NCI Community Oncology Research Program (NCORP): Program Evaluation & Planned Modifications to the Reissuance

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NCORP External Evaluation: Today’s Discussion

- Summary of the Evaluation Report
- NCI’s Response to the Evaluation Report
- Proposed Modifications to the Program
NCI Community Oncology Research Program

• Launched in 2014

• Community-based research network to bring state of the art trials and studies to individuals in their own communities

   Clinical trials in prevention, symptom science, screening, surveillance, and QOL in treatment trials

   Accrual to National Clinical Trials Network (NCTN) treatment and imaging trials

   Cancer care delivery to develop clinical practices that achieve optimal clinical outcomes

   Cancer disparities research questions integrated into clinical trials and cancer care delivery research
NCORP Community Site, M/U Community Site and Research Bases Geographic and Organizational Diversity

 Investigators (4,025)
 Components/Subcomponents (938)

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

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

 Research Bases (7)
 - Research Bases

Updated: May 2017
Purpose of NCORP Evaluation

NCI requires an external evaluation as part of the funding opportunity renewal concept review package

✓ Assess whether the scientific contributions of NCORP support reissuance of the funding opportunity

✓ Develop recommendations for enhancing the scientific and operational functioning of this community-based research program
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Howard Bailey, MD
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Case Western Reserve University
University of North Carolina
Indiana University Cancer Center
Dana Farber Cancer Institute
Henry Ford Health System
FDA
In My Sister’s Care
1. Overall Scientific & Clinical Value and Impact

The Evaluation Committee concluded that NCORP has made important contributions in terms of scientific and clinical value and impact.

• Advancing symptom science and quality-of-life research
• Stimulating cancer prevention & screening
• Introducing the science of overdiagnosis
• Contributing to NCTN trials
• Stimulating new cancer disparities research initiatives
1. Overall Scientific & Clinical Value and Impact

Response(s) to Recommendations/Plans for Reissuance

- To Focus on Symptom Science Steering Committee priorities:
  7 Cardiovascular Toxicity; 5 Cognitive Impairment; 1 Fatigue; 2 Cancer Specific Pain; 1 Steering Committee Planning Meeting for peripheral neuropathy

- To evaluate the mechanistic basis of symptoms:
  Program will request funding for correlative sciences and biobanks to support symptom science to better understand the mechanistic basis of symptoms
2. Infrastructure Support of Research Portfolio

The Evaluation Committee concluded that the infrastructure (Community Sites, Minority Underserved Sites, and Research Bases) and the NCI infrastructure adequately support the research portfolio.

- Network reflects the spectrum of health care environments in the United States

- Strong accrual to treatment and imaging trials, as well as cancer control and prevention.
  - Accruals between 2014 and 2016 are a testament to the successful accrual efforts of the network.

- Other infrastructure changes identified to advance the research agenda include the CIRB, Radiation Oncology Working Group, Early Onset Malignancy Initiative
NCORP and Non-NCORP

Enrollment to Cancer Control Trials

- 2014: 1866 NCORP (43%) and 2399 Non-NCORP
- 2015: 1769 NCORP (39%) and 2736 Non-NCORP
- 2016 - 6 months: 655 NCORP and 1331 Non-NCORP

49% of patients enrolled in NCORP and 49% in Non-NCORP.
NCORP and Non-NCORP

Enrollment to Treatment Trials

- **2014**
  - NCORP: 3920 (25%)
  - Non-NCORP: 11608

- **2015**
  - NCORP: 4403 (28%)
  - Non-NCORP: 11283

- **2016 - 6 months**
  - NCORP: 3053 (45%)
  - Non-NCORP: 6813
2. Infrastructure Support of Research Portfolio

Response(s) to Recommendations/Plans for Reissuance

• Expand cancer care delivery research infrastructure at the Sites:
  ➢ Program will request increased funding implementation & site infrastructure CCDR

• Optimize advocates/community members across the network:
  ➢ NCI will promote this engagement at the Site, Group, and national level

• Increase minority/underrepresentation from Community Sites:
  ➢ Trans-Group concept development, trials to address research questions for underrepresented populations, and partnerships e.g., Center to Reduce Cancer Health Disparities

• Provide Support in the transition from large adjuvant trials to new molecularly targeted and precision trials
  ➢ Program is reviewing information about best practices and strategies to sustain them
3. Efficiency of Study Development and Accrual

The Evaluation Committee identified strengths in study development and accrual.

