

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH (NIH)
NATIONAL LIBRARY OF MEDICINE (NLM)
BOARD OF REGENTS (BOR) PUBLIC SERVICE WORKING GROUP ON CLINICALTRIALS.GOV
MODERNIZATION MEETING
AUGUST 20, 2021**

MEMBERS PRESENT

Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California, Chair
Jennifer S. Lucca, MSW, The Children's Inn at NIH
Rebecca J. Williams, PharmD, MPH, NLM, NIH, Executive Secretary

MEMBERS NOT PRESENT

Kent J. DeZee, MD, MPH, FACP, COL, MC, U.S. Army Office of the Surgeon General

EX OFFICIO NIH MEMBERS PRESENT

Lytic A. Jorgenson, PhD, Office of Science Policy
Pamela Reed Kearney, MD, Office of Extramural Research

EXTERNAL MEMBERS PRESENT

Carrie Dykes, PhD, University of Rochester Clinical and Translational Science Institute
Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School
Carlos R. Jaén, MD, PhD, University of Texas Health Science Center at San Antonio
Seth A. Morgan, MD, National Multiple Sclerosis Society
Stephen J. Rosenfeld, MD, MBA, Freeport Research Systems, LLC and North Star Review Board
Steven Woloshin, MD, The Dartmouth Institute

EXTERNAL MEMBERS NOT PRESENT

Alissa Gentile, MSN, RN, Dana-Farber Cancer Institute
Barbara Kress, BSN, RN, Merck
Joseph S. Ross, MD, MHS, Yale School of Medicine

OTHERS PRESENT

Annice Bergeris, ClinicalTrials.gov Information Research Specialist
Heather Dobbins, ClinicalTrials.gov Lead Results Analyst
Anna Fine, ClinicalTrials.gov Assistant Director
Elisa Golfinopoulos, ClinicalTrials.gov Results Team Lead (ICF)
Wendy Harman, User Experience (UX)/User Interface Lead (ICF Next)
Ryan Koning, UX Architect (ICF Next)
Hibah Nazir, ClinicalTrials.gov Product Manager (Computercraft)
Alison (Ward) Powell, Communications Specialist (ICF Next)
Christina Robinson, ClinicalTrials.gov Web Content and Outreach Coordinator (ICF)

Mary Sanders, ClinicalTrials.gov Project Manager (ICF)
Tony Tse, ClinicalTrials.gov Analyst

I. INTRODUCTION AND WELCOME

Lourdes Baezconde-Garbanati, PhD, MPH, Chair
Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams announced that Carlos Jaén has completed his tenure on the NLM BOR, and Lourdes Baezconde-Garbanati will serve as chair of the Working Group moving forward.

Dr. Baezconde-Garbanati thanked Dr. Jaén for his service and leadership as chair. She then welcomed Working Group members and thanked them for their attendance and continued participation. Dr. Williams noted additional members of the ClinicalTrials.gov team who were also in attendance.

II. MODERNIZATION UPDATES AND REVIEW OF ACTIVITIES, INCLUDING THE EXECUTIVE SUMMARY AND DISCUSSION

Rebecca J. Williams, PharmD, MPH, Executive Secretary
All Working Group Members

Dr. Williams presented an overview of the Report on the ClinicalTrials.gov Modernization Effort, 2019–21, which was sent to Working Group members before the meeting. The report provides a summary of the progress of the modernization effort to date. It presents NLM’s approach to modernization, presents the Working Group’s input on various aspects of the modernization effort, describes user challenges and modernization priorities discussed by the Working Group for each strategic goal, shares NLM’s product development plans and progress, and presents next steps for the Working Group and the modernization effort.

Dr. Williams noted that the purpose of the report is to summarize ClinicalTrials.gov modernization activities and Working Group input from 2019 to 2021 to help guide future modernization activities. She briefly described the contents of each section of the report and some areas for consideration, as follows:

- The Introduction section provides an overview of ClinicalTrials.gov and the modernization effort and describes the Working Group’s purpose, role, and charge.
- The Approach to Modernization section details stakeholder engagement, product development, and technical infrastructure enhancement activities, noting the creation of the strategic roadmap.
- The Working Group Input on ClinicalTrials.gov Modernization section outlines the vision and strategic goals for the modernization effort, its outcomes, related challenges, and resources and key activities. Dr. Williams specifically asked Working Group members to review the 10 modernization outcomes listed and provide feedback on any gaps or overlap.

