

***U-10 Cooperative Agreement for
NCI Community Oncology Research
Program (NCORP)***

Request for Application

Board of Scientific Advisors

June 24, 2013

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***In Collaboration with the Division of Cancer Treatment and Diagnosis
and the NCI Center to Reduce Cancer Health Disparities***

NCORP Vision: Preserve & Enhance Cancer Research in the Community

- **Build upon clinical trial success of the Community Clinical Oncology Program (CCOP) and Minority-Based CCOP (MB-CCOP) network**
 - Development and conduct of cancer prevention and control trials
 - Accrual to National Clinical Trials Network (NCTN) treatment and imaging trials
 - Enrollment of minorities into clinical trials
- **Expand to include cancer care delivery research (CCDR)**
- **Enhance focus on disparities questions in clinical trials and CCDR studies**

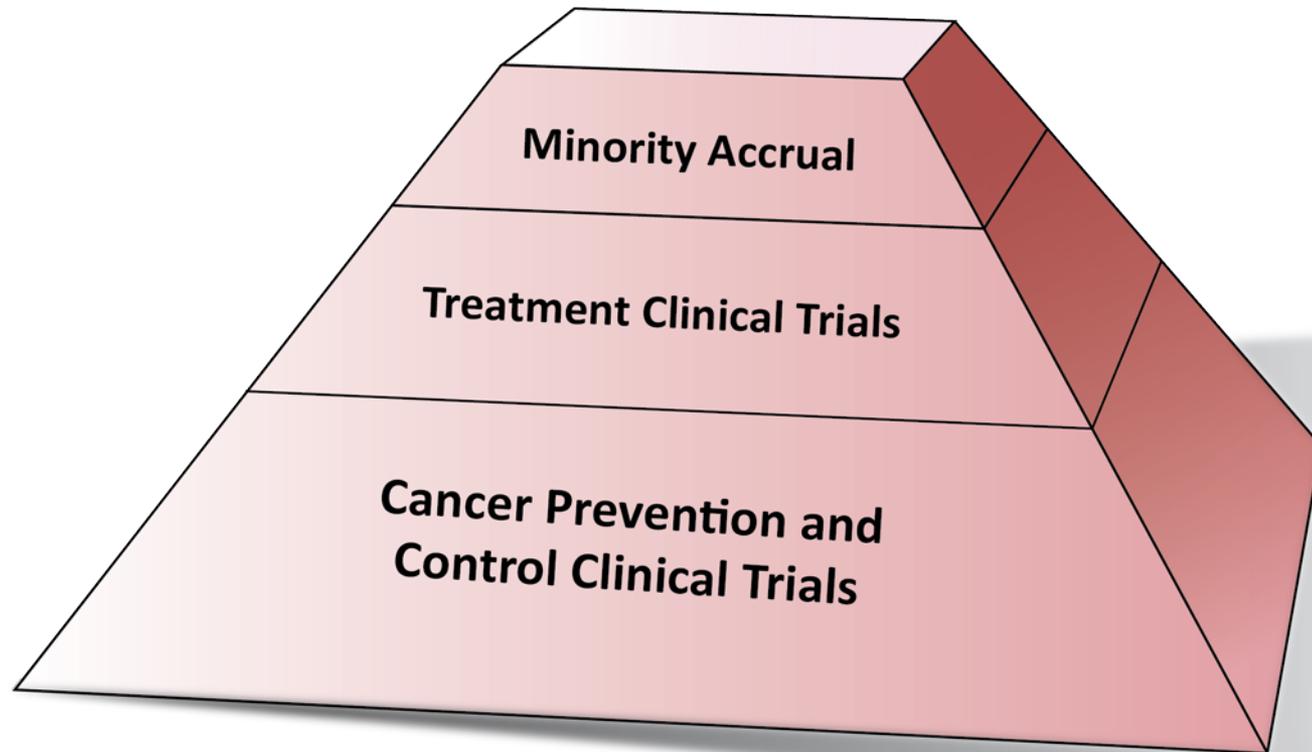
OVERARCHING GOAL

Bring state-of-the art cancer prevention, control, treatment, and imaging trials, as well as CCDR and disparities studies, to individuals in their own communities

