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
DECEMBER 11, 2020

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 Medical Center
Alissa Gentile, MSN, RN, The Leukemia and Lymphoma Society
Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School
Barbara Kress, BSN, RN, Merck
Seth A. Morgan, MD, National Multiple Sclerosis Society
Stephen J. Rosenfeld, MD, MBA, Secretary's Advisory Committee on Human Research Protections
Joseph S. Ross, MD, MHS, Yale School of Medicine
Steven Woloshin, MD, The Dartmouth Institute

OTHERS PRESENT
Annice Bergeris, ClinicalTrials.gov Information Research Specialist
Caitlin Bowler, User Experience (UX) Research Analyst (ICF Next)
Heather Dobbins, ClinicalTrials.gov Lead Results Analyst
Jolie Dobre, UX Lead (ICF Next)
Anna Fine, ClinicalTrials.gov Assistant Director
Jaime Goff, UX Architect/Analyst (ICF Next)
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)
Maureen Strange, ClinicalTrials.gov Clinical Trial Subject Matter Expert (ICF)
Tony Tse, ClinicalTrials.gov Analyst
Alison Ward, Communications Strategist (ICF Next)
Becca Xu, UX Research Analyst (ICF Next)

I. WELCOME, AGENDA OVERVIEW, AND INTRODUCTION
Carlos R. Jaén, MD, PhD, Chair
Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Jaén welcomed and thanked Working Group members for their attendance and participation. Dr. Williams introduced Jennifer S. Lucca, MSW, of The Children's Inn at NIH, the newest BOR member to join the Working Group, replacing Gary Puckrein, MD.

Dr. Williams noted several upcoming meetings, including a public webinar to update stakeholders on the progress of the modernization effort scheduled for February 18, 2021. During the February 9, 2021, NLM BOR meeting, Working Group representatives will report on the December 11, 2020, meeting. The next Working Group meeting, which will focus on challenges related to the ClinicalTrials.gov Protocol Registration and Results System (PRS) and planning for future Working Group needs, is scheduled for February 26, 2021.

II. MODERNIZATION OVERVIEW
Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams reported that the modernization vision, key audiences, goals, and outcomes were shared with points of contact at NIH Institutes and Centers on December 3, 2020. She then reviewed this information, which Working Group members had helped develop and validate using the strategy-for-change approach during the September 11, 2020, meeting:

- Modernization vision: "ClinicalTrials.gov serves as an essential, integral, and trusted part of the research ecosystem to advance medical knowledge."
- Three main user group categories or audiences: (1) data providers, (2) patients and their advocates, and (3) data researchers
- Strategic goals: (1) Clinical trial information is current, complete, and reliable; (2) Anyone can easily find and use information about clinical trials; and (3) Trial information, resources, and tools provide value to the research ecosystem.
- Outcomes: Associated with the modernization vision and goals of better supporting users

Feedback provided by the NIH points of contact included the following:

- Confirmation that the outcomes resonated, including those related to the use of plain language and to trial information being presented in the context of the studied condition
- The need to clarify the wording of some outcomes
- Other suggestions, such as providing greater support for conducting landscape analyses to identify research gaps and opportunities as well as for identifying regulatory and policy compliance issues

- An eagerness to participate in the iterative design process during the modernization effort
- Interest in issues related to reporting innovative, emerging trial designs such as "master protocols"

Dr. Williams described completed, ongoing, and upcoming public site modernization activities, including setting up an environment to test and improve automated synonymy expansion and developing plans for the information architecture and content strategy. She indicated that a separate website for the testing of new features, which will run in parallel to the existing public site, is anticipated to be launched in fall 2021. Other recent website activities and updates included prioritizing the dissemination of summary results for COVID-19 trials, as called for by the NIH Director's November 10, 2020, statement on swiftly reporting results; providing a search option for violations of regulatory reporting requirements; and adding new study design examples for the reporting of behavioral and social science research studies.

