



NCI Update

James H. Doroshow, M.D.
Deputy Director for Clinical & Translational Research
National Cancer Institute, NIH



*Clinical Trials & Translational Research
Advisory Committee*

Bethesda, MD
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Update Topics

- **Budget**
- **Personnel**
- **Team Science Meeting**
- **CTAC Clinical Trials Strategic Subcommittee**
- **NCI National Clinical Trials Network (NCTN) Working Group**

Budget and Grants

- **FY12 Budget**
 - \$5.071B
 - \$12 M(0.2%) more than FY 11
 - Expect about 1100 grants
 - Grant approval process will be similar to last year with no strict pay line; expect success rate around 15%
 - Budget now official; should speed up the process of making awards
- **FY13 President's Budget**
 - \$3M increase over FY12
- **Bypass narrative in progress – will focus on six types of cancer and some key initiatives such as genomics, global health, Cancer Centers, provocative questions, and precision medicine**

Personnel

Searches underway for:

- **Director of NCI's Center for Biomedical and Information Technology (CBIT)**
 - ✓ George Komatsoulis, Ph.D., appointed Acting Director
 - ✓ NCI working to restructure IT infrastructure
 - ✓ BSA/NCAB caBIG Subcommittee (Chair: Daniel Masys, M.D.)
- **Director of Center for Cancer Genomics (CCG)**
- **Head of Policy/Analysis Office**

NCI Workshop

Team-based Approaches to Scientific Research

- **Held February 7-8, 2012 on NIH Campus**
- **Led by Harold Varmus, Ed Harlow, Jim Doroshow**
- **Staff support from the Coordinating Center for Clinical Trials**

Overall Goal/Purpose:

Assess strategies that have been used for highly successful intra- and inter-institutional collaborative research. Primarily concentrated on the *process* and *approaches* used for building good team research projects...

What hurdles have occurred? How were these solved?

What approaches worked best? What has failed?

Team-based Approaches to Scientific Research Workshop

- **Small group of individuals from various outside organizations and different components of NCI including:
SPOREs, Cancer Centers, Cooperative Groups, P01 and U54 grantees, as well as Stand Up to Cancer, DoD, National Science Foundation, Broad Institute, Howard Hughes Medical Institute, and others**
- **Combined experiences highlighted several current NCI team science mechanisms as well as team science projects led by other organizations.**
- **Presentations and discussions focused on how the teams have been organized around scientific goals and what unique features made them successful.**

Team-based Approaches to Scientific Research Workshop: Key Findings

Characteristics of successful teams

- **Strong leadership (single most commonly cited success factor at workshop)**
- **Meaningful but difficult goals with incentives**
- **Flexibility to redirect funds and alter other parts of project for team building and timeline management**
- **Sufficient finances to identify key problems, recruit/reward essential people, and help leverage resources from other sources**

Suggestions for future team science projects

- **Develop challenging ideas**
- **Use pilot projects to develop teams and refine ideas**
- **Enhance mentoring and training for leadership and team management**
- **Consider program managers to manage projects and inform about available resources at NCI and beyond**
- **Create new methods for project oversight and review**

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 National 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 National Clinical Trials Network trials**

Clinical Trials Strategic Planning Subcommittee: Objectives

- **Assess the balance, coherence and appropriateness of NCI's clinical trials portfolio.**
- **Advise on how to improve 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.**
- **Provide strategic advice to enhance other aspects of clinical trials operations across the system including collaboration and timeliness.**

CTAC Clinical Trials Strategic Planning Subcommittee: Members

CTAC

Joel Tepper (Chair)

