Clinical Research Inclusivity

Outsourcing in Clinical Trials Southeast

April 16th, 2024

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Better Health, Brighter Future

Diversity, Equity & Inclusion in Clinical Research Department

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To achieve health equity, every person must have a fair and just opportunity to attain their full health potential. Collaboratively we work to achieve greater health equity by addressing health disparities and inequities that disproportionately impact underserved communities, including access to clinical trials.

Agenda

Define

Define what diversity in clinical trials means along with a brief history of the FDAs Diversity Action Plan.

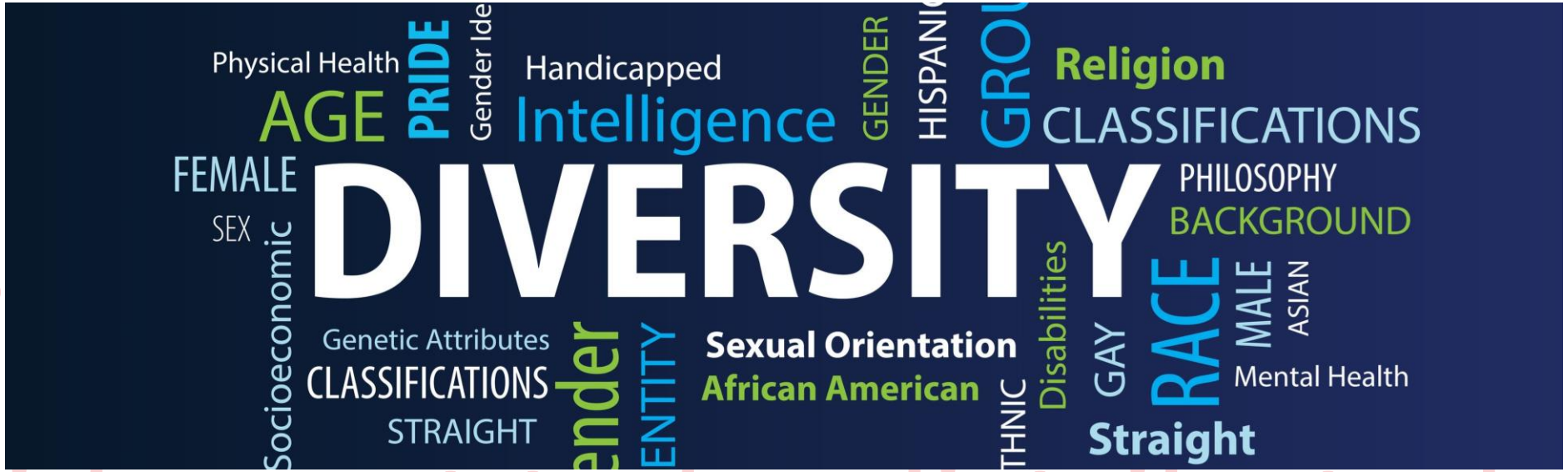
Discuss

Briefly discuss what is expected in Trial Diversity Planning and what industry is already doing to impact clinical trial diversity.

Plan

Talk about some of the challenges and how to address them.

The Importance of Diversity in Clinical Trials



DATA
Real-world evidence & data shows certain diseases impact people differently

FDA
The FDA requests those conducting research to proactively plan to enroll participants reflective of those who will use the medicine

PEOPLE
Diverse representation increases confidence that medicines are safe & efficacious

A Brief History

2013

FDA Report

- Showed the lack of participation by racial and ethnic underrepresented populations and socially disadvantaged groups

2014

FDA Action Plan

- To enhance the collection and availability of demographic subgroup data

2016

Year of Clinical Trials Diversity

- Guidance on Collection of Race and Ethnicity Data

2017-2022

PDUFA VI

- Final Guidance: Enhancing the Diversity of Clinical Trial Populations
- Draft Guidance: Diversity Action Plans

Dec. 2022

FDORA

- Clinical Trial Diversity and Modernization (Section 3601-3604)

Expected Dec 29, 2023

FDA DAP Guidance

- Revised Diversity Action Plans Draft Guidance to include FDORA provisions

FDORA: Clinical Trial Diversity and Modernization (Section 3601-3604)

