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 25, 2023

MEMBERS PRESENT
Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California, Chair
Anna M. Fine, PharmD, MS, NLM, NIH, Executive Secretary
Omolola (Lola) Ogunyemi, PhD, FACMI, Charles R. Drew University of Medicine and Science
Nancy Smider, PhD, Epic

MEMBERS NOT PRESENT
Jennifer (Jennie) S. Lucca, MSW, The Children's Inn at NIH

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
Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School
Barbara Kress, BSN, RN, Merck
Seth A. Morgan, MD, National Multiple Sclerosis Society

EXTERNAL MEMBERS NOT PRESENT
Stephen J. Rosenfeld, MD, MBA, North Star Review Board and Freeport Research Systems
Joseph S. Ross, MD, MHS, Yale School of Medicine
Steven Woloshin, MD, The Dartmouth Institute for Health Policy and Clinical Practice

OTHERS PRESENT
Stacey Arnold, PhD, NLM, NIH, ClinicalTrials.gov Results Subject Matter Expert
Annice Bergeris, AS, NLM, NIH, ClinicalTrials.gov Information Research Specialist, Acting Deputy Director, and Operations Team Product Owner
Patricia Flatley Brennan, RN, PhD, NLM, NIH, Director of NLM
Mandy Davis, BA, ICF Next, ClinicalTrials.gov User Experience (UX) Researcher
Nachiket Dharker, PhD, ICP-APO, ICP-LEA, ICF, Protocol Registration and Results System (PRS) Beta Product Owner
Elisa Golfinopoulos, PhD, ICP-LEA, NLM, NIH, ClinicalTrials.gov Policy Analyst and PRS Automation Support Team Product Owner
Slava Gorelenkov, MS, ICP-LEA, NLM, NIH, ClinicalTrials.gov Technical Program Manager
Catherine Kihara, LLM, ICF Next, ClinicalTrials.gov Lead UX Researcher

Hibah Nazir, MPH, CSPO, CSM, Computercraft, ClinicalTrials.gov Product Manager
Alison Powell, BA, ICF Next, ClinicalTrials.gov Communications Specialist
Christina Robinson, MA, ICP-LEA, NLM, NIH, Modernized ClinicalTrials.gov Product Owner
Mary Sanders, MS, PMP, CSM, ICP-LEA, ICP-APO, ICP-ATF, ICF, ClinicalTrials.gov Project Director
Tony Tse, PhD, NLM, NIH, ClinicalTrials.gov Analyst
Susan Wimmer, BA, ICF, ClinicalTrials.gov Senior Editor

I. WELCOME

Anna M. Fine, PharmD, MS, Executive Secretary
Lourdes Baezconde-Garbanati, PhD, MPH, Chair

Dr. Fine welcomed the attendees, including BOR members, external members, and ClinicalTrials.gov staff, to the final meeting of the Working Group. Dr. Baezconde-Garbanati also welcomed Working Group members and thanked them for their yearslong effort and hard work in support of the modernization of ClinicalTrials.gov, especially during the COVID-19 pandemic.

II. RECAP OF THE CLINICALTRIALS.GOV MODERNIZATION EFFORT

Anna M. Fine, PharmD, MS, Executive Secretary

Dr. Fine summarized the accomplishments of the ClinicalTrials.gov modernization effort to date and the critical role played by the Working Group. Charged with guiding NLM's efforts to maintain the integrity of ClinicalTrials.gov, maximize its utility, and support engagement with its diverse stakeholders, the Working Group participated in 16 meetings and several public activities and events. Two summary reports describing the modernization effort, including the valuable input received from the Working Group, have been released; a third report, currently in progress, will summarize all the work undertaken since the second report, which was released in October 2022. Dr. Fine then discussed the ongoing need to increase engagement among diverse groups of patients who are underrepresented in clinical research, as well as their advocates, and she asked for suggestions from the Working Group. As an example, Dr. Fine shared that the team was considering holding engagement events at different times of day to accommodate patients' varying schedules. A Working Group member suggested that the team could ask Clinical Trials Registration and Results Reporting Taskforce members to contact their medical center's office of diversity and inclusion to help connect the modernization team to diverse patient groups.

Dr. Fine noted the work of the ClinicalTrials.gov modernization team, which has expanded in size since the beginning of the effort. She then described planned activities for years 4 and 5 of modernization. The team will continue to refine the modernized ClinicalTrials.gov website, which was launched in June, through additional releases and updates. Development of PRS Beta will continue, with new features released during the rest of this year and into 2024. Usability testing, evaluation, and engagement with stakeholders are also ongoing. The team will continue to engage with stakeholders and the public through public meetings and social media communications, as well as user feedback collected through the modernized ClinicalTrials.gov website and PRS Beta.

