Clinical Research PATHWAYS

July 29, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-D-1264

To Whom It May Concern:

Thank you for the opportunity to provide comments on the draft guidance titled, Enhancing the diversity of Clinical Trial Population – Eligibility Criteria, Enrollment Practices, and Trial designs Guidance for Industry. We commend FDA for taking positive steps to increase diversity patient participation in clinical trials. Clinical Research Pathways is a tax-exempt nonprofit organization that works to increase access to new medicines through clinical trials and expanded access. Our signature program is to increase the number of minority physician investigators in order to increase the number of minority patients who enroll in clinical trials.

The draft guidance goes in the right direction by encouraging companies to use best practices to create the broadest possible inclusion criteria. This is particularly important where there is a known gap of the effect of race or ethnicity on drug metabolism. This is also the case with age at the extreme ends of the life spectrum, in children, especially the very young, and the very old.

We support the strategies put forth to ensure that trial practices, design, and methods are inclusive. Many companies already incorporate many of these strategies into their decision-making process when designing clinical trials. The guidance will provide assurance that FDA supports their efforts. For those companies that do not consider these strategies, the guidance should encourage them to consider them. We believe that the guidance is important to increasing inclusivity in clinical trials.

We offer the following comments for consideration:

1. The guidance references enhancing diversity in clinical trial populations but many of the strategies are aimed at increasing inclusivity among those populations who already enroll in trials by making trial inclusion criteria less stringent. Please consider adding more strategies to increase participation by “underrepresented populations” as stated in the introduction (line 24) by

increasing the number of minority individuals who enroll in trials; specifically, for African American, Latinos, and Asians.

2. Lines 132-133. Clarify the intention of including children (ages 2 to 11 years) and adolescents (ages 12 to 17 years) in confirmatory clinical trials involving adults when

appropriate. Is the intention simply to suggest that children be included in phase 3 effectiveness trials? How does this recommendation relate to the required pediatric study plan?

3. Lines 191 -203. There is no direct mention of race and ethnicity in this section. The burdens that are described are often disproportionately represented in certain underrepresented populations. On lines 194-195, specifically mention race and ethnicity.

4. Lines 234-243. Working directly with communities will help to ensure that trials are designed in a manner that addresses concerns and needs of the communities from whom sponsors wish to recruit patients. Community-based participatory research is a specific type of research design that might not be needed to gather information relevant to trial design. For example, focus groups or community advisory boards might be more efficient methods for obtaining input from the community.

5. Lines 245-249 Expand upon the ways that sponsors can identify appropriate geographic locations with a higher concentration of racial and ethnic minority patients. This could be accomplished by searching directly for health care providers with large minority patient populations. It means going beyond the usual list of clinical investigators and investigative sites. Encourage CROs to search for these types of sites and to include them in feasibility studies. Discourage the practice of adding minority sites at the end of the trial, when such rescue efforts often fail. Further, minority patients should be enrolled early in the trial so that the maximum amount of outcome data are collected. Include recommendations for training physicians and research staff to ensure that clinical investigators and their staff are culturally competent to enroll and retain minority patients in the trial for its duration.

6. Lines 269-278. This short section on expanded access does not belong in this guidance. It is not relevant and should be deleted.

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7. Lines 281-283. Section IV on rare diseases and conditions. Add to this section an emphasis on enrolling patients who represent minority groups. Rare diseases and conditions affect all segments of the populations. Because minority patients with a rare disease might be even more

challenging to find, encourage the use of the same strategies for trials practices, design and methods for trials on rare disease and conditions.

Please contact me if you have questions or want further information. Again, thank you for the opportunity to provide these comments.

Sincerely,

Marjorie A Speers, PhD
Executive Director