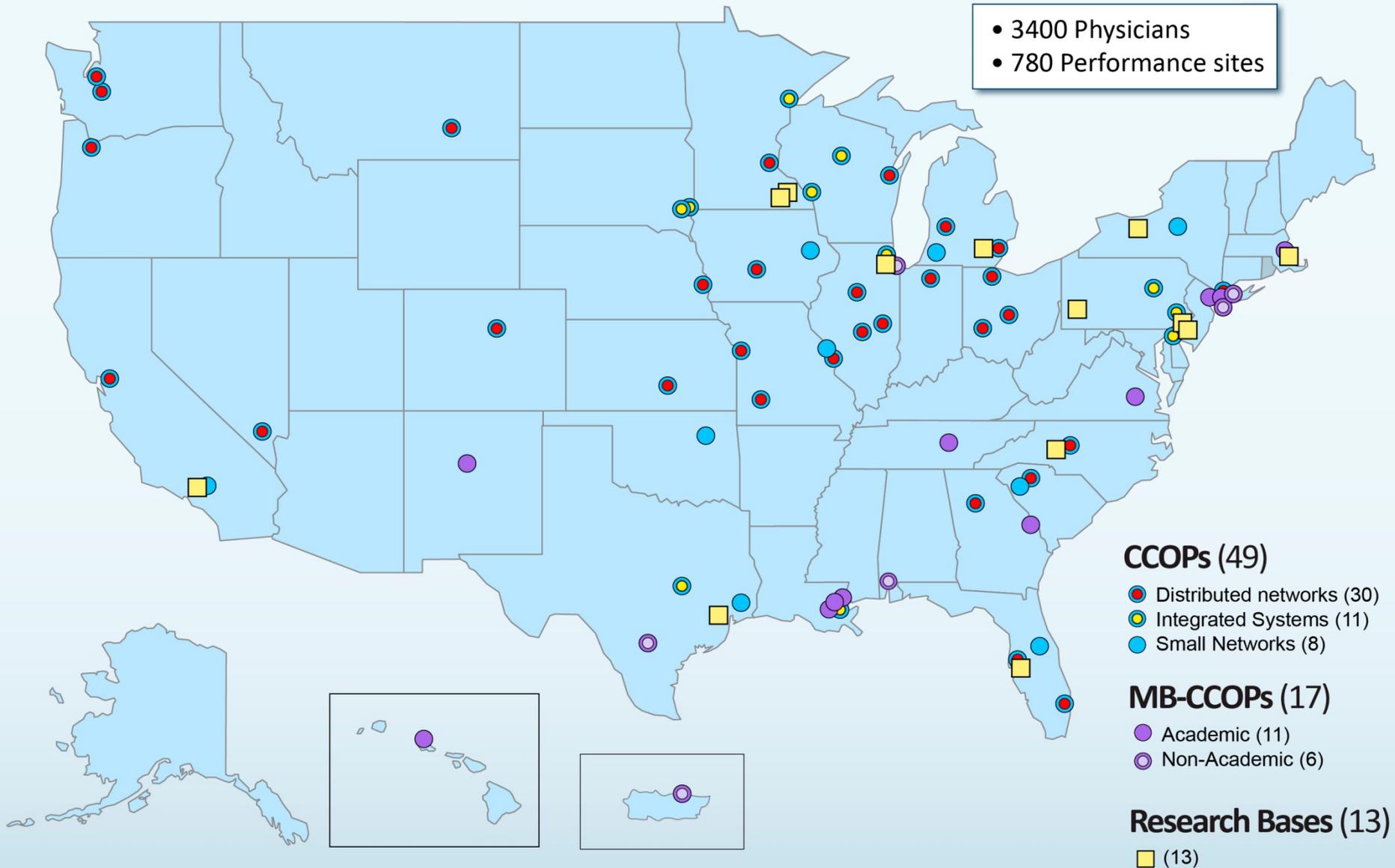
Why Support Cancer Research in the Community Setting?

