U.S. FOOD & DRUG ADMINISTRATION

# Guidance for Industry and FDA Staff

# Collection of Race and Ethnicity Data in Clinical Trials

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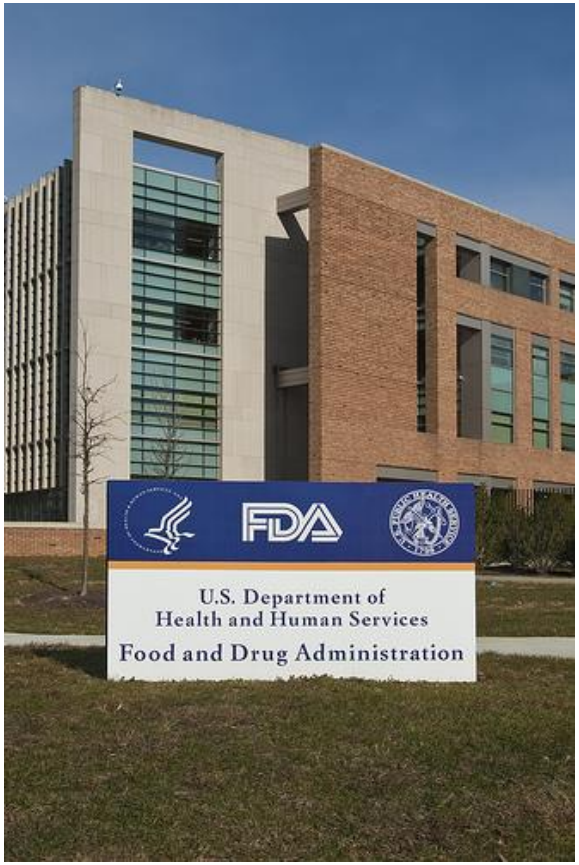
**May 23, 2017**

# Overview

- Objectives
- Background
- Clinically Relevant Enrollment
- Collection of Race and Ethnicity Data
- Presentation of Race and Ethnicity Data

# Objectives

- Clarify FDA's expectations for enrolling clinically relevant populations in clinical trials
- Recommend during study design stage development of a plan to address inclusion of clinically relevant subpopulations (age, sex/gender, race, ethnicity)
- Outline FDA's guidelines for the collection of race and ethnicity data in clinical trials



# Background

# 1998 FDA Regulation: The "Demographic Rule"

Investigational New Drug Annual Reports & New Drug Application (NDA) Submissions:

Requires information on:

- Demographic Subgroup Trial participation
- Safety
- Effectiveness

Data by:

- Sex (Gender)
- Age
- Race

Investigational New Drug Applications (INDs) and New Drug Applications (NDAs) 21 CFR 314.50 and 21 CFR 312.33

# "Demographic Rule" Cont'd

- There is **no requirement** for a specific:
  - Number
  - Percentage
- IND regulations
  - Require annual report data to be **tabulated** by age, sex, race
- NDA regulations
  - Require data for safety and efficacy to be **analyzed** by age, sex, race

# 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:

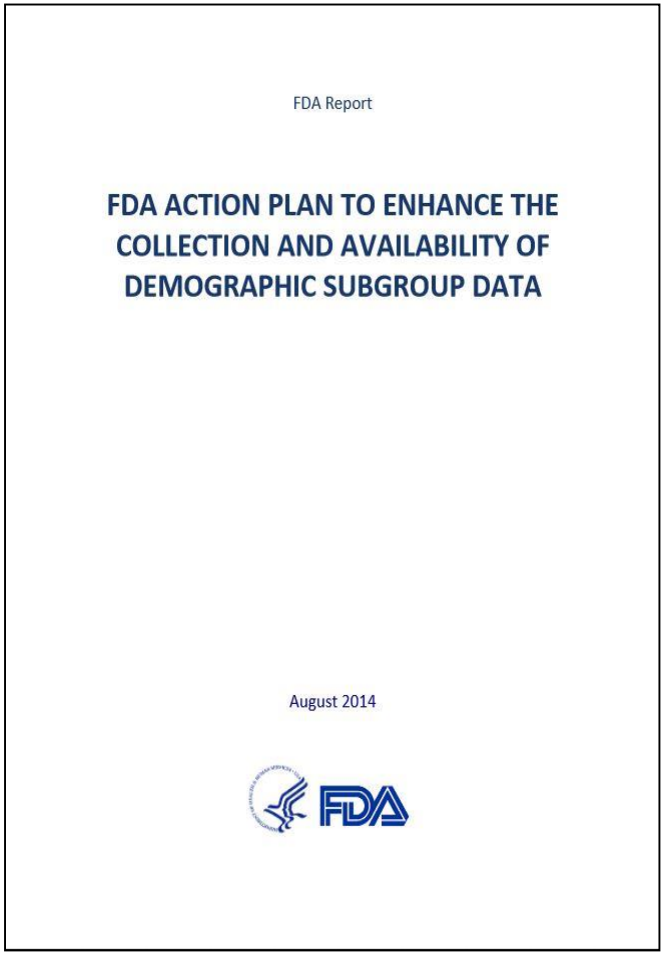
- August 2013: Provided report to Congress and posted on FDA website

- 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**)



*Contains Nonbinding Recommendations*

# Collection of Race and Ethnicity Data in Clinical Trials

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## 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**

