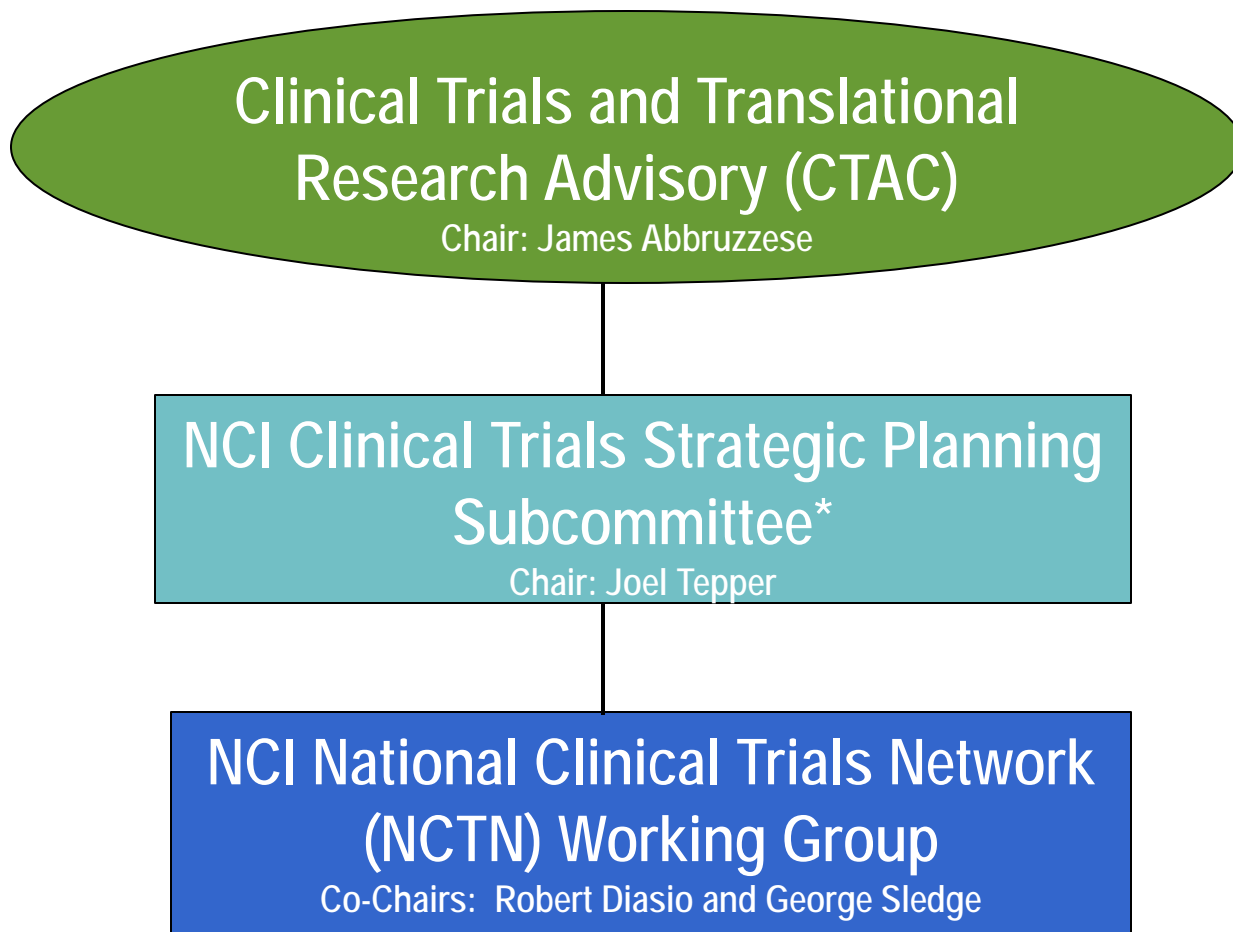


NCI National Clinical Trials Network (NCTN) Working Group

Update for CTAC

George Sledge, MD
November 30, 2012

CTAC Committee Structure



*Adhoc

Clinical Trials Strategic Planning Subcommittee

- **Purpose:** Advise NCI on the development of a fully integrated clinical trials system.
- **Scope:** Trials funded through cooperative agreements and contracts.
 - NCI National Clinical Trials Network (NCTN) trials reviewed by the Scientific Steering Committees 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
- **Members:** Joel Tepper (chair), James Abbruzzese, Nancy Davidson, Scott Lippman, Nancy Roach, and George Weiner.