- **Majority of cancer care is provided in the community**
- **Access to larger, more diverse patient populations**
- **Access to “real world” healthcare delivery settings**
- **Tests feasibility of implementing new interventions and processes**
- **Accelerates the uptake of new interventions and processes into routine practice**
- **Enhances potential that outcomes will be broadly applicable in practice**

CCOP/MBCCOP Clinical Trials Foundation



CCOP, MB-CCOP and Research Bases Geographic and Organizational Diversity



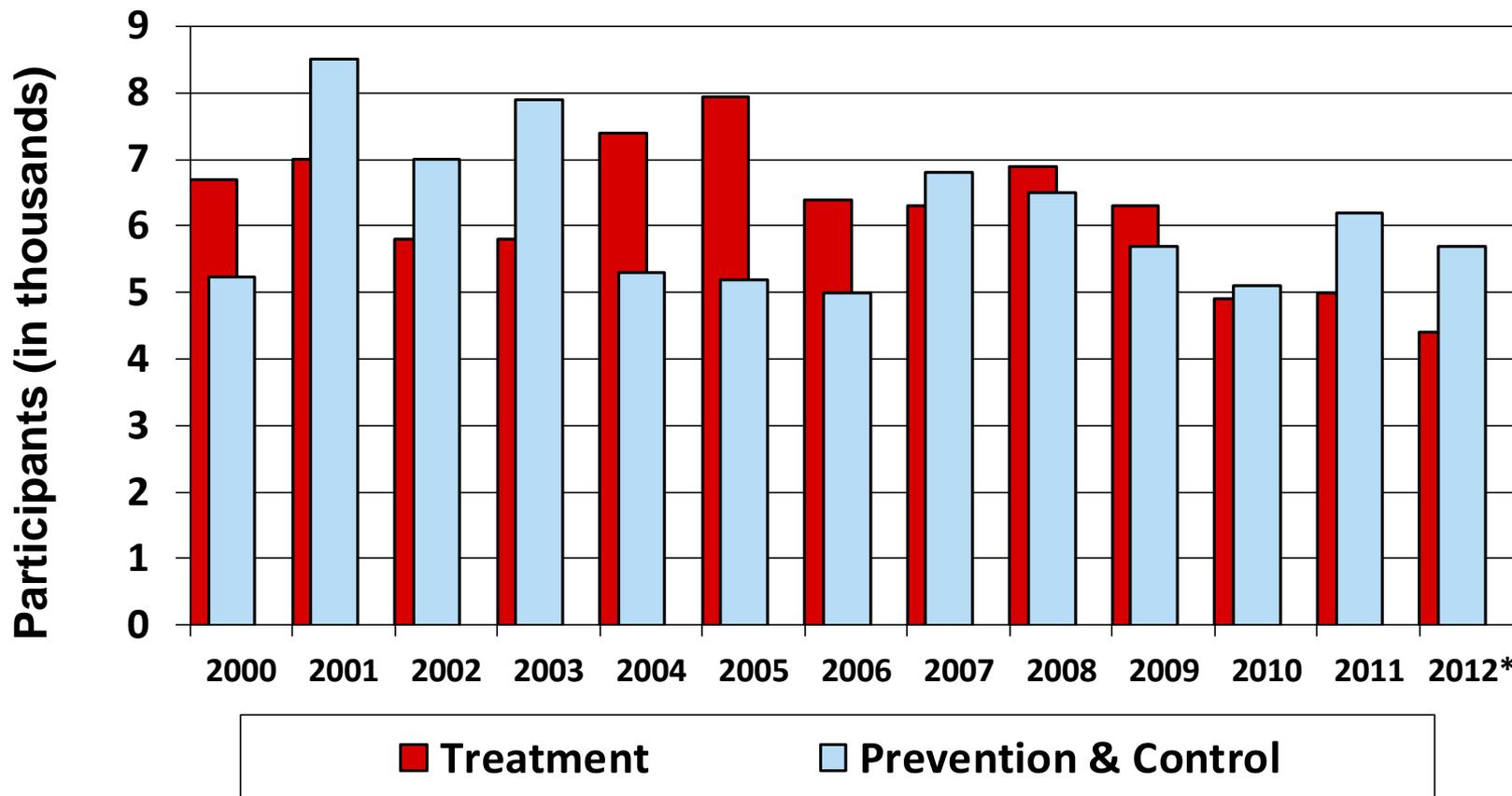
NCI Community Clinical Oncology Program Network Accrual 2000 – 2012

Minority accrual:

MB-CCOPs: 63%

CCOPs: 10%

Total accrual 161,000 -
(40% to NCTN treatment)



