

**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 #1
December 13, 2019**

I. WELCOME

Carlos R. Jaén, MD, PhD, MS, Chair

Dr. Carlos Jaén introduced himself as a member of the National Library of Medicine's Board of Regents (NLM BOR) and Chair of this Working Group. He thanked Working Group members for agreeing to participate. Dr. Jaén gave a brief background about the NLM BOR and provided a summary of the Working Group charge. He noted the priority of connecting with stakeholders through engagement to ensure evolving needs are understood and considered.

II. INTRODUCTION OF MEMBERS

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Working Group members introduced themselves, their interests relating to the topic at hand, and what they hope to contribute to the Working Group.

III. BACKGROUND

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Rebecca Williams gave an overview of ClinicalTrials.gov, noting the milestones of 320,000+ registrations and over 40,000 posted results reached in 2019. Dr. Williams emphasized the benefits of comprehensive registration and results reporting in their contribution to increased public trust in clinical research. The two main aims of ClinicalTrials.gov are to: 1) collect complete and informative information about clinical studies; and 2) facilitate use of information to help people find studies of interest for research or enrollment.

Dr. Williams reviewed the outlined approach to ClinicalTrials.gov modernization, emphasizing the evaluation of opportunities to enhance the compatibility and interoperability across the entire clinical trial lifecycle. Anticipated to be an overall 4-year process, the first year will be used to validate the modernization vision by evaluating user requirements and system infrastructure and developing a product roadmap. From July to December 2019, NLM engaged with the NIH Institutes and Centers (ICs) about modernization and identified several high-level themes of interest to the ICs to be addressed during the modernization process.

NLM will issue a Request for Information (RFI) in January 2020 to obtain input about the modernization of ClinicalTrials.gov from a broad range of stakeholders. Dr. Williams outlined the following three topics of interest for the RFI and encouraged the group to review the topics for discussion at the next meeting: 1) ClinicalTrials.gov public website functionality; 2) information submission; and 3) data standards.

IV. DISCUSSION

The group discussed how subsequent meetings will be structured and requested additional background information, including the results of voluntary user and taskforce informational surveys. The Working Group will focus on determining any gaps in the RFI topics that would be important to include, as well as optimizing stakeholder engagement/outreach. It was noted that engagement approaches do not have to be limited to online, and ideas can be developed with members' stakeholder partners.

V. NEXT STEPS

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams noted the following action items: 1) to follow up with ClinicalTrials.gov survey data to distribute to the Working Group; and 2) to provide clarification of the feedback desired from the Working Group on stakeholder engagement/outreach, RFI topics, and additional background information that would be useful.

The next meeting on December 20th will focus on the RFI and stakeholder engagement/outreach. An in-person meeting will take place on February 3rd, prior to the next NLM BOR meeting. Working Group findings will be reported to the BOR in February; Working Group members are welcome to attend this meeting.

A recording of this meeting and subsequent meetings will be made available to group members through an external link provided by support staff. Dr. Williams noted that comments and feedback can be sent in advance of next week's meeting, especially if members are unable to attend.