

# NCI's Evolving Clinical Trials System

## *NCI Community Oncology Research Program (NCORP)*

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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**

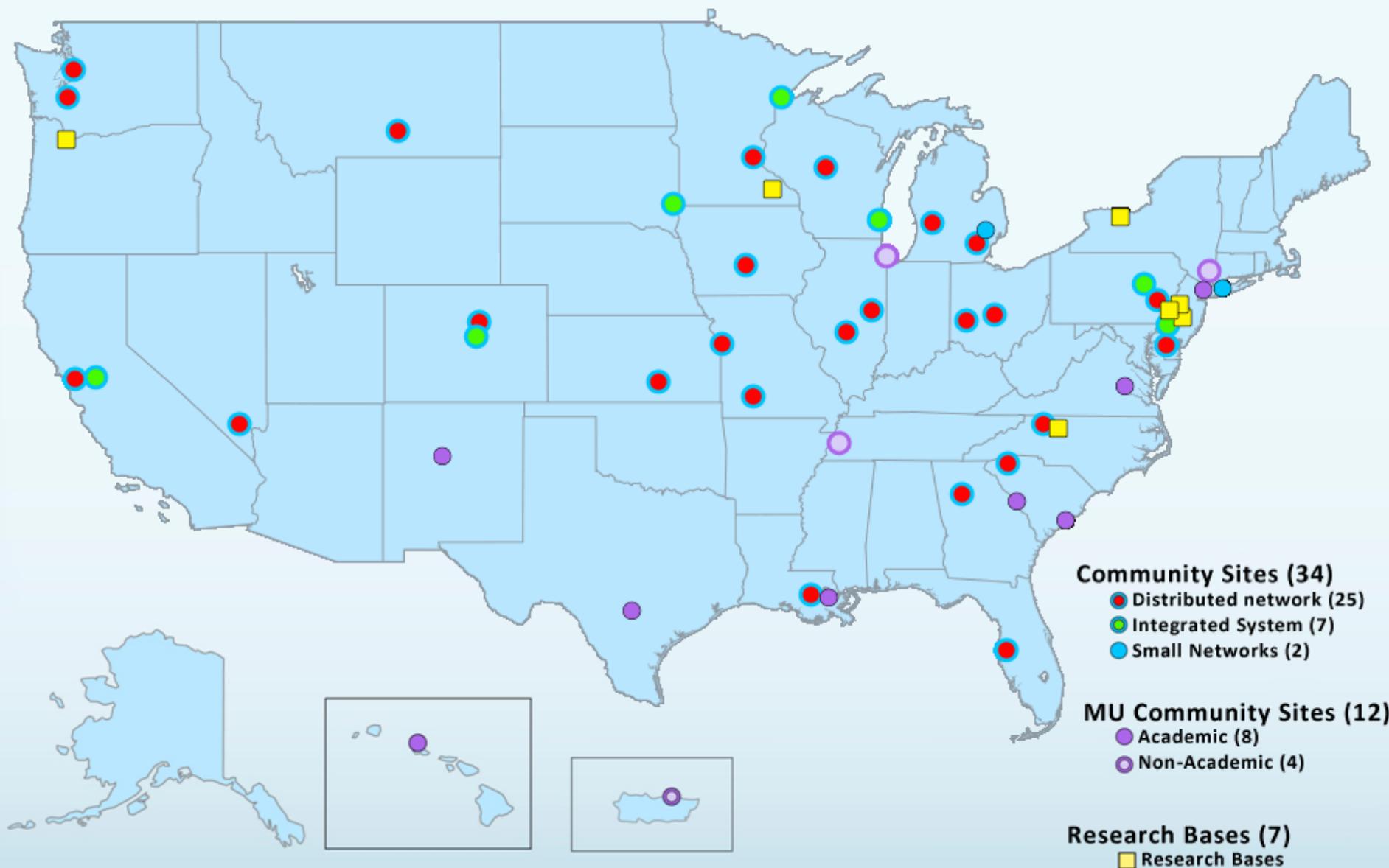
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- **Clinical Trials: prevention, control, health-related quality of life, comparative effectiveness, and screening**
- **Cancer care delivery research: patient-provider and organization-level influences on cancer outcomes**
- **Incorporation of cancer 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**

