NCI’s Evolving Clinical Trials System

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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
• 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
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. Worta 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