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Potential CTAC Subcommittees

Clinical Trials and Translational Research Advisory Committee Meeting

July 13, 2011

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Potential CTAC Subcommittees

- Clinical Trials Strategic Planning Subcommittee
- Clinical Trials Informatics Subcommittee

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Proposed CTAC Clinical Trials Strategic Planning Subcommittee

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Clinical Trials Strategic Planning Subcommittee: Scope of Authority

- Clinical trial portfolio analysis
- Evaluation of clinical trial activities
  - Quality and efficiency of NCI supported trials
  - Steering Committee processes and impact
  - Collaboration in NCI funded clinical trials
- Strategic advice on overall NCI clinical trials program
  - Primary focus Cooperative Group/CCOP trial portfolio

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Clinical Trials Strategic Planning Subcommittee: Responsibilities

- Assess priority of these tasks and need for Working Groups in the following areas:
  - Portfolio Analysis
  - Evaluation
  - Cooperative Group/CCOP Strategic Analysis
- If Working Groups are convened, oversee Working Group activities to avoid duplication of effort
- Review Working Group findings/recommendations and report to CTAC on Working Group activities, findings and recommendations

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Portfolio Analysis Tasks

- Review initial (2006) clinical trial portfolio analysis data and methods (follow up March 2011 CTAC presentation)
- Recommend whether periodic clinical trial portfolio analysis should begin in 2012
- If future clinical trial portfolio analysis is approved
  - Recommend improvements in methodology
  - Recommend frequency and scope
  - Oversee process and review results
- If portfolio analysis results warrant, recommend changes in NCI clinical trial funding priorities

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Evaluation Tasks

- Oversee analysis of measures relying on data currently collected in NCI databases and prioritize data elements to be added in the future
- Oversee expert panel process for evaluating scientific importance and clinical relevance of trial results
- Oversee evaluation of Investigational Drug Steering Committee (IDSC) operations and recommend improvements
- Oversee evaluation of Disease and Symptom Management Steering Committee processes and recommend improvements
- Oversee evaluation of the extent of collaboration in NCI funded clinical trials
- If additional areas are approved for evaluation, oversee resulting evaluation process

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Cooperative Group/CCOP Strategic Analysis Tasks

- Review scientific effectiveness of Steering Committees
  - Quality of concepts approved
  - Scientific importance and clinical relevance of trial results*
  - Contributions to development/refinement of trial concepts
  - Standards for judging scientific merit and clinical importance of trial concepts
  - Contributions of Committee activities in identifying new strategic priorities
  - Recommend needed improvements to improve scientific effectiveness
- Review quality of Cooperative Group/CCOP trial portfolio
  - Trial quality and scientific importance/clinical relevance of trial results*
  - Balance across diseases and modalities in light of scientific opportunities and clinical needs
  - Recommend needed quality improvements or changes in portfolio balance
- Recommend new strategic priorities and directions

* Drawing on results of the System Outcomes evaluation overseen by Evaluation Working Group

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Discussion Questions for CTAC

- Is a Clinical Trials Strategic Planning Subcommittee warranted?
  - Is the scope of authority correct?
  - Are the responsibilities clear and appropriate?
- Is the Cooperative Group and CCOP clinical trial portfolio of sufficient importance to warrant a Working Group dedicated to its strategic scientific oversight now?
    - National Clinical Trials Network – NCTN Working Group
- Should any other Working Groups of the his subcommittee be planned at this point in time?

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Next Steps if Subcommittee Approved

- Establish charge, membership and Chair(s) for Subcommittee
- Determine if Working Groups are needed to achieve charge
- Assign initial tasks and responsibilities to committee and Working Groups as appropriate
- Initiate deliberations in Fall, 2011

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CTAC Decisions Requested

Approval of Strategic Planning Subcommittee and its Scope of Authority

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Proposed CTAC Clinical Trials Informatics Subcommittee

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Clinical Trials Informatics Subcommittee: Scope of Authority

- Informatics initiatives requiring user/stakeholder input from the clinical trials community
  - Focus on the implementation of the CTWG informatics initiatives
    - Clinical Trials Reporting Program (database)
    - Common case report forms (CRFs) for NCI information systems
    - Development of a credentialing repository (e.g. electronic 1572 forms)
  - Other relevant areas
    - Implementation of a common clinical trials data management system for NCI Cooperative Groups
    - Adverse event reporting systems (AdEERS/cAERS)

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Clinical Trials Informatics Subcommittee: Responsibilities

- Review progress on the implementation of CTWG and other clinical trials informatics initiatives
- Provide advice on topics needing additional consideration as identified by the AACI-NCI CTRP Strategic Subcommittee Report such as:
  - Outcome reporting
  - Reporting non-interventional trials in CTRP
  - Summary 4 report design
  - Patient level disease coding for accrual
  - Process for changing CTRP technical specifications
- Working groups may be formed to accomplish specific tasks

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CTAC Decisions Requested

Approval of Clinical Trials Informatics Subcommittee