

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL LIBRARY OF MEDICINE
BOARD OF REGENTS PUBLIC SERVICE WORKING GROUP ON CLINICALTRIALS.GOV
MODERNIZATION MEETING
MAY 1, 2020**

I. WELCOME AND THANKS

Carlos R. Jaén, MD, PhD, Chair

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Jaén thanked the working group members for participating in the public meeting held on April 30. Dr. Williams introduced other ClinicalTrials.gov staff members who had joined the working group meeting. One of the goals of the working group meeting was to discuss next steps for the modernization process, in particular, developing a roadmap.

II. REPORT FROM THE APRIL 30 PUBLIC MEETING

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Of the 602 participants who registered for the meeting, 391 attended. Dr. Williams noted that this attendance rate was higher than average for a free, remote webinar. Meeting materials, including the recording and presentation slides, will be posted on the ClinicalTrials.gov Modernization webpage in the next 30 days. Dr. Jaén will report out to the Board of Regents (BOR) at the next National Library of Medicine (NLM) BOR Meeting later in May.

Based on external feedback on the meeting, Dr. Williams said that participants appreciated panelists' presentations of their experiences with ClinicalTrials.gov and the sharing of different perspectives and aspects related to the varied uses of ClinicalTrials.gov. Participants also expressed their preference to be informed of modernization activities via additional webinars, as well as email.

Working group members agreed that the panelists' presentations, with their personal perspectives, were informative and that the public meeting provided an opportunity to demonstrate to the public the challenges associated with the modernization effort. The group discussed the pros and cons of remote versus in-person public meetings. It was agreed that the webinar platform is best for keeping participants engaged and providing access for individuals who would not be able to attend in person. The possibility of hybrid meetings (both in-person and remote) to obtain the most feedback from participants was also discussed.

III. DISCUSSION

All

A written summary of the public meeting was provided to the group for review. Dr. Williams noted that the report to the BOR would cover the public meeting as well as any accomplishments since the last meeting in February. Accomplishments since the last meeting include the Request for Information (RFI) analysis and summary and the successful migration of the platform to the National Center for Biotechnology Information infrastructure.

The working group discussed the topics to be included in the report to the BOR. It was agreed that working group members' feedback on the format of the public meeting and information presented will be included. It was noted that the role of NLM in providing this resource to the public should be defined. It was also agreed that the report should highlight information received from the audience polls, as that would provide insight into the ClinicalTrials.gov user base.

The group discussed the role in the modernization process of the data submitters, who interact with ClinicalTrials.gov the most. It was noted that improvements due to feedback from data submitters may be most beneficial to ClinicalTrials.gov. It was also noted that other users (e.g., patients) should be represented, and their comments provided. The group further discussed the role of NLM and emphasized the importance of focusing on its role as a "data aggregator" in order to be the most useful to the range of stakeholders it serves.

The value of considering additional resources that may be needed (e.g., data visualization experts, website usability experts, focus groups) to implement changes to ClinicalTrials.gov was also mentioned, and how to make the information found on ClinicalTrials.gov more accessible to the general public was discussed. Additional analysis and discussion are needed to determine how best to support both data submitters and data users.

It was suggested that better understanding the needs of prospective clinical trial participants or organizations such as PCORI that focus on supporting patient-centered issues may be useful in obtaining feedback. The working group also discussed the possibility of ClinicalTrials.gov including third-party links to additional health information that can more broadly support patients. It was noted that such links would need to undergo a vetting process; several links and resources were suggested including further leveraging already useful sites produced by NLM (e.g., MedlinePlus) and NIH.

It was agreed that highlights of the public meeting summary will be included in the report to the BOR. The entire summary of the public meeting and the RFI comment summary will be included as appendixes.

IV. ACTION ITEMS, SUMMARY, AND NEXT STEPS

Rebecca J. Williams, PharmD, MPH, Executive Secretary

The action items are as follows:

- Prepare highlights of the public meeting summary for the report to the BOR.
- Include the summary of the public meeting and the RFI comment summary as appendixes in the report to the BOR.
- Further engage with the patient population to obtain feedback on improvements to ClinicalTrials.gov.
- Notify working group members via email when the public meeting recording and presentation slides are available.
- Confirm the email distribution list for future communications.

The working group will plan to meet in person (with a remote option as backup) on September 14, prior to the BOR meeting scheduled for September 15–16, to discuss the presentation to the BOR. The working group will also meet remotely 1–2 weeks before that to review materials that will be discussed during the September 14 meeting. It is anticipated that stakeholders will be updated via webinar sometime in October and roughly quarterly thereafter, with email updates in between.