*9 month annualized data

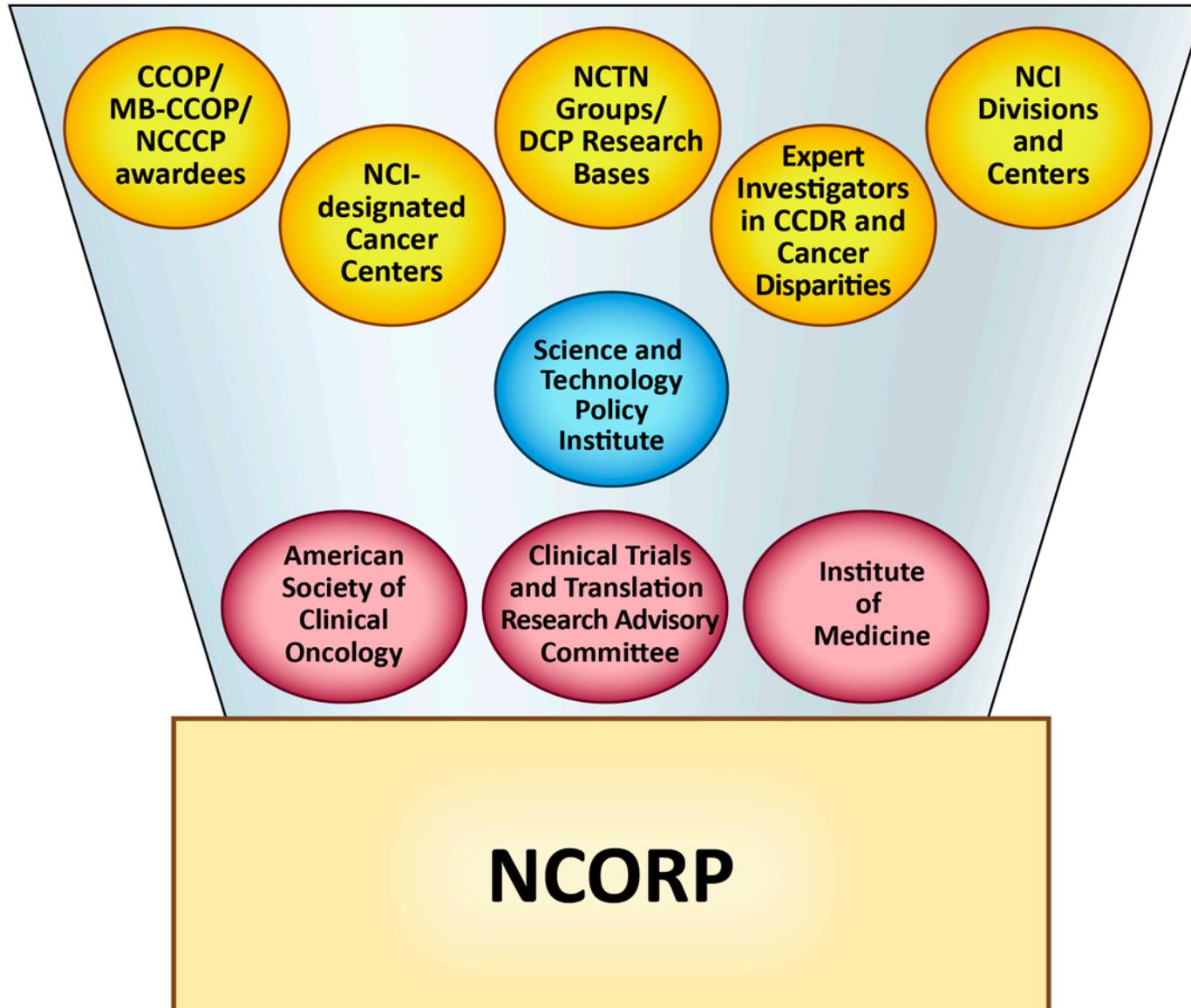
Selected Major Accomplishments from Cancer Prevention and Control Trials

