

# *NCI Community Oncology Research Program (NCORP)*

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Division of Cancer Prevention*



# Today's Discussion

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- **Overview of NCORP**
- **External Program Evaluation**
- **Highlights of NCORP Research Activities**
- **Cancer Prevention Steering Committee**

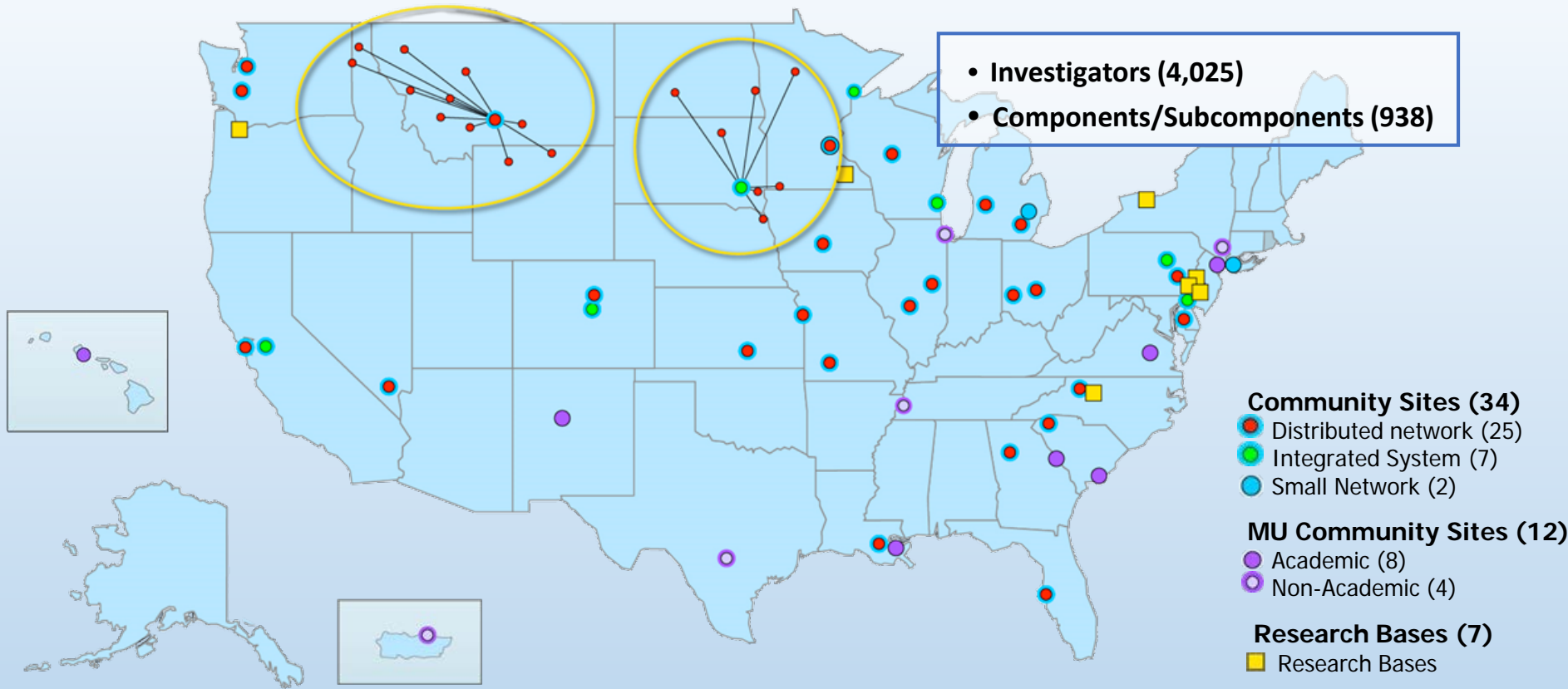
# NCI Community Oncology Research Program

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- **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



Updated: May 2017

# Snapshots of NCORP: Year 2

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**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

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**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**



