Report to Congress

Diversity Action Plans Summary

FY 2023 and FY 2024

Executive Summary

In April 2022, the U.S. Food and Drug Administration (FDA) published a draft guidance to support sponsors in developing Diversity Plans for clinical trials. This draft guidance was designed to improve the enrollment of participants from underrepresented racial and ethnic populations in clinical studies, to help improve the strength and generalizability of the evidence from studies for the populations in which medical products are intended for use.

Following this, the Consolidated Appropriations Act, 2023, which included the Food and Drug Omnibus Reform Act (FDORA), amended the Federal Food, Drug, and Cosmetic Act to require the submission of a "Diversity Action Plan" for specific clinical studies, including phase 3 drug trials and certain device investigations. In June 2024, FDA published a draft guidance titled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies."[1] The requirement to submit Diversity Action Plans will apply to certain studies for which enrollment commences after 180 days from the publication of the final guidance.

Although the Diversity Action Plan submission requirement has not yet come into effect, FDA has received voluntary diversity plans for some clinical studies conducted between October 1, 2022, and September 30, 2024, and this report summarizes those submissions.

[1] https://www.fda.gov/media/179593/download.

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I. Introduction

In April 2022, the U.S. Food and Drug Administration (FDA) published a draft guidance, "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials."[1] The purpose of this guidance was to help improve the strength and generalizability of the evidence produced in clinical trials for the populations for which medical products are intended, by providing recommendations to sponsors developing medical products on the approach for developing a Diversity Plan to enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States in clinical trials. FDA has received voluntary diversity plans that reflect sponsors' proposals to improve the enrollment of participants from underrepresented racial and ethnic populations in clinical trials.

On December 29, 2022, the Consolidated Appropriations Act, 2023, which included the Food and Drug Omnibus Reform Act of 2022 (FDORA) was enacted.[2] FDORA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require submission of a "Diversity Action Plan" for:

- A clinical investigation of a new drug that is a phase 3 study (as defined in 21 CFR 312.21), or as appropriate, another pivotal clinical study of a drug (other than a bioavailability or bioequivalence study).

- A device for which submission of an application for an investigational device exemption (IDE) is required.

- A device for which submission of an application for an IDE is not required (except for a device being studied under 21 CFR 812.2(c)) and where a premarket notification under section 510(k), request for classification under section 513(f)(2), or application for premarket approval under section 515 is submitted.

A Diversity Action Plan must include:

- The sponsor's goals for enrollment in the clinical study.
- The sponsor's rationale for such goals.
- An explanation of how the sponsor intends to meet such goals.

In addition, section 3604 of FDORA requires that FDA annually submit to Congress, and publish on the Agency's public website, a report that summarizes in the aggregate (1)

[1] https://www.fda.gov/media/157635/download.

[2] Public Law 117-328.

the Diversity Action Plans received and (2) whether for drugs, biological products, and devices approved, licensed, cleared, or classified, the clinical studies conducted with respect to those applications met the demographic enrollment goals contained in the Diversity Action Plans and the reasons provided, if any, for why the enrollment goals were not met. Given that Diversity Action Plans are not yet required, as discussed below, there are no drugs, biological products, or devices that have been approved or licensed during fiscal years (FYs) 2023 and 2024 subject to reporting under section 3604 of FDORA.

In June 2024, FDA published a draft guidance titled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies," which replaced the April 2022 draft guidance described above.[3] The intent of this guidance is to improve the strength and generalizability of evidence produced in clinical trials, by assisting sponsors conducting certain clinical studies involving drugs, biological products, and devices to meet requirements for the submission of Diversity Action Plans under section 505(z) and section 520(g)(9) of the FD&C Act as added by section 3601 of FDORA. Sections 505(z) and 520(g)(9) of the FD&C Act require that sponsors submit a Diversity Action Plan that specifies goals for clinical study enrollment, and FDORA states that such goals must be disaggregated by the race, ethnicity, sex, and age group demographic characteristics of the clinically relevant population.[4] The requirement to submit Diversity Action Plans will apply to certain studies for which enrollment commences after 180 days from the publication of the final guidance.

