NCI National Clinical Trials Network Working Group (NCTN WG) Final Report

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July 16, 2014 CTAC
NCTN WG Report Structure

• Section 1 – Assessment of the NCTN Portfolio
  – Cross-Portfolio Recommendations
  – Portfolio Specific Findings
  – Process and Methodology

• Section 2 – Approaches for Prioritization and Strategic Assessment
  – Process for NCTN Trial Prioritization
  – Periodic Strategic Assessment of Trial Portfolios

• Section 3 - Appendices
NCTN WG Portfolio Analysis (Section 1)

- Evaluated 13 Trial Portfolios
  - Gastrointestinal
  - Genitourinary
  - Lymphoma
  - Thoracic
  - Pediatric
  - Clinical Imaging
  - Symptom Management/Quality of Life
  - Breast
  - Leukemia
  - Myeloma
  - Brain
  - Gynecologic
  - Head & Neck

- Assessed strength and balance

- Recommended strategic priorities and directions
Approaches for NCTN Trial Prioritization and Strategic Assessment (Section 2)
Meetings Generating Prioritization Input

• NCTN WG Meeting – December 19, 2013

• CTAC Program Planning Working Group – February 26, 2014

• CTAC Clinical Trials Prioritization Working Group – March 11, 2014

• NCTN WG Meeting – March 26, 2014
Approaches for NCTN Trial Prioritization

• Prospective Disease-Specific Priority Setting

• Identification of trial categories generally considered high or low priority

• Cross-Disease Prioritization in Response to Resource Constraints
Prospective Disease-Specific Priority Setting

Establishing Disease-Specific Strategic Frameworks to Guide Concept Development and Evaluation
Disease-Specific Priority Setting Principles

- Set strategic priorities for NCTN trials in advance
- Majority of concepts expected to align with strategic priorities
- Trial concepts outside strategic priorities still considered but may require additional justification
- NCTN Groups responsible for concept development
- Steering Committees continue to evaluate all concepts rigorously for scientific and clinical quality regardless of alignment with strategic priorities
Process for Setting Disease-Specific Strategic Priorities

• Assess strategic clinical trials landscape within the disease to identify gaps and provide context

• Discuss strategic priorities under the aegis of the Steering Committees
  – NCTN Groups propose strategic priorities for discussion, ideally with cross-Group collaboration
  – Outside input solicited as needed

• Goal to select a few major priorities for each disease

• Priorities reviewed annually and revised as needed
Principles Guiding Strategic Priorities
(Trial Categories of Especially High or Low Priority)

• **High priority**
  – Trials driven by the best current science
  – Trials expected to substantially influence short- and long-term patient outcomes
  – Trials driven by NCI strategic priorities and initiatives (e.g., the MATCH trial)
  – Trials aligned with a disease-specific strategic priority
  – Trials unlikely to be performed outside the NCTN (e.g. surgery, radiation, rare diseases)

• **Low Priority**
  – Trials with non-inferiority trial designs
  – Trials aimed at small differences in PFS or DFS
  – Trials duplicative of other NCTN, industrial and/or international trials
  – Trials of “me-too” drugs
Cross-Disease Prioritization
Cross-Disease Prioritization Principles

• Only invoked in response to resource constraints
• Limited to resource-intensive trials
• Priority ranking of Scientific Steering Committee approved concepts by extramural experts
• Priority ranking guided by specified criteria

Priority ranking only one factor NCI will consider in deciding whether to proceed with a resource intensive trial
Cross-Disease Prioritization Pilot
March 11, 2014

• Prioritized two approved concepts for large (approximately 1000 patient) trials currently on hold

• Cross Disease Prioritization Working Group
  – CTAC Clinical Trials Strategic Planning Subcommittee
  – NCTN Group Chairs
  – NCTN WG Chairs
  – Patient Advocate
Pilot Process: Discussion & Rating of Trials

• CTEP provided background information and comments on the concept

• Primary discussant provided review followed by any additional comments from secondary, biostatistical, & advocate discussants

• Open discussion of concept

• Participants confidentially scored the concept on each criterion and overall

• Reviewed collated scoring results to determine if scores reflected discussion and the relative strength of the concepts

• Discussed feasibility of the process, appropriateness of criteria, and recommended process changes
Feasibility of Process

• Consensus that process was reasonable and feasible

• Important to guard against becoming another layer of scientific review or concept redesign

• Scoring results reflected the substance of the discussion

• Criteria useful in providing consistency
Composition of Prioritization Group

- Correct mix of high level expertise, experience and responsibilities
- Unnecessary to involve additional disease-specific experts
- Recommend substantial overlap in the individuals participating in prioritization groups over time
Proposed Cross-Disease Prioritization Criteria

**Primary criteria**
- Clinical benefit/importance
- Scientific impact/contribution

**Secondary criteria**
- Patient/public health need
- Relationship to current clinical trials landscape
- Procedural complexity
- Feasibility of accrual
- Suitability for NCTN program
- Alignment with overall NCI priorities & scientific initiatives
- Ability to leverage non-NCI funds
Recommended Improvements to Process

• Develop an operational definition of “resource-intensive trials” beyond simply approximately 1000 subjects

• Provide Prioritization Group
  – Disease-specific priorities and identified gaps
  – Current resource allocation by disease

• All scoring to follow NIH 1-5 scale
  – 1-Exceptional; 5-Poor
Essential Points to Communicate

• External stakeholders
  – Affects a very small number of resource-intensive trials
  – Invoked sparingly
  – Not a standard extra level of review

• NCTN Groups
  – Notice of resource constraints necessitating cross-disease prioritization
  – Disposition of non-prioritized concepts
Comments and Questions about Proposed NCTN Trial Prioritization Process
Periodic Strategic Assessment of Clinical Trial Portfolios Across Diseases
Proposed Activities

• In Depth Assessment of Disease Portfolios

• Cross-Portfolio Assessment

• Strategic Recommendations for Improvement
Proposed Stakeholder Participants

• NCTN Group Chairs
• Representative of each Steering Committee, ideally a Chair
• Cancer Center Directors
• Patient advocates
• Community oncologists
• CTAC Clinical Trial Strategic Planning Subcommittee
• Ad hoc participants as needed
• NCI clinical trials leadership
Discussion Point for CTAC

• Would periodic portfolio assessment add value to the NCTN enterprise?

• Should all portfolios be assessed simultaneously or in a rolling fashion (e.g., one third per year)?

• What would be the appropriate periodicity of assessment (e.g., every 3 years, every 5 years)?
  o When should the next assessment occur, 2015, 2018?

• Are the proposed stakeholders appropriate?
  o Should Group Disease Committee Chairs be included for their respective diseases?
Thank You