



Clinical Trials Working Group Update to CTAC:

Complexity Trials

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Complexity Model: Review of Objective

- Align reimbursement with trial complexity in accordance with the CTWG's 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: Criteria

- **Main Criteria – 5 Elements**
 - # Study Arms
 - Informed Consent Process
 - # Registration or Randomization Steps
 - Complexity of Investigational Treatment
 - Length of Investigational Treatment
- **Additional Criteria – 5 Elements**
 - Personnel Impact to Run and Monitor Study
 - Data Collection Complexity
 - Follow-up Requirements
 - Ancillary Studies
 - Patient Feasibility & Enrollment (element added after FY08 selection)

Points for each element & level of complexity
(0 for Standard; 1 for Moderate; 2 for High)
with total summed over all 10 elements

Complexity Model: FY08 Funding

- Draft model tested by allowing each Group to use model (and/or their own modifications) to recommend 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 the Group recommendations & complexity score. 14 Trials selected based on considerations of total funding amount available and balance with respect to:
 - Disease type & general approach / modality
 - # patients accrued (status of trial)
 - # Groups
 - Existence of additional funding for trials from industry
- Funds allocated for duration of entire trial & target accrual (additional \$1,000 allocated to base capitation)
- Funds distribution based on accrual start June 1, 2008
- Funds distribution via the CTSU & CCOPs

Complexity Model: Accrual for Trials Selected for FY08 Funding

FY08 Trials	Accrual 6-1-2008 to 8-24-09	Accrual Remaining
14 Phase 3 Tx Trials	2,508	6,472

- 1 trial (E1900 – AML) stopped early for a positive trial
- 1 trial (GOG-0218 – Ovarian) completed accrual slightly ahead of schedule
- 1 trial (N0577 brain cancer trial with international collaboration) had delayed activation - will activate in 2009
- Most trials at/above planned accrual rates, but several early in accrual period
- 1 trial (CALGB-140503 – NSCLC) is much below planned accrual rate

Complexity: FY 2009 Implementation

- Process similar to FY08 Process
- Nominations solicited from Groups of their priority of trials that should receive complexity funds
- Groups assigned complexity score using the full 10 element model
- Trial selection by NCI based on similar process as used this year based on score with need for some balance across diseases, Groups, etc.
- Adjustments made in funding for trials with early closure

Complexity: FY09 Proposed Selection: 6 Phase 3 Trials

- **Funding Required for six Phase 3 trials**
 - CALGB-30506: Adjuvant NSCLC Trial
 - E2905: MDS (Low / Intermediate Risk MDS)
 - RTOG-0848: Adjuvant Pancreatic Cancer Trial
 - ANBL0532: High Risk Neuroblastoma Trial (Pediatric)
 - GOG-0250: Leiomyosarcoma of the Uterus
 - S0500: Breast Cancer Tx Strategy Based on CTC
- **Funding Adjustment for CCOPs for FY 2008**
- **Consideration of Complexity Funding for Phase 2 Trials**

Complexity Model: Trials by Disease Type for FY08 and FY09 (Red = FY09 Selections)

Group	Brain	Breast	GI	GU	Gyn	Leukemia / MDS	Lung	Myeloma	Total
ACOSOG*		1	1						2
CALGB				1			2 (1)		3
COG	1					1			2
ECOG						2 (1)		1	3
GOG					3 (1)				3
NCCTG*	1								1
NSABP*		1							1
ROG			1	1					2
SWOG		1	1	1					3
Total	2	3	3	3	3	3	2	1	20

* Groups with no eligible phase 3 trials in FY09 or only Phase 3 trials close to target accrual.

Complexity: Further Evaluation & Follow-Up

- Need to refine model and definitions for consistency
- Need to assess impact of funding with respect to accrual and data collection