NCI’s Evolving Clinical Trials System

NCI Community Oncology Research Program (NCORP)

September 9, 2014

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

<table>
<thead>
<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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</thead>
<tbody>
<tr>
<td>NCORP &amp; NCORP-M/U Sites SUBTOTAL:</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

$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

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<th>CCOP Closeout Funding</th>
<th>FY 2014 Funding</th>
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<tr>
<td><strong>Total:</strong> $97.0 Million</td>
<td><strong>Total:</strong> $8.3 Million – Additional FY 2014 NCI Funding</td>
<td><strong>Total:</strong> $4.7 Million</td>
<td><strong>Total:</strong> $109.9 Million</td>
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<td>$2.9 Million – reserved by DCP</td>
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<td>$1.8 Million – Additional FY 2014 NCI Funding</td>
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