

*Clinical Trial Portfolio Analysis
Feasibility Study*

Clinical Trials and Translational Research
Advisory Committee

March 3, 2011

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Study Objectives



- Develop procedure for analysis of the NCI interventional clinical trials portfolio for use as a management tool
 - Determine annual NCI investment in interventional clinical trials by program
 - Develop procedures to allocate that investment by trial type, trial phase and organ site
- Perform pilot analysis of the FY06 NCI interventional clinical trial investment using the proposed procedures
- Create concise descriptions of NCI portfolio analysis tools and NCI programs supporting clinical trials.

Intramural Clinical Trial Portfolio Analysis



- System currently in place for reporting percent clinical trial relevance for project awards
- Protocols coded by trial type, trial phase and organ site
- Protocol data can be manually linked to project awards
- Developing automated system to link protocol data with project awards

Proposed Extramural Clinical Trial Portfolio Analysis Methodology



- Obtain annual budget for awards supporting interventional clinical trials from program staff
- Estimate percentage allocation to clinical trials for each program
 - 50% of portfolio is for awards devoted exclusively to clinical trials
 - 50% of portfolio requires award by award analysis for accuracy (investigator-initiated grants, SPORes and Cancer Centers)
- Allocate clinical trial funding by trial type, trial phase and organ site using information in existing databases and program specific procedures
- Construct database to aggregate and report out portfolio information for management use

Proposed Award by Award Analysis for Clinical Trial Percent Relevance



- **Option 1:** Program staff estimate clinical trial percent relevance (0, 10, 25, 50, 75, 90, 100%) for each award based on review of annual progress reports and associated budget information
 - For Cancer Center awards, percentages estimated for each core and program element
- **Option 2:** PIs and Cancer Center Administrators include in annual progress reports an estimate of the percentage of the budget that was spent on clinical trials (0,10, 25, 50, 75, 90, 100%)
 - Reviewed by program staff for concurrence
- **Option 2** recommended by Clinical Grants and Contracts Branch, SPORE and Cancer Centers program staff due to greater accuracy

*FY06 Pilot Clinical Trials Portfolio
Analysis*

FY06 Pilot Analysis

Total Clinical Trial Funding



	Interventional Clinical Trial Funding	Overall Percentage
Extramural	\$793,402,975	81.4%
Intramural	\$168,018,536	17.2%
Research Management Support	\$13,151,336	1.35%
Total	\$974,572,847	100%

FY06 Pilot Analysis

Intramural Clinical Trial Funding



Division	Program	Total Awards Supporting Trials	Total Funding	Clinical Percentage	Allocation to Interventional Clinical Trials	Percent of Total Interventional Clinical Trials Budget
CCR	Project Awards	96	\$140,583,793	34%	\$47,798,490	28.5%
	Clinical Center Assessment	N/A	\$90,762,000	100%	\$90,762,000	54.0%
	Clinical Trial Infrastructure Support	N/A	\$22,070,558	100%	\$22,070,558	13.1%
CCR Total		96	\$253,416,351	63%	\$160,631,048	95.6%
DCEG	Project Awards	8	\$5,784,105	98%	\$5,685,105	3.38%
	Contracts	2	\$1,702,383	100%	\$1,702,383	1.01%
DCEG Total		10	\$7,486,488	99%	\$7,387,488	4.40%
Grand Total		106	\$260,902,839	65%	\$168,018,536	100%

