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# Clinical Trials Advisory Committee Ad hoc Coordination Subcommittee Update

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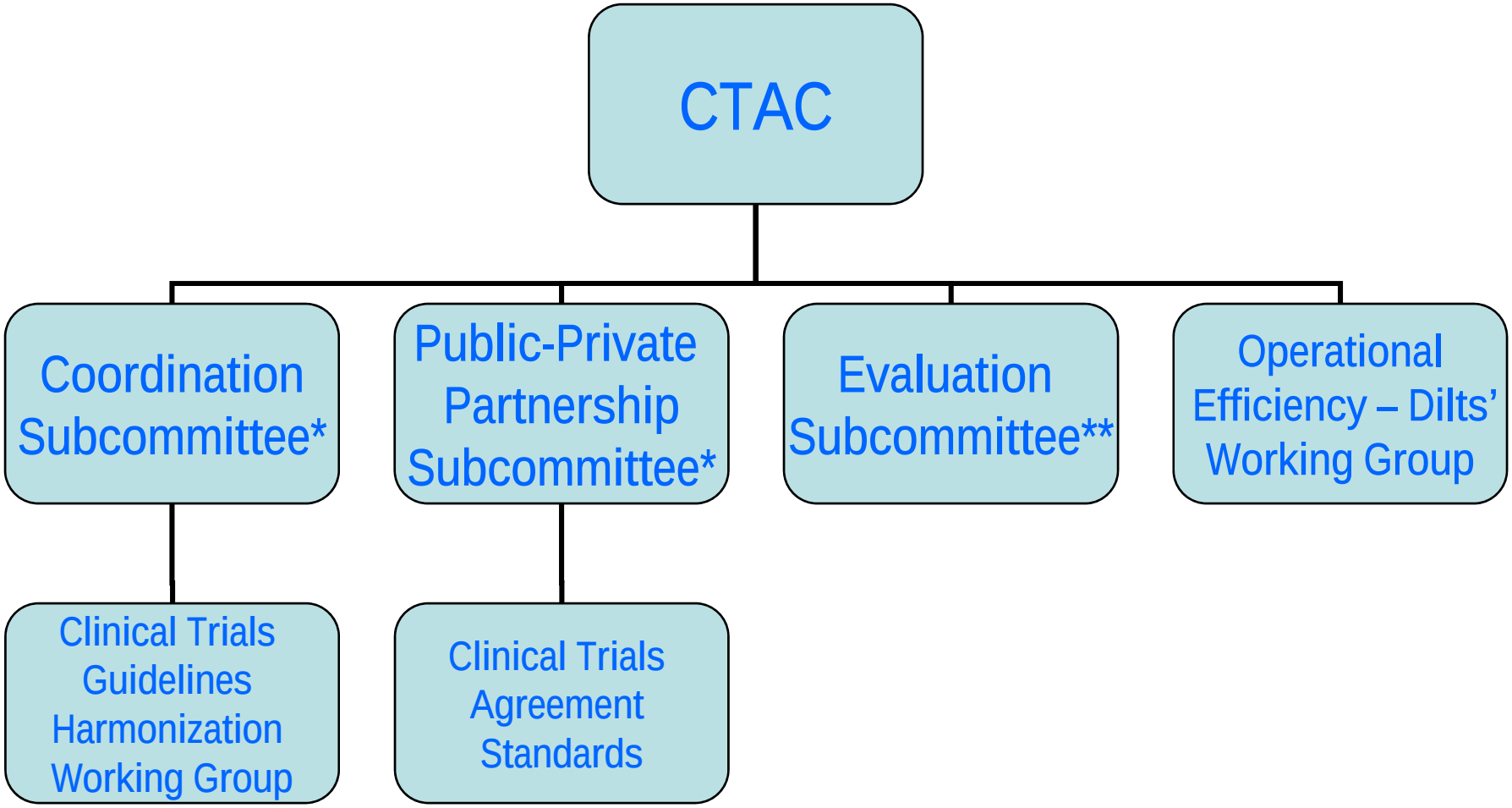
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

# CTAC Structure




*Ad hoc subcommittee
**Proposed

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# Guidelines Harmonization Working Group: Members

James Abbruzzese (Chair)

David Alberts

Laurence Baker

Charles Erlichman

Bruce Hillman

Richard Schilsky

James Doroshow

Paulette Gray

Anna Levy (Exec. Sec.)

