NCI’s Evolving Clinical Trials System

NCI Community Oncology Research Program (NCORP)

Clinical Trials & Translational Research Advisory Board
November 12, 2014

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

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

August 25-26, 2014  Research Base CCDR Meeting

September 22, 2014  Welcome NCORP Investigators and Administrators
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
NCORP Community Site, MU Community Site and Research Bases Geographic and Organizational Diversity

Community Sites (34)
- Distributed network (25)
- Integrated System (7)
- Small Networks (2)

MU Community Sites (12)
- Academic (8)
- Non-Academic (4)

Research Bases (7)
- Research Bases
NCORP Network Characteristics

- 842 Components and Subcomponents

- Health Care Systems
  - Kaiser, Essentia, Aurora, Catholic Health Initiatives, Geisinger, Sanford & Nemours

- 7 Merged Community Programs

- 200+ CCDR Components within 46 Programs
## NCORP Clinical Trials and Health-Related Quality of Life Studies

<table>
<thead>
<tr>
<th>Type</th>
<th>Focus</th>
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<tbody>
<tr>
<td>Cancer Prevention</td>
<td>Identify/evaluate interventions to reduce cancer risk and incidence</td>
</tr>
<tr>
<td>Cancer Control</td>
<td>Reduce incidence/co-morbidity of cancer and its treatment, enhance quality of life</td>
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<tr>
<td>Cancer Screening</td>
<td>Evaluate early diagnosis interventions and cancer recurrence</td>
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<tr>
<td>Health-Related Quality of Life</td>
<td>Embedded in NCTN Treatment Trials</td>
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<tr>
<td>Research Base Applicant</td>
<td>Institution (PI)</td>
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<td>Wake Forest U. Health Sciences (Glenn Lesser, James Urbanic)</td>
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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
NCORP

Health-Related Quality of Life Steering Committee

• Co-Chairs
  - Karen Mustian (URCC)
  - Deb Barton (U of Michigan)

• Added Subject Matter Experts
  - Food and Drug Administration
  - Pharmacologist

• New Activities
  - Working group to explore funding for mechanistic studies for symptom management
  - Webinars to focus on design and patient reported outcomes
NCORP Clinical Trials

• 49 clinical trials now active or approved
  - Legacy trials from CCOP network including MDAs/Suncoast
  - Approved & previously on hold trials
  - Actively reviewing new concepts

• Task Forces to advance agenda for treatment or cancer–related toxicities (e.g., cardio-oncology)

• DCP is conducting webinars to introduce DCTD’s precision clinical trials to community sites
NCORP
CCDR Study Types

NCI conceptualizes three major categories of studies:

• **Descriptive observational studies** to document the prevalence and variability of specific cancer care delivery models, approaches and/or processes

• **Analytical observational studies** to understand how the multi-level characteristics of care delivery models, approaches and processes influence quality, outcomes and access

• **Interventional studies**, including RCT designs, to test new models, approaches and/or processes of care delivery to improve quality, outcomes and access.
Cancer Disparities Research

- Expertise from NCI’s Center to Reduce Cancer Disparities
- DCP is the lead for the AACR-ASCO- ACS-NCI Joint Position Statement on Cancer Disparities Research
- Opportunities for Trans-Research Base Collaborations
  - Integration of research questions into clinical trials and cancer care delivery studies
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

<table>
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<tr>
<th>NCORP Component</th>
<th>No. of Sites</th>
<th>Clinical Trials $ Millions</th>
<th>CCDR Funding $Millions</th>
<th>FY 2014 Total</th>
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<tr>
<td><strong>NCORP &amp; NCORP-M/U Sites SUBTOTAL:</strong></td>
<td>46</td>
<td>$42.7</td>
<td>$ 7.5</td>
<td>$50.3</td>
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<tr>
<td>NCORP Research Bases</td>
<td>7</td>
<td>$38.2</td>
<td>$ 4.5</td>
<td>$42.8</td>
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NCORP Supplemental Funding For Accrual

$5.2 M
Cancer Care Delivery Research (CCDR) Planning Meeting
August 25-26, 2014

- **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
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CCDR Coordinating Committee

• Promotes and coordinates cross-NCORP scientific collaboration

• Develops operational procedures for the development, review and implementation of CCDR within NCORP

• Standardizes various aspects of CCDR
  – Data definitions
  – Collection tools and procedures
  – Audit requirements

• Determines data infrastructure to support CCDR
Coordinating Committee Membership

• Co-chairs:
  – Jan Buckner (Mayo Clinic, Alliance)
  – Ruth Carlos (U. Mich., ECOG-ACRIN)
  – Scott Ramsey (Fred Hutchinson Cancer Center, SWOG)

• Two representatives from each Research Base including at least one CCDR expert

• Four NCORP Community Sites representatives

• Three NCORP Minority/Underserved Site representatives

• NCI representatives
NCORP CCDR Steering Committee
Objectives

• Set **strategic scientific priorities** for CCDR in the community-setting, including priorities generated across NCORP collaborations

• Provide rigorous **scientific reviews** for CCDR concepts

• Facilitate the uptake of evidence-based clinical outcomes from clinical trials
  - Dissemination & Implementation Research
  - Accelerate the transition of CCDR studies into practice simultaneously
NCORP
CCDR Steering Committee Membership

• Co-Chairs
  - Paul Godley (UNC Chapel Hill)
  - Brad Pollock (UC Davis and COG)

• NCORP Research Bases
  - 2 representatives per NCORP Research Bases (1 vote/Research Base)

• Subject Matter Experts – up to 8 representatives (vote/Expert)
  - Health Service Research
  - Health Information Technology
  - Health Economist
  - Health Disparities

• NCORP Community Sites – 2 representatives (2 votes)

• Minority/Underserved Community Sites – 2 representatives (1 vote)

• Biostatisticians, Statisticians – 2 representatives (1 vote)

• Patient Advocates – 2 representatives (1 vote)

• NCI Staff (DCCPS, DCP, CRHD) – (3 votes)
Early Next Steps for Cancer Care Delivery Research

- Complete the vetting process for the CCDR scientific Steering Committee
- Begin process for identifying CCDR research priorities and initiating working groups
- Characterize the health care environments and capacities for CCDR across NCORP
How Do Community Investigators Contribute to NCI’s Research Mission?

• Membership on Research Base Scientific Committees

• NCI’s Disease & non-Disease Steering Committees and Task Forces

• Membership on Clinical Trials & Translational Research Advisory Committee

• NCI Advisory Boards Activities (e.g., National Cancer Advisory Board’s Symposium - “NCI’s Evolving Clinical Trials System”)

• Scientific Working Groups (e.g., Natural Experiments to develop research designs in the area of policy change and their effects on care and health outcomes)
Relationship of NCTN and NCORP

NCTN Focus:
- Late-Phase Treatment Trials
- Primary Advanced Imaging Trials

NCORP Focus:
- Cancer Prevention and Control Trials
- Cancer Care Delivery
- Comparative Effectiveness Research

NCTN/NCORP CENTRALIZED FUNCTIONS:
- CTSU, Study Monitoring
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
Thank you!