Source: STPI Analysis of Intramural Data from OBF and CCR/DCEG Staff

FY06 Pilot Analysis

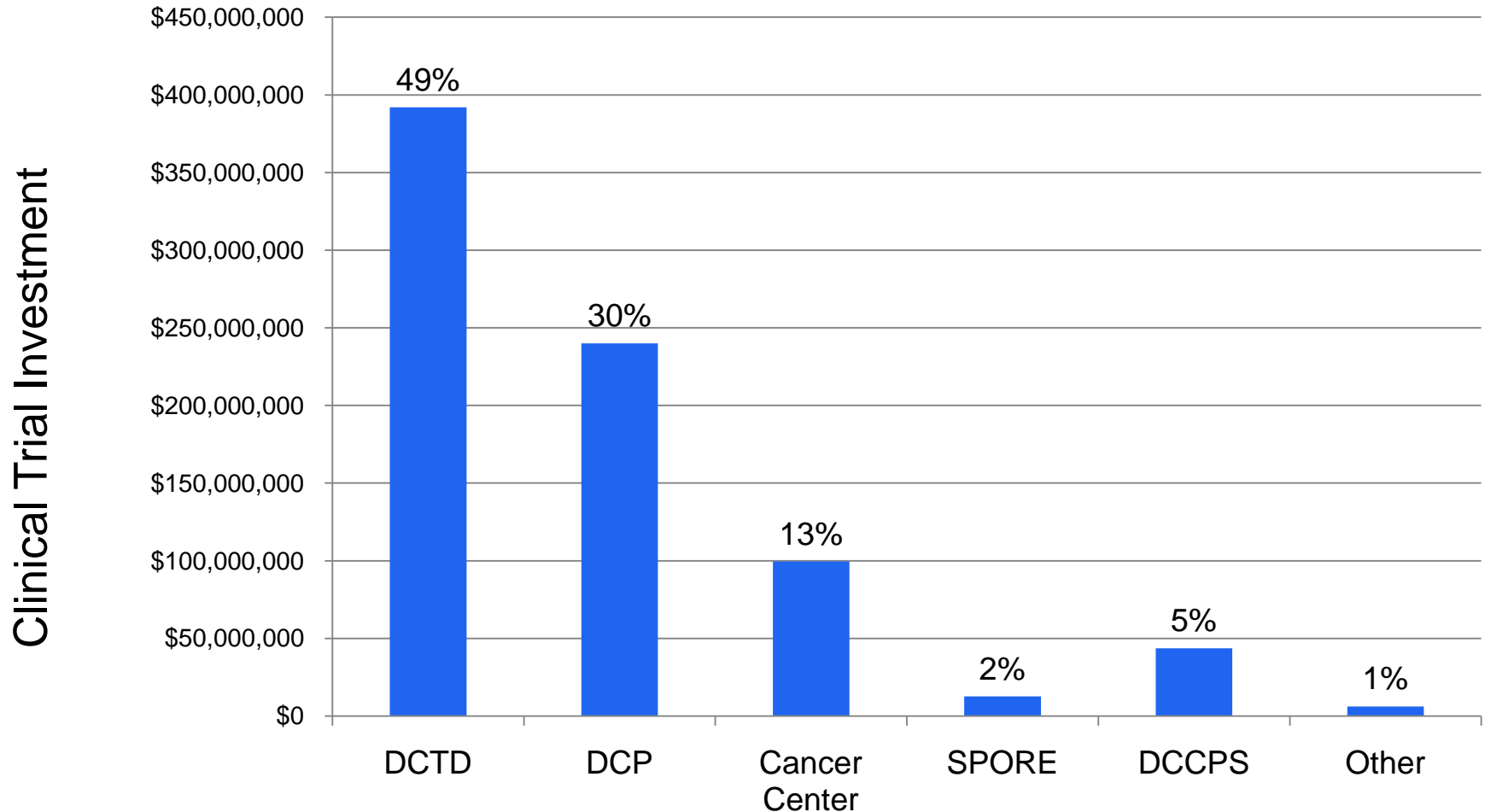
Extramural Clinical Trial Funding



- Total FY06 investment \$793M ± \$47M (6%)
 - ~50% definitive (awards devoted exclusively to clinical trials)
 - ~50% estimated at **program level** by program staff (requires award by award analysis for greater accuracy)
- Investment distributed over 35 different programs
 - 23 programs devoted 100% to clinical trials
 - 12 programs only partially in support of clinical trials
- Only three programs contribute greater than 10% of the clinical trial investment
 - Cooperative Groups (21%)*
 - Cancer Centers (13%)
 - DCTD Clinical Grants and Contracts Branch (13%)

