NATIONAL HEALTH COUNCIL
Celebrating 100 Years

National Health Council
1730 M St NW, Suite 500
Washington, DC 20036-4561
(202) 785-3910

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BY ELECTRONIC DELIVERY

Patricia Flatley Brennan, RN, PhD
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894

RE: Request for Information (RFI): ClinicalTrials.gov Modernization

Dear Director Brennan:

The National Health Council (NHC) appreciates the opportunity to comment on the National Library of Medicine's (NLM) Request for Information on ClinicalTrials.gov modernization. Clinical trials are a vital part of the medical-product development process and often serve as the point of access to treatments that give people with chronic diseases and disabilities their best chance to treat their conditions. The NHC recognizes that ClinicalTrials.gov is a valuable resource to patients, providers, and sponsors, but improvement is much needed to ensure it serves that purpose. This is why we are pleased that NLM has requested information from the stakeholder community, and we urge the NLM to focus modernization efforts on making the tool more understandable and usable for patients.

Created by and for patient organizations 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, sustainable health care. Made up of more than 140 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 representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

Our comments focus on making sure ClinicalTrials.gov is designed in a way that supports our goal of ensuring that all Americans, particularly those with chronic diseases and disabilities, have access to the health care they need. We

recognize that actively participating in clinical trials can serve as the best health care option for many of the patients we represent, and we want to ensure that the restructure of the site enhances patients' ability to understand the information about clinical trial availability to ensure patients and families make the best decisions possible.

Patient Engagement in Development and Oversight of ClinicalTrials.gov

This opportunity to provide input into the modernization of ClinicalTrials.gov is a positive first step in engaging patients, caregivers, providers, and advocates in ensuring the site serves as a beneficial tool for patients. However, there is a need for ongoing, dynamic input from patients and caregivers before, during, and after the redesign to make sure the modernization is truly effective for patients in the long term.

To ensure that the site will serve as a useful and effective tool for patients, **the NHC strongly recommends that the NLM create an advisory group of patients, caregivers, and providers**. This advisory group should be convened early in the process of the modernization and should continue to be active following the modernization to ensure that ClinicalTrials.gov continues to operate optimally for these stakeholders. The three core functions of the advisory group should be:

- Provide input and insights on the redesign and modernization of ClinicalTrials.gov;
- Help determine the best way to present and populate information for the target audiences; and
- Exercise a governance role in the development and utility of the site (i.e., not a tokenistic role).

We encourage the NLM to use best practices for patient engagement from other Federal agencies and the private sector. For instance, the Patient-Centered Outcomes Research Institute (PCORI) has changed their research paradigm to engage patients and caregivers. To encourage the spread of these patient-engagement practices, PCORI has assembled a repository of engagement-related tools and resources developed and used by PCORI awardees[1].

This kind of patient and family involvement has resulted in positive outcomes in other sectors of the Department of Health and Human Services. For instance, the Food and Drug Administration's (FDA's) Patient-Focused Drug Development program provides a good example of convening patients to learn how their conditions and treatments impact their daily lives. Many of the learnings from these convenings have included how to modify language to ensure is the information on the site is understandable to greater numbers of individuals.

Similarly, there are examples of private sector initiatives to engage patients to design care delivery and programming. The NHC conducted research[2] to identify real-world examples of patient engagement in the health care delivery setting. The study showed that a consistently successful strategy that hospitals and health care systems employed to engage patients was

[1] https://www.pcori.org/engagement/engagement-resources/Engagement-Tool-Resource-Repository
[2] https://nationalhealthcouncil.org/wp-content/uploads/2019/12/Meaningful%20Patient%20Engagement%20in%20Health%20Care%20Delivery%20(2018).pdf

the development of Patient and Family Advisory Councils (PFACs). PFACs were initially introduced in 2006 by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to offer a structured and formal framework for the collaboration of patients, families, and health care professionals in decision-making, forming a mutually beneficial relationship where patients have a voice to become active participants in their own care. Patients are able to provide input on what matters most to them throughout their experience with the health care system, as well as recommendations on strategies that health systems can use to improve patient-centered care. Adopting a similar approach to patient engagement throughout the development and lifespan of ClinicalTrials.gov would result in a more user-friendly site that benefits patients and their family caregivers.

Usability of ClinicalTrials.gov

The formation of ClinicalTrials.gov is based in the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 113 of FDAMA[3] states that information on ClinicalTrials.gov "shall be in a form that can be readily understood by members of the public." **The NHC urges the NLM to continue working to ensure that information on ClinicalTrials.gov is presented using patient-friendly language.** Specifically, we recommend tools such as such as a glossary of terms and plain-language summary documents for each study to make the information understandable to patients and their families. We also recommend that the site is routinely tested with patients, family members, and front-line care providers to ensure the site is approachable, understandable, and lay-public friendly. The advisory group referenced above can serve as a useful tool in advising the NLM on whether information is presented in a patient-friendly way.

In addition, we understand that providers play an important role in the process and are often the key to connecting patients with clinical trials. In order to facilitate this shared decision-making, **the NHC recommends that the NLM also seek regular and ongoing input from providers beyond this comment period** to ensure that the information is presented is also usable to front-line care providers.

Finally, we also recommend that the NLM leverage the expertise of patients, caregivers, providers, and information technology experts to assess the platforms that interact with ClinicalTrials.gov to make sure they are most usable by those audiences. For instance, would an app that helped navigate the site be preferable to users? How could ClinicalTrials.gov share data with platforms and sites that patients and others are already using to facilitate access? Given the advances in technology, these questions are worth asking during this modernization.

Conclusion

The NHC believes that the recommendations above are crucial in ensuring the effectiveness of a ClinicalTrials.gov modernization.

[3] https://www.govinfo.gov/content/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf#page=16

Please do not hesitate to contact Eric Gascho, our Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

Marc Boutin, JD
Chief Executive Officer National Health Council