NCI Community Oncology Research Program (NCORP)

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Today’s Discussion

• Overview of NCORP
• External Program Evaluation
• Highlights of NCORP Research Activities
• Cancer Prevention Steering Committee
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 research** on patient-provider and organization-level influences on cancer outcomes

  - **Cancer disparities research questions integrated** into clinical trials and cancer care delivery research
2-Year NCORP Overview
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
Snapshots of NCORP: Year 2

- SxQOL SC: Integrated Biomarkers BIQSFP Initiatives
- Participation in Tissue Acquisition studies for Preclinical Models
- Enrollment in NCTN Precision Medicine Initiative
- CIRB for CC/P, CCDR (adults & pediatrics), Veterans Administration
- Reinvigoration of Cancer Prevention Research
- NCORP represented in the Moonshot Initiative
External Review Process
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
<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Robin Zon, MD</td>
<td>Memorial Hospital, South Bend, IN</td>
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<td>Howard Bailey, MD</td>
<td>University of Wisconsin Cancer Center</td>
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<td>Joanna Brell, MD</td>
<td>Case Western Reserve University</td>
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<td>Arnold Kaluzny, MD</td>
<td>University of North Carolina</td>
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<td>Patrick Loehrer, MD</td>
<td>Indiana University Cancer Center</td>
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<td>Nikhil Munshi, MD</td>
<td>Dana Farber Cancer Institute</td>
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<td>Lisa Newman, MD</td>
<td>Henry Ford Health System</td>
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<td>Gregory Reaman, MD</td>
<td>FDA</td>
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<td>Mary Jackson Scroggins, Advocate</td>
<td>In My Sister’s Care</td>
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Timeline for NCORP Evaluation Committee

May 30, 2017  Orientation Call
              Assignment of Questions

June 16, 2017  Begin the Review of Questions

July 10, 2017  Face-to-Face Meeting

July 12, 2017  Update Clinical Trials Advisory Committee on NCORP Evaluation Process
RFA Reissuance Timeline Estimate

CTROC: 8/2017
SPL: 9/2017
CTAC: 11/2017
BSA: 12/2017
RFAs Issued: 3/2018
Applications Due: 6/2018
Peer Review: 8-10/2018
NCAB 2nd Level Review: 1/2019
Grants Awarded: 8/2019
Major New NCORP Activities: Examples

- TMIST Trial
- New Onset Diabetes Cohort Study
- Early Onset Malignancy Initiative
ECOG/ACRIN 1151: Tomosynthesis Mammographic Imaging Screening Trial (TMIST)
Background

- 66 percent of women aged 40 and older received a mammogram within the preceding 2 years*

- Tomosynthesis is an x-ray technique in which the detector follows an arch, reconstructing a series of thin images
  - This minimizes the overlap of structures in 2D
  - Preliminary evidence of increased sensitivity, lower recall rates

* Use of mammography among women aged 40 and over, by selected characteristics: United States, selected years 1987-2013 (http://www.cdc.gov/nchs/data/hus/2015/070.pdf)
Should Tomosynthesis Replace Digital Mammography for Breast Cancer Screening?
Primary Aim

To determine whether the cumulative rate of advanced breast cancer in women undergoing screening with tomosynthesis + digital mammography is reduced compared to digital mammography alone.

Definition of Advanced Breast Cancer

Any cancer diagnosed in the 4.5 years after study entry that meets at least one of the following criteria:

- Metastatic disease
- Positive Lymph Nodes
- ER+ and/or PR+, HER2- and over 20 mm in size
- ER- and PR- and HER2-, or HER2+ and over 10 mm in size
Secondary Aims

• Comparisons between digital mammography with/without tomosynthesis:
  ✓ Imaging performance and technical metrics
  ✓ Recall, biopsy and interval cancer rates
  ✓ Breast cancer recurrence and cancer specific mortality
  ✓ Differences in genetic markers for cancers diagnosed
  ✓ Health utilization and costs

