

**National Cancer Institute Community Oncology
Research Program (NCORP)**

Institute of Medicine

**“Implementing a National Cancer Clinical Trials
System for the 21st Century:
Workshop #2”**

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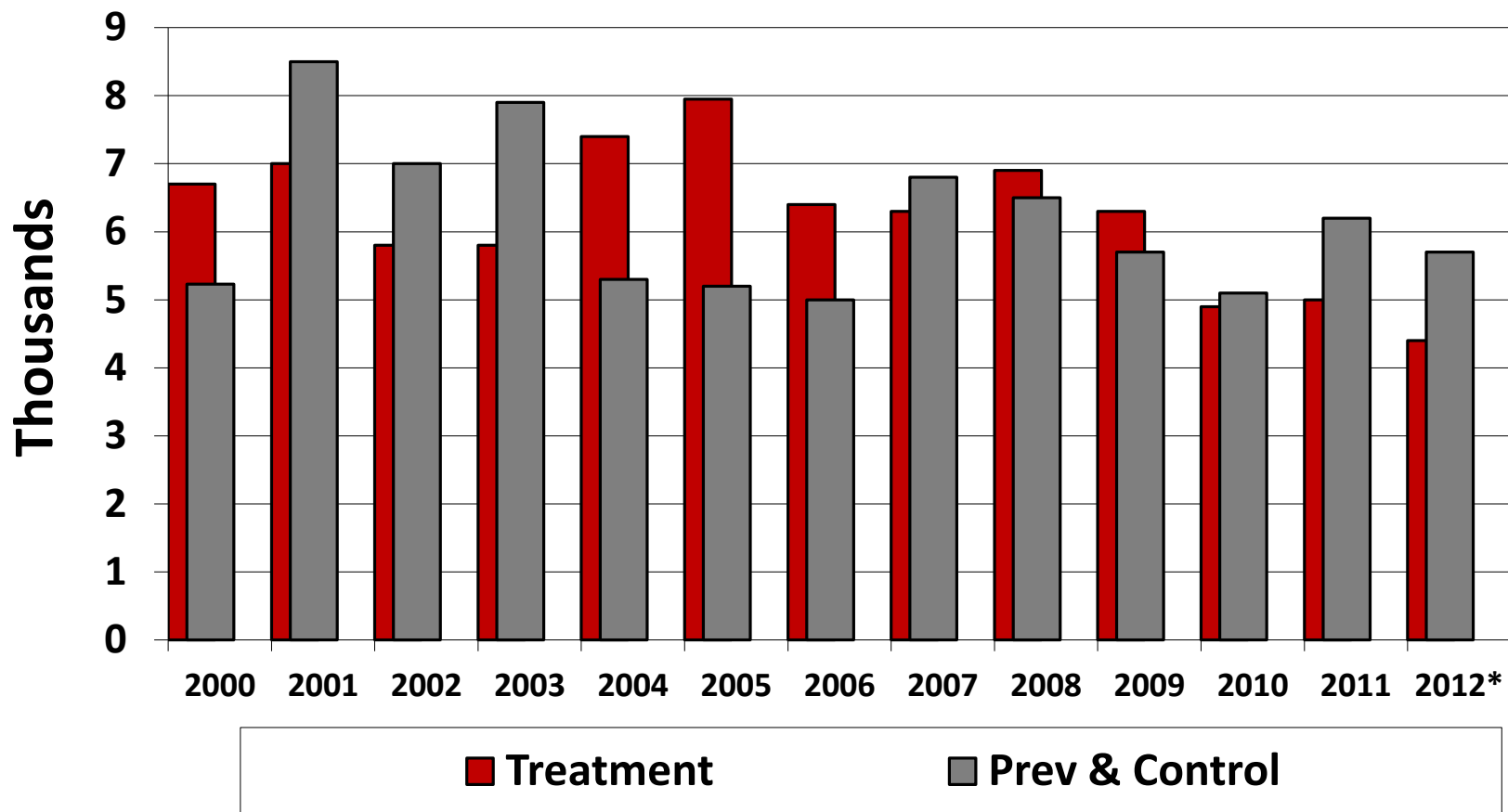
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NCORP – Background