Jim Abbruzzese

Nancy Davidson

Nancy Roach

George Weiner

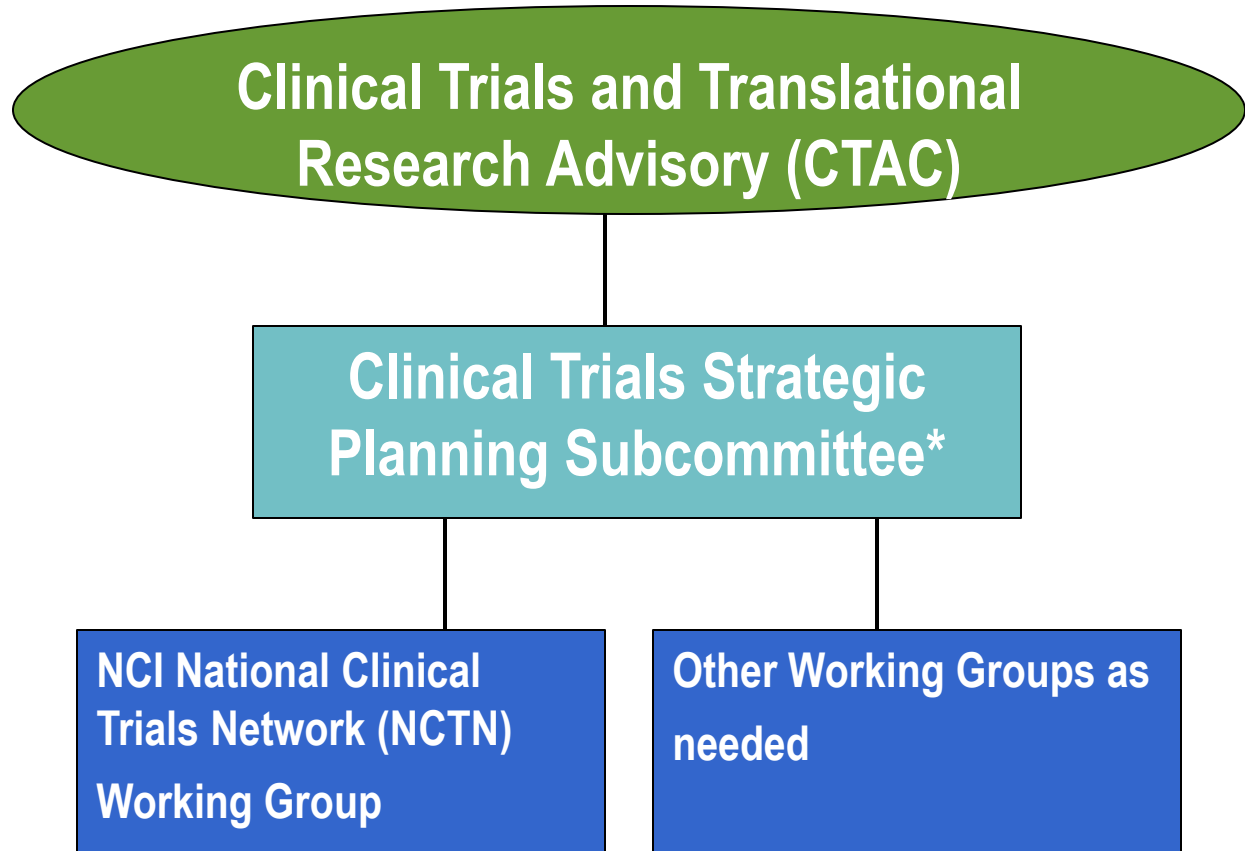
NCI

Jim Doroshow

Jeff Abrams

Lori Minasian

CTAC Committee Structure



*Adhoc

NCTN Working Group Composition

- **Co-chairs**
 - Senior leaders in the field
 - Individuals in leadership positions of the Cooperative Groups (Chair, Executive Committee members, or Disease Committee Chairs) are not eligible
 - Current Steering Committee Chairs are not eligible

- **Members**
 - 25 to 30 individuals
 - Staggered memberships to avoid turnover
 - 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 Co-Chairs

Robert B. Diasio, MD

Mayo Clinic Cancer Center

George W. Sledge, Jr., MD

Indiana University Cancer Center

NCTN Working Group Goals

- **Assess the balance, coherence and appropriateness of the NCTN clinical trials portfolio.**
- **Advise on how to improve the scientific effectiveness of the NCTN Scientific Steering Committees.**
- **Recommend new strategies and directions for the NCTN clinical trials based on the NCI's current portfolio, evolving clinical needs, and emerging scientific opportunities.**
- **Provide strategic advice to enhance other aspects of clinical trials operations affecting the NCTN including collaboration and timeliness.**

Next Steps

- **Complete solicitation of nominations for the membership categories from the various constituencies.**
- **Select members from the various constituencies to ensure appropriate expertise and balance across disease site, geography and institutions.**
- **Initial Working Group activities include:**
 - **Review responsibilities**
 - **Develop a process for assessing the NCTN clinical trials portfolio.**
- **Aim for initial meeting to occur before July 2012 CTAC meeting.**