• 51 concepts were submitted (cancer control/prevention) over 32 months with a 55 percent approval rate

• 31 studies activated since August 2014 with 23 pending activation

• An increase (6,319 to 8,768) in accrual credits between 2014-2016

• NCORP contribution to NCTN trials is 25-30 percent

• NCORP enrolled 44 percent of MATCH patients registered for screening
Examples of Trials Activated & Completed During NCORP Cancer Control & Prevention

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Title</th>
<th>Activation date</th>
<th>Accrual Cut Off Date</th>
<th>Planned Accrual</th>
<th>Actual Accrual</th>
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</thead>
<tbody>
<tr>
<td>A221303</td>
<td>Randomized Study of Early Palliative Care Integrated with Standard Oncology Care Versus Standard Oncology Care Alone in Patients with Incurable Lung or Non-Colorectal Gastrointestinal Malignancies</td>
<td>5/15/2015</td>
<td>4/10/2017</td>
<td>400</td>
<td>405</td>
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<tr>
<td>E4112</td>
<td>Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma In Situ (DCIS)</td>
<td>2/17/2015</td>
<td>4/28/2016</td>
<td>350</td>
<td>368</td>
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<tr>
<td>NRG-CC002</td>
<td>Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women with Gynecologic Cancers</td>
<td>2/10/2015</td>
<td>11/2/2015</td>
<td>228</td>
<td>190</td>
</tr>
<tr>
<td>URCC-13070</td>
<td>Improving Communication for Cancer Treatment: Addressing Concerns of Older Cancer Patients and Caregivers</td>
<td>10/29/2014</td>
<td>4/30/2017</td>
<td>1056</td>
<td>973</td>
</tr>
</tbody>
</table>
3. Efficiency of Study Development and Accrual

Response(s) to Recommendations/Plans for Reissuance

• Research Bases and NCI should identify ways to expedite the timeline for trial and study development; collaborate in monitoring timelines for development and activation of studies; tracking actual vs. accrual rates for trials; and assessing barriers

  ➢ NCI has formed a Working Group to assess the variations in timelines and review processes, and to establish guidelines & stopping rules for the heterogeneous research portfolio within NCORP

  ➢ NCI has a Screening Log to capture number of individuals screened per trial

  ➢ Program proposes increased funding for screening and enrollment activities
4. Collaboration

The Evaluation Committee identified several indicators of collaboration, including across-Research Bases and external collaborations.

The Working Group noted evidence of active Community Site & Minority/Underserved Site participation in Research Base committees, NCORP Working Groups and other NCI initiatives.
4. Collaboration

Response to Recommendations (s)/Plans for Reissuance

• NCORP plans to continue to promote trans-Research Base research, e.g., AYA, elderly, in the development of screening and surveillance studies

• The NCORP Working Groups are designed to work together with experts to serve as champions for NCORP research, partner with respective professional societies, and to prospectively address barriers to enrollment

• Several ongoing collaborations exist with other organizations, e.g., PCORI, ASCO, AACR, International Research Groups, and other NIH Institutes
5. Cancer Care Delivery Research

The Evaluation Committee noted the NCORP offers clear advantages for the conduct of cancer care delivery studies, and the network serves as a microcosm of the larger health care delivery environment.
5. Cancer Care Delivery Research

Response to Recommendations (s)/Plans for Reissuance

- NCORP should expand the participation of community oncologists, primary care physicians and chief operating officers in Study design:
  - CCDR Landscape Assessments, sites have engaged new stakeholders (including COO, CEO) in CCDR work, and the CCDR subcommittees at the Research Bases are continuing the conversations as the studies are developed.
  - NCORP should explore opportunities for CCDR studies in payer, utilization, and big data.
Continuum of Care Delivery Research

