Diversity in CNS Clinical Trials

Carla M. Canuso M.D.

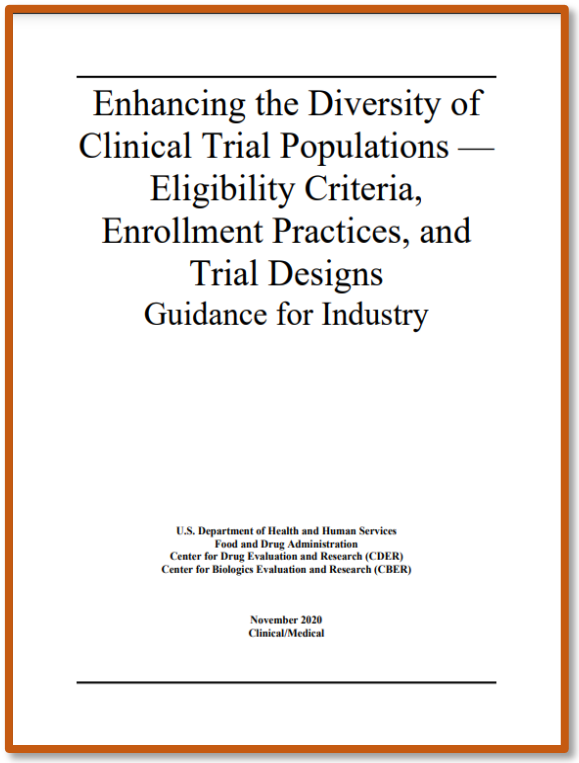
Disclosures

- Full-time employee of Johnson & Johnson (J&J)
- Shareholder of J&J Stock

ISCTM Diversity-Related Sessions & Working Groups

- 2019 Comment on FDA Guidance - Enhancing Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices and Trial Designs (Hoffmeyer, Mahableshwarkar)
- 2020 Autumn Conference Social Hour - Understanding and responding to diversity issues in clinical research methods (Mahmoud, Canuso)
- 2021 Autumn Conference - Applications of Lessons Learned from 2020: Diversity in CNS clinical trials (Canuso, Sanacora, Starr)
- 2024 20th Annual Scientific Meeting - Diversity in CNS Clinical Trials Working Group (Pratap, Ratcliffe)

