



# Cooperative Group Clinical Trials Complexity Funding:

## Model Development & Trial Selection Process



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## Complexity Model: Objective

- Align reimbursement with trial complexity in accordance with the Clinical Trials Working Group (CTWG) Operational Efficiency Initiative
- Not impact the current \$2000 base capitation rate
- Develop a system to ascertain trial complexity
  - Simple, standardized model
- Based on this system, studies deemed “complex” may receive additional funds- when available

# Complexity Model Working Group

- **Working Group Organized to Develop Criteria for Complexity Model for Phase 3 Treatment Trials**
  - Identify the key elements of studies thought to require additional work at participating sites
  - Categorize key elements into 3 main tiers reflecting work effort
  - Provide recommendations on implementation
- **Members of Working Group**
  - Cooperative Group Members
  - Cancer Trials Support Unit Representatives
  - NCI (CTEP, DCP, CCCT)

# Trial Complexity Tier Development WG

## ACOSOG

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## CALGB

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# Complexity Model: Initial Criteria Selected

- **Main Criteria – 5 Elements**
  - # Study Arms
  - Informed Consent Process
  - # Registration or Randomization Steps
  - Complexity of Investigational Treatment
  - Length of Investigational Treatment
- **Additional Criteria – 4 Elements**
  - Personnel Impact to Run and Monitor Study
  - Data Collection Complexity
  - Follow-up Requirements
  - Ancillary Studies
- **Additional 10<sup>th</sup> Element Added (after FY08 Exercise)**
  - Participant Feasibility & Enrollment

# Complexity Model: Current Model

Element	Title	Tier/Level
# 1	# of Study Arms	Low-Medium-High
# 2	Informed Consent Process	" "
# 3	Registration or Randomization Steps	" "
# 4	Complexity of Investigational Treatment	" "
# 5	Length of Investigational Treatment	" "
# 6	Feasibility & Personnel Impact	" "
# 7	Data Collection Complexity	" "
# 8	Follow-up Requirements	" "
# 9	Ancillary Studies	" "
# 10	Participant Feasibility & Enrollment	" "

Elements subdivided into low, medium, or high levels of complexity  
 1 point for each level for each element - Total summed over all 10 elements

# Complexity Model: FY08 Funding

- Decision to “test” draft model by allowing each Group to use model (and/or their own modifications to draft model or their own criteria) to recommend up to 5 phase 3 treatment trials for FY08 funds:
  - Trials had to be on-going or about to be activated
  - Most Groups used draft model but supplemented it to account for additional factors
- CTEP reviewed Group recommendations & complexity score. Selection made based on considerations of total funding amount available and balance with respective to:
  - Disease type & general approach / modality
  - # patients accrued (status of trial)
  - # Groups
  - Existence of additional funding for trials from industry

# Complexity Model: Trials by Disease Type

Group	Brain	Breast	GI	GU	Gyne	Leukemia	Lung	Myeloma	Total
ACOSOG		1	1						2
CALGB				1			1		2
COG						1			1
ECOG						1		1	2
GOG					2				2
NCCTG	1								1
NSABP		1							1
RTOG				1					1
SWOG			1	1					2
<b>Total</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>14</b>



# Complexity Model: Trials by General Type

Type Trial	Total
NeoAdjuvant/Pre-Op Treatment	3
Post-Operative Treatment	1
Recurrent/Advanced Disease	3
Surgery	2
Radiation	2
Leukemia / Myeloma	3
Total	14

# Complexity Model Funds: FY08 Distribution

- Funds allocated for duration entire trial & target accrual
  - Additional \$1,000 in capitation payment
- Funds distribution based on accrual start June 1, 2008
  - Date selected to synchronize with CCOP grants
- Funds distribution via the CTSU & CCOPs
  - Funds to non-CCOPs Group sites via CTSU
  - Funds to CCOPs via “credits” for accrual in 1<sup>st</sup> year
  - Distribution to CCOPs for accrual beyond 1<sup>st</sup> year either through CCOP grants or CTSU
  - Amount of complexity funds provided via CTSU or CCOP grants for the case reimbursement will be the same
  - Schedule of funds distribution to be determined by NCI

# Complexity Model Funds: FY08 Distribution & Monitoring

## *Update:*

- Funds distribution based on accrual start 6/1/2008
  - 2 retroactive cohort accrual payments
  - E1900 selected to receive funds closed early per DSMB recommendation for positive results.
    - NCI Press Release:  
<http://www.cancer.gov/newscenter/pressreleases/AMLdaunorubicin>
- Complexity Model Working Group continues to refine model and work how to monitor impact of program

# Complexity: Potential Future Implementation

Groups Submit a Trial Complexity Scoring Sheet with 1<sup>st</sup> Draft Protocol for Phase 3 Treatment Trials Based on Model



CTEP Reviewers Review Scoring Sheet and Final Score Calculated at CTEP Protocol Review (PRC) Committee Mtg



Score included within Consensus Review (PIO) and recorded by CTEP



Annual solicitation from Groups of priority for their "complex" trials



Trial selection by NCI based on similar process as used for FY08 based on score with balance across diseases, Groups, etc.

**Slowly accruing guidelines apply to all Group phase 3 treatment trials**