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
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
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

EXTERNAL MEMBERS NOT PRESENT
Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School

OTHERS PRESENT
Heather Dobbins, ClinicalTrials.gov Lead Results Analyst
Anna Fine, ClinicalTrials.gov Deputy Director
Slava Gorelenkov, ClinicalTrials.gov Technical Program Manager
Wendy Harman, ClinicalTrials.gov UX Strategist
Jesse Issacman-Beck, AAAS Fellow assisting Lyric Jorgenson
Mary Sanders, ClinicalTrials.gov Project Manager
Tony Tse, ClinicalTrials.gov Policy Analyst
I. WELCOME AND THANKS
   Carlos R. Jaén, MD, PhD, Chair
   Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Jaén thanked the Working Group members for their continued participation. Dr. Williams introduced the ClinicalTrials.gov staff members attending the meeting. The purpose of this meeting was to regroup after the summer to discuss progress on the modernization effort and prepare for the next Working Group meeting on September 11, 2020.

II. FY 2021 MEETINGS
   Rebecca J. Williams, PharmD, MPH, Executive Secretary

Dr. Williams noted some of the planned meetings scheduled into FY 2021. Although the Working Group was established at the end of 2019 and was originally scheduled to convene for a year, Dr. Williams indicated that extending Working Group meetings through the beginning of February 2021 would be valuable, allowing members to continue to provide input on roadmap strategies and priorities.

The September 11 meeting will be a collaborative strategy session to discuss roadmap priorities and solicit recommendations from the Working Group, and the outcomes will be reported during the September 15 NLM Board of Regents meeting. Planning has begun for a public webinar in fall or winter 2020 to update stakeholders on the progress of the modernization effort. (This webinar is anticipated to be briefer and more limited in scope than the one held in April 2020.) The Working Group is also scheduled to meet in December 2020 and February 2021. Working Group members were asked to check their calendars in relation to the proposed meeting schedule and either discuss any conflicts or concerns during the next Working Group meeting or email Anna Fine before that meeting.

III. MODERNIZATION PROGRESS AND UPDATES
   Rebecca J. Williams, PharmD, MPH, Executive Secretary

Goals for the current year include engagement with stakeholders to determine and validate the modernization approach and specifications, enhancement of internal business processes, and development of the modernization roadmap. Dr. Williams stated that the modernization effort is currently on track, despite competing priorities such as COVID-19, and noted activities centered around engagement, user requirements, and infrastructure.

Dr. Williams then shared details of completed modernization activities, including the successful technical transfer to the National Center for Biotechnology Information infrastructure and integration with the organizational matrix model. In addition, several teams focused on different aspects of the modernization effort have been established.

Dr. Williams recapped key points from the May 1 Working Group meeting, including the tensions inherent in balancing the needs of different stakeholder groups, as highlighted in
the Request for Information (RFI) comments and during the public meeting; the consensus on NLM’s primary role as a data aggregator; and the need for greater integration of ClinicalTrials.gov and other resources for patients and the public. The importance of providing trustworthy information via ClinicalTrials.gov was noted in RFI comments and by Working Group members.

Next steps for the modernization effort include the development of a modernization roadmap for further input and validation. Updates on ClinicalTrials.gov operations and the impact of COVID-19 and the Federal court decision regarding results information submission\(^1\) were also presented.

IV. DISCUSSION

Working Group members observed that a majority of the RFI comments were provided by the research community, which is currently more invested in processes supporting the submission of clinical study information. Members expressed interest in discussing overlapping and diverging stakeholder needs and providing recommendations during the September 11 meeting. It was noted that some investigators may use their study’s listing on ClinicalTrials.gov as a way to suggest (sometimes inappropriately) a certain level of quality of their research. It was agreed that the Working Group will continue to think about various additional functions for ClinicalTrials.gov to promote engagement with the researcher ecosystem (as seen with COVID-19).

V. ACTION ITEMS, SUMMARY, AND NEXT STEPS

Rebecca J. Williams, PharmD, MPH, Executive Secretary

The Working Group will meet on September 11, 2020, to participate in a facilitated collaborative strategy session where the following key topics are expected to be discussed:

- Current experiences of key user groups that interact with the Protocol Registration and Results System and the ClinicalTrials.gov public website
- Design and data principles to use throughout the modernization effort
- Strategic direction and priorities to achieve the desired outcomes of the modernization effort