

NCI's Evolving Clinical Trials System

NCI Community Oncology Research Program (NCORP)

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Worta McCaskill-Stevens, MD

Chief, Community Oncology and Prevention Trials Research Group
Division of Cancer Prevention

In Collaboration with NCI's Divisions of Cancer Control and Population
Sciences and Cancer Treatment & Diagnosis and the
Center to Reduce Cancer Health Disparities

NCORP Milestones

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- April 2012** ● NCI begins the planning of a single community-based research program – NCI Community Oncology Research Program (NCORP).
 - May 2013** ● NCI Scientific Leadership approves the NCORP concept.
 - June 2013** ● Board of Scientific Advisors approves the NCORP concept
 - November 2013** ● The NCORP Funding Opportunity Announcement released with a due date of January 8, 2014.
 - April- May 2014** ● Peer Reviews of NCORP Applications
 - August 1, 2014** ● NCORP launch

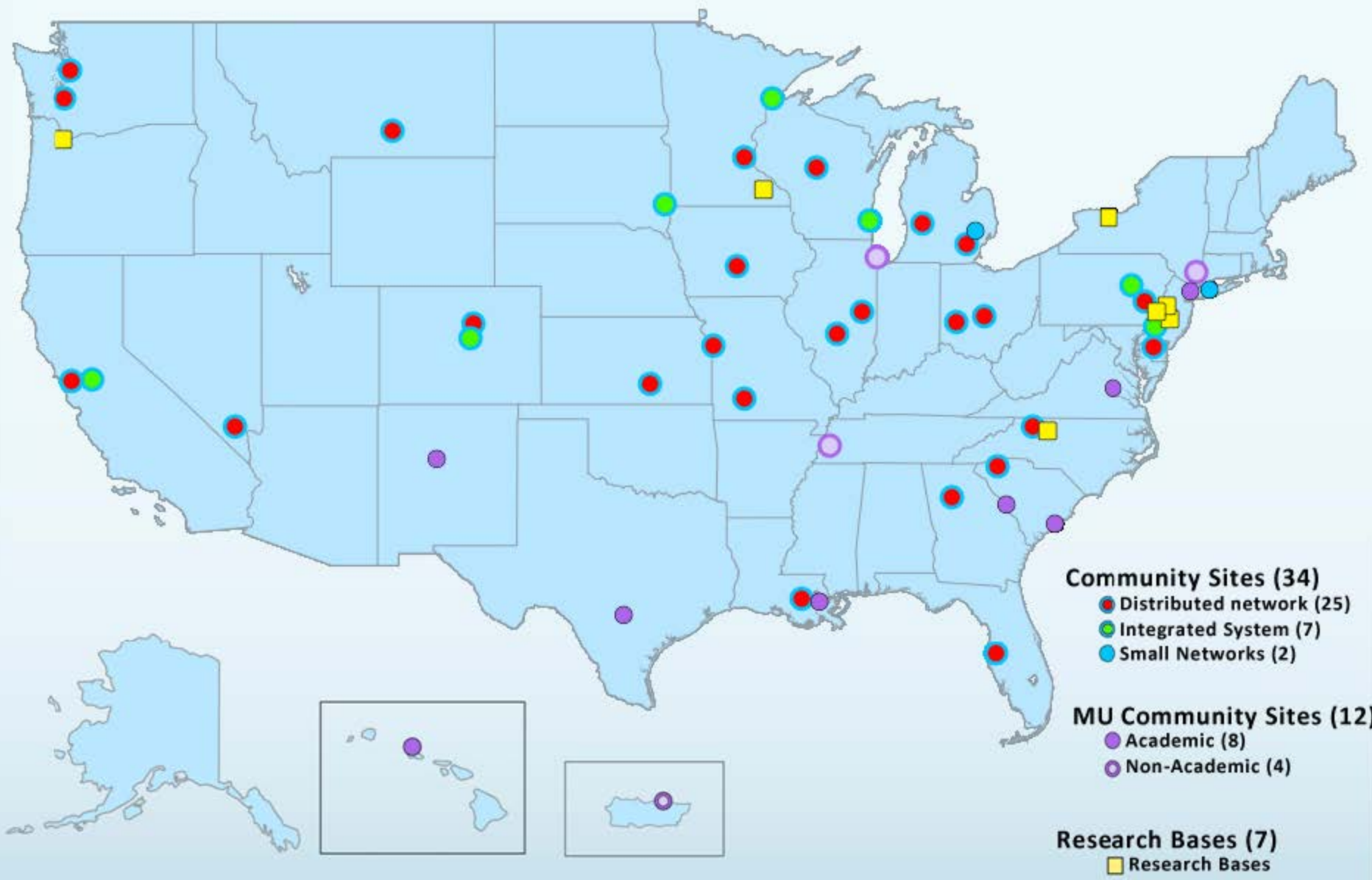
NCORP: A Single Community-Based National Network

