NCI National Clinical Trials Network (NCTN) Working Group

Update for CTAC

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CTAC Committee Structure

Clinical Trials and Translational Research Advisory (CTAC)
Chair: James Abbruzzese

NCI Clinical Trials Strategic Planning Subcommittee*
Chair: Joel Tepper

NCI National Clinical Trials Network (NCTN) Working Group
Co-Chairs: Robert Diasio and George Sledge

*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)
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.