* *Includes Tissue Banks, CIRB and CTSU*

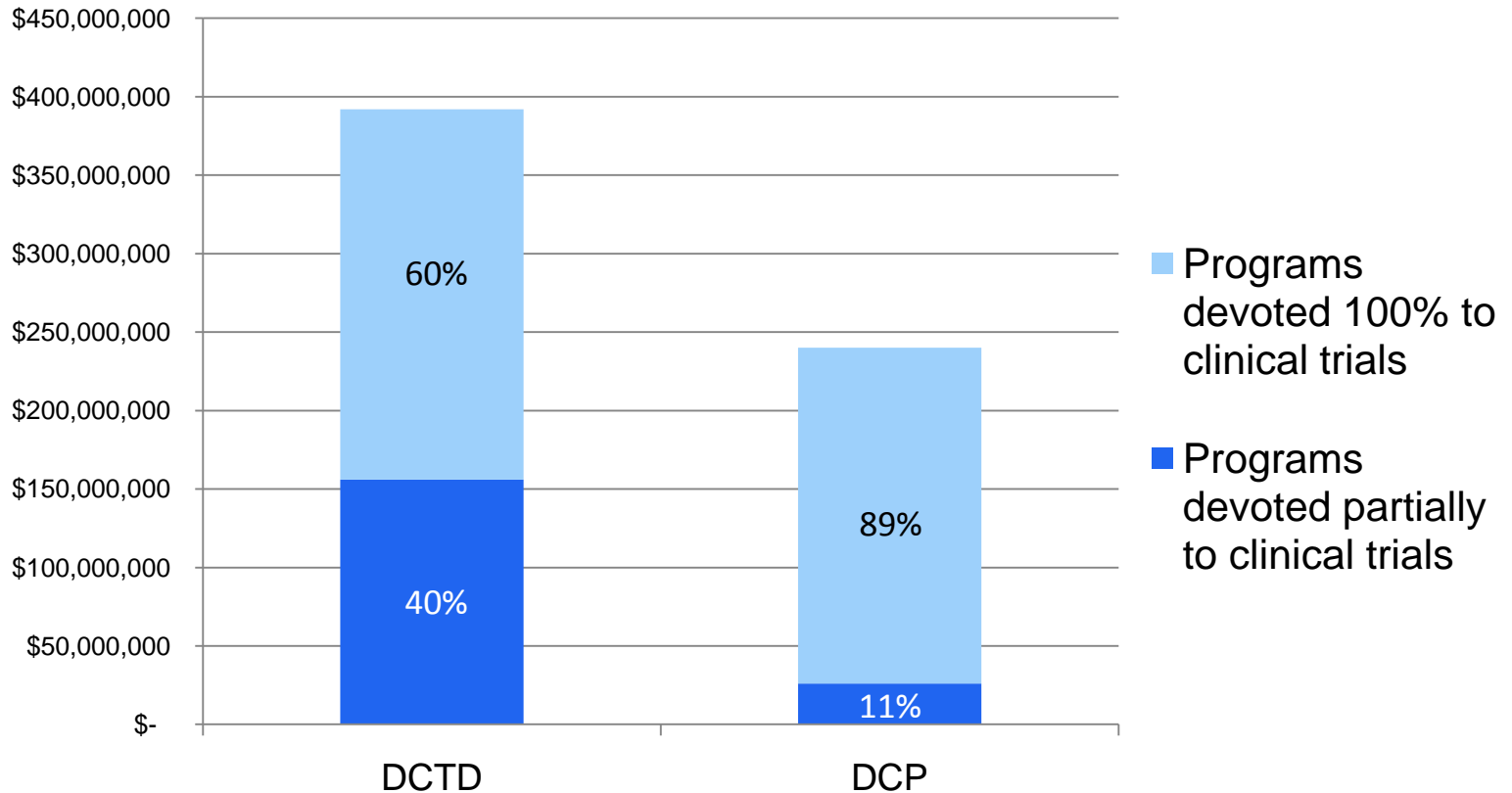
Distribution of Total FY06 Clinical Trial Funding by Division/Program



DCTD/DCP FY06 Clinical Trial Funding Distribution



Clinical Trial Investment



Allocation of FY06 Clinical Trial Funding

Trial Type, Trial Phase and Organ Site



- Intramural allocation clearly feasible
 - Project awards coded by CCR/DCEG staff using existing data
 - NIH clinical center assessment and CCR infrastructure allocated based on relative accrual
 - Accrual by protocol could be provided annually
- Feasibility of extramural allocation determined by FY06 pilot analysis using proposed methodology

