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
APRIL 29, 2022

MEMBERS PRESENT
Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California, Chair
Anna M. Fine, PharmD, MS, NLM, NIH, Executive Secretary
Jennifer (Jennie) S. Lucca, MSW, The Children's Inn at NIH
Omolola (Lola) Ogunyemi, PhD, FACMI, Charles R. Drew University of Medicine and Science

MEMBERS NOT PRESENT
Kent J. DeZee, MD, MPH, MACP, COL, MC, Defense Health Agency
Lauren A. Maggio, PhD, Uniformed Services University of the Health Sciences

EX OFFICIO NIH MEMBERS PRESENT
Lyric A. Jorgenson, PhD, Office of Science Policy

EX OFFICIO NIH MEMBERS NOT PRESENT
Pamela Reed Kearney, MD, Office of Extramural Research

EXTERNAL MEMBERS PRESENT
Carrie Dykes, PhD, University of Rochester Clinical and Translational Science Institute
Alissa T. 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
Stephen J. Rosenfeld, MD, MBA, North Star Review Board and Freeport Research Systems
Steven Woloshin, MD, The Dartmouth Institute for Health Policy and Clinical Practice

EXTERNAL MEMBERS NOT PRESENT
Joseph S. Ross, MD, MHS, Yale School of Medicine

OTHERS PRESENT
Stacey Arnold, PhD, NLM, NIH, Protocol Registration and Results System (PRS) Subject Matter Expert
Annice Bergeris, AS, NLM, NIH, ClinicalTrials.gov Information Research Specialist, Acting Deputy Director, and Operations Team Product Owner
Mandy Davis, BA, ICF Next, User Experience (UX) Researcher
Nachiket Dharker, PhD, ICP-APO, ICP-LEA, ICF, ClinicalTrials.gov Registration Team Lead and PRS Beta Product Owner

Elisa Golfinopoulos, PhD, ICP-LEA, ICF, ClinicalTrials.gov Results Team Lead and Automation Support Team Product Owner
Slava Gorelenkov, MS, ICP-LEA, NLM, NIH, ClinicalTrials.gov Technical Program Manager
Karen Hanson, MS, MBA, ICF, ClinicalTrials.gov Technical Writer
Wendy Harman, JD, ICF Next, ClinicalTrials.gov Beta UX Lead
Catherine Kihara, LLM, PhD (ABD), ICF Next, UX Researcher
Hibah Nazir, MPH, CSPO, CSM, Computercraft, ClinicalTrials.gov Product Manager
Catina O'Leary, PhD, MSW, HLM, Health Literacy Specialist
Christina Robinson, MA, ICP-LEA, NLM, NIH, ClinicalTrials.gov Beta Product Owner
Mary Sanders, MS, PMP, CSM, ICP-LEA, ICF, ClinicalTrials.gov Project Manager
Colin Small, BA, ICF Next, ClinicalTrials.gov Beta UX Architect
Tony Tse, PhD, NLM, NIH, ClinicalTrials.gov Analyst
Diane Webb, MPH, HLM, Health Literacy Specialist
Susan Wimmer, BA, ICF, ClinicalTrials.gov Editor

I. WELCOME AND INTRODUCTIONS

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

Dr. Baezconde-Garbanati welcomed Working Group members and reviewed the meeting agenda, which included an interactive exercise to demonstrate usability preference testing to the Working Group.

Dr. Fine welcomed attendees. She noted that during its third year, the ClinicalTrials.gov modernization effort is focusing on implementing the beta versions of the public website and the PRS. Recent progress includes the second ClinicalTrials.gov Beta release, on April 27, and the new Record List in PRS Beta.

II. MODERNIZATION UPDATES

Stacey Arnold, PhD
Christina Robinson, MA, ICP-LEA
All Working Group Members

Dr. Arnold highlighted features of the Record List View, which was added to PRS Beta in February, including a modern design, a customizable display, and improved filtering capability. She also noted that users can save current views and send emails directly from the Record List. User comments on the layout and usability of the new Record List have been largely positive. Based on initial feedback, the next PRS Beta release will aim to optimize screen real estate. Other planned updates include expanding the portfolio management capabilities and, later, implementing a new design for the registration portion of the PRS, the Protocol Section.