- **Cancer management is increasingly becoming more sophisticated across the entire prevention and management continuum.**
- **Molecular-based delivery systems are needed for the application of these advancements in the new world of health care. The best laboratory in which care systems can be evaluated are the community settings.**
- **The structure of oncology care delivery is changing.**
 - **Practice mergers on the rise**
 - **Increased practice acquisitions by hospitals**

NCI Community Clinical Oncology Program Network Accrual 2000 – 2012



2012* = 6 month
annualized data

Achievements

- **Breast Cancer Prevention**
 - **Breast Cancer Prevention Trials (tamoxifen) BCPT**
 - **Study of Tamoxifen and Raloxifene (STAR)**
 - Serum and lymphocytes for 90% of 33,000 women; tumor blocks for the majority of cancers, atypical hyperplasia, and lobular carcinoma in-situ
- **Prostate Cancer Prevention**
 - **Prostate Cancer Prevention Trial (finasteride) PCPT**
 - **Selenium and vitamin E Cancer Prevention Trial (SELECT)**
 - Annual serum on 18,000 men for biomarker validation, nutrition and adherence data, and DNA from prostate cancer patients with age and race matched controls
- **Large portfolio of symptom management and toxicity mitigation studies**

NCORP – Concepts and Goals

- **Develop a single NCI community-based program that integrates the Community Clinical Oncology Program (CCOP), Minority-Based CCOP (MB-CCOP), and NCI Community Cancer Centers Program (NCCCP)**
 - **Build on their strengths**
 - **Expand the spectrum of research opportunities**
- **Support clinical, cancer disparities, and cancer care delivery research (CCDR)**
 - **Clinical trials will continue to be a core function**
 - **Additional research priorities/opportunities in health services, behavioral, dissemination, and outcomes research**

NCORP – Core Elements

- **Community-based organizations with a variety of research capacities linked to the NCI's Clinical Trials Network (NCTN)**
- **Develop and support oncology practices within varied organizational settings as a collaborative network**
- **Engage clinicians, patients within and outside of clinical trials, and organizations**
- **Public-private partnership, including a commitment of management to co-investment**
- **A focus on integrating cancer care disparities, care delivery research, and clinical trials**

NCORP Components

Community Sites

- **NCORP**
 - ✓ Clinical trials (cancer control, prevention, treatment, and post-treatment surveillance)
 - ✓ Support CCDR and cancer disparities research
- **NCORP - Minority and Underserved**
 - ✓ Serve large minority/underserved populations
 - ✓ Commitment to mentor other sites within the NCORP network for enhancing minority/underserved participation in research

