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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<td>URCC</td>
<td>University of Rochester (Gary Morrow)</td>
<td>Cancer-related fatigue in the elderly, treated-related cognitive dysfunction</td>
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<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)
<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>
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<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
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

<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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<tbody>
<tr>
<td><strong>NCORP &amp; NCORP-M/U Sites</strong></td>
<td><strong>46</strong></td>
<td><strong>$42.7</strong></td>
<td><strong>$ 7.5</strong></td>
<td><strong>$50.3</strong></td>
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<tr>
<td><strong>SUBTOTAL:</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>NCORP Research Bases</strong></td>
<td><strong>7</strong></td>
<td><strong>$38.2</strong></td>
<td><strong>$ 4.5</strong></td>
<td><strong>$42.8</strong></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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<tr>
<th>CCOP Interim Funding</th>
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<th>CCOP Closeout Funding</th>
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<td><strong>Total:</strong> $4.7 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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<td><strong>Total:</strong> $109.9 Million</td>
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