National Cancer Institute

CTAC Working Group and CCCT Updates

Sheila A. Prindiville, MD, MPH
Coordinating Center for Clinical Trials (CCCT)

March 10, 2010

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

National Cancer Institute

Outline

- **Working Group Updates**
  - CTWG Evaluation (proposed)
  - Guidelines Harmonization (GHWG)
  - Process to Accelerate Translational Science (PATS)
  - Cost-Effectiveness Analyses (CEA)

- **CCCT Updates**
  - Clinical Investigator Team Leadership Award
  - Biomarkers, Imaging, and Quality of Life Studies Funding Program (BIQSFP)

National Cancer Institute

CTWG Overall Evaluation Plan

- **Baseline Feasibility Analysis & Recommended Future Evaluation System final report completed in October 2008 (previously presented to CTAC)**

- **Proposed a structured evaluation system**
  - Designed by experienced evaluation specialists
  - Blend of quantitative/qualitative measures
  - Perceptions of clinical trial experts and structured empirical data

- **Next steps are to:**
  - Review the Baseline Feasibility Analysis & Recommended Future Evaluation System final report
  - Determine which of the proposed measures should be included in the final evaluation system
  - Determine the periodicity of the measurements

National Cancer Institute

CTWG Evaluation Plan Categories of Measures

- **System Outcome Measures**
  - Is the overall output of the NCI clinical trials system improving?
- **System Process Measures**
  - Are the individual CTWG initiatives having the desired effect on the performance of the NCI clinical trials system?

National Cancer Institute

System Outcome Measures

- **Quality of Trials**
  - Publications
  - Strength of trial designs
- **Impact of Trials**
  - Guide new therapeutics or diagnostics development
  - Lead to changes in patient management
- **Efficiency of Trial Development and Initiation**
  - Time to first patient on study
- **Efficiency of Trial Conduct**
  - Rate of accrual, cost-effectiveness

National Cancer Institute

System Process Measures

- Measures proposed for the 22 individual initiatives
- Drs. Sargent & Adamson have 'previewed' the system outcome and process measures to facilitate discussions by proposed CTWG Evaluation Working Group
- Examples of some of the proposed system process measures for the Disease-specific Steering Committees

National Cancer Institute

Disease-specific Steering Committees: Proposed Evaluation Components

- **Database analyses**
- **Expert panel to assess quality of the system output**
- **Stakeholder interviews to assess process and quality**

National Cancer Institute

Disease-specific SC Database Analyses

- **Time to initiate trials**
  - Time from steering committee review to final decision
  - Time from steering committee review to first patient on study
  - Time from task force presentation to steering committee review
- **Collaboration**
  - Number of Cooperative Groups endorsing studies
  - Number and percentage of patients accrued by non-lead Group
- **Quality of clinical trials**
  - Percentage of trials meeting monthly/yearly accrual targets
  - Percentage of trials closed early due to lack of accrual
  - Percentage of trials published in peer-reviewed journals

National Cancer Institute

Disease-specific SC Expert Panel Assessments

- **Strategic vision of SC and whether approved trials align with vision**
- **Quality of concepts**
  - Are concepts received by steering committees improving in quality over time?
  - Influence of steering committees & task forces on trial design
- **Quality of trials in disease area**
  - Efforts to bring forward new interventions in patient populations with no Phase 3 or large Phase 2I trials
  - Are Phase 3 trials designed based on strong evidence from earlier phase trials or more experimental in nature?
  - Are Phase 3 trials designed to identify practice changing improvements rather than incremental improvements?

National Cancer Institute

Disease-specific SC Interviews about Process

- **Extramural Investigators**
  - Quality, transparency, fairness, speed of processes
  - Influence of Clinical Trials Planning meetings on trial design
  - Influence of Task Forces/Steering Committees on trial design
  - Increased collaboration between Cooperative Groups

- **SC Members & NCI Staff**
  - Quality, transparency, fairness, speed of processes
  - Influence of Clinical Trials Planning meetings on trial design
  - SC track record in disapproving scientifically weak concepts
  - Incorporation of community oncologist and patient advocate input in trial design
  - Increased collaboration between Cooperative Groups
  - Collaboration between Disease-specific SCs and other system committees (IDSC, Symptom Management, and Imaging)

