

**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 19, 2022**

**MEMBERS PRESENT**

Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California, Chair  
Anna M. Fine, PharmD, MS, NLM, NIH, Executive Secretary

**MEMBERS NOT PRESENT**

Kent J. DeZee, MD, MPH, MACP, COL, MC, Defense Health Agency  
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**

Lytic A. Jorgenson, PhD, Office of Science Policy  
Pamela Reed Kearney, MD, Office of Extramural Research

**EXTERNAL MEMBERS PRESENT**

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

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

**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  
Nachiket Dharker, PhD, ICP-APO, ICP-LEA, ICF, PRS Beta Product Owner  
Elisa Golfinopoulos, PhD, ICP-LEA, NLM, NIH, ClinicalTrials.gov Policy Analyst and Automation Support Team Product Owner  
Wendy Harman, JD, ICF Next, ClinicalTrials.gov Beta User Experience 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

Scott Smith, BA, CSPO, ICF Next, PRS Beta Product Manager

Tony Tse, PhD, NLM, NIH, ClinicalTrials.gov Analyst

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. She announced that Dr. Nancy Smider, who was unable to attend the meeting, is the Working Group's newest member. Dr. Baezconde-Garbanati thanked Working Group members and ClinicalTrials.gov staff for their continuing efforts to support modernization.

Dr. Fine summarized progress made on ClinicalTrials.gov modernization since the previous meeting, in September. A public webinar was held in October to provide updates on the modernization effort and preview the latest releases of ClinicalTrials.gov Beta and PRS Beta. Dr. Fine noted the strong public engagement on display during the webinar and the interest in current endeavors such as support for providing information for some data elements in plain language. A report summarizing progress on modernization during 2021–22 was released in December. The report detailed accomplishments and milestones and outlined future modernization activities.

## **II. PREVIEW OF 2023 PLANS**

*Anna M. Fine, PharmD, MS, Executive Secretary*  
*Nachiket Dharker, PhD, ICP-APO, ICP-LEA, PRS Beta Product Owner*  
*Christina Robinson, MA, ICP-LEA, ClinicalTrials.gov Beta Product Owner*

Dr. Dharker reviewed the five PRS modernization releases in 2022, including the November and December releases in the PRS Test system that focused on protocol registration. It is anticipated that the protocol registration data-entry forms currently available in PRS Test will be released in PRS Beta (i.e., the production system) in April 2023. Subsequent updates will include the results reporting data-entry forms as well as enhanced quality assurance/quality control processes.

Dr. Dharker highlighted other features that are in progress or planned for PRS Beta involving secure log-in, account creation and management, notifications, dashboards, migration to the cloud, and study document upload. Dr. Fine noted that the retirement of the classic PRS will eliminate the PRS Beta dependency and enable full optimization of the database design. Although the PRS modernization effort is proceeding in parallel to modernization of the ClinicalTrials.gov website, PRS modernization will have a longer timeline and an anticipated completion date in 2024.

Ms. Robinson provided updates on recent progress on modernizing the ClinicalTrials.gov website. ClinicalTrials.gov Beta was launched a little over a year ago, and recent releases have included updates intended to streamline the beta site home page experience. Since the September Working Group meeting, features have been added to the search and study record experience. In addition, work on version 1 of the ClinicalTrials.gov Beta application

programming interface (API) is in progress, and the API is targeted for release in January. It is anticipated that all of ClinicalTrials.gov Beta's planned primary features will be completed in 2023.

Ms. Robinson summarized the user research activities conducted by the ClinicalTrials.gov team, including the monthly analysis of user comments submitted via the website and tree testing of the ClinicalTrials.gov information architecture. Usability testing of the study record and search experiences is also in progress. Ms. Robinson noted the substantial increase in ClinicalTrials.gov Beta site traffic following the addition in November of a link from study records on the classic site to the corresponding records on the beta site. Dr. Fine noted that the beta site is targeted for becoming the primary ClinicalTrials.gov landing page by June.

Dr. Fine then reviewed the efforts of the Working Group since its first meeting in December 2019, as well as plans for 2023. Based on a poll of Working Group members, the next meeting will be held on January 13. The next NLM BOR meeting is scheduled for February 7. Dr. Fine noted that, with the agreement of the Working Group, a public meeting will be planned for April, during which Working Group members will have the opportunity to present features of ClinicalTrials.gov Beta and PRS Beta and answer stakeholder questions. The public meeting will be discussed in further detail during the next Working Group meeting.

### **III. NEXT STEPS**

*Anna M. Fine, PharmD, MS, Executive Secretary*

Dr. Fine said that this meeting would be summarized for Working Group members and that the dates for the planned spring meetings would be confirmed. She requested that Working Group members consider presenting their ideas or experiences related to the beta sites during the April public meeting.