# NCORP Evaluation Committee

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**Robin Zon, MD - Chair**

Howard Bailey, MD

Joanna Brell, MD

Arnold Kaluzny, MD

**Patrick Loehrer, MD**

**Nikhil Munshi, MD**

Lisa Newman, MD

**Gregory Reaman, MD**

Mary Jackson Scroggins, Advocate

**Memorial Hospital, South Bend, IN**

University of Wisconsin Cancer Center

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

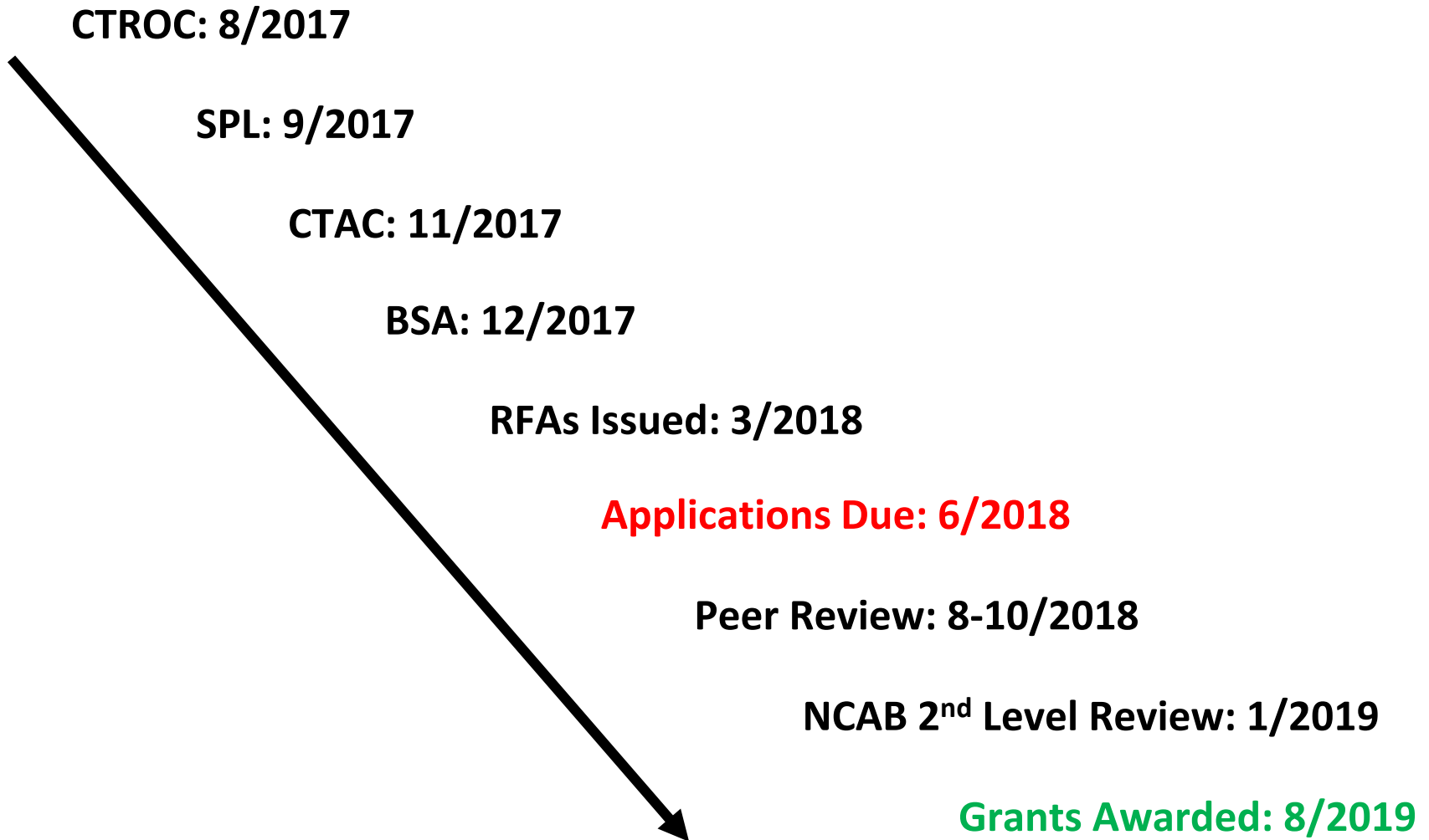
# Timeline for NCORP Evaluation Committee

