Restructuring the National Cancer Clinical Trials Enterprise

National Cancer Advisory Board
Clinical Trials Working Group
Implementation Update

James H. Doroshow, M.D.

February 7, 2006
Common Themes of Restructuring Plan

Prioritization/Scientific Quality
• Involve all stakeholders in design and prioritization of clinical trials that address the most important questions, using the tools of modern cancer biology

Standardization
• Standardize IT infrastructure and clinical research tools

Coordination
• Coordinate clinical trials research through data sharing and providing incentives for collaboration

Operational Efficiency
• Use resources most efficiently through improved cost-effectiveness and accrual rates, and more rapid trial initiation

Integrated Management
• Restructure extramural and intramural oversight of NCI clinical trials
CTWG: Implementation Goals for 2006

- **Prioritization/Scientific Quality**
  - Establish IDSC for prioritization of early phase trials
  - Establish initial disease-oriented SSC’s for phase III’s
  - Prioritization criteria for correlative science/QOL studies

- **Standardization**
  - Increase clinical representation on caBIG clinical trials work space
  - Initiate CRF work groups
  - Start task force for development of credentialing system

- **Coordination**
  - Initiate development of comprehensive database
  - Expand CTSU to cover Cancer Center & SPORE trials
  - Enhance NCI/FDA/Pharma interactions
CTWG: Implementation Goals for 2006

• Operational Efficiency
  – Management analysis of barriers to timely trial initiation
  – Implement funding for expanded minority outreach
  – Initiate interactions with patient advocates and clinical trialists to improve awareness of specific studies

• Integrated Management
  – Extramural clinical trials advisory committee
  – Operational integration of clinical trials within NCI
  – Develop evaluation system and implement baseline assessment
CTWG: Implementation Activities for 2006

• Standardization
  – Increase clinical representation on caBIG clinical trials work space
  – Initiate CRF work groups
  – Start task force for development of credentialing system

  Detailed implementation plan complete: will be seeking nominations very soon from Cooperative Group, Cancer Center, and SPORE PI’s for work groups, including one for the clinical trials database

• Coordination
  – Initiate development of comprehensive database
  – Expand CTSU to cover Cancer Center & SPORE trials
  – Expand meetings with FDA

  CTSU coverage for SPORE trials already discussed with GOG; new SOP for FDA/Industry special protocol assessments being developed by CTEP
CTWG: Implementation Activities for 2006

- **Operational Efficiency**
  - Management analysis of barriers to timely trial initiation
  - Implement funding for expanded minority outreach
  - Initiate interactions with patient advocates and clinical trialists to improve awareness

*Barriers analysis of CALGB Operations Office presented to CALGB leadership last week*

*Additional funding for minority outreach programs will begin with budget allocation*

*Increased interactions of NCI’s Office of Communications and Office of Education and Special Initiatives with advocacy groups represented on initial SSC’s begun: specific focus on new trials*
Prioritization/Scientific Quality Initiatives

Create investigational drug steering committee (IDSC) to provide extramural input into the early phase development of agents for which NCI holds the IND

• Formal mechanism established
• Responsibilities
  – Strategic input for Investigational Drug Branch
  – Review of CTEP clinical drug development plans
  – Strategic evaluation of unsolicited letters of intent for new agent studies
• First meeting 9/05; co-chairs elected; coordinating committee formed; policies and procedures under development
Prioritization/Scientific Quality Initiatives

Create network of scientific steering committees for design and prioritization of phase III trials

- Mechanism established for disease steering committees
- Composition and participants: Groups, SPORES, Cancer Centers, PO1s, community physicians, advocates, & NCI
- Responsibilities
  - State-of-the-science meetings
  - Trial development and prioritization
  - Development of correlative studies
- Initial focus: GI, GYN, H&N
- Support and facilitation by NCI
CTWG: Integrated Management Components

Create an external clinical trials oversight committee to advise the NCI Director on the conduct of clinical trials across the Institute

