NCI'S EVOLVING CLINICAL TRIALS SYSTEM

166th Meeting of the
NATIONAL CANCER ADVISORY BOARD
Conference Room 10, C Wing, Building 31
1:30-5:30 Sept. 9th 2014



The National Cancer Advisory Board (NCAB)

"The primary task of the NCAB is to advise the Secretary of Health & Human Services, the Director of the NCI, and ultimately the President of the United States on a range of issues affecting the Nation's Cancer program and, the NCI operations."



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What Happens March 1st?

March 1, 2014 is the day our legacy groups, NSABP, RTOG, and GOG, cease to exist as NCI-funded cooperative groups and NRG Oncology takes its place as one of the five NCI-funded Lead Protocol Organizations (LPOs). March 1 is also the official start of the NCI's National Clinical Trials Network (NCTN) which is replacing the 50-year old Clinical Cooperative Group Program. Much work has taken place behind the scenes to bring these new organizations into existence. Detailed below is important information about these changes.

Please note: The foundations that have supported our groups (NSABP Foundation, Inc., RTOG Foundation, Inc., and the Gynecologic Oncology Group) will continue in their research missions and will continue to be a vital resource to NRG Oncology.

UCSF

Joint Cooperative Group / NCI / NCAB Meeting 9-9-2014

Assuming the funding level is *NOT* increased ... *EXAMPLES* of Questions that *might* be addressed includes:

- 1. What area(s) have improved since the merger of Cooperative Groups?
- 2. Could Cooperative Group work be streamlined to reduce cost & waste?
- 3. What is the single greatest threat to the success of Cooperative Groups?
- 4. What area(s) were made worse by the merger of Cooperative Groups?
- 5. Ways Cooperative Groups & Cancer Centers could work more closely together & reduce cost or improve the success of cancer research?
- 6. How can Cooperative Groups get "credit" for unreimbursed expenses?
- 7. What metrics to include in the evaluation of the Clinical Trial enterprise?

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Assuming the funding level is *NOT* increased ... *EXAMPLES* of Questions (continued) that *might* be addressed includes:

- 8.The NCI timeline for evaluating impact of the revisions on the system (e.g. shall we meet annually to do so)?
- 9. What is the process by which the NCI decides which trials will be done by the cooperative groups? How do they prioritize? How do they work with the Pharma community?
- 10. What is the NCI position on correlative science in cooperative group trials? Is this a new role for NCI intramural/Frederick Is it legislated or competitive?