Research Bases

- ✓ Research development and infrastructure support

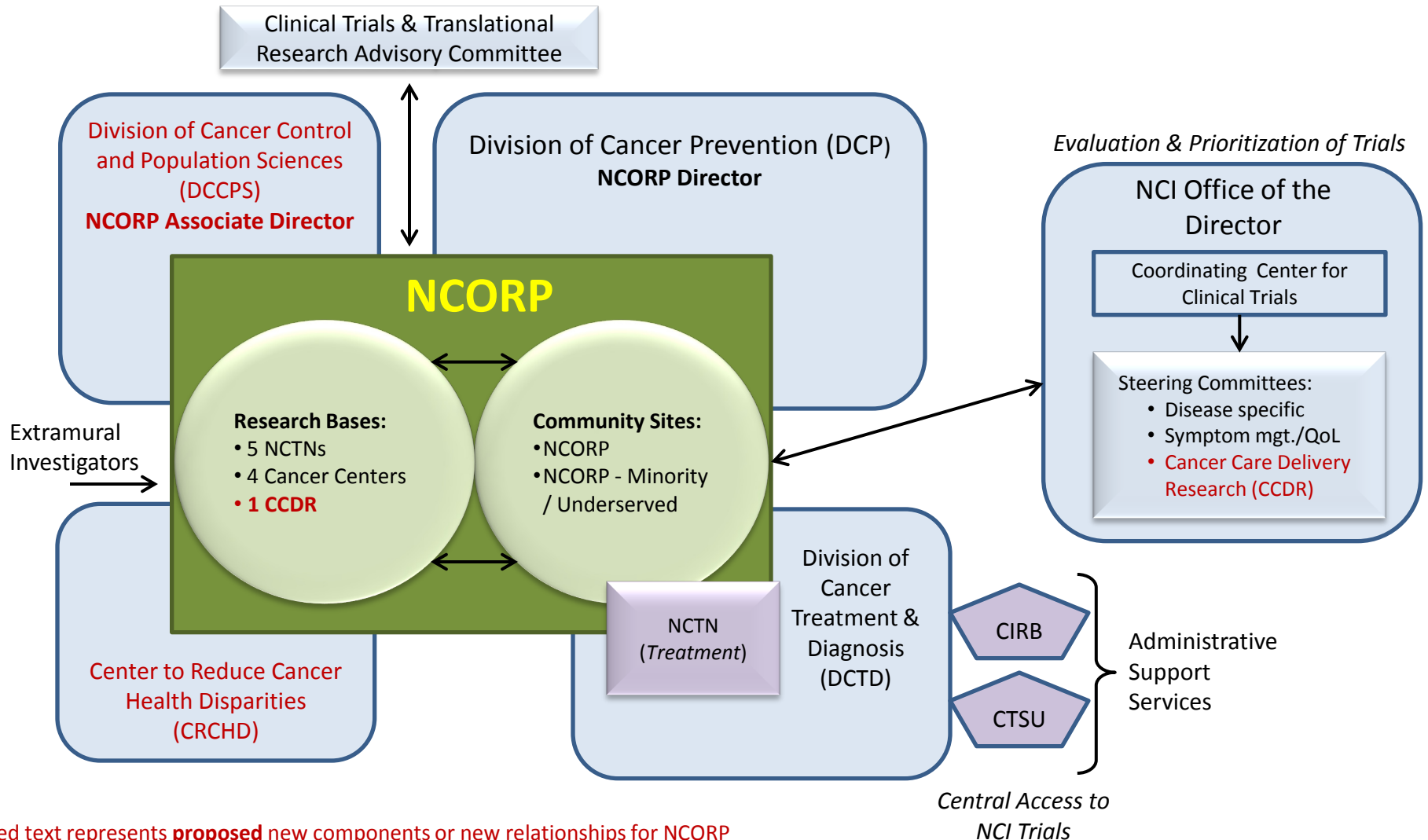
Eligibility for NCORP Community Sites

- **Capacity to participate in cancer research**
 - **Clinical research experience (clinical trial accrual)**
 - **Cancer care delivery research infrastructure**
 - **Available study populations**
 - **Senior leadership/organizational support**

NCORP Proposed Research Structure

- **Housed in the Division of Cancer Prevention (DCP)**
 - Collaborations with DCCPS, DCTD and CRCHD
- **Funding: U-10 Cooperative Agreements for 5 years**
 - Community Sites and Research Bases
- **Organizational Structure for Clinical Trials**
 - NCI-NCI Clinical Trials Network and DCP Research Bases
- **External representation for clinical trials and CCDR on the Clinical Trials and Translational Research Advisory Committee (CTAC)**
- **Organizational Options for CCDR Research**
 1. CCDR integrated into each (or multiple) Research Base/NCI Clinical Trials Network; or
 2. A dedicated CCDR Research Base

