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 #3
February 3, 2020

I. INTRODUCTION AND WELCOME

Patricia Flatley Brennan, RN, PhD, Director, NLM
Francis S. Collins, MD, PhD, Director, NIH

Dr. Patricia Brennan welcomed Working Group members and briefly described the importance of ClinicalTrials.gov in the biomedical research field, but noted the need for its modernization. Dr. Francis Collins also noted the importance of ClinicalTrials.gov as a critical resource in the dissemination of clinical research to those in the research field as well as the general public. He charged the Working Group to focus on improving the usability of ClinicalTrials.gov without sacrificing its functionality for enhancing the system's capabilities as a fine-tuned engine of discovery worthy of "winning the Lasker Award."

Dr. Rebecca Williams introduced two new Working Group members: Ms. Alissa Gentile from the Leukemia and Lymphoma Society; and Dr. Seth Morgan from the National Multiple Sclerosis Society. She also introduced two NIH *ex-officio* members, Dr. Pamela Kearney from the Office of Extramural Research and Dr. Lyric Jorgenson from the Office of Scientific Policy, followed by introductions of all the other Working Group members.

Mr. Jerry Sheehan, Deputy Director at NLM, Dr. Dina Paltoo, NLM Assistant Director for Policy Development, Dr. Kim Pruitt, Chief of the Information Engineering Branch at NLM's National Center for Biotechnology Information (NCBI), and additional members of the NLM ClinicalTrials.gov staff were also in attendance. Dr. Williams noted the 20th anniversary of ClinicalTrials.gov at the end of February 2020.

II. STAKEHOLDER ENGAGEMENT UPDATES AND REVIEW OF 2020 ACTIVITIES

Rebecca J. Williams, PharmD, MPH, Executive Secretary & Acting Director, ClinicalTrials.gov

Dr. Williams summarized the approach for the ClinicalTrials.gov modernization effort. This first year will continue to focus on the engagement process to identify modernization themes and priorities. The Working Group will assist with prioritizing these themes and will aid in the development of a comprehensive project roadmap by the end of September 2020, to be implemented in the following years. Dr. Carlos Jaén would like the Working Group to articulate a common vision for the future direction of ClinicalTrials.gov and determine how to get there.

Dr. Williams reviewed key activities intended to benefit internal and external stakeholders of ClinicalTrials.gov that have occurred and will occur during the 2020 fiscal year to aid the modernization effort. Process improvements include optimizing internal business processes, moving the ClinicalTrials.gov system infrastructure, and planning to support enhancing the information submission process. Dr. Jaén expressed interest in various internal planning activities and requested that summaries of the work products be shared with Working Group members when feasible.

The group discussed the Request for Information (RFI), external engagement strategy, and what organizations/stakeholders have been contacted so far. Dr. Williams outlined a plan for analyzing RFI comments and noted that over 50 comments have been received from a variety of stakeholders ranging from data submitters to the general public. It is anticipated that more comments will be received near the end of the 75-day comment period that will close on March 14th. Working Group members were encouraged to follow up with organizations that they have specific involvement with to promote the RFI. Working Group members suggested additional organizations to engage in modernization activities.

III. APRIL 30TH PUBLIC MEETING AGENDA AND PLANNING

Rebecca J. Williams, PharmD, MPH, Executive Secretary

A draft agenda for the public meeting was shared with the group for their review and feedback. Dr. Williams noted that the goals of the public meeting are to thank individuals for their feedback to the RFI, present common themes expressed in the RFI comments, and promote interactive sharing of various perspectives on important issues in a forum that allows all stakeholders to hear each other's needs. Dr. Williams outlined the plan of organizing the meeting into three sequential panels to address the three RFI topics and requested that Working Group members participate through panels and presentations, or as active listeners.

The group discussed the possibility of having smaller group discussions during the public meeting to encourage active participation among attendees but noted the difficulty of accurately recording the interactions and ensuring that others hear different viewpoints. It was suggested that the crowd break into multiple parallel groups with individuals from different backgrounds discussing similar topics and trained moderators facilitating discussion. Discussion highlights from each breakout session could then be shared with the overall group to help ensure that other viewpoints are heard.

IV. RFI TOPIC BREAKOUT GROUPS AND DISCUSSION

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Working Group members separated into three small groups based on the three RFI topics to discuss and determine aspects to focus on during the April public meeting. Discussion highlights were shared with the entire group.

The Website Functionality subgroup discussed seeking the perspectives of relevant groups that have experience with technologies and methods that could be used or adapted to improve the website functionality, such as those centering around patient information (*e.g.*, Patient-Centered Outcome Research Institute [PCORI]) and data visualization. The subgroup also discussed ways for identifying and providing quality indicators (*e.g.*, IRB approval) to the clinical trials posted on the website.

The Information Submissions subgroup considered ways of improving workflow and research portfolio management tools and using smart or "assistive" templates to aid in the submission process. The subgroup also discussed integration between ClinicalTrials.gov and other systems (such as those involved in grant applications), making educational materials available to submitters during the submission process, and automated quality control review and rating systems tied to quality indicators.

The Data Standards subgroup discussed the importance of articulating the benefits of standardizing data through highlighting potential use cases, a necessary precursor to motivating the value of data standards. The group also discussed specific techniques for improving data standardization during submission, including drop-down menus and templates, and determining which elements to focus on during the standardization process.

It was also noted that baseline metrics, such as those around submission, would need to be established (throughout the three RFI topics) in order to determine whether modernization objectives are being met. The group suggested obtaining this information and feedback through website surveys.

V. ACTION ITEMS, SUMMARY, AND NEXT STEPS

Anna Fine, PharmD, Assistant Director, ClinicalTrials.gov

Dr. Anna Fine noted that the next NLM Board of Regents (BoR) meeting will occur on Tuesday, February 4th through Wednesday, February 5th and that Working Group members are invited to attend a report out of the Working Group findings on February 5th.

A draft summary of this meeting, along with a revised draft agenda for the public meeting, will be provided to the Working Group for review by next week. It is anticipated that a high-level agenda for the public meeting will be available by the end of February 2020. Registration for the public meeting is anticipated to begin during this time.

Once the panels are confirmed, Working Group members will be contacted separately to discuss participation. Panel meetings will be scheduled at the end of March 2020, approximately 30 days prior to the public meeting, to discuss panel goals, *etc*. On April 24th, one week prior to the public meeting, the Working Group will meet virtually to review the final agenda and logistics for the public meeting.

After the public meeting on April 30th, the Working Group will meet to debrief on May 1st to determine what will be presented at the BoR meeting on May 12–13, 2020. NOTE: Information about next steps and associated dates will also be provided to Working Group members via email.