NATIONAL HEALTH COUNCIL

August 1, 2023

Robert M. Califf M.D., MACC Commissioner
United States Food and Drug Administration 5630 Fishers
Lane, Rm. 1061
Rockville, MD 20852

Re: Decentralized Clinical Trials for Drugs, Biological Products, and Devices; Draft Guidance for Industry, Investigators, and Other Stakeholders

Dear Commissioner Califf:

The National Health Council (NHC) thanks the Food and Drug Administration (FDA) for the opportunity to provide input on the proposed guidance on conducting decentralized clinical trials. In the NHC comments on the Prescription Drug User Fee Act from fiscal years 2023-2027 (PDUFA VII), we expressed support for greater use of decentralized clinical trials, requested that the FDA release this guidance, and urged the creation of a pilot program to develop best practices for patient-informed decentralized clinical trials.[1] In our policy recommendations for the end of the COVID-19 public health emergency, the NHC called for the increased use of decentralized trials.[2] The NHC appreciates the FDA's work to release this guidance in a timely manner and is excited for the potential enhancements that the guidance presents for the experience of patients participating in clinical trials.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of more than 155 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

Increasing the use of decentralized trials has multiple benefits for patients. These include:

- Protections against the need to be potentially exposed to contagions and other health risks in a hospital or other medical setting;
- Easing trial participation by removing barriers such as needing to take time off from work, travel, and other concerns; and
- Increasing participation in trials by marginalized populations that may not economically or geographically be able to participate due to travel costs and barriers or distance from trial sites.

[1] NHC-Comments-PDUFA-VII-Goals-FINAL.pdf (nationalhealthcouncil.org)
[2] Priorities-to-Address-Before-the-End-of-the-COVID-19-Public-Health-Emergency.pdf (nationalhealthcouncil.org)

Additionally, decentralized trials may lead to data collection that more accurately reflects how patients respond to investigational products in a real-world setting. However, it could lead to less accurate data collection if participants do not accurately report data when needed. Therefore, it is important that trials be structured appropriately and are informed by the patient's perspective.

The NHC supports the release of this guidance and our specific comments on ways to improve the proposed guidance are below.

Patient Engagement

Patient engagement has particular importance to developing decentralized clinical trials. If the decisions made about crafting a decentralized trial are not based on patient engagement, they may not meet the goal of increasing patient participation and diversity. The need for high levels of patient engagement from trial design is not directly addressed in this guidance. Patients may have more responsibility in a decentralized clinical trial, and understanding their ability and willingness to meet these responsibilities is crucial. For instance, if we are asking a patient to log into a portal regularly to provide data, we need to make sure it is user-friendly and that the system is designed in a way that supports the patient's successful use of it. In addition, if there are issues with data collection on the patient's end such as participants not wearing fitness trackers when needed, the patient perspective can inform barriers to participation that can be overcome. In both of these examples, engaging patients both in clinical trial design and implementation will result in better outcomes.

In our comments on the final patient-focused drug development guidance, the NHC referenced the need to create a connection between other trial guidances, such as this one and the PFDD guidance[3]. In the final guidance, we request that the FDA direct users to the final PFDD guidances and encourage their use.

Access to Digital Health Technology

One of the many barriers to participation in decentralized trials is uncertainty on behalf of sponsors on whether they can provide digital health tools to participants for use in the trial. While the NHC greatly appreciates the guidance, which provides instruction that sponsors should provide digital health technology if needed for participation, there are still concerns about the legality of providing this equipment under anti-kickback statutes. The NHC requests that the FDA provide further guidance on what is and is not permissible when paying for or providing digital health technology.

[3] PFDD-Guidance-4-Comments.pdf (nationalhealthcouncil.org)

Community Outreach Partnerships

One area where the NHC recommends that the FDA provide more guidance and detail is on the process of recruitment and developing outreach partners. While the guidance specifically mentions pharmacies as critical partners, we recommend that the FDA provide examples of a wider group of potential partners for monitoring, outreach, and recruitment. This can include existing trusted voices in the community such as community health workers, patient advocacy groups, and direct care workers. In addition, particularly for recruitment and outreach, sponsors should be encouraged to work with non-traditional partners that are trusted in the community such as community-based organizations.

Diversity of Trials

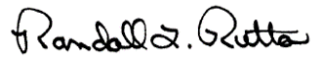
Last year, the FDA released proposed guidance on increasing diversity in clinical trials. Increasing access to decentralized trials has the potential to greatly increase diversity of clinical trial participants. However, unless they are developed specifically including the goal of increasing diversity, the trials may not achieve this potential. The NHC recommends that the final guidance include specific language encouraging sponsors to consider and use decentralized trials to increase the diversity of the population participating in the trials and link it to the clinical trial diversity guidance.

In addition, using decentralized trials should not be a substitute for more deliberate considerations of health equity. Even if you are using digital tools for data collection, there will likely be a need for site visits for some purposes, such as blood sampling. Therefore, sponsors still need to improve their site selection and place them in areas with diverse populations. This is why it is critical that the two guidances be connected.

Conclusion

The NHC thanks the FDA for the opportunity to provide input on this important issue. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these comments in greater detail. He is reachable via e-mail at egascho@nhcouncil.org.

Sincerely,



Randall L. Rutta
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