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FDA Issues Overdue Guidance on Diversity Action Plans in Drug and Device Clinical Trials – What You Need to Know

This update provides key takeaways on the new draft guidance and Diversity Action Plan requirements, including when the new requirements will go into effect, the types of clinical studies that require submission of a Diversity Action Plan, whether FDA intends to issue waivers for the requirements, and the consequences of failure to submit a Diversity Action Plan.

On June 26, 2024, FDA released its long-awaited draft guidance on Diversity Action Plans to increase enrollment of underrepresented populations in clinical trials of drugs and devices.[1] The highly anticipated guidance comes months after FDA's statutory deadline for issuance of the guidance in December 2023.[2] The draft guidance reflects new congressional mandates and replaces FDA's 2022 draft guidance on diversity plans.[3] The statutory requirement for drug and device sponsors to submit Diversity Action Plans will go into effect 180 days after FDA publishes a final guidance.[4] Failure to comply with Diversity Action Plan submission requirements is a prohibited act under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and could result in civil or criminal penalties.[5]

In April 2022, FDA released draft guidance recommending that sponsors of drugs and devices develop and submit Diversity Plans for clinical trials. In December 2022, Congress passed the Food and Drug Omnibus Reform Act (FDORA), which amended the FD&C Act to require the submission of Diversity Action Plans for certain drugs and devices.[6] This provision goes into effect 180 days after the publication of final guidance.[7]

FDA has described Diversity Action Plans as strategies for the enrollment and retention of clinically relevant study populations.[8] The new draft guidance describes the format and content of Diversity Action Plans, including the timing and process for submitting and receiving feedback on such plans. The guidance also outlines the criteria and process for FDA evaluation of requests for waivers of Diversity Action Plan requirements. Finally, the guidance provides recommendations for sponsors that publicly post information about their Diversity Action Plans.

Interested parties may submit comments on the draft guidance by September 26, 2024.[9] FDA is required to issue final guidance not later than June 2025 (9 months after the comment period closes on the draft guidance).[10] Sponsors of clinical trials for drugs and devices should monitor developments in this area, and work to ensure their clinical trial submissions meet these new standards.

When do the new Diversity Action Plan requirements go into effect?

The new Diversity Action Plan requirements will take effect 180 days after publication of final guidance and will apply to clinical trials for which enrollment begins after that date. However, because sponsors plan clinical trials in advance of enrollment, FDA provides in the new draft guidance three circumstances in which the agency does not expect submission of a Diversity Action Plan:

- Clinical studies of drugs with protocols submitted within 180 days after publication of the final guidance, when enrollment is scheduled to begin 180 days after publication;
- Clinical studies of devices received by FDA in investigational device exemption (IDE) applications within 180 days after publication of the final guidance; or
- Clinical studies of devices that do not require submission of an IDE that are approved by an institutional review board or independent ethics committee within 180 days after publication of the final guidance.[11]

In these circumstances, there will continue to be a legal requirement to submit a Diversity Action Plan but, as indicated in the new draft guidance, FDA does not intend to take action to enforce that requirement.

What categories of study subjects must be included in a Diversity Action Plan?

Diversity Action Plans are not required to include any particular demographics. Under Sections 505(z) and 520(g)(9) of the FD&C Act, sponsors must submit Diversity Action Plans that include goals for clinical study enrollment. FDA encourages sponsors to list enrollment goals for race, ethnicity, sex, and age group in Diversity Action Plans. If goals for race, ethnicity, sex, and age group are listed in a Plan, Section 3602 of FDORA requires that each of those goals be disaggregated.

FDORA also requires that FDA issue guidance on the inclusion in Diversity Action Plans of certain categories of study subjects (i.e., age group, sex, race, and ethnicity) and provides that FDA “may include” guidance on other characteristics of study subjects (e.g., geographic location, socioeconomic status).[12] In the new draft guidance, FDA encourages sponsors to consider additional factors when developing enrollment goals, including geographic location, gender

identity, sexual orientation, socioeconomic status, physical and mental disabilities, pregnancy, lactation, and comorbidity.

