April 11, 2013

Drs. Worta McCaskill-Stevens and Steve Clauser  
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Drs. McCaskill-Stevens and Clauser:

We have noted with interest NCI presentations over the past several months related to plans to develop the NCI Community Oncology Research Program (NCORP), a single NCI community-based program that integrates the Community Clinical Oncology Program (CCOP), Minority-Based CCOP (MB-CCOP), and NCI Community Cancer Centers Program (NCCCP). Community-based investigators are a significant component of the ASCO membership and promoting clinical trials is a major part of ASCO’s mission. Because of this, ASCO is providing our comments on the information released to date about the NCORP proposal, most recently at the February 2013 Institute of Medicine workshop, Implementing a National Cancer Clinical Trials System for the 21st Century.

We have heard from many of our CCOP and NCCCP investigators that you have conducted significant outreach to current sites and incorporated that input into NCORP development. We appreciate that you are actively listening to the articulated concerns of the community. Your thoughtful incorporation of feedback is important to ensure continued and improved success of the clinical trial system and preservation of the role of community-based sites in NCI-funded research.

We support the following aspects of NCORP development:

- Clinical trials will continue to be a core function.
- The trials will incorporate emerging science and novel trial designs.
- The term for the cooperative agreements will be 5 years.

CCOP sites, in particular, have been essential components to conducting NCI-funded treatment, cancer control, and prevention trials. The ability to enroll patients in their own communities is important to increasing the diversity and representativeness of trial participants. In addition, the community mechanism provides an important opportunity for community-based investigators and research staff to participate in trials that might not otherwise be available in a local venue. We know from past ASCO surveys that investigators believe that NCI-funded trials ask important scientific and clinical questions and provide important opportunities for their patients.

ASCO supports the important objective of increasing capacity to perform cancer care delivery research and supports efforts to gather data on treatment outcomes for the large number of patients who are candidates for participating in clinical trials but...
decline to do so. We have concerns, however, about how this element of NCORP will be implemented. The types of research that NCI envisions (health services, behavioral, dissemination, and outcomes research) require different expertise, data, and resource requirements than treatment and prevention clinical trials, and metrics for success in conducting this type of research are undefined. It is possible that several current CCOP and NCCCP sites will have the infrastructure to conduct this type of research, but this is likely not the case for all CCOP and NCCCP sites. In addition, it is unclear to what extent cancer care delivery research activities will be in proportion to NCORP clinical trial activities, as well as the extent of additional funding offered by the NCI to accomplish this activity. If clinical trials will continue to be the core function of NCORP, this should be reflected in the resource allocation – both in terms of preserving funding for clinical trials and providing additional funding for cancer care delivery research. In addition, we would be concerned if NCI reduces the overall number of research sites in order to accommodate the added cancer care delivery research activities. CCOP sites play a vital role in accruing trial participants for treatment, cancer control, and prevention trials.

We suggest two points for consideration 1) whether it is necessary for all NCORP sites to engage in cancer care delivery research and 2) whether there are non-community-based sites that could play a valuable role in this research. If some CCOP and NCCCP sites currently do not have infrastructure in place to conduct cancer care delivery research, it may not be cost effective for them to add this capability. In addition, not all CCOP sites are organized in the same way. Some may be more able than others to conduct cancer care delivery research. Other CCOP sites may have an infrastructure that prevents conducting this research, particularly for sites that include competitors as CCOP members. At the February 2013 Institute of Medicine workshop on the National Clinical Trials System, current Cooperative Groups commented that they have resources that would provide valuable data for cancer care delivery research. Perhaps the NCORP could incorporate ways to allow other types of entities to contribute to cancer care delivery research. It is important to maximize the available resources to provide as complete information as possible.

In the NCORP funding opportunity announcement, it would be helpful for NCI to provide information it has gathered related to the cancer care delivery research landscape and key topic areas that may be lacking, which the NCORP is expected to address. In addition, it would be helpful to understand how NCORP cancer care delivery research will contribute to, but not duplicate other activities that are funded by the federal government, such as the Agency for Healthcare Research and Quality and the Patient-Centered Research Outcomes Institute.

We appreciate your consideration of our comments as you finalize plans for the NCORP.

Sincerely,

Sandra M. Swain, MD, FACP
ASCO President

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