CTWG Evaluation Plan
Results of Baseline Feasibility Analysis

Rationale for Systematic Evaluation of NCI Clinical Trials System

- Past evaluations based predominantly on opinions of expert panels
- NCI never previously performed a systematic evaluation that integrates qualitative/perceptual and quantitative information about its clinical trials activities
- Establishes a structured framework for continuous monitoring and feedback for mid-course corrections

Initial results of a feasibility analysis for an ongoing evaluation process requiring regular CTAC input

CTWG Overall Evaluation Plan

- Establish structured evaluation system
  - Designed by experienced evaluation specialists
  - Blend of quantitative/qualitative measures
  - Perceptions of clinical trial experts and structured empirical data
- Perform baseline feasibility analysis
- Perform periodic evaluations as CTWG implementation proceeds

Two Categories of Measures: Comparison of Baseline to Future

- **System Outcome Measures**
  - Is the overall output of the NCI clinical trials system improving?

- **System Performance Measures**
  - Are the individual CTWG initiatives having the desired effect on the performance of the NCI clinical trials system?

System Outcome Measures

- **Quality of Trials**
  - Publications
  - Strength of trial designs
- **Impact of Trials**
  - Guide new therapeutics or diagnostics development
  - Lead to changes in patient management
- **Efficiency of Trial Development and Initiation**
  - Time to first patient on study
- **Efficiency of Trial Conduct**
  - Rate of accrual, cost-effectiveness

Interlocking Data Collection Methods

- Interviews
  - Qualitative: Perception of current system and practices
- Database analysis
  - Quantitative: How long, how fast, how many
- Document review
  - Factual information
- Use multiple data sources to triangulate analysis

Baseline Interviews

- **Discussions with 81 individuals in 2007**
  - NCI staff (25 interviews across CTEP/IDB, CTEP/CIB, OCTR, DCP, OC)
  - Phase I/II trialists (25 interviews with N01 holders, U01 holders, CG trialists, R01/R21/P50 trialists)
  - Phase III trialists (17 interviews with all nine Cooperative Group PIs and eight CG disease committee chairs)
  - CCOP/CCOP Research Base PIs (9)
  - Industry trialists (5)
- **Primarily open-ended questions, some designed to elicit perceptions of specific facts/events**

Baseline Database Analysis

- **Databases analyzed**
  - CTEP Clinical Data Update System (CDUS)
  - DCP Enterprise System Knowledgebase (DESK)
- **All trials active 1/1/2000-12/31/2005**
  - Patient registration by institution, by trial
  - Rate of accrual
  - Publication of trials
- **All LOIs/concepts active 1/1/2000-12/31/2005**
  - Time from LOI/concept submission to decision point
  - Time from LOI/concept submission to first patient on study
- **No current database captures all clinical trials performed at Cancer Centers**

Baseline Document Review

- NCI Program Guidelines
- Cancer Treatment Guidelines (e.g., ASCO, ACS, NCCN, US Preventive Services Task Force)
- Academic medical center tenure and promotion guidelines

Baseline Feasibility Analysis for Evaluation: Expert Panel

- Participated in development of measures and interview guides at beginning
- Membership
  - 9 NCI-funded trialists
  - 1 industry trialist
  - 1 patient advocate
- Reviewed key findings at end

Quality of Trials: Publications

- **Data Source:**
  - CTEP database; Cooperative Group publication lists
- **Feasibility:**
  - Cooperative Group trials can be linked to publications
  - CTEP database useful for future but not baseline
  - No easy linkage for non-CTEP trials
- **Baseline Findings:**
  - 50% of closed Cooperative Group Phase II and Phase III trials resulted in publications (4 Groups)
- **Recommendation:**
  - Include field for reporting publications in clinical trials databases

Impact of Trials: Patient Management

- **Data Source:**
  - Cancer Treatment Guidelines (e.g., ASCO, ACS, NCCN, US Preventive Services Task Force)
  - JCO "Clinical Cancer Advances 2006: Major Research Advances in Cancer Treatment, Prevention, and Screening"
- **Feasibility:**
  - Feasible but time-intensive to link Guidelines to trials
  - Feasible to use JCO Clinical Cancer Advances Series
- **Baseline Findings:**
  - 4 of 9 "major advances" supported by NCI clinical trial
  - 9 of 15 "other notable advances" supported by NCI clinical trial
- **Recommendations:**
  - Use annual JCO article to assess impact
  - Assess including ASCO plenary session presentations

CTWG Coordination Initiatives
Incentives for Collaboration in NCI Guidelines

- **Data Source:**
  - NCI Award Guidelines (Cancer Center, Cooperative Group, SPORE, P01)
- **Feasibility:**
  - Guidelines clear concerning whether and in what way collaboration rewarded
- **Baseline Findings:**
  - Cancer Center: Weak incentives for collaboration across Centers
  - Cooperative Group: Strong incentives for collaboration across Groups
  - SPORE: Strong incentives for collaboration
  - P01: No incentives for collaboration
- **Recommendations:**
  - Repeat analysis at regular intervals during CTWG implementation

CTWG Prioritization Initiatives
Phase I/II Investigational Drug Trials

- **Data Source:**
  - Phase I/II trialist interviews
- **Feasibility:**
  - Perceptions can be determined by interviews
- **Baseline Findings:**
  - Perceptions concerning CTEP Clinical Development Plans highly variable
  - Perception that the pre-IDSC process was not transparent
  - Mixed perceptions of pre-IDSC trial quality
- **Recommendations:**
  - Focus future interviews on role of IDSC in enhancing transparency, collaboration and quality of Clinical Development Plans and trials