Diversity Action Plans

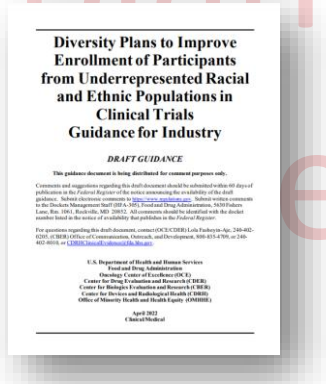
Must be submitted for Phase III trials or another pivotal study

Requirement can be waived if an indication is too small or for other discretionary reasons

Updated or New Guidance

Additional details about Diversity Action Plans, including on whether to grant a sponsor's request to waive the requirement

An update to the 2022 Diversity Action Plans guidance **was expected by December 29, 2023**, but it has not yet been released to the public


Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)

April 2022
Clinical/Medical

Updated Diversity Action Plans Guidance – What to Expect?

The 2022 guidance covered an overview of **disease and condition** (pathophysiology in underrepresented racial/ethnic populations), **product development** (study design, endpoints), **enrollment goals**, and **operational steps** (metrics)

Along with the FDORA provisions, the draft guidance may address gaps in the 2022 version, including **clear definitions of "Race" and "Ethnicity"**, clarification of the **waiver / deferral process**, **cross-referencing INDs** and addressing **multi-study protocols**, and **alignment with ICH E5 and E17**

