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Clinical Trial Diversity Action Plans Will Take 100 Hours to Prepare, US FDA Predicts

by Sue Sutter

The agency's Center for Drug Evaluation and Research (CDER) expects to receive 200 plans annually, with 40 plans expected to go to the biologics center.

Drug and biologic product sponsors will spend on average 100 hours to prepare and submit each clinical trial diversity action plan required under a 2022 law, the US Food and Drug Administration (FDA) estimates.

Each request for a waiver from the diversity action plan (DAP) requirement is expected to take 16 hours, according to a Federal Register *notice* related to a recent draft guidance on DAPs.

Under the 2022 Food and Drug Omnibus Reform Act, sponsors must submit a DAP for Phase III or other pivotal studies that specifies goals for enrollment disaggregated by race, ethnicity, sex, and age group demographic characteristics of the clinically relevant population.

The FDA released draft guidance in late June describing the format and content of DAPs, including the timing and process for submitting the plans and the agency's evaluation criteria and process for waiver requests. In addition to enrollment goals, plans must include the

Key Takeaways

- The FDA estimates that drug and biologic product sponsors will spend an average of 100 hours preparing and submitting each diversity action plan that is required under FDORA.
- Each waiver request is estimated to take 16 hours to prepare and submit.

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rationale for the goals and measures to accomplish them.

- CDER and Center for Biologics Evaluation and Research (CBER) expect to receive a total of 240 DAPs annually.

Enrollment goals generally should be informed by the estimated prevalence or incidence of the disease in the US intended use population, the guidance states. However, greater than proportional enrollment may be needed in some populations to identify potentially clinically important differences in responses between subsets.

DAPs should be succinct, generally running no more than 10 pages. Waiver requests should be filed early and only will be granted in rare instances, the FDA said.

Submission estimates

Action plans for drug and biological products must be submitted to the investigational new drug application and, in some cases, sent in eCTD format through the FDA's Electronic Submissions Gateway.

Based on the agency's experience with current IND submissions, the agency estimates it will receive 240 DAPS annually for the drug and biological programs. Most will go to CDER.

The agency estimates CDER will receive four waiver requests annually, while the Center for Biologics Evaluation and Research will receive one.

"We intend to revise the scope of the information collection to account for DAP submissions and waiver requests and to adjust our estimated burden for the activities in the relevant information collection after evaluating DAP submissions received," the agency said.

Open For Comments

The reporting burden estimates are open for comment until mid-September (Regulations.gov Docket #FDA-2024-N-1298). The FDA seeks comments on:

- Whether the proposed collection of information is necessary for the proper performance of the FDA's functions, including whether the information will have practical utility
- The accuracy of FDA's burden estimates, including methodology validity/assumptions used
- Ways to enhance the quality, utility and clarity of the information to be collected
- Ways to minimize the collection burden, including through automated collection techniques, when appropriate, and other forms of information technology.

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The notice does not include an estimate of the agency's estimated review time for each submission. Depending on the specifics of each clinical development program, the relevant division in CDER or CBER may or may not provide feedback on a DAP, the draft guidance states.

Experience under 2022 guidance

The FDA gained some experience reviewing diversity plans under an April 2022 draft guidance on enrolling representative numbers of participants from historically underrepresented racial and ethnic populations.

Sponsors submitted a total of 91 race and ethnicity diversity plans to CDER from April 2022 to April 2023. About 84% went to the oncology divisions.

The FDA provided feedback on 31 of the 76 oncology diversity plans. The average time from plan receipt to FDA sending comments was 61 days. Only a small proportion of plans that included FDA feedback were deemed acceptable.

The 2022 draft guidance did not require a collection of information, so no burden estimates were supplied at the time of its publication.

DAPs must be submitted for Phase III or other pivotal clinical trials of drugs or biologics where enrollment begins 180 days after publication of the agency's final guidance. FDORA directed the FDA to issue final guidance within nine months of the end of the comment period on the draft, which is 26 September. (Docket *FDA-2021-D-0789*)

The agency was six months late in issuing the draft, which was supposed to be released by December 2023, according to FDORA.

Diversity Action Plans - Annual Burden Estimates

The FDA estimates it will receive a total of 240 diversity action plans, and 5 waiver requests, for drug and biologic products annually.

Information Collection Activity	Number Of Respondents	Number Of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
CDER DAP Submission	146	1.37	200	100	20,000
CBER DAP Submission	35	1.14	40	100	4,000
Waiver Request CDER	4	1	4	16	72
Waiver Request CBER	1	1	1	16	16

Source: Federal Register notice