Proposed Periodic Assessment of the NCI National Clinical Trials Network (NCTN) Scientific Steering Committee Portfolios

Dr. Jeffrey Abrams
March 4, 2015
Extramural Input on Strategic Portfolio Assessment

• **Periodic assessment of trial portfolios would be valuable**
  - Provides essential feedback to the Steering Committees & Groups/Research Bases
  - Ensures that trials address the strategic priorities established for the portfolios

• **Assessments would benefit from greater involvement of portfolio-specific experts**

• **Next strategic assessment should begin 3-5 years from the NCTN WG assessment**

• **Little enthusiasm for convening a cross-portfolio assessment group as large as the NCTN WG to conduct a detailed assessment of trials in each portfolio**
Proposed Portfolio Assessment Based on Input

• **Approach**
  - Initial assessment of individual trials in each portfolio performed by Steering Committees
  - Review of Steering Committee assessments for quality and objectivity conducted by a CTAC Working Group
  - Next round of assessment to begin in 2016

• **Rationale**
  - Facilitates critical self-examination by those most directly involved in concept development and evaluation
  - Provides a more in-depth, informed assessment
  - Review of Steering Committee assessments by a single group of cross-portfolio experts to ensure objectivity and adherence to the strategic priorities
  - Results of the assessment of current trials should be useful for future strategic priority setting
Proposed Steering Committee Portfolio
Self-Assessment Process

• Assessment of concepts reviewed by Steering Committee since NCTN WG assessment

• Assessment criteria for approved concepts
  - Alignment with strategic priorities
  - Addresses NCTN WG recommendation(s) for improvement of the portfolio
  - Unique suitability for federal clinical trials system
  - Clinical importance
  - Scientific contribution
  - Feasibility

• Assessment of the rationale for disapproval of concepts

• Assessment Report presented to CTAC Working Group
  - Assessment of approved concepts according to the six criteria
  - Assessment of the soundness of the rationales for disapproving concepts
  - Overall assessment of portfolio
Proposed CTAC Cross-Portfolio Oversight Process

• Performed by CTAC Working Group, consisting of:
  – Several CTAC Members
  – NCTN Group Chairs
  – NCTN Group Statisticians

• Analyzes quality and objectivity of the individual Steering Committee portfolio assessments as well as adherence to the strategic priorities

• Performs cross-portfolio analysis based on individual assessments
  - Overall cross-portfolio quality
  - Cross-portfolio recommendations
  - Value of the assessment process
  - Recommendations for future assessments

• Reports results of individual portfolio assessments and the cross-portfolio analysis to CTAC
Strategic Assessment
Scientific Steering Committee Portfolios

- Review and approve individual Steering Committee and cross-portfolio assessments and associated recommendations
- Analyze individual Steering Committee assessments for quality and objectivity
- Perform cross-portfolio analysis based on individual assessments

Initial assessment of Steering Committee portfolios

Clinical Trials and Translational Research Advisory Committee (CTAC)

CTAC Working Group

BCSC  GISC  BMSC  MYSC  GUSC  SxQOL

GCSC  LKSC  TMSC  Pediatric SCs  HNSC  LYSC
Operational Elements of the Assessment Process

- **Volume of concepts assessed**
  - 1-4 approved concepts per Steering Committee annually
  - Based on average number of concepts approved per year since inception of each Steering Committee

- **Information provided for each portfolio assessment**
  - Analysis of the portfolio-specific clinical trials landscape
  - Trial specific information
    - Concept summary
    - Summary of Steering Committee deliberations
    - Trial status including accrual performance
    - Population/public health impact
    - Other sources of support (BIQSFP, industry, foundations)
    - Correlative studies performed contemporaneously with trial (e.g., integrated biomarkers)
    - Correlative studies to be conducted using trial specimens
Proposed Timeline of Assessment Activities

- July/August 2015: Formation/Orientation of CTAC Assessment WG
- November 2015 – October 2016: Portfolio-Specific Self-Assessments
- January 2016 – April 2017: Present Portfolio-Specific Assessment Reports to CTAC Assessment WG
- March 2016 – November 2017: Present CTAC Assessment WG Portfolio-Specific Assessment Reports to CTAC
- March 2018: Present CTAC Assessment WG Cross-Portfolio Analysis to CTAC
Roles

- Steering Committee Chairs
  - Lead assessment of portfolio
  - Present to CTAC Assessment WG

- CTAC Working Group Chairs
  - Lead analysis of Steering Committee portfolio assessments
  - Lead cross-portfolio analysis based on individual assessments
  - Presents results of self-assessments and cross-portfolio analysis to CTAC

- DCTD/DCP Medical Officers
  - Provide trial specific information
  - Assist in preparing presentations to CTAC Assessment WG
  - Participate in landscape analysis

- CCCT Program Directors
  - Participate in landscape analysis
  - Provide coordination and facilitation