- **Clinical Trials: prevention, control, health-related quality of life, comparative effectiveness, and screening**
- **Cancer care delivery research: patient-provider and organization-level influences on cancer outcomes**
- **Incorporation of cancer disparities research into clinical trials and cancer care delivery research**
- **Accrual to National Clinical Trials Network (NCTN) treatment and imaging trials**
- **Community/academic partnerships**
- **3 components: Community Sites, Minority/Underserved Community Sites and Research Bases**

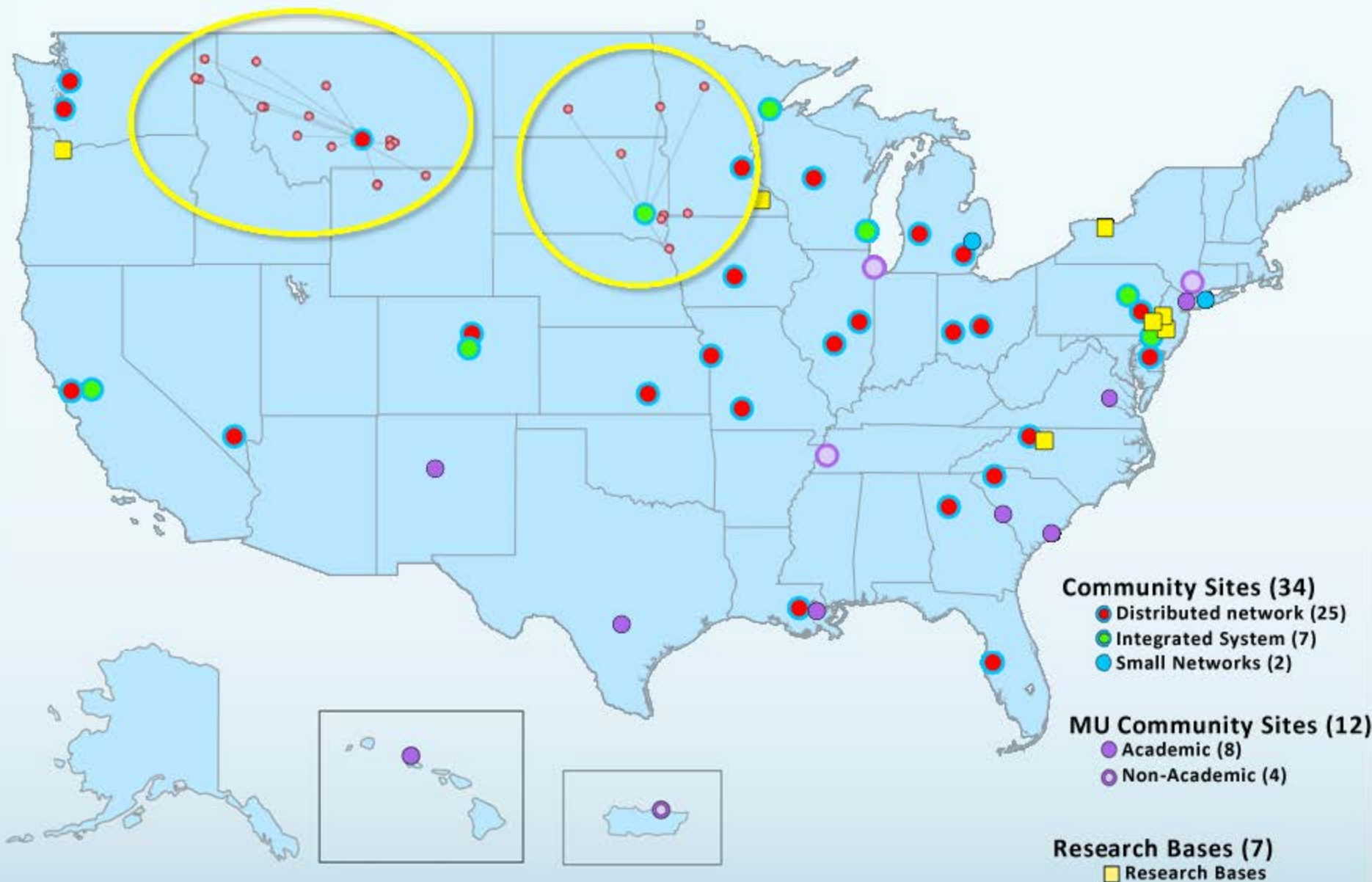
Research Bases

Research Base Applicant	Institution (PI)	Research Focus & Strengths
Alliance	Mayo Clinic (Jan Buckner)	Chemoprevention risk assessment methods, tobacco harm reduction, disparities, natural history and risk identification of treated-related toxicities
SWOG	Oregon Health & Science University (Charles Blanke)	Biorepositories for prevention, Comparative effectiveness research
NRG	NRG Oncology Foundation, Inc. (Deb Bruner)	Risk reduction of women's cancers, radiation neurotoxicities, surgically-induced sequelae
ECOG-ACRIN	ECOG-ACRIN Medical Research Foundation (Lynn Wagner)	Imaging science, patient reported outcomes, symptom database
COG	Children's Hospital of Philadelphia (Brad Pollock)	Cancer-related infection, neurological sequelae, adolescents and young adults
URCC	University of Rochester (Gary Morrow)	Cancer-related fatigue in the elderly, treated-related cognitive dysfunction
Wake Forest	Wake Forest U. Health Sciences (Glenn Lesser)	Cardiotoxicity, radiation-related toxicities, transitions in care

