



NCI's Evolving Clinical Trials System

James H. Doroshow, M.D.

Deputy Director for Clinical and Translational Research
National Cancer Institute, NIH

Mack Roach III M.D., FACR

Professor of Radiation Oncology and Urology
Chair Department of Radiation Oncology
UCSF Helen Diller Family Comprehensive Cancer Center



National Cancer Advisory Board

Bethesda, MD

September 9, 2014

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

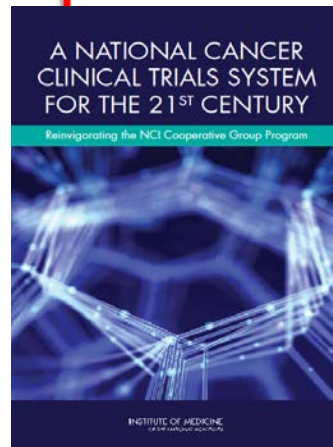
June 2005



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

Program for Today

NCI's Evolving Clinical Trials System

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