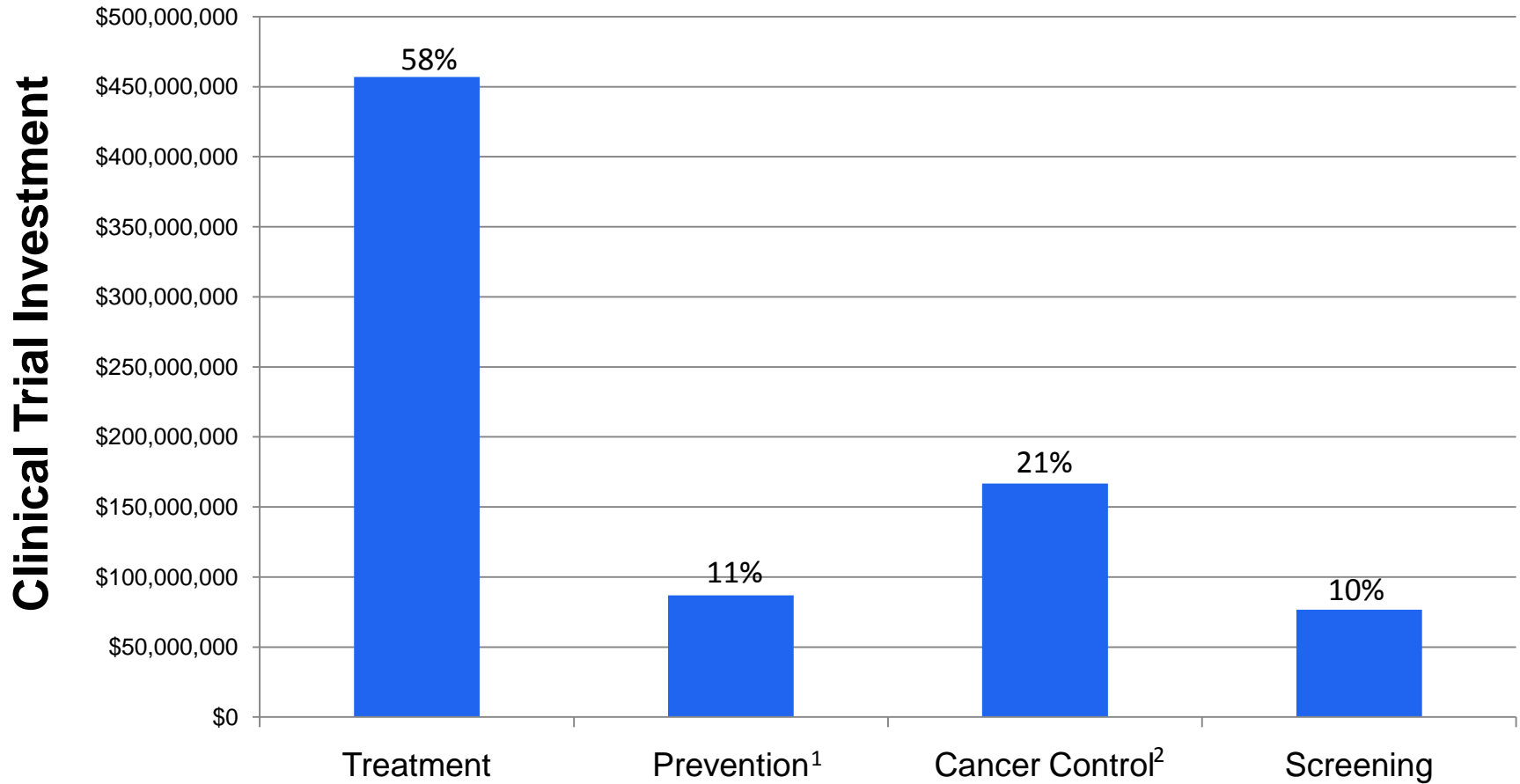
Methodology for Extramural Allocation

Trial Type, Trial Phase, Organ Site



- Trial type (treatment, prevention, cancer control, screening)
 - Allocate by program except for Cancer Centers and CCOPs which can be based on relative accrual
- Trial phase (early versus late)
 - Allocate by program except for Cancer Centers and Cooperative Groups which can be based on relative accrual and relative accrual and number of trials, respectively
- Organ site
 - Program or Research Assessment and Evaluation Branch (RAEB) data for most awards (R01's, contracts, etc.)
 - Relative accrual (IDB Phase II, Cancer Centers, CCOPs)
 - Relative accrual and number of trials (Cooperative Groups)
 - Fixed infrastructure costs allocated by number of trials
 - Per case reimbursements and member site costs allocated by accrual

