**MEDICAL LIBRARY ASSOCIATION AND
ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARIES
COMMENTS IN RESPONSE TO**

**Request for Information (RFI): ClinicalTrials.gov Modernization**
**Notice Number:**NOT-LM-20-003
**Key Dates
Release Date:**December 30, 2019
**Response Date:**March 14, 2020
**Issued By**
National Library of Medicine (NLM)

These comments are submitted by Mary M. Langman, Director, Information Issues and Policy on behalf of the Medical Library Association (MLA) and Association of Academic Health Sciences Libraries (AAHSL) and were written by health sciences librarians who are members of these organizations.

1. **Website Functionality.**NLM seeks broad input on the ClinicalTrials.gov website, including its application programming interface (API).

Health sciences librarians assist patients, researchers, research administrators, clinicians, and others in identifying clinical trials for personal or professional purposes. The ClinicalTrials.gov registry has become a vital tool in the librarians’ kit for responding to these various needs and populations. Particularly with the rising importance of systematic reviews in promoting evidence-based practice, the breadth of trials reported to ClinicalTrials.gov support unbiased synthesis of research findings, providing access to unpublished clinical trials findings and data, including studies that produce negative or null findings. ClinicalTrials.gov also provides a pathway toward participation in trials for patients and their doctors. With the increasing importance of the registry to vastly different user populations, it is necessary to keep in mind the different needs and perspectives of those ClinicalTrials.gov users in planning for this announced modernization.

Some search interface modernization suggestions include:

* Allowing for both robust advanced searching and broad topic/keyword box for basic searching. (functionality for different types of users)
* Expanding search parameters, including the ability to search by specific outcome measure, study design, etc.
* In results, suggesting ranked relevant results; provide a “more like this” feature that allows identification of similar trials
* Having information for age ranges or additional specific populations such as adolescents would be useful
* Adding a “save all” feature for searches with numerous results instead of clicking each box to save to clipboard for eventual download.
* Adding an email alert feature (in addition to RSS feed subscription) for new studies on a condition or topic.
* Adding RIS format as a data export format for use in citation managers
* Adding the ability to export a custom number of results or selected results from a set of search results
* Adding an export tool in the study details page
* Supporting the ability to search for terms, or a company, or PI name, and then creating a basic chart that would show the number of trials in a year for the years in the results
* Showing visualizations of how many trials have concluded, not yet been recruited for, and active

Additional website functionality improvements might include:

* Adding a standardized geographic locator for each trial location to in a format that can be easily imported in in mapping and geographic analysis software
* Improving the capability to search in specific geographic areas for trials, particularly those which are actively enrolling patients
* Adding the ability to customize export fields, e.g., only export contacts or PI information from records
* Adding a tool that automatically works with or links to PubMed to generate an easily exportable list of all publications related to the trial (instead of having to search manually)
* Considering additional linked PubMed features, e.g., links to all publications by an investigator listed on a registered protocol
* Linking to deidentified patient data or other research outputs or documents relevant to the study when possible (e.g., if data are shared in PubMed Central or on other reasonably persistent and reliable platforms)
* Facilitating links to external sources that can assist in publicizing a trial in recruitment, eg social media outlets
* Implementing a trend visualizer with exportable output. This would be a basic tool that the user could add a few inputs to from the search and get a few basic data visualizations out of. One might then be able to download the chart in a .jpeg, .png, or similar format and the raw data in a .CSV or tab delimited format for use in analysis programs such as R and Tableau.
* Add features that help patients or non-medical professionals efficiently and effectively use the website, e.g., embedded tutorials, scroll-over definitions of terms, FAQ designed with patients in mind

2. **Information submission.** NLM seeks broad input on initiatives, systems, or tools for supporting assessment of internal consistency and improving the accuracy and timeliness of information submitted through the ClinicalTrials.gov Protocol Registration and Results System (PRS).

​​​​​ClinicalTrials.gov is only as good as it is complete and trustworthy. Lack of compliance with FDAAA 801 and the Final Rule can be traced back to two main areas: 1) difficulty in using the site and 2) lack of sanctions for noncompliance. In general, academic researchers have learned that there is no penalty for not using the system and therefore do not. Industry submission rates have been much greater. This is a recipe for noncompliance, lack of credibility, and eventual obsolescence. A suggestion is to improve user interface and penalization for noncompliance in tandem. Other suggestions include:

* Modernizing and simplifying the submission process to support flexibility and ease of importing data
* Ensuring the stability of the system. The system is out of date and researchers report regularly receiving errors during the submission process
* Reviewing data elements and determining a core set of elements to allow for a minimal compliance
* Using drop down options where plausible for common data elements
* Implementing the financial penalties as already mandated by the Final Rule
* Publicly flagging studies that are non-compliant as “Failure to Submit”
* Creating incentives for compliance