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
FEBRUARY 26, 2021

MEMBERS PRESENT
Carlos R. Jaén, MD, PhD, University of Texas Health Science Center at San Antonio, Chair
Rebecca J. Williams, PharmD, MPH, NLM, Executive Secretary
Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California
Jennifer S. Lucca, MSW, The Children's Inn at NIH

MEMBERS NOT PRESENT
Kent J. DeZee, MD, MPH, FACP, COL, MC, U.S. Army Office of the Surgeon General

EX OFFICIO NIH MEMBERS PRESENT
Lyric 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
Alissa Gentile, MSN, RN, Dana-Farber Cancer Institute
Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School
Barbara Kress, BSN, RN, Merck
Seth A. Morgan, MD, National Multiple Sclerosis Society
Steven Woloshin, MD, The Dartmouth Institute

EXTERNAL MEMBERS NOT PRESENT
Stephen J. Rosenfeld, MD, MBA, Freeport Research Systems, LLC and North Star Review Board
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
Jolie Dobre, User Experience (UX) Lead (ICF Next)
Anna Fine, ClinicalTrials.gov Assistant Director
Elisa Golfinopoulos, ClinicalTrials.gov Results Team Lead (ICF)
Wendy Harman, UX Lead (ICF Next)
Casey Jennings, UX Analyst/Strategist (ICF Next)
Christine Leake, Web Content Strategist (ICF Next)
Alma Morales, UX Designer (ICF Next)
Toobie Nguyen, UX Architect (ICF Next)

Christina Robinson, ClinicalTrials.gov Web Content and Outreach Coordinator (ICF)
Mary Sanders, ClinicalTrials.gov Project Manager (ICF)
Valerie Schneider, Sequence Enhancements, Tools, and Delivery Program Head (NLM)
Maureen Strange, ClinicalTrials.gov Clinical Trial Subject Matter Expert (ICF)
Lucy Street, Web Content Strategist (ICF Next)
Tony Tse, ClinicalTrials.gov Analyst
Alison Ward, Communications Specialist (ICF Next)
Becca Xu, UX Research Analyst (ICF Next)

I. WELCOME

Carlos R. Jaén, MD, PhD, Chair
Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Jaén welcomed Working Group members and thanked them for their attendance and continued participation. Dr. Williams noted members of the ClinicalTrials.gov team, including the User Research team, who were also in attendance.

II. REVIEW OF DECEMBER 11 MEETING OUTPUTS

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams noted that at the February 9, 2021, NLM BOR meeting, Working Group members reported on the December 11, 2020, Working Group meeting. She mentioned the discussion of ecosystem challenges and the identification of opportunities in areas where assistance is needed, even if ClinicalTrials.gov cannot directly provide support through the modernization effort. She added that this discussion will be ongoing as the modernization effort continues.

Dr. Williams then presented information on the public webinar held on February 18, 2021. Of the nearly 900 registrants and more than 600 viewers, most attendees described themselves as data providers, reflecting this user group's tremendous interest in changes to ClinicalTrials.gov. The makeup of the webinar audience reinforced the need to conduct targeted outreach to ensure that other stakeholder groups continue to be engaged. The webinar focused on the progress of the modernization effort to date, describing the role of the Working Group and the current modernization roadmap, with the technical infrastructure serving as a foundation, alongside continued stakeholder engagement, to inform product development. It is anticipated that the new test version of the ClinicalTrials.gov website will be released in fall 2021, in parallel with the existing site.

User feedback loops were described, and the goal of incorporating user feedback into the development cycle was noted. The user-centered design cycle starts with formative research on user needs, moves to design and prototype testing with users, and continues with coding and usability testing with users; then the cycle repeats. This design and development work is completed in 2-week Agile "sprints." Webinar attendees were invited to participate in user-feedback sessions to support the current design process, and Dr. Williams asked Working Group members to distribute information about the opportunity to participate in user-feedback sessions to their own stakeholder communities. Working Group members noted the importance of telling participants in user-feedback sessions how their input was used, even if the modernization team was unable to implement their specific feedback.