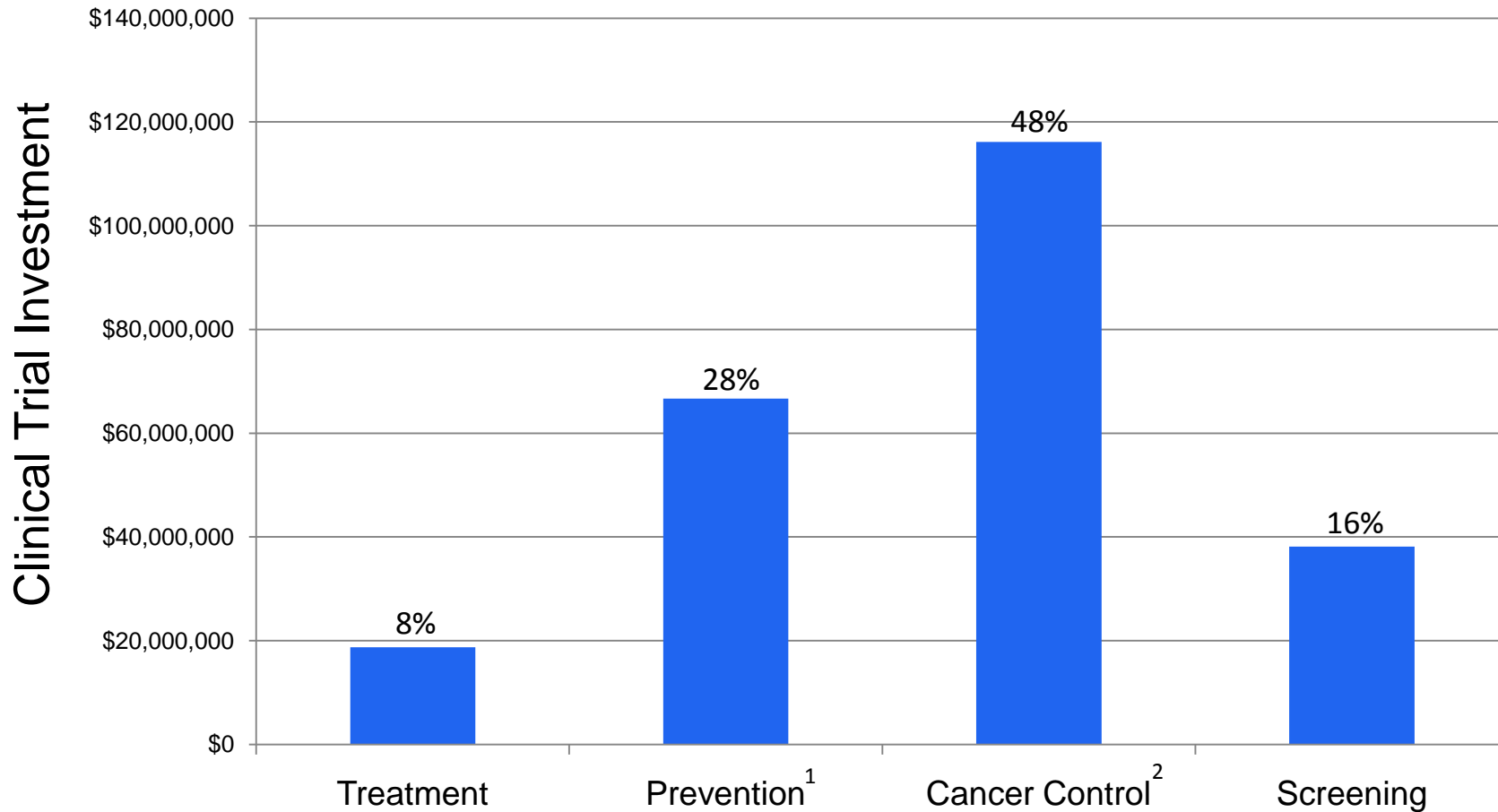
FY06 Extramural Clinical Trial Funding Distribution by Trial Type



