

Clinical Trials and Translational Research  
Advisory Committee (CTAC)

Guidelines Harmonization Working  
Group Report (Part I)

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July 15, 2009

## Guidelines Harmonization Working Group: Goals

- Harmonize program guidelines and develop incentives to foster collaboration among all components of the clinical trials infrastructure including Cancer Centers, SPOREs, and Cooperative Groups
- Promote collaborative team science:
  - Ensure that guidelines for different clinical trials funding mechanisms are aligned
  - Eliminate redundancy and duplication while proactively encouraging collaboration

# Guidelines Harmonization Working Group: Members

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# Purpose

**Provide guidance on the integration of NCI's clinical trials system**

Goal: increase and facilitate the movement of ideas from early translation → early clinical trials → phase III trials

# Approach

- Define collaboration
- Identify model collaborative efforts
- Examine current guidelines for clinical & translational research infrastructures and disincentives to collaboration
- Develop a vision document with recommendations
- Present to CTAC

# Approach

- **Activities & roles of major NCI-supported clinical trials and translational research infrastructures**
  - Cooperative Groups
  - SPOREs
  - Cancer Centers
  - Phase I U01 grants/Phase II N01 contracts
  - CCOPs/MB-CCOPs
  - Clinical P01s, Clinical R01s, etc.

## Current Program Guidelines

- Initial survey of guidelines related to collaboration focused on:
  - Program objectives
  - Application/review criteria
  - Incentives/disincentives

# Current Disincentives to Collaboration

## General Observations:

- Limited reimbursement for patient accrual
- Lack of incentives for collaboration
- Inconsistent incentives for resource sharing
- Variability in collaboration across translational/clinical spectrum - depends on institutional & program leadership
- Guidelines and review criteria for collaborative activities need to be harmonized, strengthened and implemented across funding mechanisms

## Recommendations (1)

### Revise guidelines across programs

- **Provide meaningful & specific guidance on what is needed to receive credit for active collaboration across translational and clinical trials infrastructures**

## Recommendations (2)

### Revise guidelines across programs

- **Incentivize trans-mechanism collaborations to facilitate transition from pre-clinical & early clinical development to phase III trials**
- **Revise program goal statements and guidelines to emphasize collaborations across funding mechanisms**

## Recommendations (3)

### Revise guidelines across programs

- **Assess program leadership based on facilitation of trans-mechanism interactions**
- **Review credit for inter- & trans-mechanism collaborations**
- **Encourage trans-mechanism phase II trials utilizing CTSU/Cooperative Groups**

## Recommendations (3a)

### Revise guidelines across programs

(Proposed 7-14-09)

- Describe trans-mechanism collaborations, where applicable, in a discrete section of grant applications
- This section will receive a rating which will impact the overall score

## Recommendations (4)

### Revise guidelines across programs

- **Supplemental funding for phase III studies performed in Cooperative Groups based on early clinical results from other NCI-funding mechanisms**
- **Review credit for NCI mechanisms where early results led to phase III Cooperative Group trials**
- **Incentives to enhance collaborations between CCOPs/MB-CCOPs, Cancer Centers, Groups to accelerate transfer of knowledge from trials to community practice**

## Recommendations (5)

### Revise guidelines across programs

- **Credit Cancer Centers based on the level of externally peer reviewed trials**
- **Support pilot projects for multidisciplinary and translational collaborations**

**Credit for collaboration must be reflected in priority scores**

# Recommendations (1)

## Incentives to collaboration

### **Salary support & investigator recognition**

- **To institutional PIs through Cooperative Group mechanism**
- **“Chairs Fund”**
- **Increase number & budget for institutional U10s**
- **To support PIs who collaborate across programs/mechanisms on common scientific questions**
- **Utilize K-awards for senior investigators to facilitate collaborations**

## Recommendations (2)

### Incentives to collaboration

- **Enhance recognition and career development for contributors to collaborative clinical trials who are not currently PIs**
- **Establish performance criteria, designations; “Scholar”, “NCI Quality Investigator”**
- **New awards, e.g., “Cancer Clinical Investigator Team Leadership Award”**

## Recommendations (3)

### Incentives to collaboration

#### **Enhance patient accrual**

- **Increase per patient reimbursement**
- **Review consideration for significant accrual to non-group, non-endorsed CTSU studies**
- **Expand capacity of CTSU to accommodate patients in large phase II studies**

## Recommendations (4)

### Incentives to collaboration

- **Formalize a process to facilitate development and conduct of collaborative clinical trial concepts from investigators not currently engaged in NCI-funded clinical trials mechanisms**
- **Provide access to resources; CTSU, data coordination, accrual reimbursement across NCI clinical trials mechanisms**

## Recommendations (5)

### Incentives to collaboration

#### **Build on GO Grants for Clinical/Translational Research**

**Develop new mechanism to move exciting clinically applicable ideas through the clinical trials system based on collaborations amongst Cancer Centers, SPORES, Cooperative Groups, PO1's**

# Outcomes Measures

## Using CTWG, TRWG evaluation process, measure progress in collaboration

- Consistent guidelines across mechanisms that promote collaboration
- Review credit reflected in priority scores
- Collaborative activities between programs
- Phase III trials based on early phase studies
- Increased contributions by program leaders across translational/clinical trials system

# Proposed Next Steps

To evaluate progress in the implementation of these recommendations, the Working Group will continue to meet and provide input

## Next steps:

If CTAC accepts report, Part I – July 2009:

- NCI staff will develop guidelines revisions
- NCI staff will further develop & propose plans for incentives
- Periodic progress report to Working Group and CTROC
- CTAC Report, Part II