- **Chemoprevention**
 - **BCPT, STAR:** Breast Cancer Prevention Trials
 - **PCPT, SELECT:** Prostate Prevention Trials -
 - Large, clinically annotated biorepositories for use in research
- **Symptom Management**
 - **CALGB 170601:** Pain reduction in chemotherapy induced peripheral neuropathy
 - **NCCTG:** Non-hormonal reduction of vasomotor symptoms (gabapentin & venlafaxine)
- **Health Related Quality of Life**
 - **RTOG 0214:** Prophylactic cranial irradiation results in memory decline; reduced brain metastasis; no survival benefit

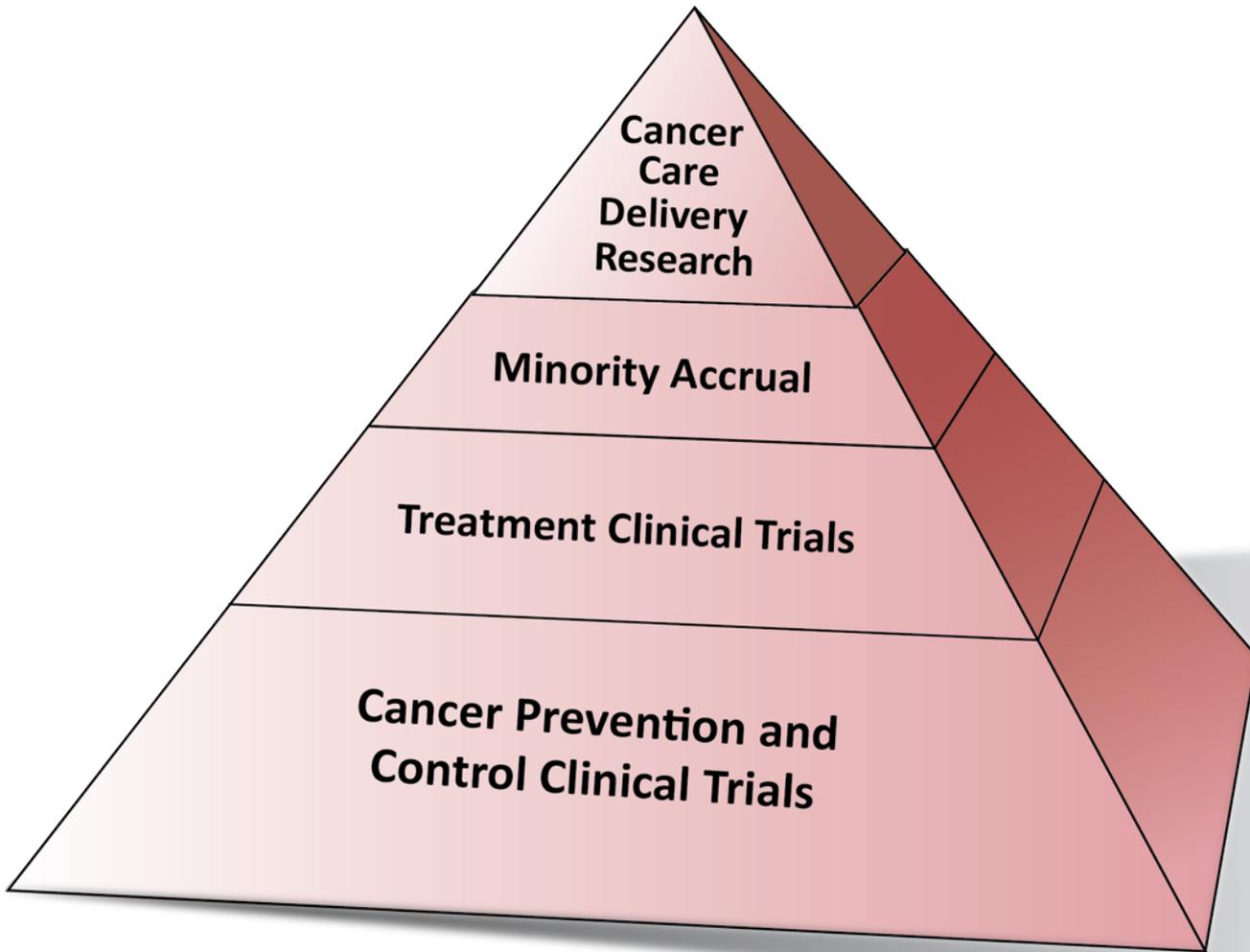
Future Research Agenda for Cancer Prevention and Control Trials

- **Molecularly targeted agents**
- **Post-treatment surveillance**
- **Over-diagnosis and under-diagnosis**
- **Management of precancerous lesions**
- **Mechanisms of cancer-related symptoms**
- **Biomarkers of risk for treatment-related toxicities**
- **Enhance accrual of racial/ethnic and other under-represented populations**

Process for the Development of NCORP



Expansion to Cancer Care Delivery Research



Why Support Cancer Care Delivery Research in the Community Setting?

