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 28, 2022

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
Lauren A. Maggio, PhD, Uniformed Services University of the Health Sciences

MEMBERS NOT PRESENT
Jennifer (Jennie) S. Lucca, MSW, The Children's Inn at NIH
Omolola (Lola) Ogunyemi, PhD, FACMI, Charles R. Drew University of Medicine and Science

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

OTHERS PRESENT
Annice Bergeris, AS, NLM, NIH, ClinicalTrials.gov Information Research Specialist, Acting Deputy Director, and Operations Team Product Owner
Heather Dobbins, PhD, NLM, NIH, ClinicalTrials.gov Lead Results Analyst and PRS Beta Product Owner
Elisa Golfinopoulos, PhD, ICF, ClinicalTrials.gov Results Team Lead and Automation Support Team Product Owner
Slava Gorelenkov, NLM, NIH, ClinicalTrials.gov Technical Program Manager
Derek Griffing, PharmD, MPH, NLM, NIH, ClinicalTrials.gov Lead Policy Research Analyst
Wendy Harman, JD, ICF Next, ClinicalTrials.gov Beta User Experience (UX) Lead

Catherine Kihara, PhD, LLM, ICF Next, UX Researcher
Christina Robinson, MA, ICP-LEA, ICF, ClinicalTrials.gov Beta Product Owner
Mary Sanders, MS, PMP, CSM, ICP-LEA, ICF, ClinicalTrials.gov Project Manager
Tony Tse, PhD, NLM, NIH, ClinicalTrials.gov Research Analyst
Sam Kennefick Wilairat, MLIS, NLM, NIH, Associate Fellow

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 thanked them for their continued interest in the ClinicalTrials.gov modernization effort. She noted the new Acting Director of ClinicalTrials.gov, Anna Fine, and the two new Working Group members, Lauren Maggio and Lola Ogunyemi.

Dr. Fine mentioned the recent ClinicalTrials.gov and Protocol Registration and Results System (PRS) beta releases. Working Group members were reminded of the vision and strategic goals of the modernization effort, and Dr. Fine noted the summary of progress report that was issued in September 2021.

II. OTHER RESEARCH TO SUPPORT MODERNIZATION

Anna M. Fine, PharmD, MS, Executive Secretary
Elisa Golfinopoulos, PhD
Derek Griffing, PharmD, MPH
Sam Kennefick Wilairat, MLIS
All Working Group Members

Dr. Fine introduced three selected research areas to support ClinicalTrials.gov modernization as the effort enters its third year and focuses on implementation of the roadmap. As summarized in the summary of progress report, the modernization roadmap was established after extensive stakeholder engagement during the first year, followed by substantial development work in the second year. Working Group members were asked to provide feedback on how each of these research projects fits into the roadmap.

Automation Support Team

Dr. Golfinopoulos presented research exploring possible applications of artificial intelligence (AI) to support ClinicialTrials.gov data quality efforts. The team conducted a pilot analysis using AI to automatically index body mass index (BMI) requirements described in the free-text field of the Eligibility Criteria data element. Following training, the automated approach successfully indexed free-text BMI information in more than 90% of the study records in a test sample. Next steps include applying similar AI approaches to other information, such as outcome measures, and scaling up the process to increase the use of automation during quality-control reviews.

Working Group members discussed the promises and limitations associated with automated approaches to quality control. In particular, they emphasized the importance of balancing data submitter workload (e.g., false-positive flags) and improved data quality. Members also noted the need to consider the potential interactions between AI-driven validations and the

third-party submission tools used by some organizations. Dr. Golfinopoulos emphasized the importance of tailoring the application of AI technology to mitigate data entry errors and improve data quality, goals of the modernization effort. An alternative approach was suggested by a Working Group member: adding structured data elements to guide data entry from the beginning, rather than allowing submission of free-text information followed by AI extraction and analysis activities. However, the implementation of such an approach would require consultation with stakeholders at a minimum, and possibly rulemaking, to make those structured data elements required fields.

