

**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
JANUARY 13, 2023**

MEMBERS PRESENT

Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California, Chair
Kent J. DeZee, MD, MPH, MACP, COL, MC, Defense Health Agency
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
Nancy Smider, PhD, Epic

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
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
Joseph S. Ross, MD, MHS, Yale School of Medicine
Steven Woloshin, MD, The Dartmouth Institute for Health Policy and Clinical Practice

EXTERNAL MEMBERS NOT PRESENT

Alissa T. Gentile, MSN, RN, Dana-Farber Cancer Institute

OTHERS PRESENT

Stacey Arnold, PhD, NLM, NIH, Protocol Registration and Results System (PRS) Subject Matter Expert
Ben Babics, ICF Next, PRS Beta Engineering Lead
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, PRS Beta Product Owner
Sergey Dikunov, BS, Guidehouse, ClinicalTrials.gov Beta Technical Lead
Sarah DiPasquale, MS, ICP-APO, ICF Next, UX Researcher

Elisa Golfopoulos, PhD, ICP-LEA, NLM, NIH, ClinicalTrials.gov Policy Analyst and Automation Support Team Product Owner
Slava Gorelenkov, MS, ICP-LEA, NLM, NIH, ClinicalTrials.gov Technical Program Manager
Catherine Kihara, LLM, ICF Next, ClinicalTrials.gov UX Research Lead
Hibah Nazir, MPH, CSPO, CSM, Computercraft, ClinicalTrials.gov Product Manager
Alison Powell, BA, ICF Next, ClinicalTrials.gov Communications Specialist
Rupinder Randhawa, MASc, PMP, SAFe POPM, AWS CLF, ICF Next, ClinicalTrials.gov Modernization Project Manager
Christina Robinson, MA, ICP-LEA, NLM, NIH, ClinicalTrials.gov Beta Product Owner
Mary Sanders, MS, PMP, CSM, ICP-LEA, ICP-APO, ICP-ATF, ICF, ClinicalTrials.gov Project Manager
Colin Small, BA, ICF Next, ClinicalTrials.gov Beta UX Architect
Scott Smith, BA, CSPO, ICF Next, PRS Beta Product Manager
Tony Tse, PhD, NLM, NIH, ClinicalTrials.gov Analyst
Chris Wadham-Lynn, BS, ICF Next, PRS UX Lead
Susan Wimmer, BA, ICF, ClinicalTrials.gov Senior Editor

I. WELCOME AND INTRODUCTIONS

Lourdes Baezconde-Garbanati, PhD, MPH, Chair

Anna M. Fine, PharmD, MS, Executive Secretary

Dr. Fine welcomed the attendees, including BOR members, external members, and ClinicalTrials.gov staff. Dr. Baezconde-Garbanati also welcomed attendees and introduced the newest Working Group member, Nancy Smider of Epic. Dr. Smider shared with the group that she had participated in the modernization effort as an external stakeholder, including submitting a response to NLM's 2020 modernization request for information (RFI) on behalf of Epic, and that she looked forward to contributing as a Working Group member now. Dr. Baezconde-Garbanati thanked the Working Group and ClinicalTrials.gov staff for their continued work to support the modernization effort.

II. QUICK ORIENTATION

Anna M. Fine, PharmD, MS, Executive Secretary

Dr. Fine outlined recent Working Group activities as well as those anticipated for 2023, including this first meeting of the year, the 16th Working Group meeting to date. Working Group members will update the NLM BOR on recent activities during the next BOR meeting, on February 7. The Working Group will also meet between February and April to prepare for the public meeting scheduled for April 25, during which updates on the ClinicalTrials.gov modernization effort will be shared with external stakeholders. A report-out will be provided during the May NLM BOR meeting. The Working Group will meet again in August or September to further discuss progress on the beta sites, as well as potential changes to the current group model or sunsetting the group.

III. FOLLOW-UP ON PREVIOUS ITEMS

Elisa Golfinopoulos, PhD, ICP-LEA, ClinicalTrials.gov Policy Analyst and Automation Support Team Product Owner

Christina Robinson, MA, ICP-LEA, ClinicalTrials.gov Beta Product Owner

Dr. Golfinopoulos presented a proposal to give data submitters the option to provide access to data monitoring committee (DMC) charters via a dedicated location within ClinicalTrials.gov study records. Composed of independent experts, DMCs play an essential role in the oversight of clinical trials by assessing the risks and benefits to trial participants through interim analyses of accumulating data in order to recommend whether trials should be modified or terminated prematurely. ClinicalTrials.gov already includes an optional data element that allows data submitters to indicate whether a trial has DMC oversight. Of the more than 119,000 trials registered in the past five years, 82% provided information for the DMC data element. Of those, 39% indicated that the trial had DMC oversight.