- Precision medicine increasingly complicates care
- Rapidly changing health care system
 - Affordable Care Act
 - Accountable care organizations
 - Merging of practices
 - Diverse, often fragmented provision of care
- Urgent need for evidence about how these changes influence:
 - Patient outcomes
 - Disparities in care

Dynamic healthcare environment demands a better understanding of routine oncology care delivery

Cancer Care Delivery Research Portfolio

CCDR grants in the oncology specialty setting (N=197)

(FY2007-2012)

NCI	NIH
161 grants	36 grants
\$175.6 million	\$52.4 million

Key Findings: Care Delivery (N=157)

- 72% Academic
- 21% Community
 - Most within a single geographic area

Key Findings: Population-Based Datasets (N=40)

- 71% use national data sources
- 3 grants use hospital-based registry data

NCORP addresses a key gap by providing a diverse, geographically distributed, multi-site platform for CCDR

NCORP Cancer Care Delivery Potential Research Agenda

- **Observational studies**
 - **Patterns of care or service utilization data**
 - **Alternate organizational structures (e.g., integrated healthcare systems versus free-standing hospitals)**
 - **Alternate models for implementing multidisciplinary care planning (e.g. tumor boards versus multi-disciplinary clinics)**

- **Interventional studies**
 - **Implementation of new technologies (e.g., decision-making tools)**
 - **Incorporation of patient reported information into clinical decision-making**
 - **Implementation of new supportive/palliative care models**
 - **Introduction of patient navigators targeted at an underserved population**

Why Focus on Cancer Disparities Research in NCORP?

- **Persistent disparities**
 - Cancer incidence, mortality, and quality of life
 - Access to and quality of care
- **Increase in the number of underserved/underrepresented populations**
- **Determinants of disparities (social factors, health care systems, co-morbidities) disproportionately affect outcomes for underserved populations**
- **Challenging to fully and equitably implement new technologies and targeted therapies for the underserved**

Need for further research to reduce disparities and improve outcomes for underserved populations across the continuum of care

