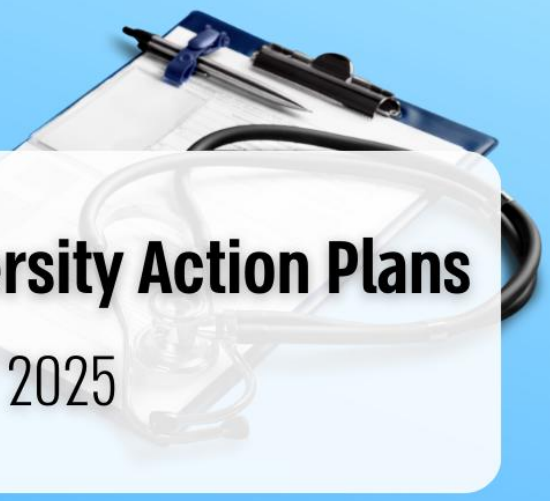
AGMON with TULCHINSKY



FDA Guidance - Clinical Trial Diversity Action Plans

Client Update - January 2025

Dear clients,

Last July, the FDA issued draft guidance on Diversity Action Plans, replacing its 2022 draft guidance (click here for the full draft guidance). The stated purpose of Diversity Action Plans is to increase enrollment of underrepresented populations in clinical trials of drugs and medical devices, in order to improve the generalizability of study results and to detect clinically important differences across populations. Final guidance is expected to be published later this year, and the requirement to submit Diversity Action Plans as part of a sponsor's clinical trial package is expected to be implemented from early 2026. Clinical study sponsors should therefore begin preparing accordingly.

The requirement will apply to applicable clinical trials for which enrollment begins after the Diversity Action Plan requirement comes into effect, with some exceptions. Once in effect, failure to comply with Diversity Action Plan submission requirements could result in civil or criminal penalties in the US.

The draft guidance outlines the FDA's expectations regarding the types of clinical studies for which a Diversity Action Plan is required as well as the format, content, and process for submitting such Plans to the FDA.

What is a Diversity Action Plan and what should it include?

Diversity Action Plans are plans that seek to increase clinical trial enrollment of populations that have historically been underrepresented in clinical studies, and are required to state:

1. a sponsor's goals for diverse clinical study enrollment – in terms of race, ethnicity, sex and age group
2. the rationale for these goals, and
3. an explanation as to how the sponsor intends to meet the stated goals.

According to the draft guidance, enrollment goals should primarily be informed by the estimated prevalence of the relevant disease in the intended use population.

Diversity Action Plans are not required to include any particular categories of study subjects, however in the recent draft guidance, FDA encourages sponsors to consider additional factors when developing enrollment goals, in addition to those stated above, including geographic location, gender identity, sexual orientation, socioeconomic status, physical and mental disabilities, pregnancy, lactation, and comorbidity.

The FDA also recommends that Diversity Action Plans include enrollment, retention and monitoring strategies as part of the description on how sponsor intends to meet its stated goals. The draft guidance encourages sponsors to consider utilizing a number of different strategies to meet enrollment diversity goals, including improving access to the clinical study through site location, language assistance, modifications for persons with disabilities and transportation assistance, selecting study sites that serve demographically diverse populations and using a decentralized study design.

Diversity Action Plans are expected to be succinct, generally not exceeding 10 pages in length, excluding references.

Which types of trials will require a Diversity Action Plan, and what are the submission deadlines?

For pharma studies (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 medical device studies, sponsors must submit a Diversity Action Plan for any clinical study of a medical 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.

other than where such studies are not designed to collect definitive evidence of the safety and effectiveness of the device for a specified use

Also, although not required, the FDA recommends that sponsors develop and implement a comprehensive diversity strategy across their entire clinical development program, including early studies, when possible.

Diversity Action Plan Requirement Waivers

The FDA may waive the submission and content requirements for Diversity Action Plans, if it determines that a waiver is necessary given the prevalence or incidence of the disease or condition for which the product is under investigation; if conducting the study per a Diversity Action Plan would be impractical, or in the case of a public health emergency.

However, the FDA notes that full and partial waivers will only be granted in "rare instances", given the importance of increasing enrollment of historically underrepresented populations in clinical research. Requests for waiver should be submitted at least 60 days before the Diversity Action Plan is required to be submitted.

Consequences of failure to submit or comply with a Diversity Action Plan.

Failure to comply with these Diversity Action Plan statutory requirements constitutes a prohibited act under the US Federal Food, Drug, and Cosmetic Act, although neither the enabling statute nor the guidance itself provides any details on enforcement penalties for sponsors who fail to comply with the requirements.

In addition, presently there are no stated consequences for a sponsor that fails to meet its stated enrollment target, however if such targets are not being met or not expected to be met, the sponsor is encouraged to include an explanation as to the reasons therefor and mitigation strategies in its periodic report.

We advise clinical trial sponsors to monitor developments in this area, and work to ensure their relevant clinical trial submissions meet these new requirements.

The information provided in this client update is for general informational purposes only and should not be construed as legal advice or a substitute for professional legal counsel.

Adv. Yifat Tsafrir, Partner
Head of the Commercial Law Department
Yifatt@agmon-law.co.il

Adv. Lana Tavor, Partner
High-Tech, Technology and Venture Capital Department
Lanat@agmon-law.co.il

Adv. Saar Rosman, Partner
High-Tech, Technology and Venture Capital Department
Head of Privacy and Cyber Law Practice
Saar@agmon-law.co.il

Adv. Miriam Sade Fischer, Partner
High-Tech, Technology and Venture Capital Department
Miriamf@agmon-law.co.il