Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD MEDICAL SCHOOL

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Re: **NOT-LM-24-001**
Evolving the Network of the National Library of Medicine

To whom it may concern:

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) appreciates the opportunity to respond to the National Library of Medicine's (NLM's) request for information in regards to "*Evolving the Network of the National Library of Medicine*" published under Notice# NOT-LM-24-001.

The MRCT Center is a research and policy center that seeks to improve the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise.

We offer the recommendations below in full support of NLM's efforts to evolve the Network of the National Library of Medicine (NNLM). Four of our five recommendations are particularly aligned with Goal 2 of the NLM Strategic Plan 2017-2027: "Reach more people in more ways through enhanced dissemination and engagement." Our fifth recommendation supports Goal 1: "Accelerate discovery and advance health through data-driven research."

Clinical research is an essential part of the healthcare ecosystem. The MRCT Center fully endorses the notion that activities to enhance dissemination of and engagement with NLM resources via the NNLM are critical to the transparency of the health research enterprise and the building of public trust in the institutions that are involved in such health-related research. With our recommendations, we intend to specifically highlight areas for further development to ensure equitable education about and access to clinical research in the communities that the NNLM serves around the country.

Recommendation #1: Expand MedlinePlus to include additional clinical trials-related content to educate the public about clinical research and the critical role clinical research plays in the delivery of evidence-based healthcare.

MedlinePlus is an excellent educational resource that offers a wealth of information about healthcare and medicine. We recognize and appreciate that MedlinePlus provides a link to ClinicalTrials.gov for individuals who are seeking clinical trials in which enroll. There is, however, limited information on MedlinePlus about what clinical research is, why it is important, and how people can get involved. We recommend that MedlinePlus integrate additional research-related resources, like the MRCT Center's Clinical Research Glossary (CRG) into its offerings.

The CRG is a plain language resource that is co-created with patient advocates and other subject matter experts with lived experience with the goal of providing easy-to-understand clinical

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research-related definitions and other supportive information, including graphics. In addition, the CRG is a CDISC global standard, indexed in the NCI Thesaurus, and thus also within NLM's highly regarded and utilized, Unified Medical Language System (UMLS).

We further applaud MedlinePlus for being available in Spanish, and we recommend including additional languages that are common in the US. By expanding MedlinePlus to become a trusted source of clinical research information, the resource could play a critical role in combatting mis- and disinformation about clinical trials. Further, disseminating vetted, patient-centric educational materials supports the public's engagement with clinical research more broadly. In these efforts, MedlinePlus could also leverage other existing reputable resources from OHRP (for example, https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos/index.html), FDA (for example, https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials), and other government agencies as applicable.

Recommendation #2: Integrate plain language definitions, and translation of all exisiting defintions, into the current ClinicalTrials.gov glossary.

We recognize ClinicalTrials.gov as an important repository of clinical trial information, and we applaud recent efforts to modernize the site to be more patient-friendly. The current iteration of ClinicalTrials.gov's glossary of terms provides a comprehensive overview of terminology in English, but it does not appear to contain definitions that follow health literacy best practices or that have been translated into Spanish and other common US languages to support understanding. Similar to the above recommendation, we would like to suggest that ClinicalTrials.gov link to the MRCT Center's Clinical Research Glossary for terms that exist in both sources.

Recommendation #3: Expand ClinicalTrials.gov to include an element for the sharing of plain language aggregate results to past study participants.

Study participants routinely ask for understandable results of the studies in which they participated. In considering ways that NLM can support further patient-centric development, we advocate for easy-to-understand, aggregate study results in the form of Plain Language Summaries to have a designated element within ClinicalTrials.gov. Return of results has been mandated in the EU, and a portal of this type has been provided in Europe to support this ethical responsibility. Such an enhancement of ClinicalTrials.gov would be especially helpful within the non-profit and academic clinical research environment that is typically under-resourced and would be a benefit to all federally-funded clinical research studies. It would also support multiple audiences: 1) **researchers and study teams** in being able to more easily disseminate aggregate results to study participants; 2) **study participants** to have an easy-to-find, centralized source of results information for the studies they took part in, that is not a technical article in a medical journal behind a paywall; and 3) **the public** to have access to understandable non-technical study results information.

We suggest that a data element be included in the 'Results Posted' tab. Under this tab, at the top, we suggest NLM create a section 'For Study Participants.' Data elements under this should be (1) Aggregate Study Results and (2) Individual Results. Aggregate Study Results should be written in plain language with similar best practices as provided in the ClinicalTrials.gov resource Plain Language Guide to Write a Brief Summary. We further recommend that investigators make these Plain Language Summaries available, at minimum, in the languages spoken by participants in the study. Individual results could simply point participants to the correct source of information or assistance (and see Recommendation #4).

Recommendation #4: Expand ClinicalTrials.gov to include an element for current participants of active research studies to access study status updates and individual data/results as relevant.

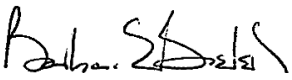
An ongoing challenge within the clinical trial ecosystem, yet an area that is repeatedly endorsed by participants as critically important, is the communication of study updates and individual data and results over the course of a study. We recognize that ClinicalTrials.gov provides an Individual Patient Data Sharing section in the registration record that allows sponsors to enter information about the IPD Sharing Plan description, time frame, and access criteria. This information is not, however, the type of information participants and patients can use to understand their own data or results. For participants, an element in the Results Posted' tab would provide a site for sponsors whether and when individual results will be shared, and how participants can access them.

Recommendation #5: Map manually entered study-specific Baseline Characteristics data in ClinicalTrials.gov to harmonize standard data elements to support comparison between studies.

Currently, the **ClinicalTrials.gov** Protocol Registration and Results System (PRS) allows for manual, investigator-entered Baseline Characteristics data that are not standardized. Given the NLM Strategic Plan Goal 1 of 2017-2027: "Accelerate discovery and advance health through data-driven research," we recommend continuing to allow self-selected categories, and then requiring investigators to map their Baseline Characteristics to **ClinicalTrials.gov**-provided standardized data elements that are consistent and harmonized across all studies, thus supporting **ClinicalTrials.gov** as a primary data source. For example, for Race/Ethnicity data, ensure study-specific entries map to the NIH/OMB categories for all clinical trials.

The MRCT Center supports NLM's efforts to evolve the NNLM, and appreciates the opportunity to contribute our recommendations. We welcome the opportunity to discuss. Please feel free to contact the MRCT Center or me (bbierer@bwh.harvard.edu) if we can be helpful.

Respectfully submitted,



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