**Clinical Trials Advisory Committee**

- New, HHS/NIH approved advisory committee; first for NCI in a decade
- Oversee implementation of CTWG initiatives
- Advise NCI Director on structure and conduct of clinical trials programs institute-wide, and on use of new correlative science funds
- Combined membership from NCAB, BSA, BSC, DCLG; majority newly appointed from extramural clinical trials community
- Charter will be published soon in Federal Register
- First meeting June, 2006
CTWG: Integrated Management Components

Develop a coordinated organizational structure within NCI to manage the clinical trials enterprise across the Institute

Clinical Trials Operations Committee: Strategic Oversight for NCI Clinical Trials Programs and Infrastructures

- Reviews & prioritizes clinical trial programs proposed by Divisions, Centers, and Offices to coordinate clinical trial efforts NCI-wide including the intramural program
- Evaluates organizational infrastructures to reduce duplication; advises NCICB on development of IT infrastructure and tools for support of clinical trials
- Provides guidance, review and comment on policies, procedures, processes, tools, etc. for prioritization, coordination, administration and support of NCI-funded clinical trials with the operating Divisions/Centers/Offices
- Evaluates all RFA’s and PA’s involving clinical trials prior to EC review
- Membership from all NCI Divisions, Centers, Offices involved in clinical trials
- Reports to NCI Director through Deputy Director for Clinical and Translational Sciences
- First meeting December, 2005
CTWG: Integrated Management Components

Develop a coordinated organizational structure within NCI to manage the clinical trials enterprise across the Institute

Coordinating Center for Clinical Trials: Project Management

- Implements, supports, and operationalizes CTWG initiatives in conjunction with NCI Divisions, Centers, and Offices; supports CTOC
- Works within NCI and with extramural clinical trials community to develop new procedures and policies for coordination of NCI-funded clinical trials
- Staff of five doctoral level scientists with additional support staff; Drs. Deborah Jaffe, Ray Petryshyn, and Lee Ann Jensen recruited to date
- Actively engaged in facilitation of initial development of IDSC & SSC’s
- Reports to NCI Director through Deputy Director for Clinical and Translational Sciences
Coordinating Center for Clinical Trials: Phase III Trials

- Facilitate Scientific Steering Committee (SSC) meetings and development of Task Forces
- Coordinate State of the Science (SOS) meetings
- Coordinate the movement of ideas, proposals and concepts to Task Forces and Scientific Steering Committees
- Prepare summaries and action items from Task Force and Steering Committee meetings
- Assist in development of policies and procedures
- Assist in consensus evaluation documents
- Assure timelines met—essential new infrastructure
Establish structured evaluation system
  • Designed by experienced evaluation specialists
  • Blend of qualitative/quantitative measures
  • Evaluation involving clinical trial experts and structured empirical data

Perform baseline evaluations
  • Implementation questionnaires and data gathering plan developed
  • “Kick-off” February, 2006
CTWG: Implementation Timeline

- Restructuring plan encompasses 22 initiatives organized by these common themes
- Implementation projected to be complete in 4-5 years
- Majority of initiatives implemented by end of year 3
- Established as routine practice by end of year 7
Initiatives: Interactive and Interdependent

- NCI Clinical Trials Management
- NCAB Clinical Trials Subcommittee

- Coordination
  - Database
  - Aligned Incentives
- Prioritization
  - IT Infrastructure
  - Case Report Forms
- Standardization
  - Federal Agency
  - Coordination
- Efficiency
  - Community
  - Oncologist
  - Patient Advocate
  - Involvement
  - Rapid Trial
  - Completion

- IT Infrastructure
- Case Report Forms
- Contracts
- Community
- Oncologist
- Patient Advocate
- Involvement
- Rapid Trial
- Completion
- IT Infrastructure
- Case Report Forms
- Contracts
- Community
- Oncologist
- Patient Advocate
- Involvement