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March 14, 2020

National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894

Re: Request for Information- ClinicalTrials.gov Modernization (NOT-LM-20-003)

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment to the National Library of Medicine (NLM) on modernizing ClinicalTrials.gov. The AAMC is a not-for-profit association representing all 155 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC supports the goal of ClinicalTrials.gov to provide greater transparency around the clinical research enterprise by functioning as a platform to store and make available clinical study trial data. As an association that represents medical schools and hospitals that conduct the majority of clinical trials funded by NIH, we want to ensure that there are continued efforts to assess the unique needs of all the audiences who use the site, including researchers, patients, and the public, and appreciate the NLM's intention to modernize both the technical infrastructure and outward-facing components of the site. We also recognize that NLM has already made substantial updates to ClinicalTrials.gov in response to feedback from the community and appreciate the commitment to continue making improvements to the site to better serve its users.

We note that many of AAMC's member institutions have responded to this request for information with specific challenges, use-cases, and suggestions for improvement based on feedback from a broad spectrum of users, including clinicians, scientists, administrators, and individuals who participate in and search for clinical trial data and urge the careful consideration of these comments from the platform's regular users. We especially recommend that the NLM

consider comments of the Clinical Trials Registration and Results Reporting Taskforce ("Clinical Trials Taskforce"), a national consortium of academic medical centers, universities, and hospitals. This Taskforce frequently engages with NLM on best practices for ClinicalTrials.gov, especially concerning the site's technical infrastructure. We hope that this feedback from a diverse range of site users will be used to inform the strategy and actions to modernize and improve ClinicalTrials.gov, and that NLM will continue to engage experts in the field during the course of this initiative.

The AAMC is pleased to offer the following comments based on our own expertise and experience as well as input received from our member institutions in response to the RFI.

Website Functionality

There are many aspects of the public-facing site at ClinicalTrials.gov that could be updated to enable the site to more effectively fulfill the goal of increasing transparency as well as providing "easy access to information" on clinical trials for a wide range of stakeholders. The current public site presents significant challenges both from a navigation perspective as well as in the comprehensibility of the content for those less familiar with research and clinical trials.

A starting point would be to implement best practices in web design to improve the appearance, accessibility, and search function, organizing and ordering information and queries so the site can be effectively used by an individual with limited specialized knowledge. As a potential model, we refer you to Trials Today,[1] developed by Vanderbilt University, both for its user-friendly interface and as a site which effectively links to data on ClinicalTrials.gov to function as a recruitment tool.

With regard to the content itself, NLM should look for opportunities to display information in a more understandable way while still maintaining the scientific integrity of the site. For example, the Brief Summary section contained in each study record should, according to ClinicalTrial.gov element definitions, be written in language "intended for the lay public." Yet this section is often complex and full of technical jargon. We recommend that NLM work with experts in health literacy to create guidelines for researchers to ensure that this part of the study record fulfills its stated purpose.

[1] Trials Today. https://trialstoday.org/

Additionally, as highlighted by recent criticism, many individuals erroneously believe that all studies listed on ClinicalTrials.gov are funded, overseen, and "endorsed" by the federal government. Despite efforts by the NLM to provide information to the contrary, there are still issues regarding public understanding of what it means to have a trial listed on the site. While ClinicalTrials.gov includes a text disclaimer that "listing a study on the site does not mean it has been evaluated by the U.S. Federal Government," and that "the safety and scientific validity of a study… is the responsibility of the study sponsors and investigators" it is clear that these constraints are not fully understood, particularly when listed on a ".gov" site. We encourage NLM to study mechanisms and additional language that would make this aspect of ClinicalTrials.gov more readily understood. For example, including an explicit "yes or no" on a listing to indicate if a study is federally funded, clearly defining the meaning of the term "sponsor" and making this an available search field, and creating a layperson primer to understanding the different types of trials which might be encountered on ClinicalTrials.gov.

In envisioning changes to ClinicalTrials.gov that would make it more accessible and usable by the public, it is important to specifically acknowledge the particular histories and resulting mistrust among many communities of color with regard to clinical research. Anything the site can do to increase transparency and communicate the value of research and its outcomes will serve to make the research enterprise more trustworthy and hopefully will yield more diverse research participation. ClinicalTrials.gov can assist in this process not only by listing information on trials but also by more actively connecting users to further resources for recruitment or engagement. We encourage meaningful partnerships with diverse communities before initiating changes to the website to ensure the relevance and utility of any revisions.