National Cancer Institute

Extramural Input Needed

- **Propose forming CTWG Evaluation Working Group**
- **Goal:**
  - To develop recommendations for evaluating the impact of the implementation of the recommendations of the Clinical Trials Working Group
  - The evaluation system should highlight areas of progress and success as well as identify areas which will require additional focus or adjustment in implementation efforts.
- **Objectives:**
  - Review the Baseline Feasibility Analysis & Recommended Future Evaluation System final report
  - Determine which of the proposed measures should be included in the final evaluation system
  - Determine the periodicity of the measurements

National Cancer Institute

Guidelines Harmonization Working Group

- **Chair: James Abbruzzese, MD**
- **Goal:**
  - Harmonize program guidelines and develop incentives to foster collaboration among all components of the clinical trials infrastructure including Cancer Centers, SPOREs, and Cooperative Groups
  - **Promote collaborative team science:**
    - Ensure that guidelines for different clinical trials funding mechanisms are aligned
    - Eliminate redundancy and duplication while proactively encouraging collaboration

National Cancer Institute

Guidelines Harmonization Working Group Status

- **Initial report and recommendations presented and accepted by CTAC on July 15, 2009**
- **NCI staff are currently developing guidelines revisions and plans for incentives**
  - SPORE and Cancer Center guidelines revised to address major changes in review and application guidelines at the NIH level
  - Recommendations of GHWG and OEWG were “mapped” to SPORE, Cancer Center, and Cooperative Group guidelines
  - Areas or sections of existing guidelines that are responsive or should be modified have been identified as well as areas needing new guidelines
  - Staff are collaborating on drafting “harmonized” guideline revisions
- **Full report back to CTAC in July 2010**

National Cancer Institute

Process to Accelerate Translational Science (PATS) Working Group Update

- November 2009: CTAC accepted Immune Response Modifier (IRM) Pathway Prioritization Working Group report
- January 2010: Constituted internal NCI IRM Pathway STRAP implementation committee
- Stephen Creekmore, M.D.,Ph.D., Susan Rossi, Ph.D., M.P.H., co-chairs
- Charged with developing an IRM Pathway STRAP
  - Choose Immune Modifying Agent provided by NCI
  - Call for applications
  - Review criteria and process
  - FY2010

National Cancer Institute

STRAPs for other TRWG Pathways

- **Process to Accelerate Translational Science Working Group (PATS WG)**
- **Co-chairs: Lynn Matrisian, Ph.D. and Ken Cowan, M.D.**
- **Feb meeting weather-related cancellation, May meeting planned**
- **Charge**
  - Review the Immune Response Modifier Pathway prioritization experience
  - Discuss potential alternative approaches to gathering information on translational research opportunities for acceleration
  - Assess NCI infrastructures for the Agents pathway (i.e. NExT program)
  - Advise on the prioritization process for other TRWG pathways and across the pathways

National Cancer Institute

Other TRWG Activities

- **NCI Translational Science Meeting: July 2011**
- **Pilot project with Division of Extramural Activities coding NCI grants by TRWG pathways ongoing**
- **Evaluation plan for TRWG initiatives in development**

National Cancer Institute

Cost-Effectiveness Analysis (CEA) Working Group

- **Chair: Scott Ramsey, MD, PhD**
- **Purpose:**
  - **Advise CTAC and the NCI on the development of a prioritization process and funding mechanism to ensure that the most important cost-effectiveness analyses can be initiated in a timely manner in association with clinical trials**
- **Objectives:**
  - **Develop prioritization criteria for determining the most important cost-effectiveness analyses to conduct in conjunction with clinical trials**
  - **Recommend possible funding mechanisms for support of high priority cost-effectiveness analyses**

National Cancer Institute

Clinical Investigator Team Leadership Award

- CTWG initiative to enhance recognition for mid-level clinical investigators at academic institutions who promote successful clinical research programs
- 11 awards made in 2009
- Partial salary support for up to $50,000 per year for two years
- 2010 applications due March 26, 2010
- Centers receiving an award in 2009 are not eligible for 2010

http://cancercenters.cancer.gov

National Cancer Institute

KEY CHANGES IN REVISED BIQSFP ANNOUNCEMENT (April 1, 2010)

- **Integral studies embedded in large (≥100 patients), randomized Phase 2 concepts for therapeutic trials with a control arm are eligible for BIQSFP funding**
- **A Quality of Life (QOL) Checklist and an integrated Biomarker/Imaging Checklist have been added**
- **For integral biomarkers, the Clinical Laboratory Improvement Amendments (CLIA) number of the lab performing the assay(s) is required**

http://ccct.nci.nih.gov