Access to DMC charters, which specify the roles, responsibilities, and standard operating procedures of the committees, could improve public understanding of current practices.

Dr. Golfinopoulos noted, however, that no other requests for access to DMC charters had been received, either in response to the RFI or through other feedback mechanisms. Additionally, to establish a mechanism for accessing DMC charters from ClinicalTrials.gov study records, NLM would be faced with certain challenges, including the need to divert resources and the low response rates associated with optional data elements. Dr. Golfinopoulos outlined two possible approaches: (1) modifying an existing optional data element to provide a dedicated DMC Charter link to documents posted on external websites or (2) allowing the upload of DMC charters as Adobe PDF files for posting directly on ClinicalTrials.gov, similar to the approach to informed consent forms (ICFs).

Working Group members noted that unlike the posting of ICFs, which is required under the revised Common Rule, the posting of DMC charters is not currently required. Furthermore, despite the Common Rule requirement, only a few ICFs have been posted on ClinicalTrials.gov or Regulations.gov. Unlike ICFs, which are public-facing documents, DMC charters are internal documents and may contain information that should only be disclosed after trial completion. The majority of Working Group members supported further consideration of including a link in ClinicalTrials.gov study records for accessing DMC charters posted elsewhere, if NLM decided to move forward with this proposal.

Next, Ms. Robinson presented updates on the proposed disclaimer that was shared with Working Group members in 2022. The analysis of feedback provided by Working Group members and by Children's Inn at NIH staff and guests (providing a patient perspective) identified challenges such as the size of the disclaimer, which occupies significant space on the page and results in a difficult experience for mobile users; most users ignore the disclaimer altogether because of such challenges.

To improve the functionality of the disclaimer display, the team designed a prototype that allows the disclaimer to be minimized so that users can easily complete tasks but still see the disclaimer and return to it as needed. The minimized state reduces the negative impact on mobile users, in particular. Ms. Robinson noted that another round of usability testing for the ClinicalTrials.gov search component, which includes the updated disclaimer design, is currently underway to collect additional feedback.

IV. PUBLIC MEETING

All

With ClinicalTrials.gov Beta targeted to become the primary landing page by June 2023 and with the new protocol registration data-entry screens targeted for release in PRS Beta in April, the ClinicalTrials.gov team is planning a public meeting that will provide an overview of the current status and accomplishments of the modernization effort. The meeting will also be an opportunity to solicit feedback and respond to questions from the public about the new beta sites. Dr. Fine shared a draft agenda for the meeting, which will begin with an introduction to the modernization timeline and milestones. An overview of usability research conducted with the three primary external user groups (patients and their advocates, data

researchers, and data submitters) and its incorporation into the development of the beta sites, presented by Catherine Kihara, will follow. Next, in-depth presentations of the updated features of ClinicalTrials.gov Beta and PRS Beta will be provided, with commentary from volunteers from the Working Group. Finally, breakout sessions, during which questions can be answered and additional feedback can be received, will be held to allow for deeper conversations with attendees.

Ms. Robinson described updates to ClinicalTrials.gov Beta that have been implemented since the last public meeting, in April 2020. Based on user feedback, the welcome banner was removed to streamline the home page experience. Ms. Robinson then demonstrated the beta search experience, highlighting the customizable search results and interactive components of the study record.

Nachiket Dharker, the PRS Beta product owner, described some of the features of the new PRS Beta modules available in the PRS Test system. The implementation of just-in-time help tools will assist data submitters throughout the submission process, and a new help drawer feature will provide both technical definitions and plain language descriptions of the information expected for each data element. The data-entry navigation has also been improved to enable direct access to all protocol registration modules on the same page.

Working Group members discussed additional considerations for presenting ClinicalTrials.gov Beta and PRS Beta during the public meeting. Suggestions included previewing the remaining items to be addressed during the modernization effort; presenting a high-level, side-by-side comparison of features on the classic and beta sites; and showing how the beta sites benefit users from each of the three external stakeholder groups. Examples of those benefits and the ways that the beta sites address information needs could be elicited from a small sample of individuals representing each stakeholder group. Members also suggested adding the video tutorials that are currently linked to from the classic ClinicalTrials.gov site directly to the beta sites to make instructions and just-in-time support more readily available to users.

V. NEXT STEPS

Anna M. Fine, PharmD, MS, Executive Secretary

Dr. Fine requested that Working Group members review the draft summary of the December 19, 2022, Working Group meeting and provide feedback to her. Staff will summarize this Working Group meeting, and that summary will be provided to Working Group members for their review as well. The team will follow up with Working Group members individually to determine their interest in presenting during the public meeting, and individual prep meetings will be scheduled accordingly. In addition, a practice session for the public meeting, including a walk-through of the agenda and the technology that will be used, will be scheduled for early April.