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Coordinating Center for Clinical Trials (CCCT)
Office of the Director
6W610, National Cancer Institute
9609 Medical Center Drive
Bethesda, MD 20890

RE: National Cancer Center Request for Information: Strategies for Matching Patients to Clinical Trials (NOT-CA-18-063)

Dear Director Prindiville:

The Leukemia & Lymphoma Society (LLS) appreciates the opportunity to submit comments on the National Cancer Institute's (NCI) request for information on strategies for improving the ease and functionality of searching for cancer clinical trials. As the world's largest voluntary organization dedicated to the needs of blood cancer patients, LLS believes strongly that clinical trials play a critical role in identifying new approaches for treating cancers and managing disease-related side effects. Accordingly, we fully support NCI's commitment to helping members of the public and their health care providers find appropriate cancer clinical trials, and facilitating the development and implementation of an automated approach to matching patient information to clinical trials information.

Recognizing that patients and caregivers are often overwhelmed by the clinical trial process, LLS launched the Clinical Trial Support Center (CTSC) in 2014. Our Clinical Trial Specialists are registered nurses with expertise in blood cancers and work one-on-one with patients throughout the process. They help patients determine if a trial is right for them, explain the trial process, identify potential trials, connect patients with sites, and follow the patient throughout the entire clinical course. In the first three quarters of fiscal year 2018 alone, our CTSC worked with 428 patients, with 63% of eligible patients entering into a clinical trial as a result of our support.

Despite recent improvements to NCI's clinical trials searching capabilities, searching and finding appropriate cancer clinical trials remains complex. As NCI acknowledges, search results are often suboptimal and retrieve trials for which a patient is not eligible, or miss appropriate trials completely. We applaud NCI's efforts to add additional structure to eligibility criteria to support improved identification of relevant clinical trials. Based on our extensive work in this area, LLS submits the following suggestions in response to NCI's request for information.

Structuring clinical trials information

LLS believes that information in clinical trials eligibility criteria can and should be structured. Specifically, such information should include diagnosis/condition, age, status (i.e., relapse, refractory, maintenance, treatment naïve, etc.), performance status (i.e., ECOG, Karnofsky Score), central nervous system (CNS)

criteria, trial locations and contacts, prior treatment history (i.e., lines of treatment, history of prior transplant, CAR T therapy), mutations and markers, and history of malignancies. In particular, we have found that the ability to filter results based on CNS disease presence would be extremely helpful.

We often work with patients who are looking for specific types of therapy, such as immunotherapy, monoclonal antibodies, CAR T, vaccine therapy, and chemotherapy. It can be very difficult and time-consuming for our CTSC nurses to interpret the type of therapy being offered when reading a clinical trial description. Accordingly, we suggest that protocols include clear explanations of the type of therapy provided.

With respect to approaches for implementation and maintenance of structuring clinical trials eligibility criteria, LLS believes that standardization of terminology and data is best performed by individuals with expertise in that particular area or diagnosis. In addition, protocols should include clear definitions of acronyms and/or medical terminology that may be difficult for patients to interpret (i.e, ECOG, CNS, Karnofsky Score). This could be accomplished by both standardization of terminology and by providing a key/legend of definitions.

Facilitation of cancer clinical trials searching/matching

In addition to the key data elements provided above, patients and providers need access to information relevant to the financial, socioeconomic, travel, and support factors effecting clinical trial participation. As such, protocols should include information about requirements related to frequency of visits to trial site, tests, biopsies, and treatments.

LLS supports efforts to narrow clinical trial search/match criteria retrievals to those for which the patient is most likely eligible. We encourage the use of electronic health records (EHR) for pulling specific data elements from the medical records, as opposed to human input, which relies on the patient's comprehensive knowledge of their medical and treatment history and understanding of medical terminology. An EHR report that captures all the data elements included in a trial description would greatly enhance trial searches.

Technologies and standards that may facilitate capture and transmission of information in a structured format

LLS strongly supports the standardization of medical language and terminology in all clinical trials. This would greatly improve readability and consistency of interpretation of clinical trial information and improve accuracy of search results. As mentioned above, LLS encourages the development of a report within the EHR that captures data elements included in a trial description.

Methods for fostering agile interdisciplinary collaboration and public-private partnerships

We believe that there is significant opportunity to advance research and development through innovative interdisciplinary collaboration. Our CTSC has developed relationships with various organizations and pharmaceutical companies that support up-to-date communication around new clinical trials, changes to trials, results from trials, and new therapies. This allows for accurate and first-hand dissemination of information regarding new treatments.

Approaches to facilitating and/or incentivizing structuring eligibility criteria in clinical trials protocols

While our CTSC does not have experience inputting data into the NCI Clinical Trials Reporting Program (CTRP), LLS believes that a user-friendly system/database that provides reliable and accurate search results would likely result in higher rates of clinical trial participation. The use of a standardized protocol format would further enhance readability and consistency of information provided.

Additional information

LLS would like to make the following additional suggestions with respect to how the NCI can best support and accelerate the ways in which patients find the appropriate clinical trials and the ways cancer clinical trials find patients:

- We believe that in addition to the data elements described above, NCI should share early pre-clinical data, articles/results, early-phase data/abstracts, and publicized articles with respect to every clinical trial.
- NCI should provide more detailed information about trial accrual and enrollment status, as well as greater clarity around trial phase.
- Clinically trained, disease-focused personnel should organize and interpret clinical trial information and facilitate communication with trial sites to help inform eligibility and enrollment decisions.

LLS is eager to help advance NCI's goal of better understanding what information about clinical trials is most consequential for clinical trials searching. We agree that by making it easier for patients and physicians to find clinical trials, trials will reach target accrual faster, resulting in more rapid completion of trials and improvements in cancer care. LLS will continue to support NCI's work in structuring clinical trial protocol eligibility criteria, and welcomes the opportunity for further collaboration. Please feel free to contact us with any questions. You may also contact our colleague, Liza Holder, Director, Policy in the Office of Public Policy at liza.holder@lls.org.

Sincerely,

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