Clinical Trials Strategic Planning
Subcommittee of CTAC

November 9, 2011
CTAC Clinical Trials Strategic Planning Subcommittee: Members

**CTAC**
- Joel Tepper (Chair)
- Jim Abbruzzese
- Nancy Davidson
- Nancy Roach
- George Weiner

**NCI**
- Jim Doroshow
- Jeff Abrams
- Lori Minasian
• **CTWG Evaluation Plan**: A plan to assess the performance and impact of several CTWG initiatives on the effectiveness of the NCI clinical trials enterprise was approved by CTAC in July 2011.

• **NCI Clinical Trials Network (NCTN)**: NCI, Group Chairs and CCOP Research Base PIs need feedback and assistance in assessing priorities across diseases and modalities for the evolving NCTN.
  - This feedback should be provided by thought leaders from within and outside the Groups, and should be part of CTAC
  - This is NOT another level of protocol-specific review
    - Strategy as opposed to tactics
    - Longer-term planning as opposed to short-term objectives
Clinical Trials Strategic Planning
Subcommittee: Purpose and Scope

• **Purpose:** Advise NCI on the development of a fully integrated clinical trials system.

• **Scope:** Trials funded through cooperative agreements and contracts.
  - [NCI Clinical Trials Network](#) trials reviewed by the Scientific Steering Committees (SSC) and generally conducted by the Cooperative Groups and CCOPs.
  - [NCI Early Phase Trials](#) sponsored by CTEP and the Division of Cancer Prevention early phase drug/agent development programs

• Initially focus on the NCI Clinical Trials Network trials.
Clinical Trials Strategic Planning Sub委员会: Objectives

• Monitor and assess the balance, coherence and appropriateness of NCI’s clinical trials portfolio.

• Monitor and assess the scientific effectiveness of the NCI’s Scientific Steering Committees.

• Recommend new strategies, priorities and directions for clinical trials based on the NCI’s current portfolio, evolving clinical needs, and emerging scientific opportunities.

• Monitor and assess other aspects of clinical trials operations across the system including collaboration and timeliness.
CTAC Committee Structure

Clinical Trials and Translational Research Advisory (CTAC)

Clinical Trials Strategic Planning Subcommittee*

NCI Clinical Trials Strategic Planning WG

Other WG’s as needed (Early Phase Trials)

*Ad hoc
NCTN Strategic Planning Working Group: Proposed Categories of Membership

**Non-NCI**
- Cooperative Group Chairs
- Cooperative Group Statisticians
- Cancer Center Directors
- CCOP PIs
- Patient advocates
- Translational scientists (SPORE/PO1)
- Cancer Control – Research Base PIs
- Steering Committee Chairs
- CTAC members

**NCI**
- DCTD
- DCP
- CCCT
Next Steps

- NCI to draft function statement and proposed membership for the NCI Clinical Trials Working Group.
  - Subcommittee to provide input to ensure balanced composition.
- NCI to continue implementation of the CTWG Evaluation Plan to generate data for Working Group review.
- Initial Working Group activities:
  - Review responsibilities and tasks
  - Review proposed measures to achieve tasks
  - Develop process for analyzing portfolio and assessing balance based on presentations by NCI staff about the current portfolio.