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

MEMBERS NOT PRESENT
Kent J. DeZee, MD, MPH, FACP, COL, MC, U.S. Army Office of the Surgeon General
Gary A. Puckrein, PhD, National Minority Quality Forum

EX OFFICIO NIH MEMBERS PRESENT
Lyric A. Jorgenson, PhD, Office of Science Policy
Pam 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, UX Research Analyst (ICF Next)
Heather Dobbins, ClinicalTrials.gov Lead Results Analyst
Jolie Dobre, UX Lead (ICF Next)
Anna Fine, ClinicalTrials.gov Deputy Director
Jaime Goff, UX Architect/Analyst (ICF Next)
Elisa Golfinopoulos, ClinicalTrials.gov Results Team Lead (ICF)
Slava Gorelenkov, ClinicalTrials.gov Technical Program Manager
Wendy Harman, UX Lead (ICF Next)
Casey Jennings, UX Analyst/Strategist (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
Becca Xu, UX Research Analyst (ICF Next)

I. WELCOME AND INTRODUCTIONS

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

Dr. Jaén welcomed the Working Group members and thanked them for attending. Dr. Williams introduced the ClinicalTrials.gov staff members attending the meeting, and Working Group members introduced themselves to the group.

II. MODERNIZATION OVERVIEW

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams gave an overview of the modernization effort, reminding the group of the key themes extracted from the responses to the Request for Information and of the four overarching goals of modernizing ClinicalTrials.gov, which are to (1) establish a modern infrastructure to support long-term sustainability, (2) make information easy to find and use to maximize its value, (3) simplify the submission process to improve the user experience and enhance data quality, and (4) enhance quality-control review process efficiency to accommodate growth.

Dr. Williams also presented a draft roadmap with an overview of the key technology and infrastructure milestones, emphasizing that these structural and process changes will be sustainable and are intended to extend beyond the initial 4-year period. Four workstreams were highlighted, and they included building a new cloud-based public website and migrating an upgraded Protocol Registration and Results System to the cloud.

III. FACILITATED DISCUSSION

Wendy Harman, UX Lead (ICF Next)
All Working Group Members

The purpose of the facilitated discussion was to gather expert views and insights on the vision for ClinicalTrials.gov from Working Group members and help validate themes expressed during engagement activities that will be addressed by the modernization effort. Using a strategy for change approach and an interactive online collaboration tool, Working Group members provided input on the overall vision (ideal impact or legacy of modernization), challenges (constraints on reaching that vision), outcomes (goals), outputs (specific solutions), activities (how to achieve outputs), and inputs (resources).

The overall vision shared by Working Group members was for ClinicalTrials.gov to serve as an essential resource supporting the clinical research enterprise in improving health outcomes. Emerging themes regarding this vision included the following:

- Improving the reliability of information about clinical research (and the accountability of the sources of this information)
- Enhancing public trust in clinical research

- Supporting equitable access to clinical research information and studies
- Meeting health literacy needs
- Ensuring that all trial results are available
- Providing context for research and supporting the desire for actionable and understandable information and results

Working Group members discussed the challenge of translating and aggregating research evidence into actionable steps for a variety of uses (e.g., looking for gaps in research, conducting systematic reviews, translating evidence into practice). One suggestion was to consider initiating a campaign to promote the benefits of ClinicalTrials.gov to various users. Members noted the need to clarify the intended uses of ClinicalTrials.gov for different types of users and suggested developing a clinical research primer that supports health and research literacy.

Working Group members also identified outcomes that are consistent with the vision for modernization, including:

- Reusability
- Greater interoperability, including across National Center for Biotechnology Information systems (e.g., PubMed and PubMed Central, dbGaP)
- Discoverability
  - Easily discoverable research products (e.g., publications, de-identified individual participant data)
- Improved Research Quality
  - Higher quality of clinical research
  - Easier identification and sharing of information about research gaps
- Reliability
  - Improvements to facilitate registration
  - Improvements to facilitate searching
- Understandability
  - Availability of information on clinical trials in accessible language

Outputs and associated activities were also identified. Dr. Williams emphasized several standard design and data principles focused on understanding the context, increasing transparency, and providing fair and equitable access that will be considered throughout the modernization process.

IV. SUMMARY AND NEXT STEPS

Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams noted that the information collected during the facilitated discussion will be used to support, validate, and refine the vision and outcomes in support of the ClinicalTrials.gov modernization roadmap. She emphasized that ClinicalTrials.gov staff are

looking forward to additional opportunities for Working Group members to provide input and feedback.

Working Group members recognized the importance of transparency and supported the use of feedback loops to give users and stakeholders the opportunity to provide feedback. Members suggested engaging with established organizations (e.g., professional societies) to obtain validation prior to implementation. Dr. Williams noted that ClinicalTrials.gov staff may reach out to Working Group members individually to further refine user personas and journey maps.

The Working Group will meet during the NLM Board of Regents (BOR) meeting on September 15 to develop the report out, which Dr. Jaén will present to the BOR. ClinicalTrials.gov staff will contact Working Group members in the coming months to obtain input on characterizing the vision and outcomes, engage members in providing additional input, and inform them of progress made.