III. SUMMARY AND FOLLOW-UP FROM THE PRODUCT OWNERS

Nachiket Dharker, PhD, ICP-APO, ICP-LEA, PRS Beta Product Owner
Elisa Golfinopoulos, PhD, ICP-LEA, ClinicalTrials.gov Policy Analyst and PRS Automation Support Team Product Owner
Christina Robinson, MA, ICP-LEA, Modernized ClinicalTrials.gov Product Owner

Dr. Dharker summarized new features introduced in recent releases of PRS Beta, such as the Record Summary page, the updated landing page that appears when users open a study record. This page provides users with easy access to record contact information and options for downloading or editing the record. Within each Protocol Section module, new just-in-time help content and field-level error messages have been added to help guide PRS users during data entry. Dr. Dharker presented targeted next steps for the PRS modernization effort, including the protocol quality-assurance (QA)/quality-control (QC) review pages, results submission modules, results QA/QC pages, and account management pages. He also explained the difference between PRS Test, where users can try out new PRS Beta features, and the PRS production system, where the new features are deployed and go live. A Working Group member recommended developing a simple infographic that shows how to access PRS Beta from the classic site as well as highlights the differences between the PRS test and production environments.

Following up on a previous Working Group discussion, Dr. Golfinopoulos shared an update on providing access to data monitoring committee (DMC) charters through ClinicalTrials.gov. As recommended by Working Group members, NLM plans to update an existing optional data element to allow standardized labeling of links within ClinicalTrials.gov to DMC charter documents posted on other websites. This plan addresses the needs described in a May 2023 commentary by DeMets et al. in *Clinical Trials* by better supporting the identification of clinical studies with DMC charters and retrieval of those study records. Dr. Golfinopoulos explained that implementation is anticipated in 2025, following completion of the ClinicalTrials.gov modernization effort. Working Group members were asked to engage with their communities to promote the use of this new DMC charter–linking capability once it becomes available.

Dr. Golfinopoulos also presented the results of efforts by the PRS Automation Support Team to automate aspects of the QC review process using machine learning and deep learning classifiers. The classifiers were trained to identify the three most common major issues identified by reviewers in registration records. While all the classifiers performed reasonably well in a simulated environment, they were challenged in cases where the major issue could manifest for many different reasons, including as the results of information that was submitted but not provided to the classifier. Future efforts will explore the utility and value of integrating the classifiers into the QC review team's native work environment.

Ms. Robinson presented recent usage trends, user feedback, and usability testing activities for the modernized ClinicalTrials.gov website, which will continue to be updated until the classic website is retired in 2024. Since the launch of the modernized ClinicalTrials.gov in

June, the team has monitored traffic to the classic and modernized sites and has collected user feedback to guide ongoing improvements. Usability testing of the Saved Studies feature of the modernized site was recently completed; testing of remaining modernized site features is upcoming. Before the classic site is retired, content migration will be completed, an XML download option will be integrated, the ClinicalTrials.gov application programming interface will be finalized, and the data ingest from the PRS will be rewritten.

Ms. Robinson demonstrated recent additions to the modernized site, highlighting the site menu's link to the PRS Info section, various site features, and information pages. She reminded Working Group members to continue to promote the modernized ClinicalTrials.gov to their networks and to convey user feedback to the modernization team.

IV. ACTIVITY: LANDSCAPE ANALYSIS

Catherine Kihara, LLM, ClinicalTrials.gov Lead UX Researcher
Mandy Davis, BA, ClinicalTrials.gov UX Researcher

Ms. Kihara and Ms. Davis facilitated an activity that assessed Working Group members' experience with two ClinicalTrials.gov features that allow users to find studies by topic or on a map and gathered feedback on those features. The group was given an overview of the features on the classic website and was asked for feedback on how the features should be integrated into the modernized site. Working Group members agreed that it would be good or important, but not critical, to have both these features available on the modernized website by the time the classic site is retired, and the Finding Studies by Topic feature was ranked as more important than the Finding Studies on a Map feature. The modernization team will continue to review the feedback gathered during this activity to determine how the findings can be used to improve these features.

V. THANK-YOUS AND CLOSING REMARKS

Patricia Flatley Brennan, RN, PhD, Director of NLM
Lawrence Tabak, DDS, PhD, Acting Director of NIH
Lyric A. Jorgenson, PhD, Acting NIH Associate Director for Science Policy
Anna M. Fine, PharmD, MS, Executive Secretary

Dr. Brennan thanked Working Group members for their efforts to support technical improvements and engagement with the public during the ClinicalTrials.gov modernization effort. Aligned with the NLM mission, the effort to modernize ClinicalTrials.gov has helped advance a more effective and useful tool for both researchers and the public. Dr. Brennan also thanked Dr. Baezconde-Garbanati and the ClinicalTrials.gov modernization team at the National Center for Biotechnology Information for their work.

Dr. Tabak, addressing the group via a prerecorded video, noted the Working Group's initial charge to help improve the usability of ClinicalTrials.gov, NIH's premier repository of clinical trial information, by facilitating engagement with its diverse stakeholders, and he

recognized the nearly four years of service that followed. He thanked the group for its efforts, highlighting its stakeholder outreach through public meetings and webinars.

Dr. Jorgenson congratulated the NLM team and the Working Group on the accomplishments of the ClinicalTrials.gov modernization effort. She highlighted the importance of ClinicalTrials.gov as a critical source of clinical trials information for patients and as an important research tool, increasing the efficiency of drug and device development and helping prevent duplicate research.

Dr. Fine ended the meeting by thanking the Working Group, encouraging them to reach out to the team, and saying that they would receive a copy of the meeting minutes and the final modernization summary report.