

Recommendations for Evaluation and Prioritization of Cost-Effectiveness Analyses (CEA) paired with NCI Treatment Trials

Prepared for the Clinical Trials and
Translational Research Advisory Committee

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Cost-Effectiveness Analysis Working Group (CEA WG)

- The Clinical Trials and Translational Research Advisory Committee (CTAC) have considered the value of including economic analyses in the NCI funding of cancer-related treatment trials.
- At their July 15, 2009 meeting, CTAC recommended forming a Working Group (WG) to address issues related to Cost-Effectiveness Analyses (CEA) and to provide recommendations to the NCI.

CEA WG Mission & Objectives

Function/Mission Statement

- Advise the CTAC and the NCI on the development of a prioritization process and funding mechanisms 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 clinical trials for including parallel cost-effectiveness analyses.
- Recommend possible **funding mechanisms** for support of high priority cost-effectiveness analyses.

CEA WG Members

- **Scott Ramsey, M.D., Ph.D.**
Fred Hutchinson CRC (Chair)
- **Martin Brown, Ph.D.**
NCI
- **David Cella, Ph.D.**
Northwestern University
- **Jeffrey S. Hoch, Ph.D.**
University of Toronto
- **Deborah Marshall, Ph.D.**
McMaster University
- **David Meltzer, M.D., Ph.D.**
University of Chicago
- **Margaret Mooney, M.D.**
NCI
- **Daniel Polsky, Ph.D.**
University of Pennsylvania
- **Richard Schilsky, M.D.**
University of Chicago
- **Jane Weeks, M.D.**
Dana-Farber Cancer Institute
- **James L. Wade, M.D.**
Decatur Memorial Hospital

Rationale for CEA Prioritization Criteria

- Provide criteria to guide allocation of available funds for CEA to cancer prevention/treatment trials where information from an economic analysis may have the greatest scientific and policy impact
- Not intended to supersede other factors specific to the National Cancer Institute, the trial investigators, or other groups that may be important in the making of decisions about such funding.

Recommendations for Eligibility

- Phase 3 treatment and prevention clinical trials.
- Parent treatment/prevention trial must be a large (≥ 100 patients), randomized phase 3 concepts with a control arm.
- Parent treatment trial and CEA proposed study are submitted by CG's or CCOP Research Bases.
- CEA proposal and parent treatment/prevention trial concept must meet the *CEA Proposal Evaluation and Prioritization Criteria*.

Summary - CEA Evaluation and Prioritization Criteria

- Phase 3 clinical trial expected to substantially influence clinical practice.
- Cost-effectiveness study of potential high impact; substantial overall cost savings or added costs to the health care systems.
- Feasible to conduct CEA as part of the clinical trial.
- Specific issues to consider include:
 - The comparator (control arm) should be relevant to current clinical practice.
 - Trial of sufficient length, with respect to follow-up of patient outcomes.
 - Economic evaluation consequences captured either directly or through modeling.
 - Reasonable statistical power for the key cost-effectiveness outcome.
- Reasonable degree of uncertainty regarding the outcome of the CEA even if the clinical outcome favors the experimental treatment.

CEA WG Discussions

- A. CEA WG considered whether CEA proposals should be required in all treatment/prevention trials concepts submitted or optional.
- Availability of experts to the CGs for development of CEA proposals in all concepts - **insufficient**.
 - NCI resources and expertise to support and CEA every concept submitted – **limited**.

Recommendations

1. CEA should not be mandatory with each treatment trial concept submitted but should be evaluated through a competitive process.
2. Task Force (TF) for SSC to recommend whether a CEA be included during the development of a clinical trial concept.
3. A brief statement added to the CTEP/DCP concept template addressing why CEA was not included should be considered.