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# Ad Hoc Coordination Subcommittee - Purpose

The purpose of the Coordination Subcommittee is to provide advice to CTAC on how to foster collaboration among the various components of the NCI-supported clinical trials infrastructure in order to develop a fully integrated clinical trials system.

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# Guidelines Harmonization Working Group: Goals

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

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# NCI Clinical Trials Mechanisms

Major Components of NCI-supported Clinical Trials System

- Cooperative Groups
- Disease and Modality-Specific Consortia
- SPOREs
- P01s
- Cancer Centers
- U01, N01 (Drug Development)
- CCOPS and MB-CCOPS

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# Approach

- Review current guidelines across mechanisms supporting clinical trials
- Develop a draft vision document with recommendations
- Present to CTAC in July 2009
- NCI staff to develop guidelines revisions consistent with the vision document
- Approval of plan by CTROC, EC

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# Current Work Product: Definition of Collaboration

- *Individuals from different institutions and across NCI/NIH programs pool knowledge and share necessary resources to formulate and address clinical and translational research questions.*
- *The ideal collaborative structure facilitates recognition of individuals based on specific contributions to core research resources and generation of new scientific knowledge.*

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# Examples of Successful Collaborations

- Bortezimib/Velcade®
  - Industry, NCI, academic trialists, foundations
- I-SPY Trial
  - SPORES, Cooperative Groups, NCI Center for Bioinformatics
- SELECT Trial
  - Large phase III trial includes ancillary cancer, non-cancer, QoL, and correlative endpoint studies (Cooperative Groups, Cancer Centers, P01s, CCOPs)

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# Current Work Product: Assessment of Program Guidelines

- Initial survey of clinical trial mechanisms guidelines related to collaboration
  - Policy/guideline areas
  - Application/review criteria
  - Incentives/disincentives
- Discussions of the Working Group, & extramural and NCI experts representing Cooperative groups, Cancer Centers and SPOREs.

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# Current Work Product: Assessment of Program Guidelines

- Do Guidelines encourage/promote collaborative activities?
  - Examined references to collaborations, inter- and intra-institutional, including across mechanisms.
  - Few specific review criteria or incentives and rewards
- Other disincentives include: more academic credit for PIs of institutional trials, not being able to “count” clinical trials led by other institutions, cost of trials, competition for patients from pharma.

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# Work in Progress: Vision Document
# Toward a Fully Integrated Clinical Trials System

- **Currently the document:**
  - **Outlines goals & roles of NCI clinical trials mechanisms**
    - **SPOREs**
    - **Cancer Centers**
    - **Cooperative Groups**
    - **CCOPs & MB-CCOPs**
    - **Other**
  - **Outlines Specific Recommendations**
    - **Elimination of disincentives to collaboration**
    - **Develop incentives & rewards for collaboration**
    - **Implement program and reviewer guideline changes to facilitate collaborations**
    - **Develop mechanisms that facilitate flow of ideas and information across translational and clinical programs**

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# Remove disincentives to collaboration

- Eliminate inconsistencies between guidelines
- Provide more specificity on issues such as collaboration for grantees and reviewers
- Address academic reward system that promotes independence over collaboration
- Where possible, correct fiscal inequities and inadequacies within the clinical trials system

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# Develop Incentives & Rewards for Collaboration

- Review criteria for assigning programmatic/investigator credit
  - Participation in Cooperative Group/Inter-group trials vs. non-productive trials
  - Encourage studies translating between P01s, SPOREs, Cancer Centers & Cooperative Groups
  - Scientific leadership of trials
  - Patient accrual to NCI sponsored trials
- Develop clear review criteria that reward collaboration

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# Develop Incentives & Rewards for Collaboration

- Provide salary support for institutional PIs who participate in multi-center studies
- Design processes to recognize clinical investigators that promote collaborative science
- Enhance career development utilizing current K-award mechanisms designed to train investigators to facilitate collaborations across programs

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# Develop Incentives & Rewards for Collaboration

- Develop supplemental awards for multi-disciplinary and translational collaborations
- Expand CTSU capacity for registration of patients in large phase II trials
- Support for PIs to provide technical resources for trans-program collaborations on common scientific questions

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# Future Plans

- Define evaluation criteria and measures of success
- Complete draft report and recommendations
- Report to CTAC – July 2009

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# Toward a Fully Integrated Clinical Trials System

Discussion:

- Are there questions about the approach we have taken?
- We would like your input on the issue of assessment metrics.
  - How will we know that we are achieving our goals?