NCTN Working Group Function Statement

- 1. Assess the strength and balance of the active NCTN clinical trials portfolio (Cross-Disease Portfolio Management).**
 - Within each disease
 - Across all diseases
- 2. Recommend new strategic priorities and directions for the NCTN based on current trial portfolio, evolving clinical needs, and emerging scientific opportunities.**
- 3. Review and assess the CTWG Evaluation process and results.**
 - Quality of completed trial outcomes
 - Operational performance of Scientific Steering Committees
 - Efficiency of clinical trial conduct
- 4. Provide strategic advice to enhance NCTN clinical trial operations including collaboration and timeliness.**

NCTN Working Group: Composition

Members

- Co-chairs: Robert Diasio and George Sledge
- 28 extramural members
- Members selected from the following categories of stakeholders:
 - Cooperative Group Chairs
 - Cooperative Group Statisticians
 - CCOP/MBCCOP Principal Investigators
 - Cancer Control Research Base Principal Investigators
 - Cancer Center Directors
 - Steering Committee Chairs
 - Advocates
 - Translational Scientists
 - CTAC Clinical Trials Strategic Planning Subcommittee
 - NCI Leadership (DCTD, DCP, CCCT, Cancer Centers)

NCTN Working Group July 11, 2012 Meeting

Summary of July 11, 2012 Meeting

- Discussed goals of the review of the NCTN clinical trials portfolio in each disease area.
- Assessed the pilot process used for the review of the colorectal cancer clinical trial portfolio.
- Discussed approach for assessing other disease sites in future meetings.
- Refined proposed criteria for evaluating and scoring trials.

Portfolio Review Process at July Meeting

- Working group received summaries of the trials in the colorectal cancer portfolio.
- SC Chair and NCI Medical Officer presented the colorectal cancer portfolio and overall disease strategy to put trials in context.
- Colorectal cancer trials in portfolio scored by working group.
- Working group refined scoring criteria and discussed approaches to assessing the overall portfolio.

Assessment of Pilot Process for Review of Colorectal Cancer Trials Portfolio

- Review of individual trials within a disease is appropriate and feasible.
- Working group is an appropriate venue for conducting such a review.
- Working group is comfortable with using expert judgment to evaluate individual trials.
- Summary sheets on individual trials provided in advance are valuable.
- Need summary information on other major ongoing trials outside of NCTN (e.g., industry, international) in disease area.
- Presentation of clinical trial portfolio and strategy in disease area by CTEP Medical Officer and Steering Committee Chair is valuable for putting trials in context.

Refined Criteria for Evaluating Trials

- **Feasibility**
 - Accrual difficulty
 - Trial complexity
 - Cost to implement at sites
- **Clinical Importance**
 - Importance of study question relative to state of the science in the disease
 - Benefit per patient and for population (e.g. life years saved)
- **Scientific Contribution**
 - Test important scientific or proof of principle
 - Importance of correlative study questions
- **Relative cost/resources**
 - Total number of patients required
 - Length of study (accrual and follow-up)
- **Appropriateness for NCTN Program**

Overall Trial Score

- Working Group concluded that members should assign an overall score to each trial based on their scores on the individual criteria.
- Scoring of trials will be applied for the review of multiple Steering Committee portfolios (Breast, GI, GU, Leukemia, & Lymphoma) at the December 2012 meeting.
- Working group members will be assigned to disease based subgroups to take the lead in the review of each disease area.