Scientific Steering Committees Strategic Priorities

James H. Doroshow. M.D.

Clinical and Translational Research Advisory Committee Meeting

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- **2015 Strategic Priority Setting Process Overview**

- **NCI Observations on Process and Priorities**

- **Proposed CTAC Analysis of Process and Priorities**

Origins of Strategic Priority Setting Process

- ## NCTN Working Group July 2014 Report
  - Recommended that strategic priorities be established for trials under the purview of each Scientific Steering Committee (SSC)

- ## Guiding principles
  - Majority of concepts expected to align with strategic priorities
  - Concepts outside strategic priorities can still be approved, but may require additional justification
  - NCTN Groups responsible for developing concepts that address the strategic priorities
  - SSCs continue to evaluate all concepts rigorously for scientific and clinical quality regardless of alignment with strategic priorities

Goal of Strategic Priority Setting

Establish a small number of defined strategic priorities for trials under the purview of each Scientific Steering Committee (SSC) to help ensure that the investment in NCTN clinical trials is sufficiently focused to provide optimal benefit

Initial Process for Strategic Priority Setting

NCTN disease committee leadership, NCORP Research Base scientific leadership and SSC members worked together diligently over the last year to develop strategic priorities for trials under the purview of each SSC

- **What is a strategic priority**
  - Specific area of unmet clinical need for the disease or for symptom management
  - Important unanswered clinical question with regard to improving disease treatment or symptom management
  - Potential new approach to disease treatment or symptom management
  - Encompasses a wide range of potential trial concepts

- **What is *not* a strategic priority**
  - Specific trial idea
  - Broad goals for NCI trials (e.g., develop targeted therapies)

Strategic priorities formulated by each SSC in conjunction with NCTN disease committee leadership, NCORP scientific leadership and NCI clinical trials leadership

- Assessed clinical trials landscape to identify gaps and provide context

- NCTN Groups/NCORP Research Bases presented their strategic priorities emphasizing the following for each priority
  - Clinical importance
  - Suitability for federal clinical trials system
  - Feasibility

- SSC discussed priorities and selected 3-5 for each organ site

- Priorities to be reviewed annually and revised as needed in response to new advances

2015 Strategic Priorities

NCTN Disease-Specific

and

Symptom Management & Health Related Quality of Life
Steering Committees

October 2015

- **Strategic Priorities submitted are of four major types**
    - **Strategic Clinical Trial Priorities** – priorities that meet the definition of a clinical trial strategic priority developed by NCI to guide this initial activity

    - **Broad Goals** – generic priorities that are not focused on a defined unmet clinical need, unanswered clinical question or potential new approach to treatment (e.g., Evaluate integration of new agents into a multi-modal backbone to improve outcomes)

    - **Trial Design Priorities** – priorities such as biomarker driven trials, adaptive trial designs and the incorporation of correlatives

    - **Translational Research Priorities** – priorities such as identification of disease subtypes, molecular targets and predictive markers as the basis for future trials

- Distribution of the four types of strategic priorities is highly variable across the SSCs

- Potential reasons for priorities outside the definition of a "clinical trial strategic priority"
  - Difficulties in reaching consensus on a limited number of clinical trial priorities given competing interests across the NCTN clinical research community
  - Concern that meritorious concepts outside the strategic priorities might not be approved
  - Desire to prioritize and enable molecularly-driven, precision medicine trials across a variety of clinical questions

- A CTAC assessment of the strategic priorities and the process for setting them would be useful

Purpose of CTAC Assessment

- Provide objective extramural assessment of SSC strategic priorities and the process for setting them

- Develop recommendations for refining the process for future rounds of priority setting

Proposed Process for CTAC Assessment

- **NCI analysis of strategic priority submissions prepared as a starting point**

- **Analysis will categorize each priority as one of the following**
  - Strategic Clinical Trial Priority
  - Broad Goal
  - Trial Design Priority
  - Translational Research Priority

- **Review analysis to determine whether**
  - Categorization of each priority is correct
  - Additional priority categories are needed

- How the priority setting process might be modified to yield 3-5 priorities that all meet the NCI definition of a strategic clinical trial priority

- Whether SSCs should separately articulate any broad goals, trial design priorities and translational research priorities they deem important

- Whether SSCs should provide a rationale for each strategic clinical trial priority and the overall mix of priorities selected

- Approaches for communicating the importance of priority setting acknowledging that meritorious concepts outside the priorities can still be approved particularly if addressing emerging opportunities

Proposed Implementation of CTAC Assessment

- **Recommend assessment be performed by Clinical Trials Strategic Assessment Working Group**

- **Working Group currently being convened to review the portfolio self-assessments performed by the SSCs during 2016-2017**
  - Will include NCTN Group Chairs, Cancer Center Directors, NCORP representatives and advocates
  - Will include both CTAC members and non-CTAC members

- **Strategic priority setting and portfolio assessment will be increasingly intertwined as the priorities drive the trials that are conducted and therefore assessed**

Should an assessment of the Steering Committee Strategic Priorities and the process for setting them be included in the charge of the Clinical Trials Strategic Assessment Working Group?