

# CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS  
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

October 31, 2013

Margaret A. Hamburg, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

RE: Docket No. FDA-2013-N-0271, Availability of Masked and De-Identified Non-Summary Safety and Efficacy Data

Dear Dr. Hamburg:

The undersigned organizations representing cancer patients, health professionals, and researchers appreciate the opportunity to comment regarding a Food and Drug Administration (FDA) proposal to make de-identified and masked data derived from medical product applications available to interested parties. We commend FDA for advancing this proposal and for reopening the comment period for additional public input. In the comments below, we offer recommendations for ensuring the best use of such data as well protecting the privacy of clinical trial participants whose data might be shared. We also identify concerns about the potential cost of the plan for sharing preclinical and clinical data.

## *Potential Benefits of Sharing Preclinical and Clinical Data*

We agree with the agency that the proposal for sharing preclinical and clinical data from product applications, which holds the promise of generating new knowledge beyond the initial clinical trial, honors the commitment and altruism of clinical trials participants. It is our hope that the pooling of preclinical and clinical data from multiple trials and multiple applications might lead to additional information about the safety and efficacy of products and even classes of drugs. Cancer patients have historically tolerated significant toxicities for treatment benefit. However, cancer survivors are increasingly concerned about the long-term and sometimes delayed significant side effects of treatment. The data-sharing plan may hold the potential for pooling of data that would reveal more information about such late effects of treatment and contribute to strategies to mitigate the adverse impact of cancer treatments.

### *Protecting Patient Confidentiality*

The agency has stated that any preclinical and clinical data that are available for sharing would be stripped of any information that could identify patients or research subjects. FDA identifies the standards of the Privacy Rule as those that would guide de-identification, while at the same time noting that the agency is not a covered entity under the Privacy Rule.

We recommend that the agency consider standards that go beyond the Privacy Rule criteria for de-identification in certain cases or that certain data not be made available for additional review and research. For example, trials for some rare cancers and most pediatric cancer trials have such limited enrollment that de-identification according to the Privacy Rule standards is inadequate and individual trial enrollees could still be identified. We recommend against sharing of data from these trials, unless FDA can develop a standard for de-identification that will truly protect the confidentiality of pediatric cancer patients and others with rare cancers. We understand that such a prohibition against sharing these data might diminish the impact and benefits of the proposal, but in the cases described above protecting the privacy of clinical trial participants should be honored.

### *Consent to Share Preclinical and Clinical Data*

For those participants whose trials have already been completed but whose data are subject to sharing, we recommend that the terms of the consent for clinical trial participation govern the availability of the data. In other words, the data should only be shared for research efforts that are related to the original consent. This is the most appropriate way to honor and respect the consent granted by clinical trial participants.

For data sharing on a prospective basis, we anticipate that clinical trial sponsors will amend their consent standards to address potential opportunities for sharing of data and as a result may be able to obtain informed consent for such practices.

The matter of patient consent for data sharing is one that deserves more attention from FDA and possible new approaches.

### *Standards for Granting Access to Data*

In its original notice regarding the proposal for availability of preclinical and clinical data (published in the Federal Register of June 4, 2013), FDA did not provide details about the procedures that it will follow for making preclinical and clinical data from product applications available to researchers. We recommend that the agency develop specific standards to ensure the appropriate use of patient-specific data and that the agency retain responsibility for determining those entities that should be granted data access. These standards should advance two goals; they should: 1) maximize the research benefit related to availability of trials data, and 2) protect the interests of innovative research companies. Data should not be made available to entities that will use them in support of marketing applications in other regulatory systems.

### *Costs of Data Availability*

The system for managing the data-sharing opportunities, which we reference above, will be accompanied by some costs to the agency. We believe that the standards for data sharing are critical to the success of the effort, and as a result the costs cannot be eliminated. We also understand that the management of the preclinical and clinical data will result in some financial burden to FDA. Although the proposal related to availability of data is an important one with potential to advance research and foster new knowledge, it should not move forward without a clear financing plan that does not adversely affect the speed and quality of new product review.

### *The Functionality and Future of [www.clinicaltrials.gov](http://www.clinicaltrials.gov)*

As advocates for transparency in research and research data sharing, we have been strong supporters of clinicaltrials.gov and legislative efforts to refine and strengthen data sharing through that system. However, the system is not a user-friendly or efficient one. As a result, many other organizations have attempted to address the weaknesses of clinicaltrials.gov through efforts that are duplicative and expensive. Our enthusiasm for development of a system of availability for preclinical and clinical data is tempered by our concern that all details of the system – including cost – be addressed before the program is launched.

We appreciate the opportunity to offer these comments and look forward to working with FDA on its plan for data sharing.

Sincerely,

### **Cancer Leadership Council**

American Society for Radiation Oncology  
Bladder Cancer Advocacy Network  
CancerCare  
The Children's Cause for Cancer Advocacy  
Fight Colorectal Cancer  
International Myeloma Foundation  
Kidney Cancer Association  
The Leukemia & Lymphoma Society  
LIVESTRONG Foundation  
Lymphoma Research Foundation  
National Coalition for Cancer Survivorship  
National Lung Cancer Partnership  
Prevent Cancer Foundation  
Us TOO International Prostate Cancer Education and Support Network