Finally, it is important to examine how the site interface can better serve all potential audiences, including but not limited to patients and the general public. For example, a physician might want to access the site with the intent of searching for specific scientific or technological terms and be connected directly to recruitment materials for a patient. Scientists may be looking for studies to generate ideas or look at outcomes and variables of previous trials, or perhaps to perform a search of more specialized fields such as investigational drugs and devices. The ideal site for these different stakeholder groups may well include separate search functions so that individuals can easily filter by the information most important to them.

Information Submission

Researchers and administrators have noted that the NLM provides helpful guidance on certain aspects of the site, such as the Example Studies for Results Data Entry. We encourage NLM to work with the Clinical Trials Taskforce to develop additional materials to aid with the registration and results submission process, and for these to be as illustrative as possible, including specific cases, screenshots or video tutorials. To reach the maximum number of users of the site, we also encourage NLM to make resources and trainings available virtually, whenever possible, including the information offered at in-person "Train the Trainer" workshops.

The ability of the ClinicalTrials.gov Protocol Registration and Results System (PRS) to align with other technical infrastructure used during the clinical research process is an essential element for many institutions. Greater interoperability would allow administrators to streamline processes and reduces duplicative data entry for researchers. We recommend that NLM query users on the most used systems or databases that would benefit from increased interoperability (such as Clinical Trials Management Systems, IRB submission systems, and electronic health record systems), as well as how NLM could achieve this goal, perhaps through a more flexible application programming interface.

We recommend that NLM look closely at the capability and adaptability of other databases which institutions currently use to manage clinical trial data and associated tasks, such as REDCap, which allows for user-specific adjustments, alerts, and customized reports. Many institutions requested that ClinicalTrials.gov create an internal dashboard to help institutions keep track of studies as well as maintain a higher-level view of metrics and compliance, that could be shared with institutional leaders if needed. It would also be beneficial to develop auto-notifications to responsible parties and record owners to alert them when their record appears on the institutional problem list and action is required.

We additionally encourage ClinicalTrials.gov to standardize requirements and/or processes as much as possible. For example, the site should use drop-down menus or provide lists of standardized fields wherever applicable, not only for data points but also administrative information such as the name of an institution. The need for clear guidelines was also mentioned in relation to the Quality Control (QC) review process, with the suggestion that NLM make available sufficient guidance up front so that data can be entered correctly as often as possible

prior to the QC process, and also provide examples of common QC comment scenarios to elucidate what particular feedback means and how to best navigate this process. These changes will hopefully simplify the workflow at the institutional level and reduce the length of time of QC review.

Finally, the AAMC strongly encourages the use of identifiers to tie individuals to the data they submit on ClinicalTrials.gov and track related outputs to a clinical trial. We appreciate the ability to link the ClinicalTrials.gov identifier (NCT number) with a PubMed ID (PMID), to link results on the site to a publication, as well as the ability to search PubMed specifically for publications linked to this NCT number. In order to link all of these products to an investigator, ClinicalTrials.gov can add the option for researchers to provide their ORCID iD, and in time possibly expand to other types of identifiers currently under development, such as grant and organizational identifiers, to create a comprehensive map of research impact.[2] The AAMC has appreciated the NLM's involvement in the multi-stakeholder Credit for Data Sharing[3] initiative and remains eager to partner with the NLM to assist in implementing the recommendations of that project.

The AAMC appreciates NLM's efforts in the ClinicalTrials.gov modernization initiative, which presents a significant opportunity to make the site more usable and useful for patients, researchers, the public, and all other stakeholders. Please feel free to contact me or my colleagues Anurupa Dev, PhD, Lead Specialist for Science Policy (adev@aamc.org) and Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org) with any questions about these comments.

Sincerely,

Ross McKinney, Jr., MD
Chief Scientific Officer

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[2] Pierce, et al. Credit Data Generators for Data Reuse. *Nature* 570, 30-32 (2019). https://www.nature.com/articles/d41586-019-01715-4

[3] See more at: www.aamc.org/datasharing.