NCORP Community Site, MU Community Site and Research Bases Geographic and Organizational Diversity



NCORP Community Site, MU Community Site and Research Bases Geographic and Organizational Diversity



NCORP Clinical Trials and Health-Related quality of Life Studies

Type	Focus
Cancer Prevention	Identify/evaluate interventions to reduce cancer risk and incidence
Cancer Control	Reduce incidence/co-morbidity of cancer and its treatment, enhance quality of life
Cancer Screening	Evaluate early diagnosis interventions and cancer recurrence
Health-Related Quality of Life	Embedded in NCTN Treatment Trials

Research Agenda for Cancer Prevention, Control & Screening Trials

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

Research Agenda for Cancer Prevention, Control & Screening Trials

Cardiotoxicity Task Force (Trans-NCI)

Mission: To collaborate in prioritizing the cardio-oncology research agenda across the Research Bases within NCORP

Goal: To develop feasible, focused pragmatic research with meaningful clinical outcomes

NCORP Cancer Care Delivery Potential Research Agenda

- **Observational studies (Descriptive & Analytical)**
 - **Patterns of care or service utilization data**
 - **Alternate organizational structures (e.g., integrated healthcare systems versus free-standing hospitals)**
 - **Alternate multidisciplinary care planning models (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**

NCORP FY 2014 Budget

NCORP Funding

Grand Total: \$97.0 Million

\$91.1 Million allocation for NCORP grants

\$ 2.0 Million from DCCPS for NCORP grants (Additional FY 2014 NCI Funding)

\$ 93.1 Million

\$ *3.9 Million allocation for contract support for NCORP*

Details of NCORP grant funding

<i>NCORP Component</i>	<i>No. of Sites</i>	<i>Clinical Trials \$ Millions</i>	<i>CCDR Funding \$Millions</i>	<i>FY 2014 Total</i>
<i>NCORP & NCORP-M/U Sites SUBTOTAL:</i>	<i>46</i>	<i>\$42.7</i>	<i>\$ 7.5</i>	<i>\$50.3</i>
<i>NCORP Research Bases</i>	<i>7</i>	<i>\$38.2</i>	<i>\$ 4.5</i>	<i>\$42.8</i>

NCORP Supplemental Funding For Accrual

\$2.9 M

Post Launch Activities

- **Cancer Care Delivery Research Planning Meeting
August 25- 26, 2014**
- **September 22, 2014 Investigator/Administrators
Meeting, Shady Grove**
- **Natural Experiments Working Group – Develop
research designs to evaluate natural experiments
in the area of policy change and their effects on
care and health outcomes**

Cancer Care Delivery Research (CCDR) Planning Meeting

August 25-26, 20014

- **Purpose: Begin foundational work for CCDR activities**
 - **Initiate process to develop CCDR strategic priorities**
 - **Prepare for the formation of Coordinating Committee**
 - **Begin discussions surrounding data infrastructure**

- **Attendees:**
 - **Research Base PIs and CCDR Leads**
 - **CCDR Leads from Community & Minority/Underserved Sites with enhanced CCDR capabilities**

- **Research Bases presented their CCDR research priorities and capacities**
 - **Clear evidence of innovation & expertise**

- **NCI presented “CCDR landscape” from national reports**

- **Four breakout discussions**
 - **Disparities, organization and system science, patient engagement, ‘omics’ in clinical practice**

Early Next Steps for Cancer Care Delivery Research

- **Assemble initial Coordinating Committee members**
- **Determine leadership and additional members of Coordinating Committee**
- **Determine the structure of the CCDR Steering Committee**
- **Begin process for identifying CCDR research priorities and initiating working groups**
- **Characterize the health care environments and capacities for CCDR across NCORP**

NCORP: Advantages of a New Community-Based Research Organization

- **Represents the “real world” of oncology practices**
- **Responsive to extensive stakeholder input**
- **Community Sites & Research Bases are better prepared to support the scientific agenda of NCORP**
- **Capacity to sustain or improve clinical trials accrual to all components of NCTN**
- **Broader base of individuals at risk of cancer**
- **Opportunity to evaluate the influence of the current health care system on the successful conduct and implementation of precision cancer therapy**

NCORP and CCOP Interim/Closeout Funding

NCORP Funding

Total: \$97.0 Million

\$91.1 Million allocation for NCORP grants

\$ 2.0 Million from DCCPS for NCORP grants (Additional FY 2014 NCI Funding)

\$ 3.9 Million allocation for contract support for NCORP

CCOP Interim Funding

Total: \$8.3 Million – Additional FY 2014 NCI Funding

CCOP Closeout Funding

Total: \$4.7 Million

\$2.9 Million – reserved by DCP

\$1.8 Million – Additional FY 2014 NCI Funding

FY 2014 Funding

Total: \$109.9 Million

NCORP Community Site and Minority Site Geographic and Organizational Diversity

