NCI’s Evolving Clinical Trials System

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Extramural Reviews of NCI’s Clinical Trials Programs

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
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Overview: Drs. Mack Roach & James Doroshow
Clinical Trials Network: Dr. Margaret Mooney
Community Oncology Research Program: Dr. Worta McCaskill-Stevens
Experimental Therapeutics Clinical Trials Network: Dr. Percy Ivy
Clinical Trials Tissue Banks: Dr. Irena Lubensky
Questions: Dr. Jeff Abrams

Impact of the New System

Clinical Trials Network Chair: Dr. Wally Curran
Lead Academic Site/Cancer Center Perspective: Dr. Nancy Davidson
Disease Steering Committee Chair Perspective: Dr. Drew Ridge
Community Oncology Research Program PI: Dr. Augusto Ochoa
Early Phase Therapy/Translational Scientist: Dr. Geoffrey Shapiro
Patient Advocate: Nancy Roach
Discussion: Drs. Mack Roach and James Doroshow