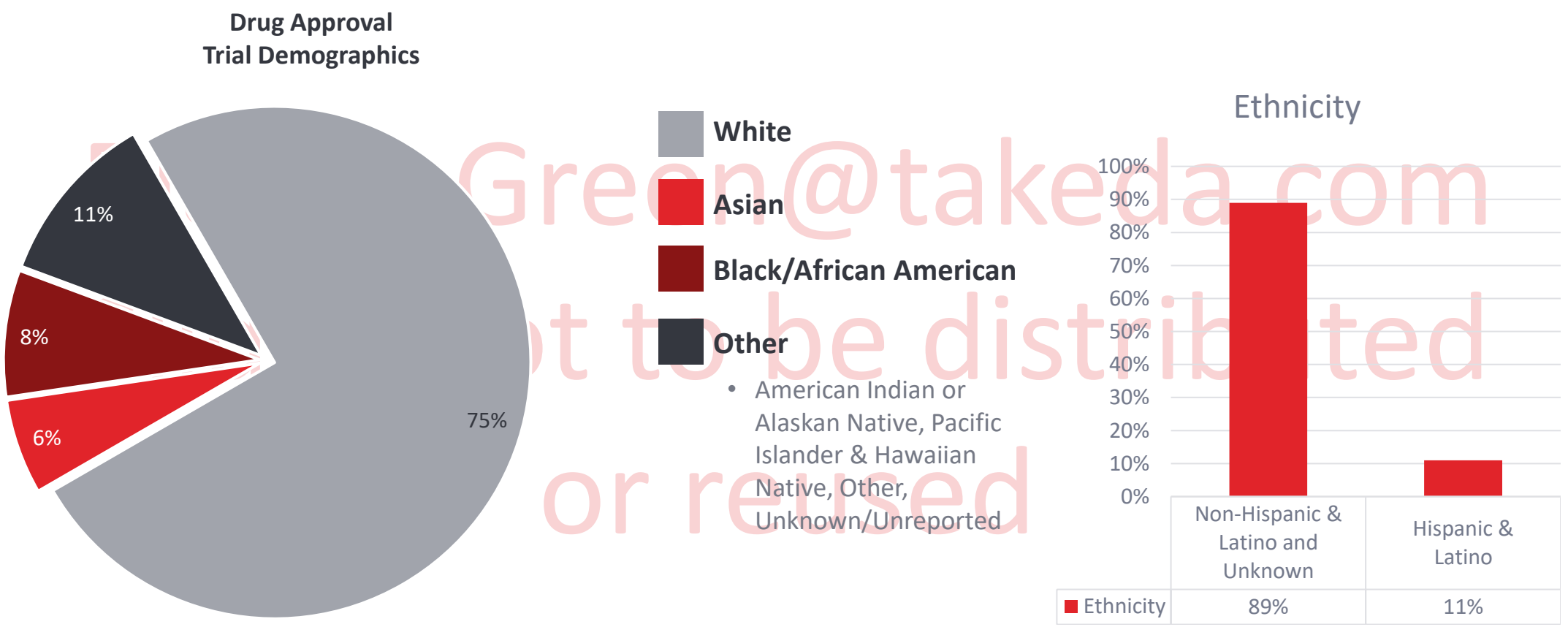
FDA Public Workshop

FDA held a public workshop, *Discussing Approaches to Enhance Clinical Study Diversity*, in November 2023 that fulfilled the FDORA requirement. The workshop was held in consultation with sponsors, medical device manufacturers, patients, and other stakeholders to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical studies

FDA Disclosure to Congress

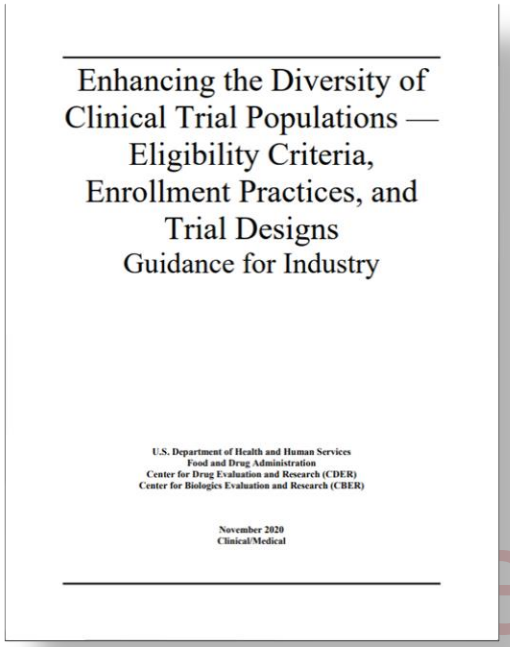
Within two years of enactment FDA must submit to Congress, and publish on the public website of FDA, a **report that summarizes information related to the diversity action plans** received pursuant to Section 505(z) or 520(g)(9) of the Federal Food, Drug, and Cosmetic Act

FDA Drug Trial Snapshots 2020 Reporting



*2020 data for 53 approved products, 32,000 participants; Global data with 54% of the participants coming from the US

Final FDA Guidance on Diversity Action Planning


Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs
Guidance for Industry

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)

November 2020
Clinical/Medical

Final Guidance Document


U.S. FOOD & DRUG ADMINISTRATION

Guidance Snapshot

Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs
Final Guidance

What is recommended in the guidance?

This guidance discusses approaches that sponsors can take to increase enrollment of underrepresented populations in clinical trials that are intended to support a new drug application or a biologics license application. It also discusses representing demographic and non-demographic characteristics[1] in study populations. This guidance provides recommendations on the following:

1. Broadening eligibility criteria and avoiding unnecessary exclusions in clinical trials to increase diversity in enrollment
2. Designing trials that are accessible
3. Adopting enrichment strategies
4. Applying the recommendations for broadening eligibility criteria to clinical trials of drugs intended to treat rare diseases or conditions

Why is clinical trial diversity important?

Enrolling participants with a wide range of baseline characteristics may create a study population that more accurately reflects the patients likely to take the drug, if approved. It also may uncover differences by demographic and non-demographic characteristics that maybe important for safe and effective use of the investigational drug.

[1]Demographic characteristics are considered characteristics such as sex, race, ethnicity, age, location of residency, while non-demographic characteristics are considered patients with organ dysfunction, comorbid conditions, disabilities, those at the extremes of the weight range, and populations with diseases or conditions with low prevalence.

