ASSOCIATION OF AMERICAN UNIVERSITIES

COGR
Council On Governmental Relations

ClinicalTrials.gov Information Team
National Library of Medicine
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Submitted to: https://nlmenterprise.co1.qualtrics.com/jfe/form/SV_e2rLEUAx99myump

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

The Council on Governmental Relations (COGR) and the Association of American Universities (AAU), two of the leading organizations representing research institutions, are most appreciative that the National Library of Medicine (NLM) is considering making much-needed changes to the ClincialTrials.gov system, and modernizing and rebuilding the system.

Issues with the use of ClinicalTrials.gov appear to stem from the fact that, at this point, the system serves two different audiences – the public and the scientific community. Registration of studies was initially developed to assist the public in identifying clinical trials of interest, especially studies on life-threatening diseases. At the same time, investigators are required to report detailed research results, which are very technical, and the system was not designed with this in mind. This portion of the system should be more researcher-focused to make the process as efficient as possible. It's not as crucial for this function in ClinicalTrials.gov to be public-facing, since the public is more likely to prefer to read research results in context, e.g., through a publication. We provide the following observations and comments below for your consideration in planning how to serve these two audiences best.

The initial goal of ClincialTrials.gov was to provide transparency and a mechanism for institutions to report clinical trial data. Specifically, the Food and Drug Administration Modernization Act of 1997 (FDAMA) required that the registry include information about federally or privately funded clinical trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for patients with serious or life-threatening diseases or conditions. The information in the registry was intended for a broad audience, including individuals with severe or fatal diseases or conditions, members of the public, health care providers, and researchers. Since the passage of FDAMA, additional laws and regulations expanded the requirements for the types of trials to be registered and the requirement for the publishing of trial results was also added.

In addition to the federally mandated use of the system, sponsors and journal editors increasingly are requiring investigators to use the system to register and report on other activities beyond trials, such as

observational studies and repositories. Regrettably, the imposition of these additional data points without overhauling the system has left investigators with the sense that they are trying to fit a square peg in a round hole. Because the system is crowded with different kinds of information, there is little transparency for investigators or the public to find the type of information they seek. As a result, system changes and updating are badly needed. We appreciate the NLM providing an opportunity for stakeholders to comment and suggest ways to modernize the system while also reducing the administrative burden for investigators and clinical trial administrative staff.

While our associations are not direct users of the system, a substantial portion of our member institutions are system users. We solicited feedback from them and have also encouraged institutions to submit comments directly to the NLM. COGR and AAU endorse the work of the Clinical Trials Results and Registration Task Force, a national consortium of experts from academic medical centers, universities, hospitals, and non-profit organizations that work towards improvements in transparency in clinical trials registration and results reporting requirements in ClinicalTrials.gov.

We have had many conversations with experts who support PIs in registering and maintaining studies in ClincialTrials.gov. We have not attempted to summarize their detailed comments. However, several common themes have emerged:

- As stated above, ClincialTrials.gov was developed in the early 2000s to support the registration of trials conducted under investigational new drug applications. The templates were made to support this activity alone, making it challenging to register the other types of activities that now require registration after the scope of the database was expanded. Examples of other activities include NIH-funded pilot and behavioral clinical trials, certain pilot studies and basic experimental studies with human subjects for which many journals require ClincialTrials.gov registration.
- Grant project status and the status of the trial within a broader grant may not always align, because awards can begin long before a trial is slated to begin or can be issued for trials that have already started. There are currently insufficient means in either system to account for these situations.
- Journal editors and other stakeholders are increasingly requiring registration of studies in ClinicalTrials.gov to demonstrate that the study is open and transparent, even for non-clinical studies. This is a laudable goal. However, ClinicalTrials.gov, which is currently the primary means for attaining that goal, may not be the best long-term approach for demonstrating transparency.

Given the magnitude of the challenges that the NLM is facing with ClinicalTrials.gov, we suggest that the NLM consider establishing a stakeholder user group, including investigators and ClinicalTrial.gov administrators, to help develop the new specifications and to participate in the initial testing of the

redesigned system. Our associations would be happy to assist the NLM with the establishment of such a group. We offer some additional high-level recommendations for your consideration.

- Provide a public-friendly view for information such as studies for which participants can opt-in, and links to resulting publications (e.g., through Pub Med Central) where the public can access relevant research papers.
- Focus on the investigator's experience, making the system as investigator friendly and efficient as possible for reporting studies and research results.
- Reduce manual data entry. Link to federal funding databases or enable links to institutional databases, so ClincialTrials.gov is always current and accurate. Add fields so NIH-defined clinical trials may be correctly coded and identified.
- Create appropriate, easily identifiable statuses for reporting research results (e.g., new, in progress, under review, late) to provide the most accurate information possible to research institutions responsible for managing projects.
- Provide automatic feedback from the system to responsible parties to alert them to upcoming deadlines.
- Create helpful indicators for studies, such as "subject to FDAAA", "NIH-funded clinical-trial" or "Other NIH-funded study."
- Consider developing an alternative, simplified method or separate database for registering non-clinical trial studies to support journal requirements and other activities that fall outside the mission of ClincialTrials.gov.

Again, we appreciate the opportunity to comment. Please contact Kristin West, Director of Research Ethics and Compliance at COGR KWest@cogr.edu, if you would like more information or have questions.

Sincerely,

Mary Sue Coleman
President
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Wendy D. Streitz
President
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