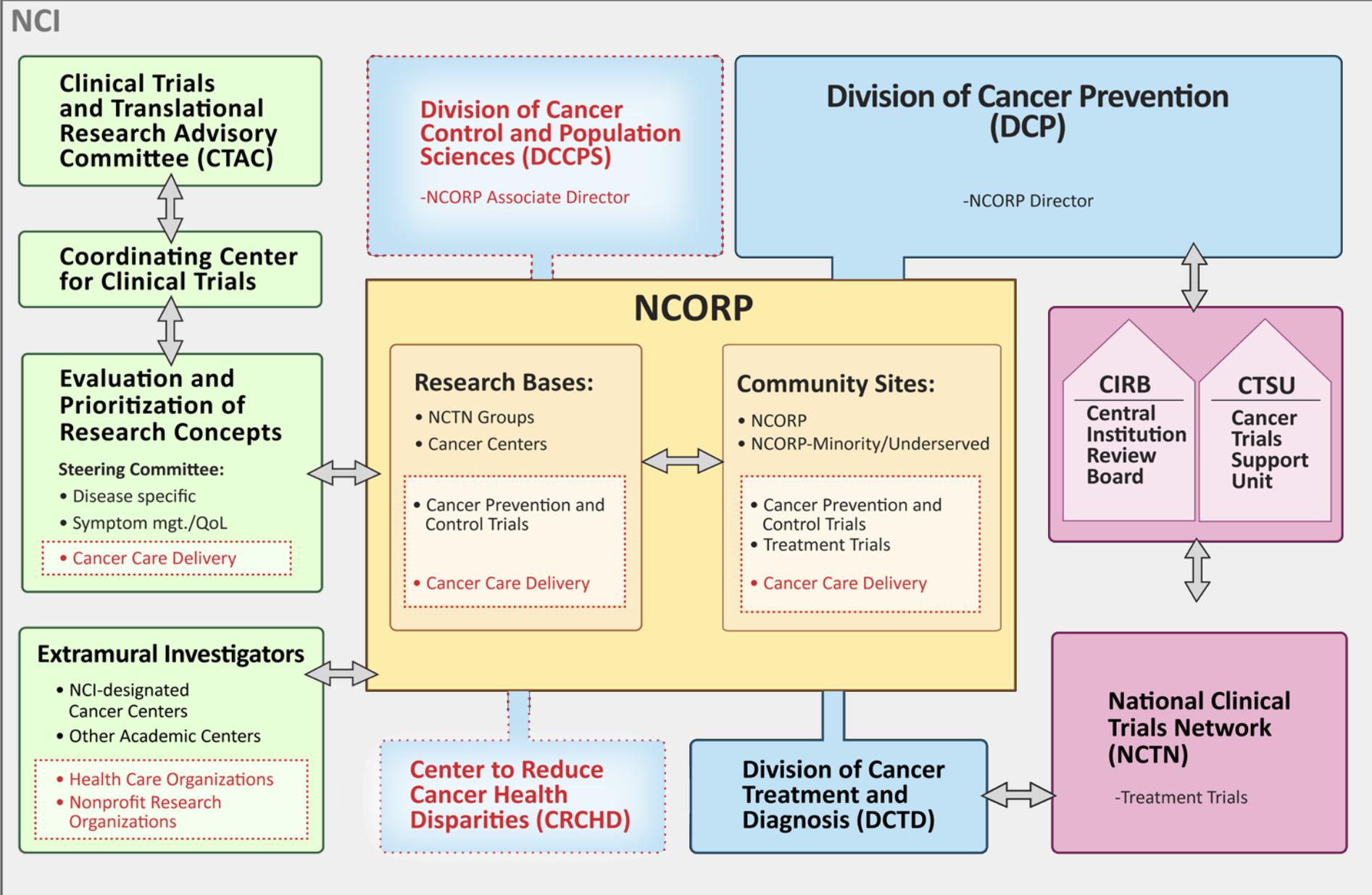
Synergy of Clinical Trials, Care Delivery, and Disparities Research - Cardiotoxicity

- **Acute and long-term cardiovascular adverse effects from therapy**
- **CCOP/MB-CCOP prospective studies**
 - **Cardiac biomarker study to predict anthracycline cardiac toxicities (BNP, troponin, ECHO, exam) - MD Anderson Research Base**
 - **ACE versus blocker/placebo study to prevent trastuzumab LV dysfunction/CHF – Sun Coast Research Base**
- **DCCPS epidemiological studies**
 - **Population-based, retrospective cohort study of risk of CHF from anthracycline and trastuzumab**

NCORP Cardiotoxicity Research Future Directions

- **Clinical trials investigating mechanisms, pathways, genomic and other biomarkers, imaging/diagnostic tools**
- **Longitudinal cohort studies of patients in routine care**
- **Cancer disparities studies to assess differential adverse effects in populations with a higher inherent risk of cardiovascular disease**

NCORP Organizational Structure



NCORP Component Characteristics

- **Research Bases**
 - Scientifically strong and feasible research agenda
 - Scientific and statistical leadership
 - Operational processes and personnel
 - Collaboration across Research Bases including for CCDR research priorities and data standards
- **Community Sites**
 - Minimum of 80 accruals annually
 - Recruitment and retention plan
 - Clinical research leadership and operations team
 - Capacity to support CCDR studies
- **Minority/Underserved Sites**
 - 30% of cancer patients and accrual from racial/ethnic minority or other underserved population
 - Potential to contribute data on disparities in outcomes and care

NCORP Evaluation Criteria

- Incorporation of **emerging science, novel ideas and trial/study designs**
- The degree to which NCORP prevention, treatment , and control trials lead to **practice change**
- Meeting or exceeding **accrual requirements**
- Increased **accrual of populations underrepresented in clinical trials**
- Development of a **coordinated portfolio of CDDR studies**
- Participation of **young investigators** in community oncology research