What types of clinical studies require submission of a Diversity Action Plan?

For drugs (including biologics regulated as drugs), sponsors conducting a Phase III study, or another pivotal study, must submit a Diversity Action Plan to FDA by the time they submit their study protocol.

For devices, sponsors must submit a Diversity Action Plan for any clinical study of a device:

- in an application for an investigational device exemption (IDE); or
- if an IDE is not required, in any premarket notification under Section 510(k) of the FD&C Act, request for *de novo* classification under Section 513(f)(2), or application for premarket approval under Section 515.[13]

Notwithstanding this statutory requirement, FDA explains in the new draft guidance that, because Diversity Action Plans may not be meaningful for certain device studies, the agency does not intend to receive or review Diversity Action Plans for device studies that are not designed to collect definitive evidence of the safety and effectiveness of a device for a specified use.[14]

In addition, although not a requirement, FDA strongly recommends that sponsors develop and implement a comprehensive diversity strategy across their entire clinical development program, including early studies, when possible.[15]

What information must be included in Diversity Action Plans?

Under Section 505(z) and 520(g)(9) of the FD&C Act, sponsors must include the following criteria in Diversity Action Plans:

- **Goals for enrollment**, disaggregated by age group, sex, race, and ethnicity;
- **A rationale for enrollment goals**; and
- **An explanation of how the sponsor intends to meet such goals**

In the new draft guidance, FDA states that, to meet the statutory requirement for inclusion of a rationale for enrollment goals, a sponsor's rationale must include sufficient information and analysis to explain how the sponsor determined its enrollment goals and provides detailed recommendations on information the rationale should include.[16] On measures to meet enrollment goals, FDA recommends that Diversity Action Plans include enrollment, retention, and monitoring strategies.[17] A Diversity Action Plan may be modified either at the sponsor's request or based on FDA feedback.[18]

As required under FDORA, Diversity Action Plans must include a sponsor's goals for enrollment, its rationale for such goals, and an explanation of how the sponsor intends to meet such goals.[19] FDORA directs FDA to issue updated guidance for sponsors on the form, manner, and content of Diversity Action Plans. Of note, sponsors are required to submit Diversity Action Plans

in the “form and manner” specified by FDA in guidance. As such, though FDA guidance is typically nonbinding, once final, provisions in FDA guidance pertaining to the form and manner (i.e., process) of submission for Diversity Action Plans will have binding effect on drug and device sponsors.[20] Any FDA recommendations as to the content of Diversity Action Plans will not be binding.

Will FDA issue waivers for the Diversity Action Plan requirements?

The new draft guidance includes information on waivers for the Diversity Action Plan requirement, including eligibility criteria and FDA’s process of review. FDORA authorizes FDA to waive the submission and content requirements for Diversity Action Plans, if FDA determines:

- A waiver is necessary based on what is known or can be determined about the prevalence or incidence of the disease or condition for which the product is under investigation (including in terms of the patient population that may use the product);
- Conducting a clinical investigation in accordance with a Diversity Action Plan would otherwise be impracticable; or
- A waiver is necessary to protect public health during a public health emergency.[21]

However, FDA notes that, given the importance of increasing enrollment of historically underrepresented populations in clinical research, **full or partial waivers will be granted only in “rare instances.”**[22] For example, FDA states that it generally does not intend to waive the Diversity Action Plan requirement even if the disease or condition being studied is “relatively homogenous with respect to race, ethnicity, sex, or age group.”[23] Because FDA is required to respond to a waiver request within 60 days of receipt, sponsors should submit waiver requests as early as feasible, and no later than 60 days before the Diversity Action Plan is required for submission.[24]

What are the consequences for failure to submit a Diversity Action Plan?

