
</tr>
<tr>
<td>Australia</td>
<td>1.8</td>
<td>3.9</td>
</tr>
<tr>
<td>“Europe”</td>
<td>34</td>
<td>38.7</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>5.6</td>
<td>7.4</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>9.5</td>
<td>13.5</td>
</tr>
</tbody>
</table>

Wissing MD, et al., Cancer, 2014
Why is participation important?

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

• Minorities may respond differently to medical products
  • Examples: cancer treatment, heart failure medications

• Health disparities continue to exist
Reasons for Decreased Participation

• Mistrust of the medical system due to historical abuses

• Inadequate recruitment and retention efforts

• Misunderstanding of minorities’ beliefs and values that contribute to their decision making process

• Perception that minorities are ineligible for enrollment

• Perception that minorities do not want to participate

• Lack of awareness on the patient’s part

• Physicians may not talk to their patients about clinical trials.
Research Shows….

• In general, minorities will participate if asked. For example…..

  • 91% of African Americans who were surveyed in one study would consider participating in a clinical trial and that mistrust is becoming less of an issue

  • Among immigrant Latinos, 71% of those surveyed who knew what a clinical trial was would consider participating in a cancer clinical trial

  • One study showed there is no difference between African-Americans and Hispanics willingness to participate in research compared to Whites

  • African- American women were less likely to be asked to participate in a breast cancer clinical trial compared to white women (21% versus 42%)
FDA’s Office of Minority Health
Office of Minority Health’s (OMH) vision is to create a world where health equity is a reality for all.
Our mission is to promote and protect the health of diverse populations through research and communication of regulatory science that address health disparities.
OMH Goals

• **Goal 1**- To improve and strengthen regulatory science informing the research and evaluation of sub-population data associations with race and ethnicity.

• **Goal 2**- To strengthen FDA’s capacity to address minority health and health disparities across the Agency.

• **Goal 3**- To promote effective communication and the dissemination of information to the public, particularly underserved, vulnerable populations.
FDA OMH Communication Strategies
OMH’s Role in Patient/Consumer Engagement

• We are conveners & connectors
## Outreach & Communication Strategies

### Stakeholder Engagement
- Meetings with minority serving institutions (MSIs), organizations, & patient and disease advocacy groups
- External Meeting Participation and Presentations
- Webinars
- Limited English Proficiency (FDA Language Access Plan)

### Raise Awareness
- Meetings, Speaker series (internal)
- OMH Website
- Newsletter and Email Blasts
- Blogs and Consumer Updates
- Social Media: Twitter, Pinterest, Facebook

### Targeted Consumer Education
- Editorial Calendar
- Campaign on targeted disease areas of significance to health disparities/Million Hearts Initiative and Health Disparities
- Materials Development (fact sheets, infographics, videos, brochures)
- Clinical Trial Diversity

### Translate & Adapt Materials
- Coordinate and support FDA Language Access Plan Implementation
- Represent FDA on HHS Steering Committee
- Health Literacy, Risk Communication, Plain Language, Limited English Proficiency, Low Literacy
Campaign Purpose

Developed a multi media campaign to raise awareness around the importance of minority representation in clinical trials to ensure medical products are safe and effective for everyone.
Motivators for Campaign

• Add positive reinforcement as to why clinical trial diversity matters

• Educate consumers about clinical trials

• Help stimulate dialogue among peers and patient-provider
Campaign Materials

• Videos
  • 5 PSA’s featuring patient rep; 1 featuring FDA’s Acting Chief Scientist
  • Featured FDA representative as spokesperson

• Print Materials
  • Brochures
  • Fact sheets
  • Blogs
  • Newsletter and e-alerts

• Social Media
  • Twitter, Facebook, Pinterest
  • Thunderclap

• Webpage
  • Dedicated to minorities & clinical trials

• Stakeholder Communications Toolkit
FDA OMH Policy Efforts
FDA Safety and Innovation Act (FDASIA) of 2012
Section 907

History
• American Heart Association, WomenHeart, and Society for Women’s Health Research lobbied Congress for legislation requiring FDA to publicly report data on the inclusion and analysis of women in FDA applications
  ▪ Sen. Debbie Stabenow (D-MI) and Rep. Lois Capps (D-CA)
• Provision added to include reporting of a race and ethnicity
  ▪ Sen. Benjamin Cardin (D-MD)
• Final FDASIA legislation reauthorizing FDA user fees (essential for Agency operations)
  ▪ Requirement for an initial public report on inclusion data from medical product applications
  ▪ Subsequent action plan required to address deficiencies
Section 907 Requirements: A Report

Within one year of enactment:

• August 2013: Provided report to Congress and posted on FDA website

• Extent of clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups (sex, age, race, ethnicity) is included in applications submitted to FDA
August 2014: FDASIA Section 907 Action Plan

Three overarching priorities:

• **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)
Collection of Race and Ethnicity Data in Clinical Trials

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 26, 2016

For questions about this document, contact the FDA Office of Minority Health at 240-402-5084 or omh@fda.hhs.gov.