NCI's Community Oncology Research Program (NCORP): Structure within NCI



Red text represents **proposed** new components or new relationships for NCORP

CTSU = Cancer Trials Support Unit

CIRB = NCI Central IRB

NCTN = National Clinical Trials Network

NCORP Research Components

Research Bases

- **Research development and infrastructure support**
 - **Cancer Clinical Trials**
 - **Cancer Care Delivery Research**
 - **Cancer Disparities Research**

NCORP Clinical Trials Research Agenda

- **Incorporate emerging science and novel trial designs into treatment, cancer control, prevention, and screening research**
- **Expanded research portfolio:**
 - **Overdiagnosis & underdiagnosis**
 - **Post-treatment surveillance**
 - **Precancerous lesions**
 - **Mechanism of treatment and cancer-related symptoms**
- **Integrate studies to enhance accrual of racial/ethnic and other under-represented populations into clinical trials**

Cancer Care Delivery Research: Definition

- *Cancer care delivery research is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, provider and individual behaviors affect cancer outcomes including:*
 - *access to cancer care*
 - *the quality and cost of cancer care*
 - *ultimately the health and well-being of cancer patients*
- *Its focus includes individuals, families, organizations, institutions, providers, communities, populations and their interactions.*

NCORP Cancer Care Delivery Research Agenda

- **Assure that optimal evidence-based therapies and system supports are available in routine practice**
- **Build the evidence base for how clinical practices and organizational processes & policies improve patient outcomes**
 - **Alternative models for organizing and supporting multi-modality therapy through multidisciplinary treatment programs**
 - **Types of organizational systems and coordination (e.g., hospital-based versus free-standing)**
 - **Alternative patient/family navigation models to improve the coordination and outcomes of cancer care**
 - **Optimal approaches to incorporate patient reported information into practice (e.g., PROs)**
- **Build data capabilities to assess organizational approaches to improve cancer care for the underserved**

Community Training and Resources for Cancer Care Delivery Research

- **CCDR study simulation at local sites**
 - Orient Research staff with expertise in financial, clinical trials, and administration for CCDR
 - Identify the location of data within hospitals and practices
 - Seek agreement from management to access data
 - Identify the technological support to extract and link data with investigators
 - Determine data collection methods to support investigators
- **Training at the Research Base meetings**
- **NCORP Guidelines**