Fast Healthcare Interoperability Resources (FHIR) Project

Dr. Griffing summarized work to implement FHIR, a standard for the electronic exchange of clinical information, to facilitate the transfer of aggregate clinical research information available on ClinicalTrials.gov to other information systems. To date, ClinicalTrials.gov data have been mapped from an Extensible-Markup Language (XML) format to the JavaScript Object Notation (JSON) FHIR structure. Next steps include considering approaches for FHIR integration, testing the implementation on the ClinicalTrials.gov Beta website, and determining the approach to future work on the project.

Working Group members supported applying the FHIR standard to ClinicalTrials.gov but also anticipated the need to maintain the mapping as the standard evolves.

ClinicalTrials.gov Citation Format Project

Ms. Wilairat presented recommendations for a standard citation format for ClinicalTrials.gov study records that would address the challenge of ensuring recognizable and citable records. She briefly described various use cases and outlined the metadata under consideration, based on feedback from stakeholders such as data submitters and medical librarians. Potential next steps include purchasing Digital Object Identifiers (DOIs) and adding a Research Information Systems (RIS) file format download option for ClinicalTrials.gov records.

The Working Group agreed with the adoption of DOIs for ClinicalTrials.gov records and discussed the use of DOIs for resources that have not been assessed for quality through peer review, such as preprints and data sets. Some members suggested that the proposed format accommodate the citation of archival versions of study records. Christina Robinson replied that improved access to archival versions of records, through the History of Changes feature, will be included in a future release of the beta website.

III. FIRST BETA RELEASES: STATUS, METRICS, AND FEEDBACK

Anna M. Fine, PharmD, MS, Executive Secretary
Christina Robinson, MA
All Working Group Members

Dr. Fine noted that the PRS Beta release had been delayed from December 2021 until the previous day (January 27, 2022) to allow for appropriate knowledge transfer from departing technical staff members. She announced that the ClinicalTrials.gov Beta website was launched on December 8, 2021, and is available in parallel to the classic website. New features will be added in subsequent releases, and the beta website team will collect user feedback and incorporate it, as appropriate. A variety of communications about the beta releases were described, including a live ClinicalTrials.gov Beta website demonstration webinar and a prerecorded preview and demonstration of PRS Beta.

Ms. Robinson presented preliminary qualitative and quantitative metrics, based on 30 days of data, and feedback on the ClinicalTrials.gov Beta website. She said that approximately half of respondents identified themselves as patients or members of the public and the other half self-identified as data researchers. Quantitative metrics derived from user surveys and site user analytics indicate that most respondents focused on the search feature and the study records. Ms. Robinson noted that updated metrics will be provided in future Working Group meetings. She also observed that most comments are actionable and will be incorporated into the modernization roadmap.

Working Group members commended the beta site release, and several commented approvingly on the modern look and feel.

IV. NEXT BETA RELEASES

Christina Robinson, MA
All Working Group Members

Ms. Robinson said that new features will be introduced on the beta website in periodic releases and that user feedback will be collected and analyzed continuously. The next release is anticipated at the end of the first quarter of 2022 and will be announced through the regular ClinicalTrials.gov communication channels. Future releases will also be detailed on a Release Notes webpage. Ms. Robinson described several features that will be built and released over the coming year, including the advanced search feature, tabular search results and study records, expanded download formats, and easy-to-find and easy-to-understand content.

Working Group members shared their interest in aspects of future ClinicalTrials.gov Beta releases such as the advanced search feature and greater transparency about its availability.

V. NEXT STEPS

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

Working Group members were asked to send edits to their bios, or confirmation that their bios were up to date, by close of business on February 4, 2022.

Dr. Fine noted that the Working Group will continue to meet three times a year, in advance of each scheduled NLM BOR meeting. The next Working Group meeting is expected to take place in April, and the ClinicalTrials.gov team will follow up with Working Group members to determine their availability after the February 8 NLM BOR meeting. The Working Group meeting to be held prior to the September NLM BOR meeting is expected to occur in August or September.

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