As discussed above, under sections 505(z) and 520(g)(9) of the Federal Food, Drug, and Cosmetic Act, submission of a Diversity Action Plan is required for certain clinical studies for drugs and devices. A Diversity Action Plan must include the sponsor’s goals for enrollment, rationale for such goals, and an explanation of how the sponsor intends to meet such goals. The Plan must be submitted in the form and manner specified by FDA in guidance, not later than, for drugs, the date on which the sponsor submits the protocol to FDA for a Phase III or other pivotal study, and for devices, in an investigational device exemption or, if an investigational device exemption is not required, in any premarket notification under section 510(k), request for classification under section 513(f)(2), or application for premarket approval under section 515. Any modifications to the Plan must be in the form or manner specified by FDA in guidance.

Failure to comply with these Diversity Action Plan statutory requirements constitute a prohibited act under the FFDCA. For drugs, it is a prohibited act under Section 301(d) of the FFDCA to introduce or deliver for introduction, or cause the introduction or delivery for introduction, into interstate commerce any drug in violation of Section 505, including Section 505(z). For devices, it is a prohibited act under 301(q)(1) to fail or refuse to comply with any

requirement prescribed under Section 520(g), or to fail or refuse to furnish any notification or other material or information required by or under 520(g).

FDA's new draft guidance does not discuss consequences for failure to comply with the new Diversity Action Plan statutory requirements. The absence of information in the draft guidance on enforcement mechanisms for failure to comply with the Diversity Action Plan requirements signals that, at this time, FDA is looking to encourage compliance on the part of drug and device sponsors, as opposed to appearing enforcement focused. This approach may change in the final guidance, given strong stakeholder interest in this issue.

Notably, there is no requirement that a sponsor meet the goals outlined in a Diversity Action Plan. FDA notes in the new draft guidance that if such goals are not being met or not expected to be met at the conclusion of a trial, sponsors should include as part of applicable periodic reporting requirements (e.g., investigational new drug application (IND) or IDE annual reports) an explanation for that outcome and mitigation strategies.[25]

[1] FDA, Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies: Draft Guidance for Industry (June 2024) (hereinafter referred to as "Guidance").

[2] *See* Section 3602(b) of the Food and Drug Omnibus Reform Act of 2022 (FDORA), passed as part of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, 136 Stat. 4459 (2023).

[3] FDA, Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability (April 2022).

[4] *See* Section 3602(c) of FDORA. This submission requirement applies only with respect to clinical studies for which enrollment begins after 180 days after the publication of final guidance.

[5] See Sections 505(z)(3), 520(g)(9) of the Federal Food, Drug, and Cosmetic Act; see also Sections 301(d), (q)(1), 303 of the FD&C Act.

[6] *See* Section 3601 of FDORA.

[7] *See* Section 3602(c) of FDORA. This submission requirement applies only with respect to clinical studies for which enrollment begins after 180 days after the publication of final guidance.

[8] FDA Notice of Availability: Draft Guidance on Diversity Action Plans, 89 Fed. Reg. 54010 (June 28, 2024).

[9] 89 Fed. Reg. 54010, 54011 (June 28, 2024).

[10] *See* Section 3602(b)(2) of FDORA.

[11] Guidance at 2.

[12] *See* Section 3602(a) of FDORA.

[13] Sponsors of devices being studied as described in section 21 CFR 812.2(c) are not required to submit Diversity Action Plans. See 520(g)(9)(A)(ii).

[14] Guidance at 6-7.

[15] Guidance at 7.

[16] Guidance at 22-23.

[17] Guidance at 23.

[18] Guidance at 18.

[19] See Sections 505(z)(2), 520(g)(9)(B).

[20] 89 Fed. Reg. 54010 (June 28, 2024).

[21] *See* Sections 505(z)(4), 520(g)(9)(C).

[22] Guidance at 20.

[23] Guidance at 20.

[24] Guidance at 20.

[25] Guidance at 19.

The following Gibson Dunn lawyers assisted in preparing this update: Katlin McKelvie and Carlo Felizardo.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding the issues discussed in this update. Please contact the Gibson Dunn lawyer with whom you usually work, the authors, or any leader or member of the firm's FDA and Health Care practice group:

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