¹ Chemoprevention and nutritional trials

² Includes symptom management trials

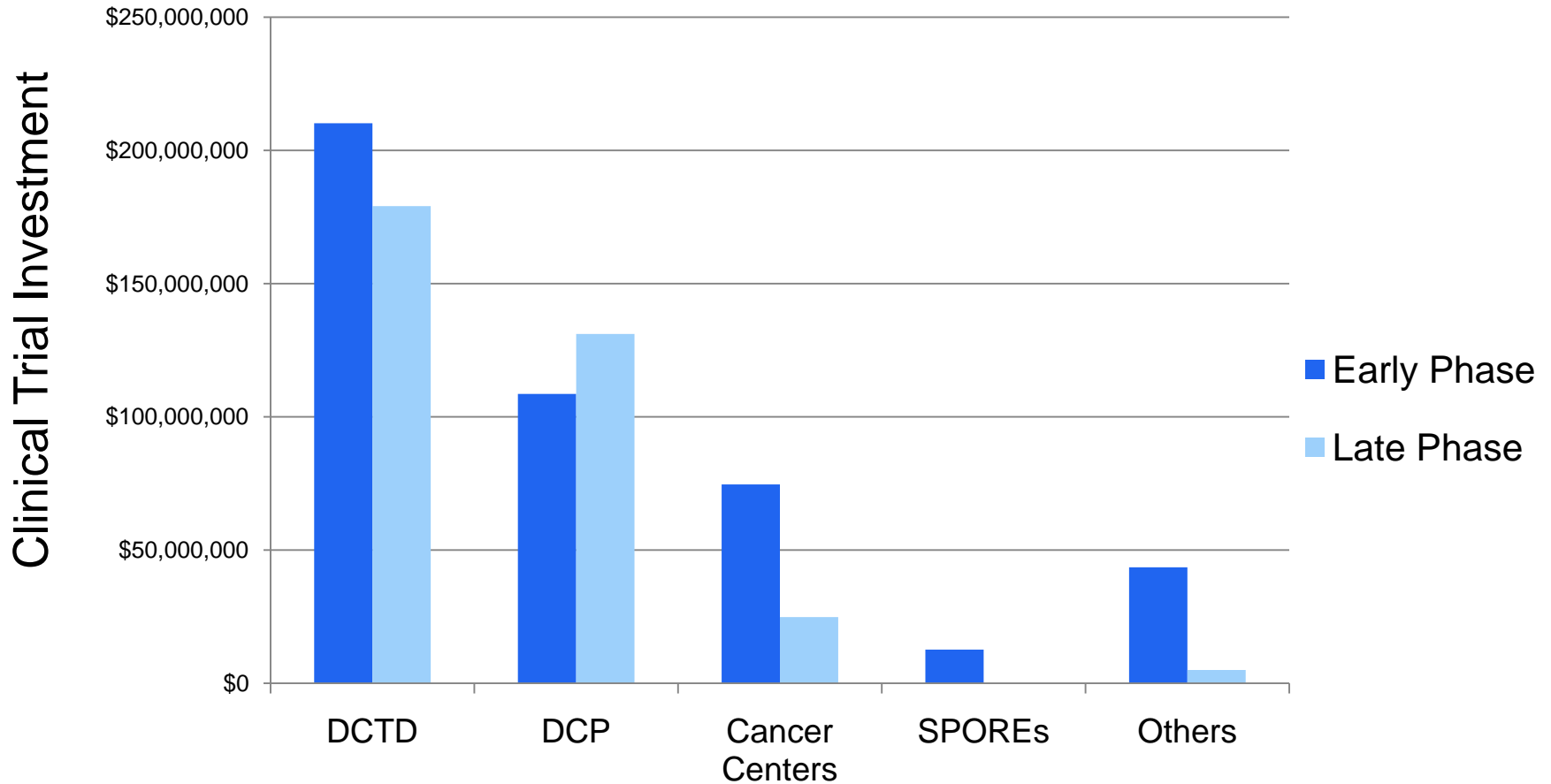
FY06 DCP Clinical Trial Funding Distribution by Trial Type



¹ Chemoprevention and nutritional trials

² Includes symptom management trials

FY06 Extramural Clinical Trial Funding Distribution by Trial Phase



Major Conclusions

- Intramural clinical trial portfolio analysis straightforward using currently available data and systems
- Current portfolio analysis tools and methods insufficient for proactive management of extramural clinical trial investment
- Trial and accrual data required for allocation of extramural clinical trial investment available in existing databases
- Accurate analysis for investigator initiated grants, SPOREs and Cancer Centers requires annual clinical trial relevance estimates by investigators or program staff

Questions for CTAC Consideration



- Is more accurate determination of the annual investment in clinical trials sufficiently important to warrant award by award reporting of clinical trial relevance?
- If award-by-award analysis is warranted, should estimates be made by program staff or provided by PIs and Cancer Center Administrators in annual reports?
- Would periodic characterization of the interventional clinical trial investment by trial type, trial phase and organ site be valuable as a management tool?