Ms. Robinson provided an overview of usage of and feedback on ClinicalTrials.gov Beta between December 2021 and March 2022. Of the roughly 60,000 users during this period, the majority were new users; the device type used to access the website was evenly split between desktop and mobile devices. User feedback focused heavily on search, advanced search, and search results. Ms. Robinson noted that most of the user feedback has been actionable, and she shared plans for future updates. The Release Notes page of the beta site will serve as a one-stop source of information about all updates to ClinicalTrials.gov Beta.

Working Group members asked for information about users of the classic and beta websites. Ms. Robinson noted that the number of visitors to the beta site is increasing but remains significantly smaller than the number visiting the classic site.

III. NAVIGATING USABILITY IN A REGULATED ENVIRONMENT

Anna M. Fine, PharmD, MS, Executive Secretary
Catherine Kihara, LLM, PhD (ABD)
Colin Small, BA
Stacey Arnold, PhD
All Working Group Members

Dr. Fine discussed the challenges involved in developing plain language content for the ClinicalTrials.gov website. Numerous principles (e.g., plain language principles, U.S. Web Design System 2.0 principles, usability principles, compliance with Section 508 of the Rehabilitation Act of 1973), policy and legal constraints, and varying, sometimes conflicting, user needs must all be considered. Dr. Fine highlighted information on the beta website that incorporates these principles and reflects a health literacy review, including the About ClinicalTrials.gov and Learn About Studies pages and the disclaimer language.

Ms. Kihara and Mr. Small facilitated a usability exercise demonstrating preference testing in which meeting attendees ranked five options for displaying the disclaimer on ClinicalTrials.gov Beta, in order of preference. The highest rated option was to display the disclaimer as a onetime pop-up that the user must acknowledge to dismiss.

In discussing additional considerations related to the disclaimer's effectiveness, Working Group members noted that the optimal way to display the disclaimer may depend on whether a desktop or mobile device is used. Members emphasized that the disclaimer should be displayed in such a manner that it cannot be ignored or skipped over; it should also deliver the intended message in language that is understandable to users. Catina O'Leary confirmed that usability testing participants had understood the updated disclaimer language, and Ms. Kihara shared that the next round of usability testing would address user comprehension and the functionality of the new disclaimer options.

Dr. Arnold presented information about the Brief Title and Brief Summary data elements, which are submitted by data providers and are required to convey key study information and objectives in language written for the lay public. She summarized applicable plain language principles and regulatory guidelines and also shared a newly developed checklist that could assist data providers in writing the Brief Summary in plain language. The Working Group suggested ways to support the use of accessible language by data providers, including identifying common keywords in user searches and incorporating them into the Brief Summary.

Dr. Arnold then reviewed recent initiatives and guidance related to plain language summaries (PLS) for clinical trials and their results. In 2017 the Final Rule for Clinical Trials Registration and Results Information Submission declined to require submission of PLS to ClinicalTrials.gov because of a lack of evidence that this could be done without being misleading or promotional. However, several responses to the 2020 modernization request for information suggested considering the display of PLS, either directly within

ClinicalTrials.gov or indirectly via links to external sources. Dr. Fine noted that while the Working Group could, in response to these comments, conduct an updated review of the PLS landscape five years after the issuance of the Final Rule, the modernization effort would not involve changing the previous decision, which would require additional rulemaking. Working Group members were asked to volunteer to give lightning talks during the next Working Group meeting to share their experiences with PLS.

IV. NEXT STEPS

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

Dr. Fine noted that this Working Group meeting would be summarized during the report-out at the NLM BOR meeting on May 10. The next Working Group meeting will be held in August or September; the ClinicalTrials.gov team will notify Working Group members of the date and whether the meeting will be fully virtual or include a hybrid option for those who wish to attend in person.

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