Recent FDA Guidance

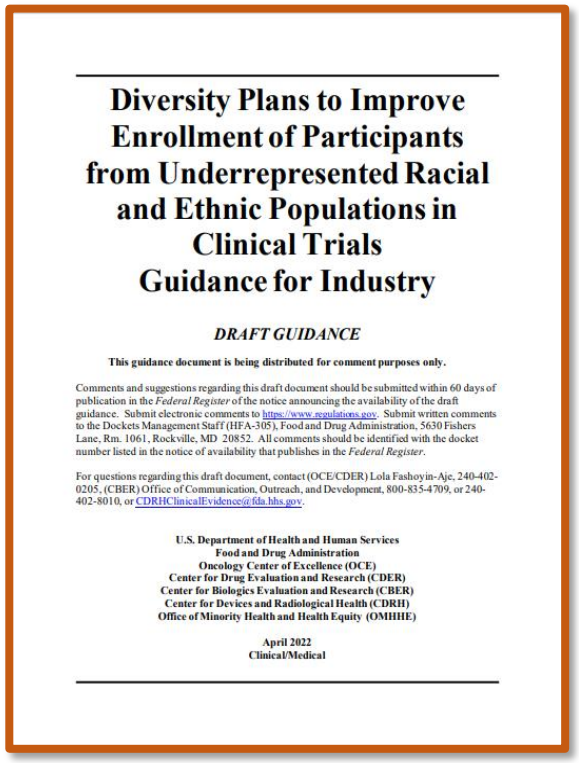


Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs

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



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

DRAFT GUIDANCE

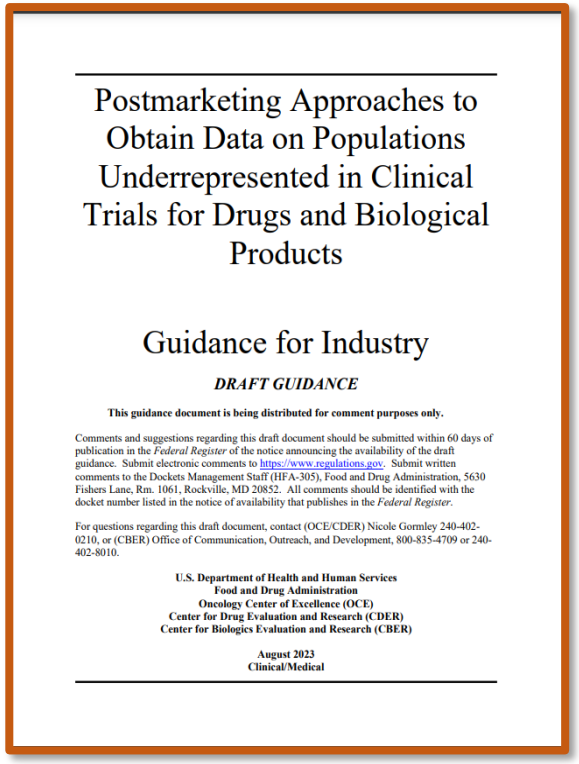
This guidance document is being distributed for comment purposes only.

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be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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 (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDRHClinicalEvidence@fda.hhs.gov.

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



Postmarketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products

Guidance for Industry

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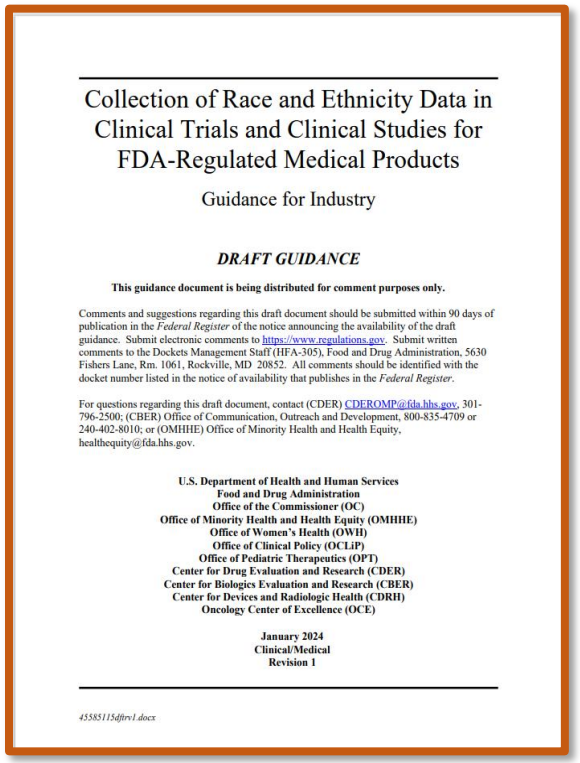
U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