- Hypothesis-generating
- Existing NCI portfolio
- Less familiar to NCORP Sites

- Patient, clinician & organizational factors
- Expanding NCI portfolio
- Increasingly familiar to NCORP Sites

- Intervene on patients, clinicians & organizations
- Gap in NCI portfolio
- Unique strength of NCORP Sites

- Policies that support delivery of high value care
- Contextual factor in NCI grants
- Challenging methods
- Natural experiments
# Examples of Qualified Scientists

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
<th>NCORP CCDR Role</th>
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</thead>
<tbody>
<tr>
<td>Patricia Ganz, M.D.</td>
<td>Univ. of California Los Angeles</td>
<td>CCDR Steering Committee</td>
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<td></td>
<td>NRG CCDR Committee</td>
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<tr>
<td>Scott Ramsey, M.D., Ph.D</td>
<td>Fred Hutchinson Cancer Research Center</td>
<td>CCDR Steering Committee</td>
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<tr>
<td></td>
<td></td>
<td>Co-chair Coordinating Committee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SWOG CCDR Committee Co-chair</td>
</tr>
<tr>
<td>Dawn Hershman, M.S., M.D.</td>
<td>Columbia Univ.</td>
<td>CCDR Steering Committee</td>
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<tr>
<td></td>
<td></td>
<td>Coordinating Committee member</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SWOG CCDR Committee Co-chair</td>
</tr>
<tr>
<td>Brad Pollock, M.P.H, M.D.</td>
<td>Univ. of California, Davis</td>
<td>CCDR Steering Committee</td>
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<tr>
<td></td>
<td></td>
<td>co-chair COG PI</td>
</tr>
<tr>
<td>Ethan Basch, M.S., M.D.</td>
<td>Univ. of North Carolina, Chapel Hill</td>
<td>CCDR Steering Committee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Alliance CCDR Committee co-chair</td>
</tr>
<tr>
<td>Kathryn Weaver, Ph.D</td>
<td>Wake Forest Univ.</td>
<td>CCDR Landscape Assessment Lead</td>
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<tr>
<td></td>
<td></td>
<td>CCDR Steering Committee</td>
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<tr>
<td></td>
<td></td>
<td>Coordinating Committee Member</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wake Forest CCDR Lead</td>
</tr>
<tr>
<td>Supriya Mohile, M.S., M.D.</td>
<td>Univ. of Rochester</td>
<td>Coordinating Committee member</td>
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<td>URCC CCDR lead</td>
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Overall Recommendation

The NCORN External Evaluation Committee Recommends that NCI Proceed with the NCORB RFA Reissuance
Process for Seeking Input for RFA Reissuance

- NCORP Community and M/U Community Sites
- NCTN Groups NCORP Research Bases
- NCI Divisions and Centers
- Specialty & Non-Specialty Experts
- Advocacy Groups
- ASCO
- FDA
- CMS

NCORP
NCORP: Future Directions

- Ongoing: TMIST and its associated biorepository
- Surveillance: colon cancer screening surveillance, pancreatic cyst progression
- Cancer Prevention: topical applications, e.g., breast, HPV dose scheduling, and utilization in pediatric cancer survivors
- PreCancer Atlas: molecular characterization of preneoplastic lesions
- Symptom Science: assess immunotherapy-related toxicities
- NCORP Expansion: capture underrepresented geographical areas
Potential Topics for Cancer Care Delivery
Randomized Clinical Trials

Implementation

• Early Palliative care (15% survival improvement at one year)
• Telehealth (<1/3 of CCDR practices report using it for care)
• Any type of DNA sequencing (< ¼ of CCDR practices report routine use)

De-implementation

• Contralateral prophylactic mastectomy (no survival benefit yet use >10%)
• Use of serum tumor markers for breast cancer surveillance (no survival benefit yet use >20%)

Intervene on financial toxicity (bankruptcy associated with 50% decreased survival)

Questions!