III. FACILITATED DISCUSSIONS
Wendy Harman, UX Lead, ICF Next
Alissa Gentile, MSN, RN, The Leukemia and Lymphoma Society
Stephen J. Rosenfeld, MD, MBA, Secretary's Advisory Committee on Human Research
    Protections
All Working Group Members

The purpose of the facilitated discussions was to help generate ideas and priorities to address challenges faced by patients and meta-researchers, as discussed during prior Working Group meetings. Two Working Group members each presented a user scenario that highlighted such challenges, based on their expertise. Using an interactive online collaboration tool, Working Group members provided input on the role that the modernization effort might play in addressing these challenges. They discussed whether each idea 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).

Ms. Gentile presented challenges faced by patients and their advocates when using ClinicalTrials.gov, such as a limited understanding of what ClinicalTrials.gov is or how they can get the best experience from the site, difficulty with technical language due to low health literacy, and uncertainty regarding next steps.

The Working Group discussed how a modernized ClinicalTrials.gov might better serve patients. The discussion focused on enhanced user assistance; improved search capabilities; greater readability, accessibility, and inclusiveness; and other suggestions. The group also recognized the heterogeneity of the needs and capabilities of different patients. Other aspects of the discussion focused on the importance of health care providers in supporting patients who are considering participating in research, a function that ClinicalTrials.gov can

support but not replace. Group members agreed that, as part of the modernization effort, ClinicalTrials.gov could directly help users:

- Learn how to navigate the public website
- Compare trials
- Narrow search results based on specific needs
- Save and share search results

ClinicalTrials.gov could also provide a resource that includes questions about research participation and facilitates discussion, as well as other tools for users, and make the site content more accessible to all users.

Further exploration, which could include support from partners or data-sharing agreements, may be needed for other ideas that were discussed, such as providing a search interface that steps users through a brief set of health-related questions up front to help them find relevant trials and creating a way to alert users to new and upcoming trials. It was agreed that ideas such as providing a function to sort search results by financial burden and insurance coverage, providing research-participation navigation services, and vetting the quality and value of individual study designs would be outside the direct scope of the modernization effort.

Dr. Rosenfeld presented challenges faced by meta-researchers from his unique perspective as a former chair of an institutional review board (IRB), including limitations in determining the research that has been done (i.e., landscape analysis) and the data that are available using ClinicalTrials.gov, difficulty in using ClinicalTrials.gov to identify knowledge gaps across the clinical research enterprise, and difficulty understanding which search terms will return the expected results. Knowing about related research helps an IRB better contextualize any new research that is being considered.

The Working Group discussed how ClinicalTrials.gov might better serve meta-researchers. The discussion focused on enhanced user resources, improved tools for managing searches, and data standardization. Group members agreed that, as part of the modernization effort, ClinicalTrials.gov could develop features that:

- Allow users to save search queries
- Make comparing trials easier
- Provide training, educational tools, and other support
- Provide a way to view graphical representations of retrieved studies to visualize search results and the study landscape
- Make the application programming interface (API) and other data analysis tools more accessible

Further exploration, which could include support from partners or data-sharing agreements, may be needed for other ideas that were discussed, such as providing the ability to receive updates or alerts about new research and upcoming trials and increasing the standardization of values submitted for the data elements to facilitate user-conducted analyses. Integrating content on ClinicalTrials.gov with external sources such as U.S. Census data or geospatial data and assessing the social utility of listed research would be outside the direct scope of the modernization effort.

IV. **SUMMARY AND NEXT STEPS**
Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams noted the overlapping needs and challenges of the patient and advocate and the meta-researcher user groups reflected in the user scenarios and Working Group discussion. Identifying core issues shared by multiple user groups and prioritizing activities that address those issues would help streamline the overall modernization effort and increase efficiency (i.e., maximize the return on investment).

A save-the-date message will be sent for the next Working Group meeting, on February 26, 2021. At that meeting, group members will have the opportunity to revisit the outputs from the December 11 meeting, discuss challenges related to data submission via the PRS, and begin to plan for future Working Group needs.