



# NCI's Evolving Clinical Trials System

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Clinical Trials and Translational Research  
Advisory Committee  
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# Extramural Reviews of NCI's Clinical Trials Programs

Report of the  
Clinical Trials Working Group  
of the  
National Cancer Advisory Board

Restructuring the  
National Cancer Clinical Trials  
Enterprise

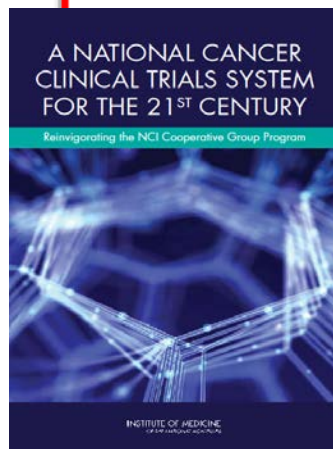
June 2005



Report of the Operational Efficiency  
Working Group  
of the  
Clinical Trials and Translational  
Research Advisory Committee

Compressing the Timeline for Cancer  
Clinical Trial Activation

March 2010



*Emphasized critical need for a public clinical trials system*

*NCI has taken a comprehensive approach to transforming its clinical trials system to create a highly integrated network that can address rapid advances in cancer biology based on:*

- Reports from Clinical Trials & Operational Efficiency Working Groups
- Recommendations from the IOM Report

## Rationale for Change: 2004

- Advances in cancer biology offer enormous potential to improve clinical oncologic practice
- Opportunity to move beyond cytotoxic treatments to more effective therapies targeting the specific characteristics of a patient's tumor
- Challenge of evaluating an ever-increasing number of new, highly specific agents in molecularly-defined subsets of patients

# Goals for Restructuring: 2005

- Coordination
  - Coordinate clinical trials research through data sharing database and providing incentives for collaboration as a network
- Prioritization/Scientific Quality
  - Stakeholders design and prioritize clinical trials that address the most important questions, using the tools of modern cancer biology
- Standardization
  - Standardize IT infrastructure and clinical research tools
- Operational Efficiency
  - Use resources most efficiently through improved cost-effectiveness, accrual rates, and more rapid trial initiation
- Integrated Management
  - Restructure extramural and intramural oversight of NCI clinical trials

# Agenda for Today

## *NCI's Evolving Late Phase Clinical Trials System*

- **National Clinical Trials Network (NCTN)**  
Dr. Meg Mooney
- **Setting Strategic Priorities for NCTN**  
Dr. Jeff Abrams
- **NCI Community Oncology Research Program (NCORP)**  
Dr. Wortia McCaskill-Stevens
- **Community Oncology Investigator Perspective**  
Dr. Phil Kuebler

## *Experimental Therapeutics Clinical Trials Network (ET-CTN)*

- **Overview**  
Dr. Percy Ivy
- **ET-CTN Drug-Specific Project Teams:  
Clinical/Translational Research Perspective**  
Dr. Geoff Shapiro

# Restructuring Outcomes

- An **integrated network** that is capable of supporting studies that will modify oncologic practice based on the principles of precision medicine
- Enhanced **national critical infrastructure** for clinical trials (e.g., central IRB, data management systems, accrual and regulatory support)
- Implemented **operational efficiency** benchmarks
- Supporting **novel clinical trials** such as Lung-MAP, ALCHEMIST, and NCI Match despite fiscal constraints