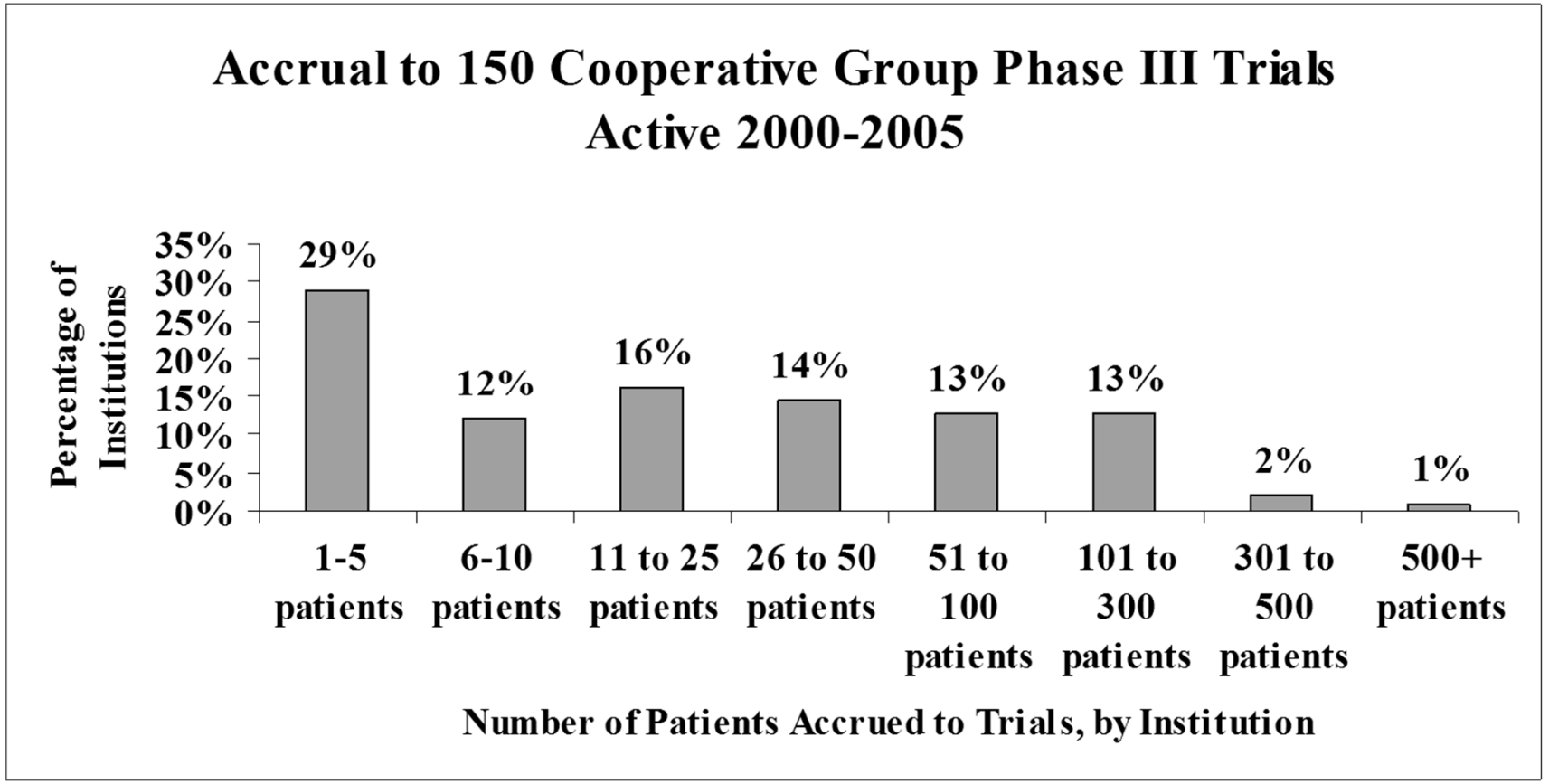
CTWG Prioritization Initiatives
Phase III Cooperative Group Trials

- **Data Source:**
  - Cooperative Group trialists, CTEP/CIB, OCTR interviews
- **Feasibility:**
  - Perceptions can be determined by interviews
- **Baseline Findings:**
  - CTEP prioritization process perceived as opaque by some trialists and transparent by others
  - CIB staff perceived the quality of Phase III trial concepts to be mixed
  - CIB staff perceived little duplication in Phase III trials
- **Recommendations:**
  - Focus future interviews on role of Scientific Steering Committees in enhancing transparency and quality of trial concepts

CTWG Operational Efficiency Initiatives
Efficiency of Phase III Trial Accrual

- **Data Source:**
  - CTEP database; Phase III trialist interviews
- **Feasibility:**
  - Accrual data by trial and site readily available
- **Baseline Findings:**
  - 150 Phase III trials active in 2000-2005 with 1516 accruing institutions
  - 67% of trials accrued less than 5 patients per site per trial
  - 40% of institutions accrue 1-10 patients, representing 3% of patients
  - 16% of institutions accrue 100+ patients, representing 64% of patients
  - Most sites perceived below economically viable accrual levels
- **Recommendations:**
  - Repeat analysis at regular intervals

CTWG Operational Efficiency Initiatives
Efficiency of Phase III Trial Accrual



Next Steps

- Develop specific plan for future evaluation, refining baseline measures and developing protocols for future measures
- Incorporate additional information in clinical trials databases to strengthen future evaluation efforts
- Prepare initiative-specific timeline for future evaluation
- CTAC Subcommittee will be formed to oversee evaluation process