4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6395]

Request for Applications for New Members of the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; request for applications.

SUMMARY: The Food and Drug Administration (FDA or Agency), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is requesting applications of patient advocates interested in participating on the Patient Engagement Collaborative (PEC). The PEC is an ongoing, collaborative forum coordinated through the Office of Patient Affairs, Office of Clinical Policy and Programs (OCPP), Office of the Commissioner, and is hosted by CTTI. Through the PEC, the patient community and regulators are able to discuss an array of topics regarding increasing meaningful patient engagement in medical product development and regulatory discussions at FDA. The activities of the PEC may include, but are not limited to, providing diverse perspectives on topics such as systematic patient engagement, transparency, and communication; providing considerations for implementing new strategies to enhance patient engagement at FDA; and proposing new models of collaboration in which patients and patient advocates are partners in non-product specific aspects of the medical product development and FDA review process.

DATES: Applications submitted by 11:59 p.m. Eastern time on [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*], will be considered for membership in the PEC. Incomplete applications and applications completed after the above-specified deadline will not be reviewed.

ADDRESSES: All applications should be submitted to FDA's Office of Patient Affairs in OCPP. The preferred application method is via the online submission system provided by CTTI, available at https://duke.qualtrics.com/jfe/form/SV_eLDSvmVIXdsAdVP. For those applicants unable to submit an application electronically, please call FDA's Office of Patient Affairs at 301-796-8460 to arrange for mail or delivery service submission. Only complete applications, as described under section IV of this document, will be considered.

FOR FURTHER INFORMATION CONTACT: Wendy Slavit, Office of the Commissioner, Office of Clinical Policy and Programs, Office of Patient Affairs, Food and Drug Administration, 301-796-8460, PatientEngagementCollaborative@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The CTTI is a public-private partnership cofounded by FDA and Duke University whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. FDA and CTTI have long involved patients and considered patient perspectives in their work. Furthering the engagement of patients as valued partners across the medical product research and development continuum requires an open forum for patients and regulators to discuss and exchange ideas.

The PEC is an ongoing, collaborative forum in which the patient community and regulators discuss an array of topics regarding increasing patient engagement in medical product development and regulatory discussions at FDA. The PEC is a joint endeavor between FDA and CTTI. The activities of the PEC may inform relevant FDA and CTTI activities. The PEC is not intended to advise or otherwise direct the activities of either organization, and membership will not constitute employment by either organization.

The Food and Drug Administration Safety and Innovation Act (Pub. L. 112-14), section 1137, entitled "Patient Participation in Medical Product Discussions," added section 569C to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c). This provision directs the

Secretary of Health and Human Services to "develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions." On November 4, 2014, FDA issued a *Federal Register* notice establishing a docket (FDA-2014-N-1698) for public commenters to submit information related to FDA's implementation of this provision. Upon review of the comments received, one common theme, among others, included establishing an external group to provide input on patient engagement strategies across FDA's Centers. After considering the comments, FDA formed the PEC in 2018 to discuss a variety of patient engagement topics. This group is consistent with additional legislation subsequently enacted in section 3001 of the 21st Century Cures Act (Pub L. 114-255) and section 605 of the FDA Reauthorization Act of 2017 (Pub. L. 115-52), further supporting tools for fostering patient participation in the regulatory process.

The PEC currently has 16 members. To help ensure continuity in its activities and organizational knowledge, the PEC maintains staggered membership terms. As of September 2021, eight members will complete a term and up to eight new members will be selected. The purpose of this notice is to announce that the application process for up to eight new members of the PEC is now open, and to invite and encourage applications by the submission deadline for appropriately qualified individuals.

II. Criteria for Membership

The PEC includes up to 16 diverse representatives of the patient community. Eight members from the previous application process will remain on the PEC. The current application process is to select up to eight new PEC members. Selected members will include the following: (1) patients who have personal disease experience; (2) caregivers who support patients, such as a parent, child, partner, other family member, or friend, and who have personal disease experience through this caregiver role; and, (3) representatives from patient groups who, through their role in the patient group, have direct or indirect disease experience. Please note that for purposes of this activity, the term "caregiver" is not intended to include individuals who are engaged in

caregiving as healthcare professionals; and the term "patient group" is used herein to encompass patient advocacy organizations, disease advocacy organizations, voluntary health agencies, nonprofit research foundations, and public health organizations. The ultimate goal of the application and selection process is to identify individuals who can represent a collective patient voice for their patient community.

Selection criteria include the applicant's potential to meaningfully contribute to the activities of the PEC, ability to represent and express the patient voice for his or her constituency, ability to work in a constructive manner with involved stakeholders, and understanding of the clinical research enterprise. Consideration will also be given to ensuring the PEC includes diverse perspectives and experiences, including but not limited to sociodemographic and disease experience diversity. PEC members are required to be residents of the United States and must be 18 years of age or older.

Financial and other conflicts of interest will not necessarily make applicants ineligible for membership in the PEC. However, applicants cannot be direct employees of the medical product development industry or a currently registered lobbyist for an FDA-regulated industry.

III. Responsibilities and Expectations

Working meetings of the PEC will typically be held two to four times per year, either in person (in the Washington D.C. area) or virtually (teleconference or webinar). Given the ongoing COVID-19 pandemic, meetings will be conducted virtually and may resume in-person when it is safe to do so. Additional meetings may be organized as needed, and currently include monthly, 1-hour teleconferences.

Reasonable accommodations will be made for members with special needs for travel or for participation in a meeting. Applications for PEC membership are encouraged from individuals of all racial, ethnic, cultural groups, sexual orientations, gender identities, with and without disabilities. Travel support will be provided as applicable.

To help ensure continuity in its activities and organizational knowledge, the PEC will maintain staggered membership terms for patient community representatives. Membership terms for new members will be 2-year appointments. Members may serve up to two terms, with the possibility of extensions.

Additional responsibilities and expectations are set forth in the PEC Framework, which should be reviewed prior to submitting an application, available at https://www.ctti-clinicaltrials.org/framework-cttifda-patient-engagement-collaborative.

IV. Application Process

Any interested person may apply for membership on the PEC. To apply, go to https://duke.qualtrics.com/jfe/form/SV_eLDSvmVIXdsAdVP. The application process is completed online and includes answering questions to help determine eligibility for the PEC, demographic and other background questions, and four brief essay questions. Many of the demographic questions are optional. The brief essay questions, which must be answered in 500 characters or fewer (including spaces), are as follows:

- Please explain why you would have an outstanding ability to represent and express the patient voice for the disease area(s) you selected above.
- Please give a few examples of experiences that demonstrate your outstanding ability to work across stakeholders in the medical product development process.
- Please explain how you have developed a strong understanding of the medical product development process.
- Please tell us why you are interested in becoming a member of the PEC and how you would be able to contribute.

Completing the application form also requires submitting: (1) a current, complete curriculum vitae or résumé that shows relevant activities and experience (PDF format preferred) and (2) a letter of endorsement (maximum 800 words) from a patient group with which the applicant has worked closely on activities that are relevant to the PEC (PDF format preferred).

The letter of endorsement should emphasize information relevant to the criteria for membership described above. The letter may address topics such as the applicant's involvement in patient advocacy activities, experiences that stimulated an interest in participating in discussions about patient engagement in medical product development and regulatory decision making, and other information that may be helpful in evaluating the applicant's qualifications as a potential member of the PEC. Only complete applications submitted by the deadline (see DATES) will be reviewed.

Additional information may be needed from applicants, including information relevant to understanding potential sources of conflict of interest, in which case applicants will be contacted directly.

Dated: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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