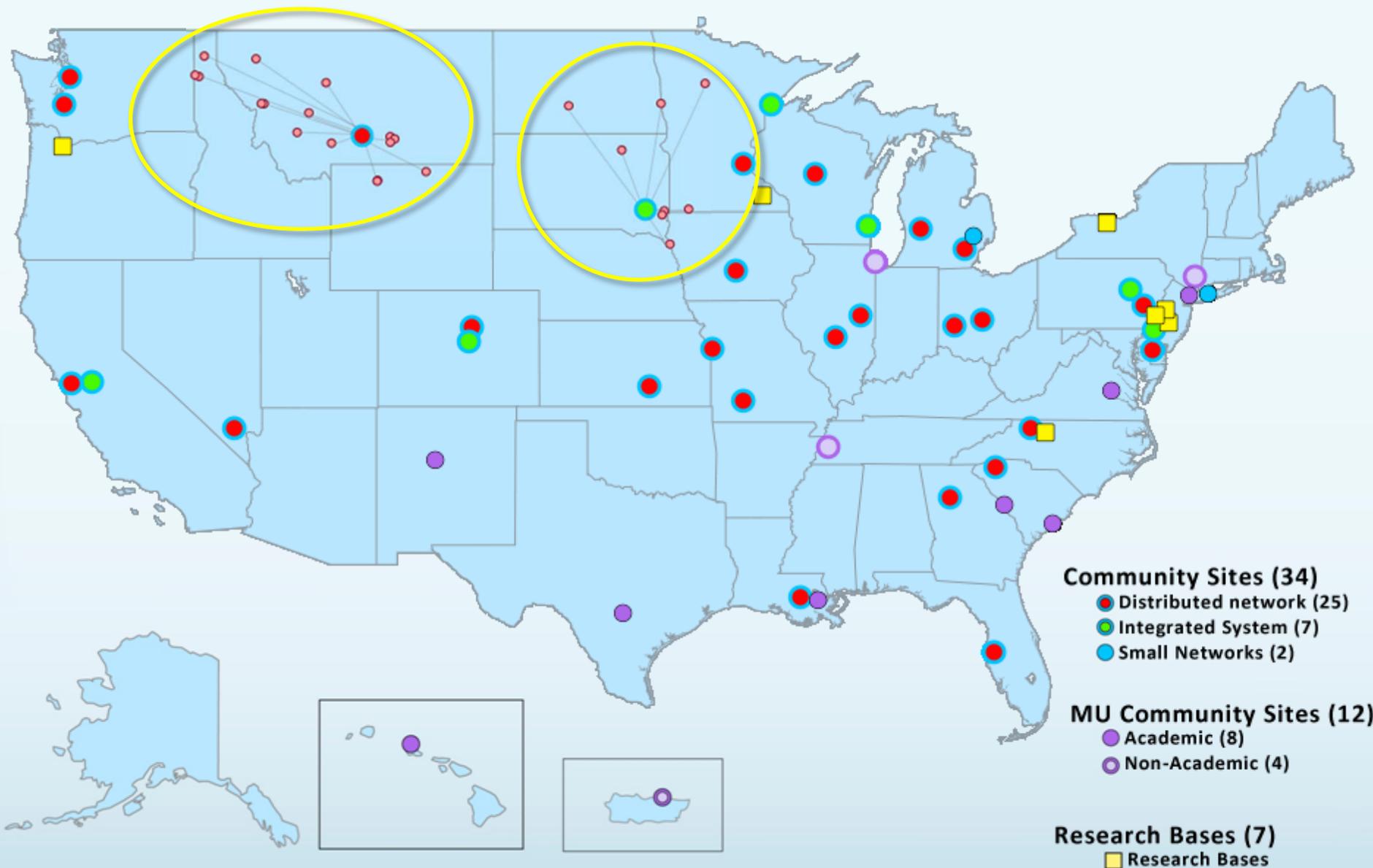
# Research Bases

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

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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

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# Research Agenda for Cancer Prevention, Control & Screening Trials

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- 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

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## 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**

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- **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 &amp; 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

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- **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**

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- **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

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- **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**

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- **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

