I. WELCOME

*Carlos R. Jaén, MD, PhD, Chair*

Dr. Carlos Jaén welcomed the group and noted the ClinicalTrials.gov survey data distributed to the Working Group for their review prior to this meeting.

II. STAKEHOLDER ENGAGEMENT PLAN

*Rebecca J. Williams, PharmD, MPH, Executive Secretary*

The objective of this meeting was to discuss the planned Request for Information (RFI) to determine any informational gaps and to further develop the stakeholder engagement/outreach plan. Dr. Rebecca Williams highlighted survey data that were shared with the group as follow-up from the December 13 meeting, as well as the 2020 overall plan to engage stakeholders, and specifically the RFI engagement plan.

It is anticipated that the RFI will be issued in January 2020 and will be announced via NLM blog posts and more information distributed in a public webinar. There will be targeted consortium meetings with umbrella organizations throughout January and February 2020, culminating in the public meeting in April 2020.

III. DISCUSSION

*Rebecca J. Williams, PharmD, MPH, Executive Secretary*

Working Group members had various questions and discussion related to whether website content is available in different languages and related upcoming requirements in the EU. Members discussed aspects of making the site more accessible to general users and promotion of the site and its potential uses.

Regarding the RFI topics of interest, the group discussed the potential role of the site in supporting development of data standards and NLM’s role in improving underserved and minority communities’ access to clinical trials information. The group also discussed rearranging bullet points within some topics to elicit needed feedback and responses from stakeholders.

Working Group members were also asked to suggest potential consortiums or organizations to include in the targeted meetings and other outreach, especially those...
with which members have specific interest or involvement. Working Group members suggested the following organizations: the Society for Clinical Trials, the Cochrane Community, Public Responsibility in Medicine and Research (PRIM&R), Alliance for Clinical Research Excellence and Safety (ACRES), the Health Research Alliance (HRA), Clinical and Translational Science Award Programs (CTSAs), NCI-designated Cancer Centers, NCI’s National Outreach Network (NON), disease-specific organizations such as the Michael J. Fox Foundation, and networks focusing on specific groups such as the National Hispanic Science Network and the Association of Black Cardiologists. Dr. Williams encouraged members to provide additional organizations via email.

IV. NEXT STEPS

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams noted that Working Group members will be provided with a standard slide set to further disseminate information about ClinicalTrials.gov modernization. Working Group members noted some of the organizations they may be able to reach out to in the upcoming months.

During the February 3rd in-person meeting, the Working Group will solidify the stakeholder engagement strategy and prepare for the April public meeting.

The group discussed their availability for the April public meeting and potential options for their next meeting, which will fall between the April public meeting and the May 2020 Board of Regents (BOR) meeting. The date will be confirmed in the beginning of January 2020.