

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

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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

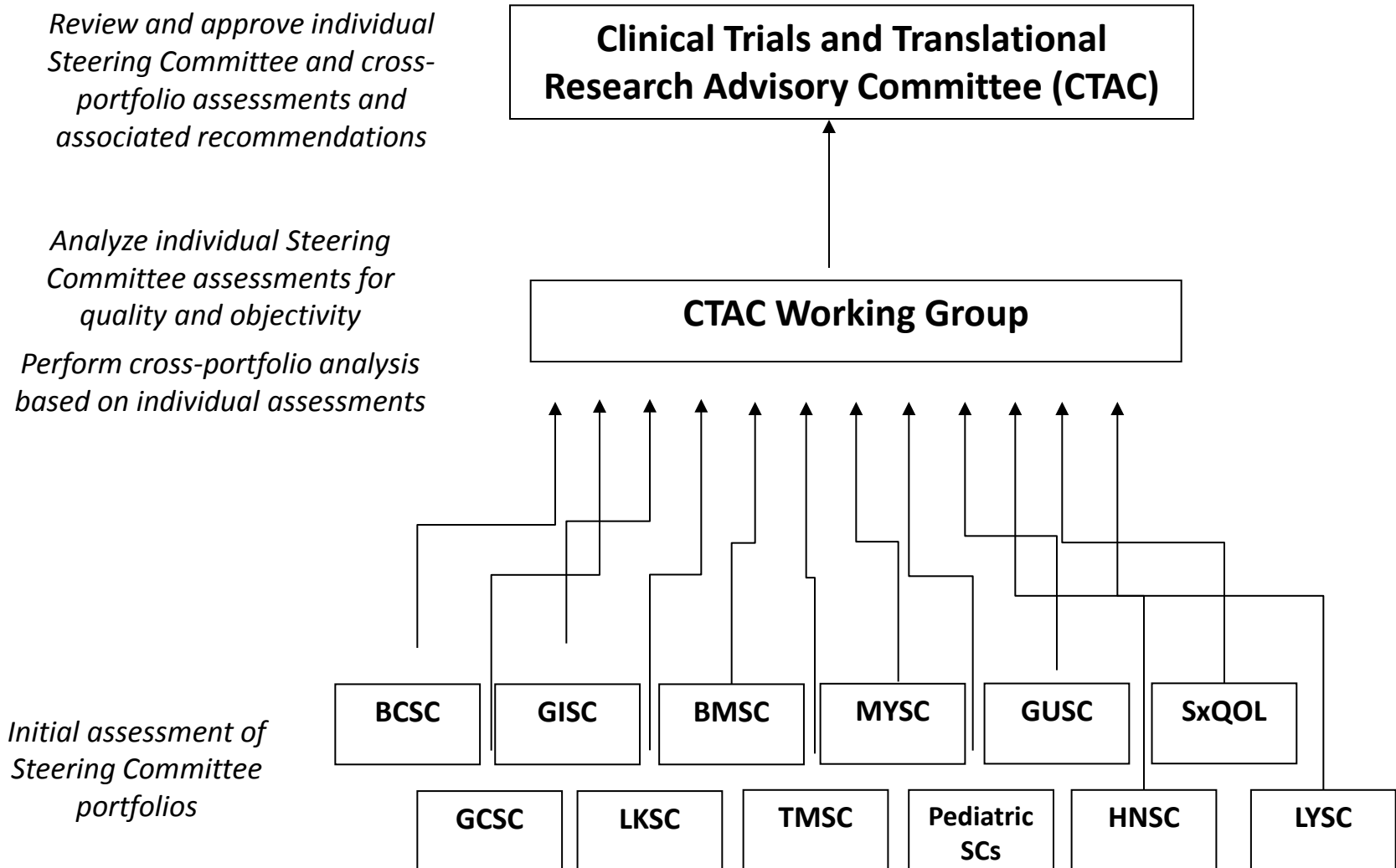
- **Assessment of concepts reviewed by Steering Committee since NCTN WG assessment**
- **Assessment criteria for approved concepts**
 - Alignment with strategic priorities
 - Addresses NCTN WG recommendation(s) for improvement of the portfolio
 - Unique suitability for federal clinical trials system
 - 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



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