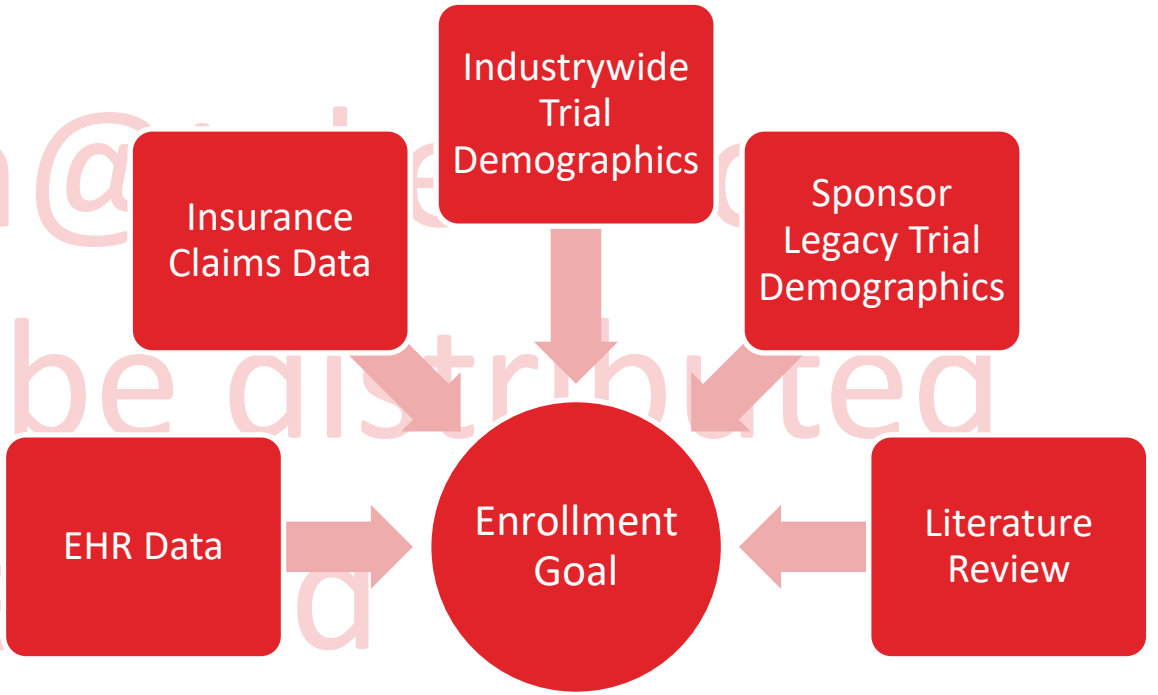
www.fda.gov

Guidance Snapshots are a communication tool and are not a substitute for the guidance document. To learn more about enhancing the diversity of clinical trials, read the guidance.

Final Guidance Snapshot

- **Overview of the Disease/Condition**
  Describe pathophysiology of disease along with similarities and differences in underrepresented populations. Demographics in the overall population with the disease are used if sufficient literature or RWD is not available.
- **Scope of medical product development program**
  Outline planned trials, the study design, population and geographic locations. Also summarize pharmacogenetic differences associated with certain racial & ethnic groups.
- **Goals for enrollment of underrepresented racial and ethnic participants**
  Define and provide justification for planned enrollment.
- **Specific Plan of action to enroll and retain diverse patients**
  Describe strategies to enroll and retain diverse participants.
- **Status of meeting enrollment goals**
  Describe metrics to ensure diverse participant enrollment goals are achieved.

How Enrollment Goals are Derived



What are Sponsors Already Doing?

Feasibility

Site Engagement

Diverse PIs

Community Engagement

Patient Recruitment & Retention

Barriers

- Language
- Cultural Nuance
- Socioeconomics
- Health Literacy
- Investigator Bias
- Awareness

Addressing Barriers

Hold clinical trial & general disease educational events to foster trust.

Provide culturally competent & sensitive clinical research and recruitment materials.

Find out what patients need when designing a clinical trial.

Consider completing cultural competency and sensitivity training & don't make assumptions.

Look beyond national patient advocacy organizations & make sure the organizations have diverse boards and or members.

Consider non-traditional research sites or principal investigators.

Key Takeaways

1

Clinical Research diversity is about making trials more accessible for everyone to be included. This leads to a better drug or therapy.

2

Think about how you are strategically addressing barriers to impact trial diversity.

3

Think about one thing you have power to change.

Questions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