NCORP Cancer Disparities Research Agenda

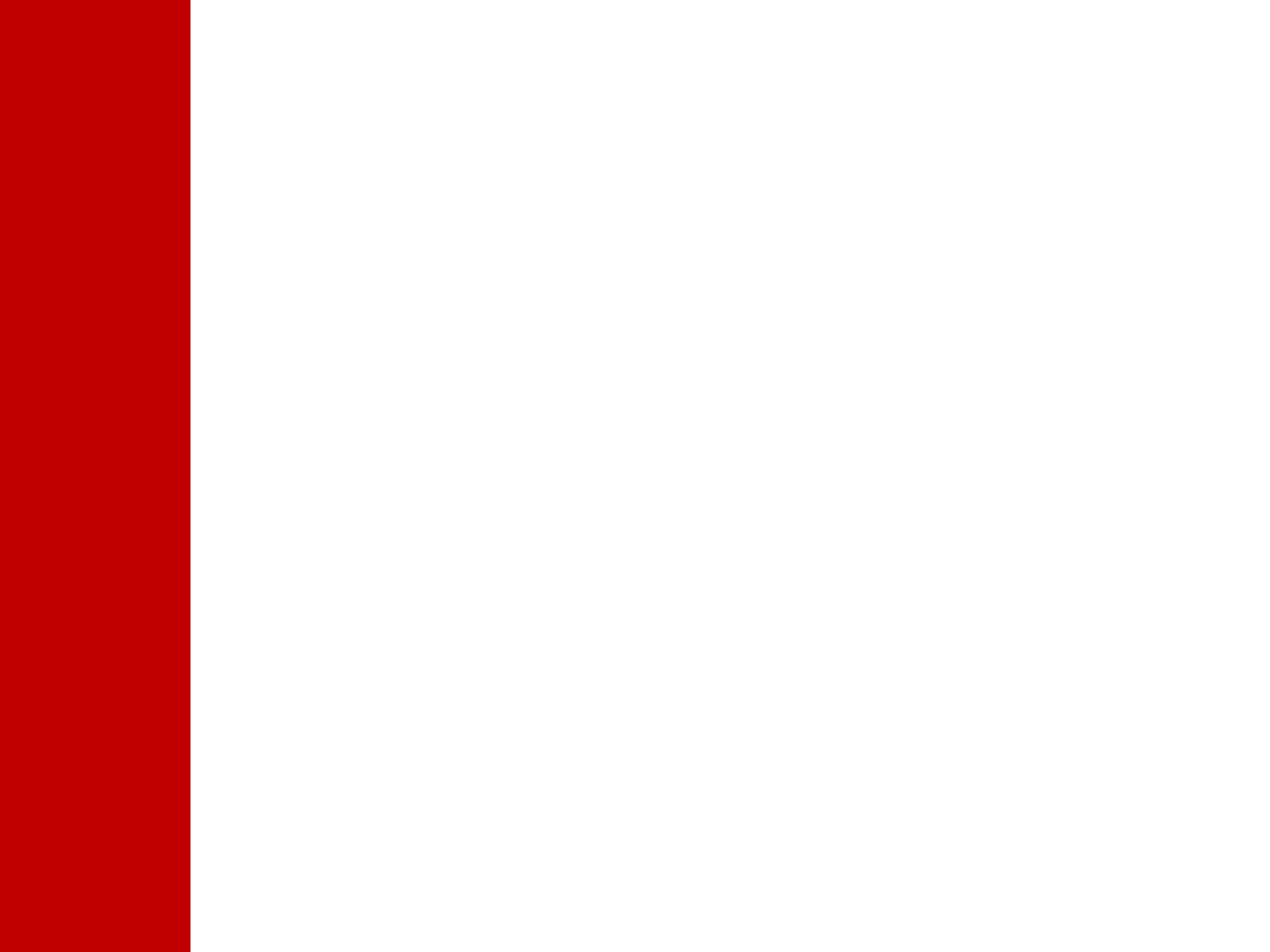
- **Promote participation of underserved populations in clinical trials and cancer care delivery research**
- **Incorporate specific disparities research questions into clinical trials and cancer care delivery research**
 - **Health care system factors**
 - **Health-related quality of life**
 - **Social determinants**
 - **Environment/physical determinants**
 - **Biological factors**
 - **Behavioral factors**
 - **Protective and/or Resiliency factors**
 - **Co-morbidities**
 - **Biospecimen education & collection**

Issues and Challenges

- **Increasing the number of trials on the CTSU**
- **In discussion with DCTD to utilize CIRB for primary review of cancer control/prevention portfolio**
- **Evaluating the infrastructure requirements at the local level for collection and processing of biospecimens**
- **Developing a single portal of entry for institution rostering for the NCTN to improve efficiency of having to roster with multiple Networks**
- **Transitioning to use of NCTN's Oncology Patient Enrollment Network (OPEN).**

NCORP Tentative Timeline

- **A concept for internal NCI review in April 2013 and for NCI Board of Scientific Advisors in June 2013.**
- **Funding Opportunity Announcement for release in the Fall of 2013 with a goal of making awards in 2014.**



NCORP – Current Activities

- **Analysis of programmatic requirements**
- **Analysis of research capacity for CCDR at the site level**
- **Analysis of research capacity and priorities for CCDR at the Research Base level**
- **NIH-wide portfolio analysis for CCDR and cancer disparities**
 - **Funded Grants**
 - **Research Initiatives**
- **Baseline clinical trial accrual requirements**

2013 NCI Sites Map

