Restructuring the National Cancer Clinical Trials Enterprise

National Cancer Advisory Board
Clinical Trials Working Group
Implementation Update

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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, Offices, and Centers involved in NCI-supported 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

CTWG: Integrated Management Components

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