# Guidance Development

- FDASIA 907 Action Plan committed to update of 2005 Guidance
- Working group convened July 2015:
  CDER, CBER, CDRH, OWH, OMH
- Consultation, review, and clearance included NIH, CDC, and HHS

# 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

# Points to Consider: Subgroup Differences

For potential race and ethnicity differences relevant to the evaluation of the medical product for the disease/condition, consider:

- Prevalence
- Diagnosis and treatment patterns
- Previous subgroup inclusion in past studies for target indication
- Any clinically meaningful subgroup differences in safety or efficacy

# Collection of Race and Ethnicity Data

# US Office of Management & Budget Directive 15: Self-Reporting

- FDA recommends that trial participants **self-report** race and ethnicity information and those individuals be permitted to designate a multiracial identity
- When the collection of self-reported designations is not feasible (e.g., because of the subject's inability to respond), we recommend that the information be requested from a first-degree relative or other knowledgeable source
- Race and ethnicity should not be assigned by the study team conducting the trial

# Two Question Format

In order to be consistent with OMB and other recommended best practices, FDA recommends using the two-question format for requesting race and ethnicity information, with the ethnicity question preceding the question about race. Example:

- **Question 1 (answer first):** Do you consider yourself Hispanic/Latino or not Hispanic/Latino?
- **Question 2 (answer second):** Which of the following five racial designations best describes you? More than one choice is acceptable.

# Question 1: Ethnicity

For ethnicity, we recommend the following minimum choices be offered:

- **Hispanic or Latino:** A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish origin,” can be used in addition to “Hispanic or Latino.”
- **Not Hispanic or Latino**

# Question 2: Race

For race, we recommend the following minimum choices be offered:

- **American Indian or Alaska Native:** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
- **Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- **Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”
- **Native Hawaiian or Other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

# Use of More Detailed Categories

- In certain situations, as recommended in OMB Policy Directive 15, more detailed race and ethnicity information may be desired
- For example, disease/condition may warrant more granular race data
- For clinical trials conducted outside the United States, FDA recognizes that the recommended categories for race and ethnicity were developed in the United States and that these categories may not adequately describe racial and ethnic groups in foreign countries
- Furthermore, White can reflect origins in Europe, the Middle East, or North Africa;
- Asian can reflect origins from areas ranging from India to Japan
- Where concerns exist in the representation of race or ethnicity categories, sponsors are encouraged to discuss the race or ethnicity issues with the appropriate review division

# Ethnicity Data Standard

Are you Hispanic, Latino/a, or of Spanish origin? (One or more categories may be selected)

a. ____No, not of Hispanic, Latino/a, or Spanish origin
b. ____Yes, Mexican, Mexican American, Chicano/a
c. ____Yes, Puerto Rican
d. ____Yes, Cuban
e. ____Yes, Another Hispanic, Latino/a or Spanish origin

These categories roll up to the Hispanic or Latino category of the OMB standard

# Race Data Standard

What is your race? (One or more categories may be selected)

a. ____White
b. ____Black or African American
c. ____American Indian or Alaska Native

These categories are part of the current OMB standard

d. ____Asian Indian
e. ____Chinese
f. ____ Filipino
g. ____Japanese
h. ____Korean
i. ____ Vietnamese
j. ____ Other Asian

These categories roll up to the Asian category of the OMB standard

k. ____Native Hawaiian
l. ____ Guamanian or Chamorro
m. ___ Samoan
n. ____Other Pacific Islander

These categories roll-up to the Native Hawaiian or Other Pacific Islander category of the OMB standard

# Recent Activities

- Hosted webinar
  - 440+ attended (900+ registered)
  - Archive available here
- Invited to become members of the FDA CDER Change Control Board (CCB)
  - Currently crafting business rules based on the guidance

# FR Notice- OMB Updating of Categories

**FRN 2017-03973: Revision of Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity**

**FDA supports:**

- OMB recommendation to **merge the current 2-step collection** process of race and ethnicity data into a single question. FDA believes the combined single question will help to streamline the collection process and provide for more consistent data capture of this important information.
- FDA supports the classification of a distinct reporting category for "Middle Eastern or North African."
- FDA supports the creation of an additional and separate category representing those persons with ancestry from the nation of India. Currently, persons with origins from this geographic region are classified under the "Asian" category. Due to highly distinct genetic/physiological/cultural differences between persons normally associated with Asian descent (Chinese, etc) and persons from the nation of India, FDA feels the creation of a separate and distinct reporting category is warranted.
- FDA supports the amending of the OMB description for the "Black or African American" reporting category. The current description states that the terms "Haitian" or "Negro" may be used in addition. Based on substantial internal and external feedback FDA has received when quoting this description, FDA recommends removing the term "Negro" from the text

# Summary

- Overview of legislative mandate and AP commitment
- Recommendation of a plan to address clinically relevant populations in clinical trials
- Regulatory framework for how to report the data (OMB Directive 15)

# Comments to the Docket

Stakeholders can submit comments on the guidance by October 25, 2021:

- Federal eRulemaking Portal: FDA-2016-D-3561
- http://www.regulations.gov
  - Comments are public and appear unchanged, including attachments
- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852

# Thank you!

**U.S. Food and Drug Administration**

**Office of Minority Health**

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# Comments & Questions