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<b>May 30, 2017</b>	<b>Orientation Call Assignment of Questions</b>
<b>June 16, 2017</b>	<b>Begin the Review of Questions</b>
<b>July 10, 2017</b>	<b>Face-to-Face Meeting</b>
<b>July 12, 2017</b>	<b>Update Clinical Trials Advisory Committee on NCORP Evaluation Process</b>

# RFA Reissuance Timeline Estimate

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## **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)**

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# Background

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- **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?

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# Primary Aim

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**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

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- **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

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## **Premenopausal Women** Ages 45 and older

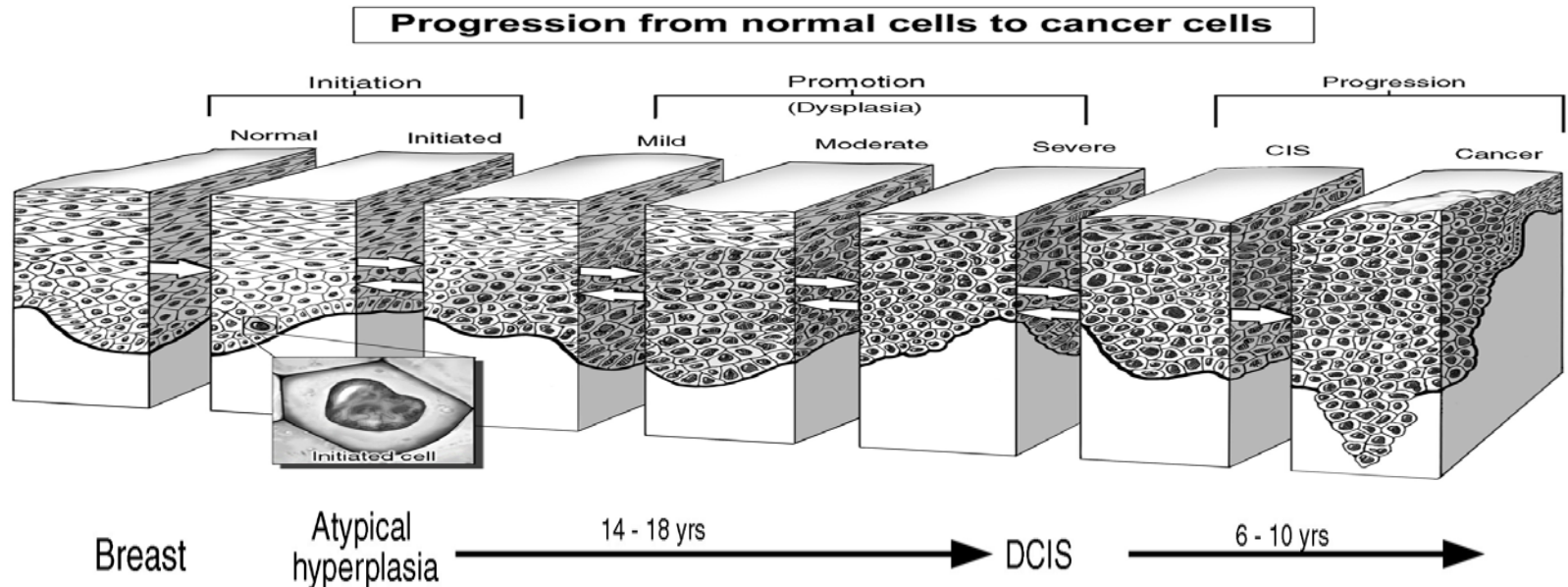
- Annual at Baseline, 12, 24, 36 & 48 months