August 2023
Clinical/Medical



Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products

Guidance for Industry

DRAFT GUIDANCE

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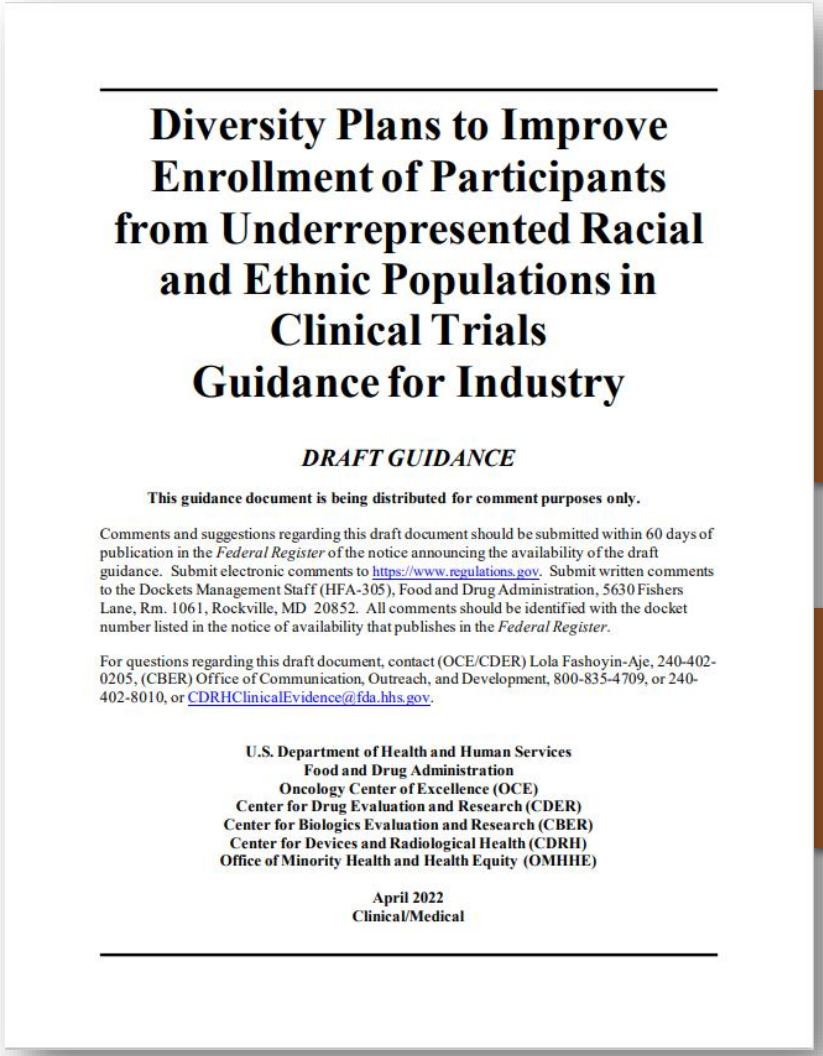
For questions regarding this draft document, contact (CDER) CDEROMP@fda.hhs.gov, 301-796-2500; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (OMHHE) Office of Minority Health and Health Equity, healthequity@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Office of Minority Health and Health Equity (OMHHE)
Office of Women's Health (OWH)
Office of Clinical Policy (OCLiP)
Office of Pediatric Therapeutics (OPT)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health (CDRH)
Oncology Center of Excellence (OCE)

January 2024
Clinical/Medical
Revision 1

4558115dftrv1.docx

Diversity Plan in Clinical Studies Guidance



Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials
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April 2022
Clinical/Medical

..as soon as practicable during drug development but no later than when sponsor seeking feedback regarding pivotal trial(s) (e.i.EOP2)

Plan should include recommended elements

Disease Overview

Provide data on pathophysiology of disease or condition in underrepresented racial and ethnic populations.

Development Program Scope

Describe the planned trails/ studies that will support the medical product's safety, effectiveness and, if a drug, dosage in a future martketing submission.

Enrollment Goals

Define and provide justification for the planned enrollment of participants from underrepresented racial and ethnic populations.

Measurements to Achieve Goals

Provide detail of operational measures that will be implemented to enroll and retain underrepresented racial and ethnic participants.

Status of meeting enrollment goals

FDORA: Authority to Require Diversity Action Plans

> *"Pertaining to the sponsor's goals for clinical study enrollment, disaggregated by **age group, sex,** and **racial and ethnic** demographic characteristics of clinically relevant study populations, and may include characteristics such as **geographic location and socioeconomic status…**"* Section 3602, Food and Drug Omnibus Reform Act (FDORA) of 2022

Additional groups that could potentially be added:

- LGBTQIA+ inclusion - sexual orientation and gender identity
- Pregnancy & lactation

- Revised **Diversity Action Plan Guidance** is expected to be released in the coming days.
  - Update to the guidance will reflect learnings from diversity plan submissions with considerations for the stated groups above.
  - Criteria for assessing whether to grant a diversity action plan waiver.
  - Expected consistencies with April 2022 draft guidance include:
    - Diversity plan based on US prevalence/ incidence
    - Participation and analysis of data from subpopulations will be a source for useful information that pertains to the safety and effectiveness for product labeling.

What Is Needed To Ensure Diverse and Representative Trial Populations?

Increased Trust & Awareness Among Disproportionately Impacted Communities

Increased Screening, Enrollment & Retention of Diverse Participants

Diversified Site Footprint & De-Centralized Trials

Reduced Diversity Data Gap through Pre-Competitive Collaboration

Demonstrated Commercial Value of Health Equity

Strategic Planning Frameworks and Tools Adopted Across Industry