FOAs and Estimated # Grants

Network Component	Mechanism (Duration)	Est. Max. # Grants	Frequency New Application Accepted?	Multiple PI Option?
NCORP Research Base	U10 (5 Yrs)	Up to 7	Every 5 Years	Yes
NCORP Community Site	U10 (5 Yrs)	Up to 40	Every 5 Years	Yes
NCORP Minority/Underserved	U10 (5 Yrs)	Up to 14	Every 5 Years	Yes

Clinical Trial Funding Principles for NCORP Research Bases

- **Annual infrastructure funding**
- **Study specific support**
 - Protocol development
 - Statistics and data management
 - Trial monitoring and auditing
 - Specimen collection and banking
- **Per case payments to non-NCORP sites for cancer prevention and control accrual**
- **Source of funds**
 - DCP CCOP/MB-CCOP Research Base operating budget

CCDR Funding Principles for NCORP Research Bases

- **Annual infrastructure funding**
- **Single pool of funds for competitively awarded study specific support**
- **Staged funding model for first award cycle**
 - Year 1: 100% infrastructure and training
 - Year 2: 75% infrastructure, 25% study specific
 - Year 3: 50% infrastructure, 50% study specific
 - Year 4/5: 25% infrastructure, 75% study specific
- **Source of funds**
 - NCCCP operating budget
 - DCCPS

Clinical Trial Funding Principles for NCORP Community Sites

- **Fixed baseline funding per award**
 - Establish and maintain a clinical trials infrastructure
- **Standardized per case funding based on the trailing three-year average annual accrual**
- **High accruing sites (≥ 200 accruals/year) receive increased per case funding**
- **Source of funds**
 - DCP CCOP/MB-CCOP community site operating budget

CCDR Funding Principles for NCORP Sites

- **Fixed baseline funding per award**
 - Support Lead Investigator, study coordinator, and data system staff
 - Estimate \$100K per award
- **Increased funding for awardees with substantial CCDR experience and capacity**
 - Estimate average of \$300K per award
- **Source of funds**
 - NCCCP operating budget

**CCOP/NCCCP and NCORP Funding
(dollars in thousands)**

<i>Fiscal Year</i>	<i>CCOP/MBCCOP Total Program Grant Funds</i>	<i>NCCCP Total Contract Funds</i>	<i>Total Combined Funding</i>
2011	89,000	34,413	123,413
2012	87,400	38,575	125,975
2013 Estimate	81,370	11,783	93,153

<i>Fiscal Year</i>	<i>NCORP Clinical Trial Funding</i>	<i>NCORP Cancer Care Delivery Funding</i>	<i>Total Combined Funding</i>
2014	81,000	12,000	93,000

Annual Funding Request NCI Community Oncology Research Program (NCORP)

<i>NCORP Component</i>	<i>No. of Sites</i>	<i>Clinical Trials \$ Millions</i>	<i>No. of Sites</i>	<i>CCDR Funding \$Millions</i>	<i>Total Annual Funding</i>
NCORP Sites	40	\$35.4	40	\$5.4	\$40.8
NCORP-M/U Sites: Subtotal	14	\$7.3	14	\$2.0	\$9.3
SUBTOTAL:	54	\$42.7	54	\$7.4	\$50.1
NCORP Research Bases	7	\$38.3	7	\$4.6	\$42.9
Total RFA Funding		\$81.0		\$12.0	\$93.0*

* The 5-Year Total Grant Funding Request for NCORP for FY 2014 to FY 2018 is \$465 Million.

Clinical Trial Funding: NCORP and NCORP-M/U Sites - \$280,000 Infrastructure funding + \$2,500/accrual for sites with < 200 accruals annually or + \$4,000/accrual for sites with >200 accruals annually.

CCDR Funding for NCORP & NCORP M/U Sites: Standard funding at \$100K per award and enhanced funding at \$300K per award on average.

Tentative Timeline for Potential Implementation

- **Board of Scientific Advisors: June 2013**
- **NCI DEA & NIH Review Funding Opportunity Announcement and Guidelines**
 - **Fall of 2013 with a goal of making awards in 2014**

NCORP Vision for Cancer Research in the Community

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- **Expand to include cancer care delivery research**
- **Enhance focus on disparities research** (both stand-alone and integrated studies) with clinical trials and CCDR
- **Capitalize on synergies** between clinical trials, CCDR, and disparities research questions