U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)
Office of Minority Health (OMH)
Office of Women’s Health (OWH)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health (CDRH)

October 2016
Clinical Medical
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 pertaining to medical product safety and effectiveness for product labeling.
Summary

• Minority Clinical Trial Participation is IMPORTANT

• FDA OMH Outreach Campaign

• FDA OMH Policy Efforts
Stay Connected!

Follow us on twitter @FDAOMH

OMH@fda.hhs.gov

www.fda.gov/minorityhealth

Join webinars and stakeholder calls

Note: all webinars and stakeholder calls are announced in our newsletter and you can sign up for our newsletter via the website
Questions?

Martin.Mendoza@fda.hhs.gov
Terminology

• **Impressions** – the number of times the ad displays in YouTube. There is no cost for impressions.

• **View Rate** – the number of times the ad is clicked divided by the number of times it was seen (impressions).

• **Cost Per View** – the average cost when an ad was clicked and video was watched.
Video Comparison

Views from the duration of the AdWords campaign:
June 12 to June 27

• Shirley’s Story: How to Find Information about Clinical Trials: 474 views
• Shirley’s Story: Getting Access to Cutting Edge Therapies: 354 views
• Shirley’s Story: You Don’t Have to be Sick to Participate: 354 views
• Shirley’s Story: Diversity is Critical to Making Better Medical Products: 785 views (2 min version)
• Shirley’s Story: Diversity is Critical to Making Better Medical Products: 6,182 views (promoted by AdWords)
## Ad Performance

![Image of video ad](image)

**Video ad created Jun 13, 2016**

*Consider a Clinical Trial*

*Diverse volunteers are critical to making better medical products*

<table>
<thead>
<tr>
<th>Impressions</th>
<th>Views</th>
<th>View Rate</th>
<th>Avg. Cost Per View</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>7,302,911</td>
<td>5,577</td>
<td>.08%</td>
<td>$1.89</td>
<td>$10,556.89</td>
</tr>
</tbody>
</table>

### Age

<table>
<thead>
<tr>
<th>Age</th>
<th>Impr.</th>
<th>Views</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
<td>3,435,328</td>
<td>1,832</td>
</tr>
<tr>
<td>55 - 64</td>
<td>586,102</td>
<td>767</td>
</tr>
<tr>
<td>65+</td>
<td>431,805</td>
<td>717</td>
</tr>
<tr>
<td>45 - 54</td>
<td>661,396</td>
<td>572</td>
</tr>
<tr>
<td>35 - 44</td>
<td>651,418</td>
<td>581</td>
</tr>
<tr>
<td>25 - 34</td>
<td>632,479</td>
<td>525</td>
</tr>
<tr>
<td>18 - 24</td>
<td>904,384</td>
<td>473</td>
</tr>
</tbody>
</table>

### Gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>Impr.</th>
<th>Views</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>3,306,785</td>
<td>2,624</td>
</tr>
<tr>
<td>Male</td>
<td>1,451,161</td>
<td>1,688</td>
</tr>
<tr>
<td>Unknown</td>
<td>2,454,965</td>
<td>1,285</td>
</tr>
</tbody>
</table>

Note: Google does not collect race/ethnicity data.
Video Performance

- Average View Duration: 0:15
- Average Percentage Viewed: 62%

Traffic sources:
- YouTube advertising: 79%
- External: 11%
- Direct or unknown: 3.5%
- Other: 5.6%

Gender Distribution:
- Male: 43%
- Female: 57%

Views:
- Total Views: 6,182

Top locations and gender:
- United States: 6,125 views (16% Male, 16% Female)
Discussion

• Stimulated dialogue around clinical trial diversity

• Increased utilization of our materials

• Next Steps:
  • Further research can assess the effectiveness of our materials and outreach strategies through cognitive testing and focus group testing.
  • PSA educating Latinos about the importance of participating in clinical trials
  • PSA targeting physicians and engaging their patients in participating in clinical trials