This Working Group meeting focused on challenges and issues associated with information submission through the Protocol Registration and Results System (PRS). Input from this meeting will be reported on during the next NLM BOR meeting, which is scheduled for

May 11–12. The next Working Group meeting will be held in August to discuss next steps for the group before the NLM BOR meeting scheduled for September 14–15.

III. FACILITATED DISCUSSIONS
Jolie Dobre, UX Lead, ICF Next
Carrie Dykes, PhD, University of Rochester Clinical and Translational Science Institute
Barbara Kress, BSN, RN, Merck
All Working Group Members

Facilitated discussions were conducted to help generate and prioritize ideas to address challenges faced by academic investigators and industry sponsors related to information submission using the PRS. Two Working Group members each presented a user scenario that highlighted challenges based on that Working Group member's experience and expertise. Using an interactive online collaboration tool, the Working Group had the opportunity to provide input and envision the role that the modernization effort might play in addressing the issues described in the scenarios. Each of their ideas was categorized by whether it could be implemented directly by ClinicalTrials.gov during modernization, would require evaluation and help from others (e.g., partners, data-sharing agreements), or would need to be implemented by others (indirectly supported by ClinicalTrials.gov).

Dr. Dykes presented the challenges that academic investigators and PRS Administrators face when submitting or updating trial information on ClinicalTrials.gov using the PRS. Challenges included high rates of PRS administration staff turnover, a lack of institutional leadership support for research transparency and clinical trial reporting, difficulty managing data across multiple systems, difficulty reporting trials with nontraditional study designs, and limited functionality to support end-to-end workflows.

Working Group members discussed how ClinicalTrials.gov might better serve academic investigators and PRS Administrators. Group members agreed that, as part of the modernization effort, ClinicalTrials.gov could directly help these users by:

- Providing PRS Users with automated email reminders about critical next steps
- Improving the functionality and workflow of the PRS online forms to make them more user-friendly
- Supporting the use of study protocol templates that map to PRS data submission fields for information upload
- Expanding the reference library of PRS study record examples

Ideas that will require further exploration, which could include support from partners or data-sharing agreements, included providing a helpline function for PRS Users, identifying common clinical trial management systems to support mapping to the PRS, and providing training for new investigators on good reporting practices. It was agreed that standardizing institutional review board (IRB) systems across institutions and strengthening IRB

requirements to promote data submission were ideas that were outside the direct scope of the modernization effort.

Ms. Kress presented challenges faced by industry sponsors when managing large numbers of clinical trial records across teams, multiple sites, and companies. Challenges included promoting collaboration and creating standardized submission processes within a large organization and submitting information to multiple registries. Ms. Kress summarized her company's processes for managing its clinical trial portfolio, which include a quality-control team that reviews all registration and results information before release and the development of subject matter expertise, standard operating procedures, and third-party platforms to support compliance success.

The Working Group discussed centralized record-management and how industry sponsors tend to receive more support from leadership, compared with their academic counterparts. Working Group members also discussed how ClinicalTrials.gov might better serve industry sponsors. Group members agreed that, as part of the modernization effort, ClinicalTrials.gov could directly help these users by:

- Providing PRS Users with automated notification of upcoming deadlines and alerts for deadlines that have already passed
- Providing additional education on PRS reporting requirements
- Expanding the reference library of PRS study record examples
- Helping PRS Users understand when results or updates are expected (according to regulations and policies)
- Helping sponsors understand whether each study record may be subject to key registration or results reporting requirements

Ideas that will require further exploration, which could include support from partners or data-sharing agreements, included integrating workflows (with the ability to send and receive approvals within the organization).

IV. SUMMARY AND NEXT STEPS
Carlos R. Jaén, MD, PhD, Chair
Rebecca J. Williams, PharmD, MPH, Executive Secretary

The minutes of the December 11, 2020, BOR Working Group meeting were shared with members for review. Members were asked to provide comments before the minutes are finalized and posted on the BOR website.

Dr. Jaén thanked Working Group members for their time and ClinicalTrials.gov staff for their continued progress on the modernization effort. Dr. Williams noted that as the modernization effort moves to the next phase of implementation, staff will likely be contacting individual Working Group members for support regarding specific aspects of the effort.