## **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 cancer 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



# TMIST Timeline

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- **Activated on July 6, 2017**
- **Over 90 sites are committed to participate in the trial**

# ***Cancer Prevention***

# **New-Onset Diabetes (NOD) Cohort Study**

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- **Collaboration with the Chronic Pancreatitis, Diabetes and Pancreatic Cancer Consortium**
- **New-onset Diabetes: Background**
  - **Age 50-85 with evaluated risk of pancreatic ductal adenocarcinoma**
  - **6-8 Fold higher risk of PDAC within 3 yrs of developing diabetes**
  - **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**

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- **Goals:**
  - Identify and follow a large cohort
  - Develop a biorepository
  - Clinically validate promising biomarkers of PDAC
  - 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**

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- **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

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- **Discover mechanisms for early onset cancer**
  - Genetic Susceptibility/predisposition?
  - 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

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Cancer Sites	Age Cut Offs
Breast	≤45
Colorectal	≤45
Liver	≤55
Multiple Myeloma	≤50
Prostate	≤55
Renal*	≤50

**Populations:**

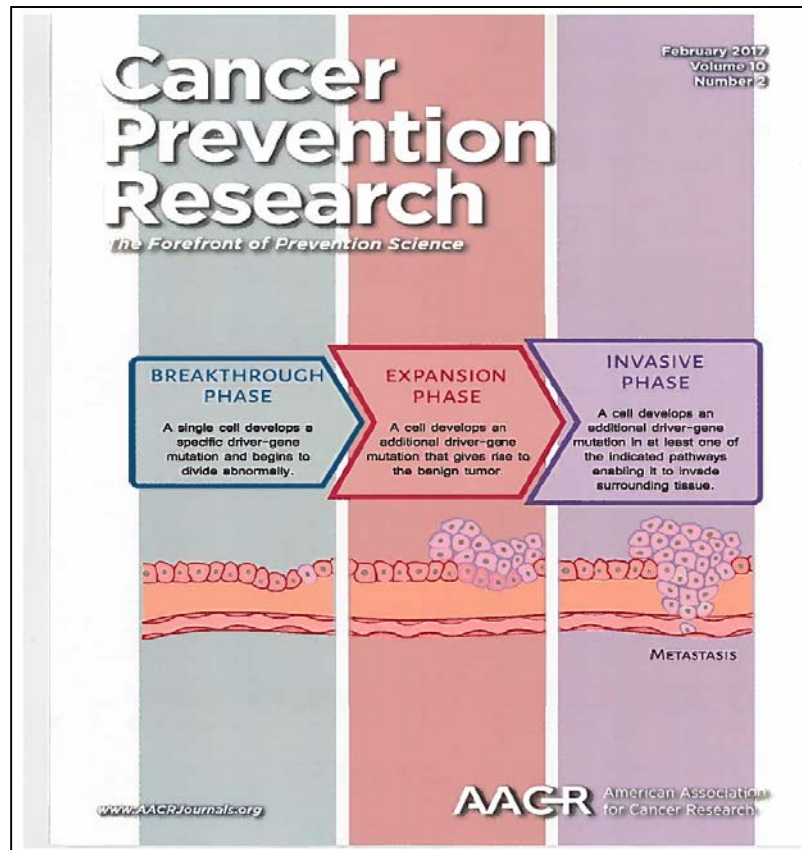
**African-American, Caucasian, Hispanic, Native American**

**\*Renal in Native Americans Only**

# Identifying and Creating the Next Generation of Community-Based Cancer Prevention Studies: Summary of a National Cancer Institute Think Tank

Worta McCaskill-Stevens, Deborah C. Pearson, Barnett S. Kramer,  
Leslie G. Ford and Scott M. Lippman

Cancer Prev Res February 1 2017 10 (2) 99-107; DOI:10.1158/1940-6207.CAPR-16-0230



The Prevention Think Tank considered opportunities including:

- What research might offer the highest return on investment
- The concept of precision prevention
- 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!***