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Restructuring the National Cancer Clinical Trials Enterprise

Clinical Trials Working Group Implementation Update

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

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Clinical Trials Working Group

- Working group of the National Cancer Advisory Board (NCAB)
  - Initiated in 2004
  - Address whether and in what ways the NCI-supported clinical trials enterprise should be restructured to realize the promise of molecular medicine for advancing oncologic practice in the 21st century
- Implementation plan approved by NCAB in June, 2005

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Common Themes of the Restructuring Plan

Coordination

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

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 informatics infrastructure and clinical research tools

Operational Efficiency

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

Enterprise-Wide

- Restructure the extramural and intramural oversight of NCI clinical trials

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Update: Prioritization/Scientific Quality Initiative

- Establish steering committees (SC's) for clinical trial prioritization
  - Investigational Drug Steering Committee (IDSC) established
  - Initial disease-specific SC
    - GI and GYN up and running
    - H&N constituted with plans for first face-to-face meeting in December
    - Symptom Management and Health-Related Quality of Life is in early the planning stages
- Increase community oncologist/patient advocate representation on steering committees
  - Community oncologists/advocates are members of the GI and GYN SC's
  - Continue to enhance community oncologist/advocate representation with formation of the Symptom Management and Health-Related Quality of Life SC
- Develop prioritization criteria for funding of the most important correlative science/quality of life studies in a timely fashion
  - Task Force to define prioritization criteria for correlative science studies has been established
  - Define prioritization criteria for quality of life studies

Symptom Management and Health-Related Quality of Life Steering Committee

NCI is committed and dedicated to supporting research in symptom management and health-related quality of life

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CCOP Cancer Control Trials

- Cancer Control Requirement Began in 1987
  - Symptom Management Trials
  - Quality of Life
- CCOP Network is the primary mechanism for conducting phase III clinical trials in symptom management, palliative care, and other cancer control issues

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Symptom Management and Health-Related Quality of Life Steering Committee (SC) Planning

- Meeting with NCI representatives with symptom management and quality of life clinical trials portfolios (DCP, DCCPS, DCTD) in August 2006

- Symptom Management and Health-Related Quality of Life SC presents new challenges to be considered
  - No intergroup to readily identify SC members
  - Various sources of funding
    - CCOP program
    - DCCPS and DCP grant portfolios
    - CTEP
  - Diverse portfolios and disciplines (e.g. pain, depression, fertility, end of life care, mucositis etc.)

- Outcome
  - Presentation of portfolios to CTOC
  - NCI planning committee formed

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Symptom Management and Health-Related Quality of Life SC Responsibilities

- Convene State-of-the-Science meetings
  - Identify critical questions and unmet needs
  - Prioritize key strategies and future concepts to test
- Develop and prioritize symptom management intervention clinical trials conducted through the CCOP mechanism
- Develop and review studies with quality of life secondary endpoints in cooperative group treatment studies
- Develop criteria for NCI Clinical Trials Operational Committee (CTOC) review of studies that are competing for the Correlative Science/QOL set aside funds

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Next Steps and Timeline

- Solicit nominations from Cooperative Groups, CCOP Research Bases, and Cancer Centers to assemble a core group of SC members
- Initial teleconference in January 2007
- Face-to-face meeting in June 2007 at ASCO

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Enterprise-Wide (Integrated Management)

- Restructure the extramural and intramural oversight of NCI clinical trials

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Enterprise-Wide: Integrated Management

- External clinical trials oversight committee to advise NCI Director
- Coordinated organizational structure within NCI to manage the clinical trials enterprise

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Clinical Trials Advisory Committee (CTAC)

- Federal advisory committee chartered in February 2006
  http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm
- Advise and make recommendations on the structure and conduct of the clinical trials programs Institute-wide
- Advise on the use of new correlative science and quality of life funds
- Membership:
  - Chair, Dr. John Niederhuber
  - Ten members current Boards (NCAB, BSA, BSC, DCLG)
  - Fourteen new members from extramural clinical trials community
- First meeting January, 2007

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Clinical Trials Operations Committee (CTOC)

- Established in December, 2005 to provide strategic oversight for NCI clinical trials programs and infrastructures
- Reviews and prioritizes clinical trial programs proposed by Divisions, Centers, and Offices to coordinate efforts Institute-wide
- Evaluates organizational infrastructures to reduce duplication
- Advises NCICB on development and support of clinical trial informatics infrastructure
- Evaluates all RFA's and PA's involving clinical trials prior to EC review
- Provides guidance on policies, procedures, tools etc. for prioritization, coordination, administration and support of clinical trials
- Membership from all NCI Divisions, Offices, and Center involved in NCI-supported clinical trials

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Coordinating Center for Clinical Trials (CCCT)

- Office established in January, 2006 (http://ccct.nci.nih.gov)
- Implements, supports, and operationalizes CTWG initiatives in conjunction with NCI Divisions, Centers, and Offices
- Supports the Clinical Trials Operational Committee (CTOC) and the Clinical Trials Advisory Committee (CTAC)
- Works within NCI and with extramural clinical trials community to develop new procedures and policies for coordination of NCI-funded clinical trials
- Actively engaged in facilitation of initial development of Investigational Drug and Disease-Specific Steering Committees including Symptom Management and Health-Related Quality of Life Steering Committee
- Reports to NCI Director through Deputy Director Clinical and Translational Science

Initiatives: Interactive and Interdependent