• Subset exploratory analyses will be performed for study aims, e.g., age, density, risk, etc.
Screening Intervals

**Premenopausal Women** Ages 45 and older
- Annual at Baseline, 12, 24, 36 & 48 months

**Menopausal Women**
- Biennial if no risk factors (Baseline, 24 & 48 months)
- Annual at Baseline, 12, 24, 36 & 48 months:
  - If they have any of these 3 risk factors: dense breast (BI-RADS 3 or 4), use hormone replacement therapy, or have a family history of breast care OR
  - If they are age 70-74 and have either dense breast (BI-RADS 3 or 4) OR are on hormones
TMIST National Biorepository Resource

- Clinically annotated in a well-characterized cohort
- Tissue (benign, premalignant and malignant) and blood
Activated on July 6, 2017

Over 90 sites are committed to participate in the trial
Cancer Prevention
New-Onset Diabetes (NOD) Cohort Study

• Collaboration with the Chronic Pancreatitis, Diabetes and Pancreatic Cancer Consortium

• New-onset Diabetes: Background
  o Age 50-85 with evaluated risk of pancreatic ductal adenocarcinoma
  o 6-8 Fold higher risk of PDAC within 3 yrs of developing diabetes
  o 25-40% of PDAC patients develop diabetes between 6-24 months prior to PDAC diagnosis
New-Onset Diabetes (NOD) Cohort Size and Estimated PDAC Cases

• **Goals:**
  o Identify and follow a large cohort
  o Develop a biorepository
  o Clinically validate promising biomarkers of PDAC
  o Develop an early detection protocol for sporadic PDAC

• **Planned enrollment:** 10,000 new-onset diabetes patients

• **Planned enrollment from NCORP:** 6,000

• **Estimated number of PDAC cases:** 85 (over 3 year follow up)
Cancer Disparities
Early Onset Malignancy Initiative (EOMI) Background: Priority Opportunity Area

- Increasing awareness in the clinical and scientific communities of early age onset cancers
- A need for prospective genomic data from under-represented populations that is clinically annotated
EOMI: Research Objectives

• Discover mechanisms for early onset cancer
  o Genetic Susceptibility/predisposition?
  o Somatic mutations drivers?

• Determine if there is genetic variation between/among demographic groups

• Identify rare genetic variants that drive differences

• Identify lifestyle, environmental exposures, and behavioral risk factors that impact outcome

• Use information to better understand risk factors, treatment options, and prognosis
### EOMI: Eligibility Newly Diagnosed Patients

<table>
<thead>
<tr>
<th>Cancer Sites</th>
<th>Age Cut Offs</th>
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<tr>
<td>Breast</td>
<td>≤45</td>
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<tr>
<td>Colorectal</td>
<td>≤45</td>
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<tr>
<td>Liver</td>
<td>≤55</td>
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<tr>
<td>Multiple Myeloma</td>
<td>≤50</td>
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<tr>
<td>Prostate</td>
<td>≤55</td>
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<tr>
<td>Renal*</td>
<td>≤50</td>
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**Populations:**
- African-American, Caucasian, Hispanic, Native American
- *Renal in Native Americans Only*
The Prevention Think Tank considered opportunities including:

a) What research might offer the highest return on investment

b) The concept of precision prevention

c) Possible targets for prevention
Formation of a Cancer Prevention Steering Committee
(Cancer Prevention, Screening and Surveillance)

Rationale:

• A cancer prevention Steering Committee would provide consistent and rigorous scientific reviews of NCORP prevention concepts

• Cancer prevention is a dedicated discipline with its own methodology

• DCP should embrace new technology available to cancer prevention and drive new research opportunities within NCORP

• Currently cancer prevention expertise is inadequate in the disease-specific Steering Committees
  ▶ Ad-Hoc cancer prevention experts added to existing committees, are unable to vote

• DCP expects an increase in cancer prevention concepts and protocols from NCORP Research Bases
Questions!