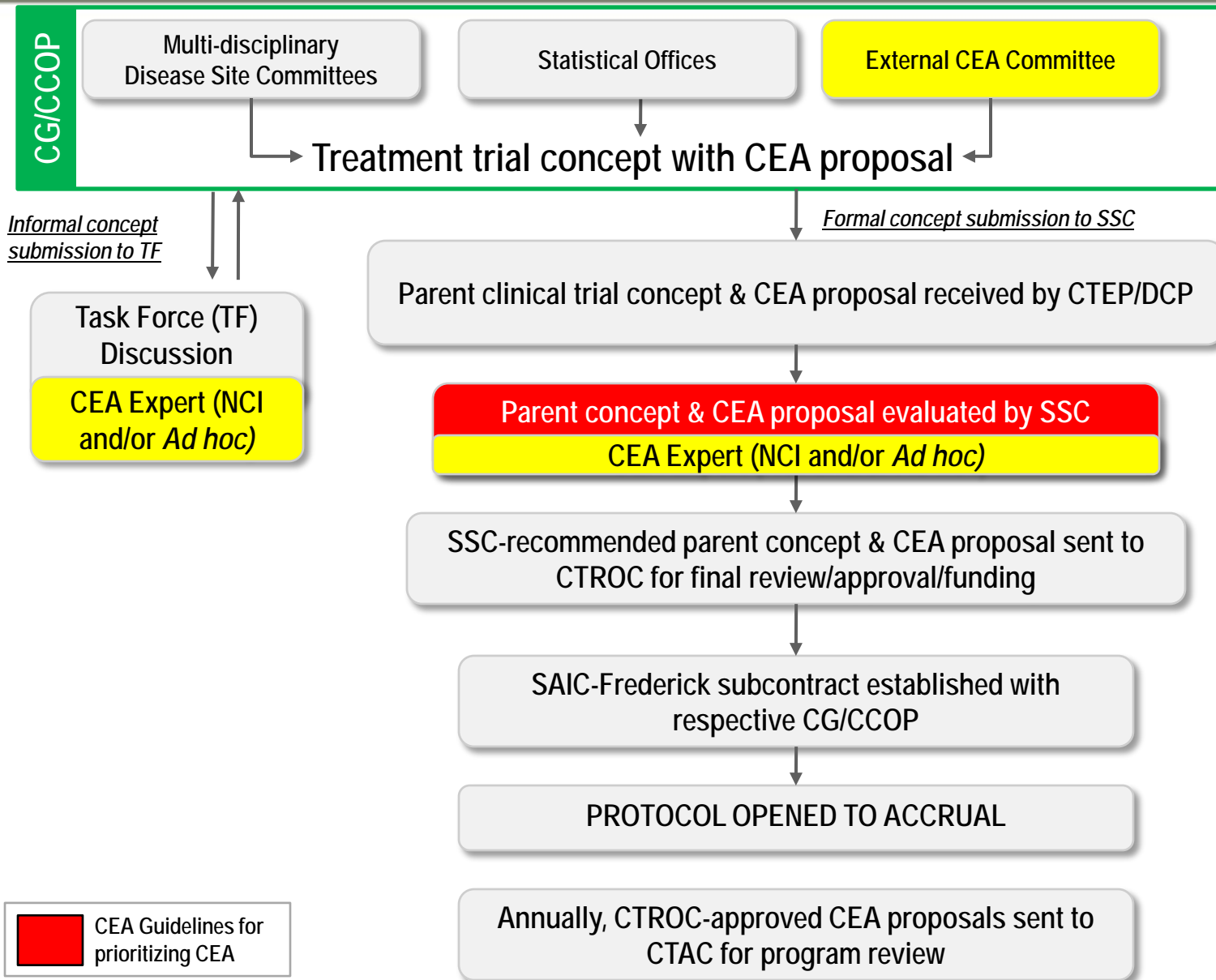
CEA WG Discussions

- B.** CEA WG reviewed funding mechanism options for CEA proposals submitted with treatment trial concepts.

Recommendations

1. The current Biomarker, Imaging and Quality of Life Studies Program Funding (BIQSFP) mechanism and prioritization process should be considered for the evaluation and prioritization of CEA proposals paired with treatment trials.
2. SSCs should evaluate CEA proposals along with the parent concept.
3. NCI and external ad hoc CEA experts will be required for the SSC evaluation process of concepts submitted with CEA proposals.

Proposed CEA Review and Funding Process



Proposed CEA Review and Funding Process

1. Treatment trial concepts with CEA proposals submitted to CTEP/DCP.
 - CG/CCOP may informally submit these to an SSC Task Force (TF), if available, for discussion prior to formal submission.
2. CEA proposal and treatment trial submitted to the appropriate SSC for evaluation.
 - SSCs will make use of ad hoc CEA expert(s), including resources available at the NCI, to evaluate CEA proposal included.
3. Meritorious CEA proposals associated with SSC approved concepts sent to CTROC for final review and funding approval.
4. Approved CEA proposals funded through subcontract with the Cooperative Group/CCOP via SAIC-Frederick.
5. Annually, CTROC-approved CEA proposals sent to CTAC for program review.

Overview – CEA Evaluation and Funding Mechanism

1. The NCI to invite funded CGs and CCOP Research Bases to apply on a competitive basis for funding to support CEA studies which are paired with treatment/prevention trial concepts (Program Announcement).
2. CEA proposal evaluation and funding of will be managed through the Coordinating Center for Clinical Trials (CCCT).
3. Evaluation, prioritization and eligibility criteria to guide the submission and review process have been drafted.
4. Funding of CEA proposal will be based on the scientific merit of both the parent treatment/prevention trial concept and the CEA proposal and each must be approved by the appropriate review bodies.