Although the requirement to submit Diversity Action Plans has not yet commenced, this report highlights that certain sponsors have initiated the process of preparing and submitting diversity plans. In this report, the term "diversity plans" refers to the plans received during FY 2023 and FY 2024, which are not required to be submitted under FDORA and therefore are not referenced as "Diversity Action Plans." This summary report focuses on those diversity plans that FDA has received for certain clinical studies regarding drugs, biological products, and devices subject to section 505, 515, 510(k), 513(f)(2), or 520(g) of the FD&C Act (21 U.S.C. 355, 360e, 360(k), 360(f)(2), and 360j(g), or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), that have been submitted to the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH), respectively, for FYs 2023 and 2024 (from October 1, 2022, through September 30, 2024).

Given that Diversity Action Plans are not yet required, there are no drugs, biological products, or devices that have been approved or licensed during FYs 2023 and 2024 subject to reporting under section 3604 of FDORA. Instead, this summary report

[3] https://www.fda.gov/media/179593/download.

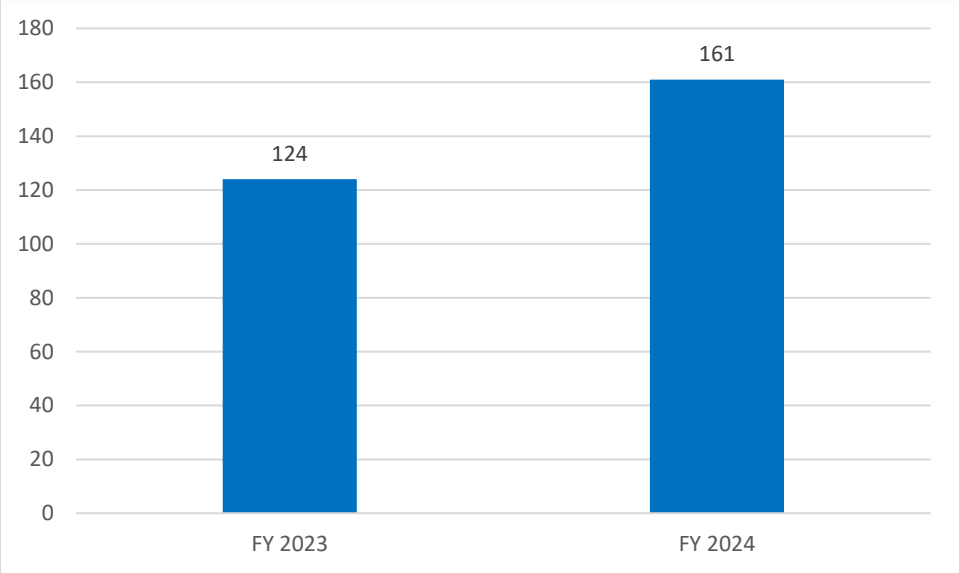
[4] Sections 505(z)(2) and 520(g)(9)(B) of the FD&C Act (21 U.S.C. 355(z)(2) and 360j(g)(9)(B)); see also section 3602 of FDORA.

includes voluntary diversity plans that were received by CDER, CBER, and CDRH from October 1, 2022, through September 30, 2024. The number of diversity plans received by each of these Centers during FYs 2023 and 2024 is described below.

1. Center for Drug Evaluation and Research

As shown in Table 1, CDER received 124 diversity plans in FY 2023 and 161 diversity plans in FY 2024.

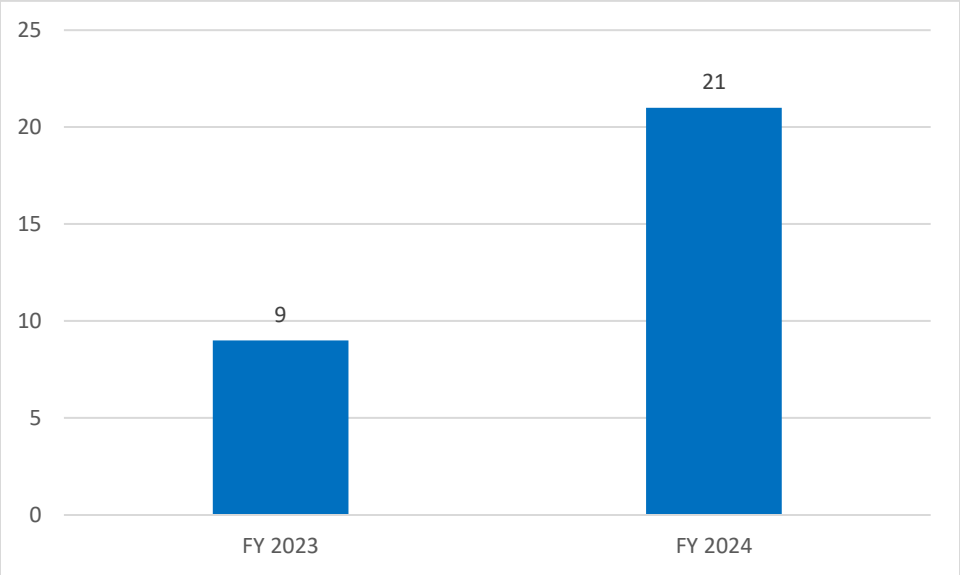
Table 1. Number of Diversity Plans Received by CDER During FYs 2023 and 2024



