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 30, 2021

MEMBERS PRESENT
Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California, Chair
Kent J. DeZee, MD, MPH, FACP, COL, MC, U.S. Army Office of the Surgeon General
Jennifer S. Lucca, MSW, The Children's Inn at NIH
Rebecca J. Williams, PharmD, MPH, NLM, NIH, Executive Secretary

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
Carlos R. Jaén, MD, PhD, University of Texas Health Science Center at San Antonio
Barbara Kress, BSN, RN, Merck
Seth A. Morgan, MD, National Multiple Sclerosis Society
Stephen J. Rosenfeld, MD, MBA, Freeport Research Systems, LLC and North Star Review Board
Joseph S. Ross, MD, MHS, Yale School of Medicine
Steven Woloshin, MD, The Dartmouth Institute

EXTERNAL MEMBERS NOT PRESENT
Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School

OTHERS PRESENT
Annice Bergeris, ClinicalTrials.gov Information Research Specialist
Heather Dobbins, ClinicalTrials.gov Lead Results Analyst
Jolie Dobre, User Experience (UX) Subject Matter Expert (ICF Next)
Anna Fine, ClinicalTrials.gov Assistant Director
Elisa Golfinopoulos, ClinicalTrials.gov Results Team Lead (ICF)
Slava Gorelenkov, ClinicalTrials.gov Technical Program Manager
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
Shanel Vicente, UX Designer (ICF Next)

I. INTRODUCTION AND WELCOME
Lourdes Baezconde-Garbanati, PhD, MPH, Chair
Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Baezconde-Garbanati welcomed Working Group members and thanked them for their continued interest and participation in the ClinicalTrials.gov modernization effort.

Dr. Williams noted that the purpose of the meeting was to discuss feedback on the Report on the ClinicalTrials.gov Modernization Effort, 2019–21, which had been presented during the August 20 Working Group meeting. Several aspects of the modernization progress report were reviewed in detail during today's meeting to elicit agreement or additional comments. Polling of Working Group members was incorporated throughout the discussion to gather feedback from the group.

II. MODERNIZATION PROGRESS REPORT FEEDBACK AND DISCUSSION
Rebecca J. Williams, PharmD, MPH, Executive Secretary
All Working Group Members

Dr. Williams reiterated the specific items she had asked Working Group members to consider when reviewing the modernization progress report, including the overall organization of the report and whether additional references were needed. Working Group members had also been asked to review the list of modernization outcomes in section 3 of the report for completeness and the characterization of the user challenges associated with each of the three strategic goals as being either directly or indirectly supported by the modernization effort in section 4 for correctness. In response to a polling question, most Working Group members indicated that the report provided a good overview of the modernization effort and the Working Group's input to date.

First, Dr. Williams reviewed the modernization outcomes, noting that they comprise a mix of practical and aspirational results that the ClinicalTrials.gov modernization effort hopes to achieve. Working Group members agreed with the outcomes listed in the report and provided no additional feedback.

Dr. Williams then reviewed the user challenges associated with the first strategic goal (clinical trial information is current, complete, and reliable). Working Group members agreed with the user challenges listed and the identification of which ones could be addressed directly by the modernization effort and which could be supported only indirectly and would need to be addressed by the wider clinical research community. One suggestion was to consider the important role that institutions play in awarding academic "credit" to investigators.

Next, Dr. Williams reviewed the user challenges associated with the second strategic goal (anyone can easily find and use information about clinical trials). Working Group members agreed with the challenges listed and their characterizations and discussed the challenges that could be addressed only indirectly by modernization. Additional feedback included conducting usability testing for plain language content, considering varying levels of numeracy among users, and weighing approaches to increasing the visibility of ClinicalTrials.gov. Dr. Williams noted that ongoing user research is an important part of the continuous improvement of ClinicalTrials.gov; health literacy experts are involved in the process, and focus groups have been employed. She offered to share with the Working Group, or individual members, more details on the ClinicalTrials.gov team's approach to usability testing for plain language content. Efforts to increase the visibility of the website will be a focus in the future, after the beta releases have been made available, and once confidence in the new products is demonstrated and they become more fully featured.

It was suggested that more information about data sharing be included on the website, especially in relation to the NIH Data Sharing policy, and it was noted that a willingness to share data that can be used to replicate findings could be an indirect measure of quality. Dr. Williams responded that one of the goals is to help people view and connect to the various research products that result from clinical trials. Currently, a data sharing statement (i.e., whether the investigator intends to share participant-level data) is captured on ClinicalTrials.gov, along with where the data will be shared after the study ends. Because data sharing occurs mainly after clinical trial results have been reported, ClinicalTrials.gov will investigate ways to encourage investigators to add data sharing information after reporting is finished as well as automated mechanisms that can more easily discover where the data are available.

Dr. Williams discussed the next steps for finalizing the modernization progress report, which will be revised based on the Working Group's feedback, then sent to Working Group members and shared with the full BOR at the September 14 NLM BOR meeting. The report and the Working Group meeting minutes will also be added to the NLM BOR webpage.

The modernization progress report will be made available to the public before the next public webinar, which is expected to take place in October. Working Group members suggested where the public version of the report could be published or shared in blog posts.

III. **BETA RELEASE PLANS, WORKING GROUP EXPERTISE, AND NEXT PRIORITIES DISCUSSION**
Rebecca J. Williams, PharmD, MPH, Executive Secretary
All Working Group Members

Dr. Williams shared the stakeholder communications timeline and our plans for collecting qualitative and quantitative metrics, including performing both passive and active evaluations. At the next Working Group meeting, we will share information about the beta releases and what is known about their reception from both a quantitative and qualitative perspective.

Dr. Williams reviewed potential Working Group priorities, including data standards and data normalization; submission and quality-control review automation support through natural language processing, machine learning, and artificial intelligence (AI); and the reporting of emerging scientific issues and complex study types. Working Group members discussed additional topics to prioritize for discussion during future Working Group meetings. Their suggestions related to communications planning, machine learning and AI, and optimizing stakeholder engagement, especially among third-party users. Working Group members were particularly interested in engagement with third parties, such as individual patient organizations and medical societies, to encourage them to provide additional information about clinical research to their communities.

Regarding Working Group membership, all the Working Group members agreed to continue to participate through September 2022. Dr. Williams noted that the need for additional expertise, especially in the areas of AI and machine learning, could be discussed further during future meetings.

IV. SUMMARY AND NEXT STEPS
Rebecca J. Williams, PharmD, MPH, Executive Secretary
Lourdes Baezconde-Garbanati, PhD, MPH, Chair

The next Working Group meeting is anticipated for January 2022. The ClinicalTrials.gov team will follow up with Working Group members after today's meeting to confirm their availability.

Dr. Williams shared that a workshop focused on landscape analysis is under development. All Working Group members will be invited, and Dr. Williams will contact specific Working Group members to request their involvement with this work.

Dr. Baezconde-Garbanati thanked Dr. Williams, the larger modernization team, and the Working Group and reminded Working Group members about the upcoming NLM BOR meeting, during which recent Working Group activities will be presented. She also asked that Working Group members share any other suggestions for Working Group priorities or additional expertise that is needed.