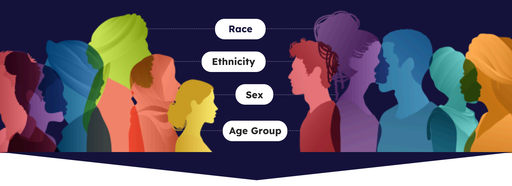
# Diversity Action Plans: What US FDA Is Expecting and When

## Enrollment goals disaggregated by:

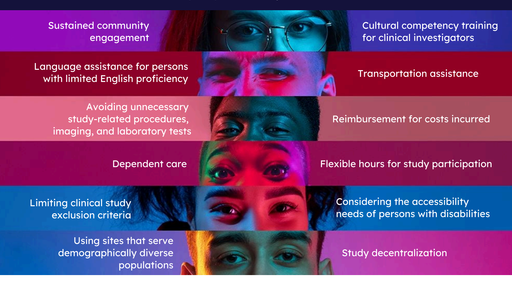



## Rationale for Enrollment Goals, Including:

- Background information necessary to understand the disease, including prevalence and incidence estimates
- If multiple studies have different goals, how this contributes to the overall goal
- Available data regarding differences in PK, PD, safety, or effectiveness
- Data on other population-level or individual characteristics* that could have an impact on the clinical outcomes

* E.g., socioeconomic status, geographic location, comorbidities

## Measures to Meet Enrollment Goals. Examples provided by FDA include:




FDA expects the race and ethnicity definitions to be consistent with Office of Management and Budget standards

FDA also wants to see the sponsor's plan to monitor the goals, including how study enrollment will be assessed and any measures that may be undertaken should the sponsor determine that the study is not on track.

DAP should be no more than 10 pages, excluding references.

While the DAPs must look at the four enrollment goals specified in the statute, FDA said sponsors **"should also consider the potential that pregnant or lactating individuals with the condition or disease may use the medical product."**

CDER is expecting **200** DAPs annually.

CBER is expecting **40**.

## When to Submit Diversity Action Plans

### Required

Sponsors must submit a Diversity Action Plan with the protocol for a drug's pivotal study, but FDA recommends submission at the End-Of-Phase II meeting or whenever the pivotal protocol is being discussed.

### 6 Months

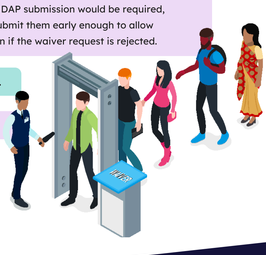
FDA is offering some leeway and will not expect plans for "studies of drugs with protocols submitted within 180 days following the publication of the final guidance where enrollment is scheduled to begin 180 days after publication of the final guidance."

## When to Seek a Waiver

FDA has 60 days to respond to a waiver request, so firms must submit requests at least 60 days before the DAP submission would be required, and sponsors would be prudent to submit them early enough to allow preparation of a diversity action plan if the waiver request is rejected.

CDER is expecting 4 waiver requests.

CBER is expecting 1 request a year.



## The Past and Future of FDA's Diversity Efforts

**April 14, 2022** — FDA issues draft guidance on "diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations in clinical trials"

**Dec. 29, 2022** — Food and Drug Omnibus Reform Act signed (FDORA) into law (requires sponsor to submit DAPs for pivotal studies and FDA to develop guidance)

**Nov. 29–30, 2023** — FDA workshop (mandated by FDORA)

**June 26, 2024** — Draft guidance on Diversity Action Plans released (nearly six months overdue)

**Sept. 26, 2024** — Comments due (Docket number FDA-2021-D-0789)

**June 26, 2025** — Guidance mandated to be final. (Statute says nine months from comment close, but FDA could miss this deadline as well.)

**Dec. 23, 2025** — Requirements go into effect (statute says 180 days after final guidance is issued)

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Source: Citeline