

Public Comment Regarding Institute of Medicine Report on the NCI Cooperative Group Program

September 20, 2010

We, the undersigned Group Chairs, thank the Institute of Medicine (IOM) for its thorough and thoughtful analysis "A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program" (April 2010). We also appreciate and acknowledge the many organizations that have since issued public statements in support of the Cooperative Group Program and the IOM's recommendations for its transformation.

We agree that the IOM presents the country with a broad-based, comprehensive approach to preparing the Program for the future. We are united in our commitment to transform the Program to become more efficient and more strongly positioned to apply the rapid advances in science into our clinical trials for the benefit of the patients we serve. As noted in the report, cancer patients in the nation are well served by a publicly-funded clinical trials system that complements research conducted in the private sector. We agree with the IOM that "it is imperative to preserve and strengthen the unique capabilities of the Cooperative Group Program as a vital component in [the National Cancer Institute's] translational continuum." In our leadership roles, we are keenly interested in participating with the NCI, IOM, the advocacy community and other stakeholders throughout the academic, governmental, and commercial sectors to identify the greatest synergies and opportunities for the Program.

We have already begun to take steps to improve operational efficiency. For instance:

- The Group Chairs have agreed upon implementation of a single electronic clinical data management system, which will simplify and streamline clinical trial operations across the Groups.
- The Group Chairs are exploring opportunities to harmonize and consolidate operational functions such as biostatistics and data management, as well as ways to make tissue acquisition, banking and access more efficient. Three groups (ACOSOG, NCCTG and CALGB) have recently announced the consolidation of their biostatistical and data management centers.
- For current and future patients, the lengthy time to trial activation means that many will not receive treatment that could represent their best hope for survival. The Group Chairs and our Disease Committee Leaders are committed to the principles of the Operational Efficiency Working Group. Currently, we are accelerating the activation timelines for all of our clinical studies with the help of the OEWG.
- An internal dialogue is underway to address the optimal configuration of our scientific programs and portfolios, building on our diversity and strengths.

The IOM's recommendations present a path for progress. Indeed, the IOM successfully incorporated input from all stakeholders in its analysis and as a result the report will go down as the culmination of reviews which have been going on for years. We thank the NCI for commissioning the report and the IOM for bringing these issues to national attention. However, without continued leadership, this report might, too, fall by the wayside. Progress will only be possible with acceptance and implementation of the recommendations at the very senior levels of the federal agencies and administration. We welcome continued leadership from the IOM and the NCI to maintain national focus on the topic and guide us in the development of reasoned implementation plans. Let it be said that we embrace the opportunity to invigorate the system, make it more attractive to researchers and more vital as a force in helping to advance the standards of patient care in cancer in the 21st century.

Signed,

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Co-Signed as a Statement of Support by:

NCIC Clinical Trials Group, **Ralph Meyer, MD, Chair**

Quality Assurance Review Center, **Thomas J. FitzGerald, MD, Director**

www.CancerTrialsHelp.org. The Coalition of Cancer Cooperative Groups is an independent non-profit organization whose mission is to improve the survival and quality of life of cancer patients through increased participation in cancer clinical trials. Diane D. Colaizzi, MA, Media Relations, 215.789.3612 or dcolaizzi@cancertrials-help.org.