- The User Challenges and Modernization Priorities, by Strategic Goal section summarizes the Working Group’s input on the three strategic goals, focusing on external stakeholders. Dr. Williams asked Working Group members to review this section to confirm that the challenges listed have been correctly characterized as either able to be addressed directly by the modernization effort or able to be addressed only indirectly by NLM, as efforts by other leaders and stakeholders across the wider clinical research ecosystem are needed to advance ways to address those user needs.
- The NLM Product Development Plans and Progress section summarizes intended changes to the ClinicalTrials.gov public website and the Protocol Registration and Results System (PRS) and the planned beta releases of the new user experiences.
- The Next Steps section focuses on Working Group membership, public communications related to the beta releases, and sources of more information about the modernization effort.

Dr. Williams asked that during their review Working Group members consider the overall organization of the report, additional references that could be included, whether the list of outcomes for modernization is complete, and whether the characterization of user challenges as being either directly or indirectly supportable by modernization is correct.

Regarding Working Group membership, Dr. Williams asked that current Working Group members consider their availability for continued participation through September 2022. We expect to hold three Working Group meetings, which will be scheduled prior to the NLM BOR meetings and will most likely be virtual. Working Group members were also asked to consider additional expertise that may be needed for the Working Group and to suggest specific individuals who may be able to provide it. These individuals could be subject matter experts invited to attend Working Group meetings as needed or could be added to the group as external members for the full year. Suggestions should be emailed directly to Dr. Williams.

Dr. Williams discussed other current modernization initiatives, including better characterizing and providing more support for the landscape analysis use case, developing additional resources to help data submitters provide the Brief Summary data element information in plain language, providing support for additional study types (such as master protocols), and advancing interoperability with Fast Healthcare Interoperability Resources (FHIR)-based application programming interface exchange formats. Details about these initiatives can be provided to Working Group members upon request or at future meetings.

Working Group members discussed feedback provided by the NLM BOR on the Working Group’s progress. The BOR has generally given positive feedback and is encouraged by the work completed by the group so far.

III. PRESENTATION OF BETA RELEASE PLANS AND RELATED COMMUNICATIONS

*Rebecca J. Williams, PharmD, MPH, Executive Secretary
All Working Group Members*

Dr. Williams presented the beta release plans for the ClinicalTrials.gov public site and the PRS; this presentation was also shared with the NIH Institutes and Centers points of contact on July 22. Background on the modernization effort was provided, including a summary of the roadmap, approach, vision, strategic goals, stakeholders, and general issues.

Dr. Williams emphasized that users are central to the modernization approach and said that the new technology being employed is intended to better support users. She described the challenges of balancing the needs of the three primary external user groups and of making the site's purpose and limitations clear, particularly that study information is submitted by research sponsors and investigators and that being listed on the site does not mean that a study has been evaluated by the government. She also noted that maximizing the information available for use is dependent on current legal and policy requirements and the submission of high-quality content by sponsors and investigators.

The beta sites for both the ClinicalTrials.gov public site and the PRS will be launched and made available in parallel to the current sites, initially as functional secondary sites with features added as needed. Next, the beta sites will become the primary sites, with the current sites remaining available as secondary sites, and eventually the beta versions will replace the current sites.

Focusing on the key Request for Information response themes, the first beta release of the ClinicalTrials.gov public site will include a redesigned home page, an updated search experience, a redesigned search results page, and an updated format for study records. The beta site will feature a modern look and feel, ease of use on mobile devices, easy-to-understand information, and a new cloud-based infrastructure.

Goals for the first beta release of the PRS include introducing a new technology platform for internal users, providing users with an improved workflow and functionality to manage their record portfolios, and gathering user input for further development. The use of an Agile development process will give users the opportunity to interact with new features and provide feedback to inform iterative improvements.

Working Group members discussed how to publicize the beta sites' coming features to promote interest and support from users. It was noted that potential new features could be discussed without an associated timeline.

IV. SUMMARY AND NEXT STEPS

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams noted the importance of collecting qualitative and quantitative metrics through passive and active evaluation to assess modernization successes and determine areas that may need improvement. Pre-beta release communication activities are anticipated for September or October and will include a preview public webinar to keep stakeholders informed. The beta site releases are expected to occur in November, paired with another

public webinar that will provide specific information. Post-beta release communication activities, anticipated for December 2021 through February 2022, will include targeted follow-up with stakeholders and feedback mechanisms embedded in the PRS and the public site.

Working Group members supported the public webinar approach. To disseminate the progress report's contents more broadly and to create a more informed group of participants and receive better feedback, it was suggested that an article and an executive summary for the public be drafted in preparation for the webinar.

Working Group members were asked to provide feedback on the progress report, either via tracked changes in the document or in an email sent to Dr. Williams, prior to the next Working Group meeting, which is scheduled for August 30, 2021.

Major issues and themes drawn from comments on the report will be discussed on August 30, along with future Working Group priorities. Key findings and the Working Group's next steps will be shared during the September 14 NLM BOR meeting.