2. Center for Biologics Evaluation and Research

As shown in Table 2, CBER received 9 diversity plans in FY 2023 and 21 diversity plans in FY 2024.

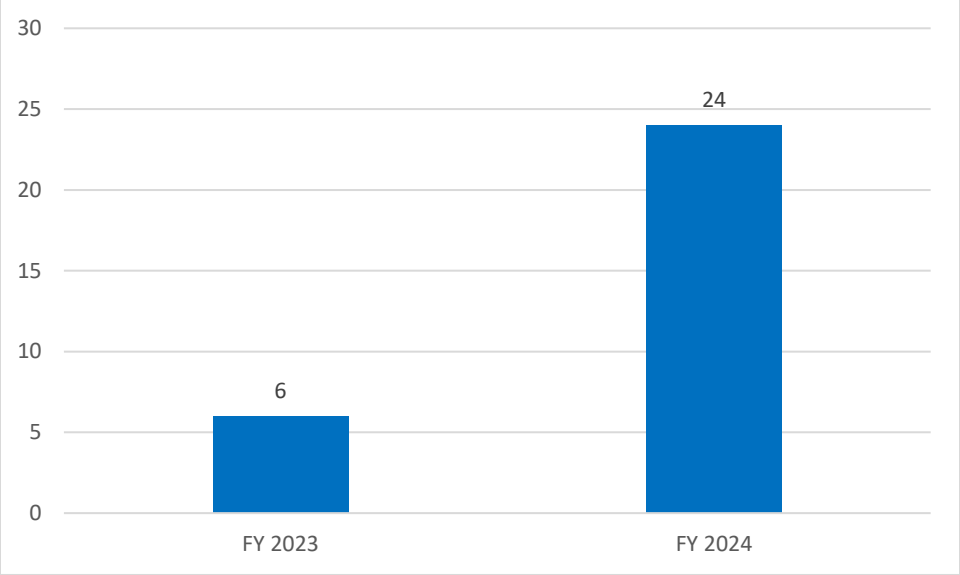
Table 2. Number of Diversity Plans Received by CBER During FYs 2023 and 2024



3. Center for Devices and Radiological Health

As shown in Table 3, CDRH received 6 diversity plans in FY 2023 and 24 diversity plans in FY 2024.[5]

Table 3. Number of Diversity Plans Received by CDRH During FYs 2023 and 2024



[5] These data focus on diversity plans received by CDRH in investigational device exemption applications (21 CFR 812.20(a)), premarket notifications (section 510(k) of the FD&C Act), requests for classification (section 513(f)(2) of the FD&C Act), applications for premarket approval (section 515 of the FD&C Act), and pre-submissions.

II. Conclusion

The Agency has a longstanding commitment to promoting the inclusion of underrepresented populations in clinical trials to help improve the generalizability of results to populations for which the products being studied are intended. Enhancing diversity within clinical studies not only facilitates broader applicability of results across a broad spectrum of patient populations but also enhances understanding of the disease or medical product under study, thus providing valuable insights to inform the safe and effective use of the medical product among patients. Although Diversity Action Plans are not yet mandatory, this report highlights that certain sponsors have initiated the process of preparing and submitting voluntary diversity plans. FDA is working to finalize the draft Diversity Action Plans guidance and is committed to encouraging representative participation in and access to clinical studies used to support marketing applications for regulated medical products.

This report was prepared by FDA's Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health. For information on obtaining additional copies, please contact:

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