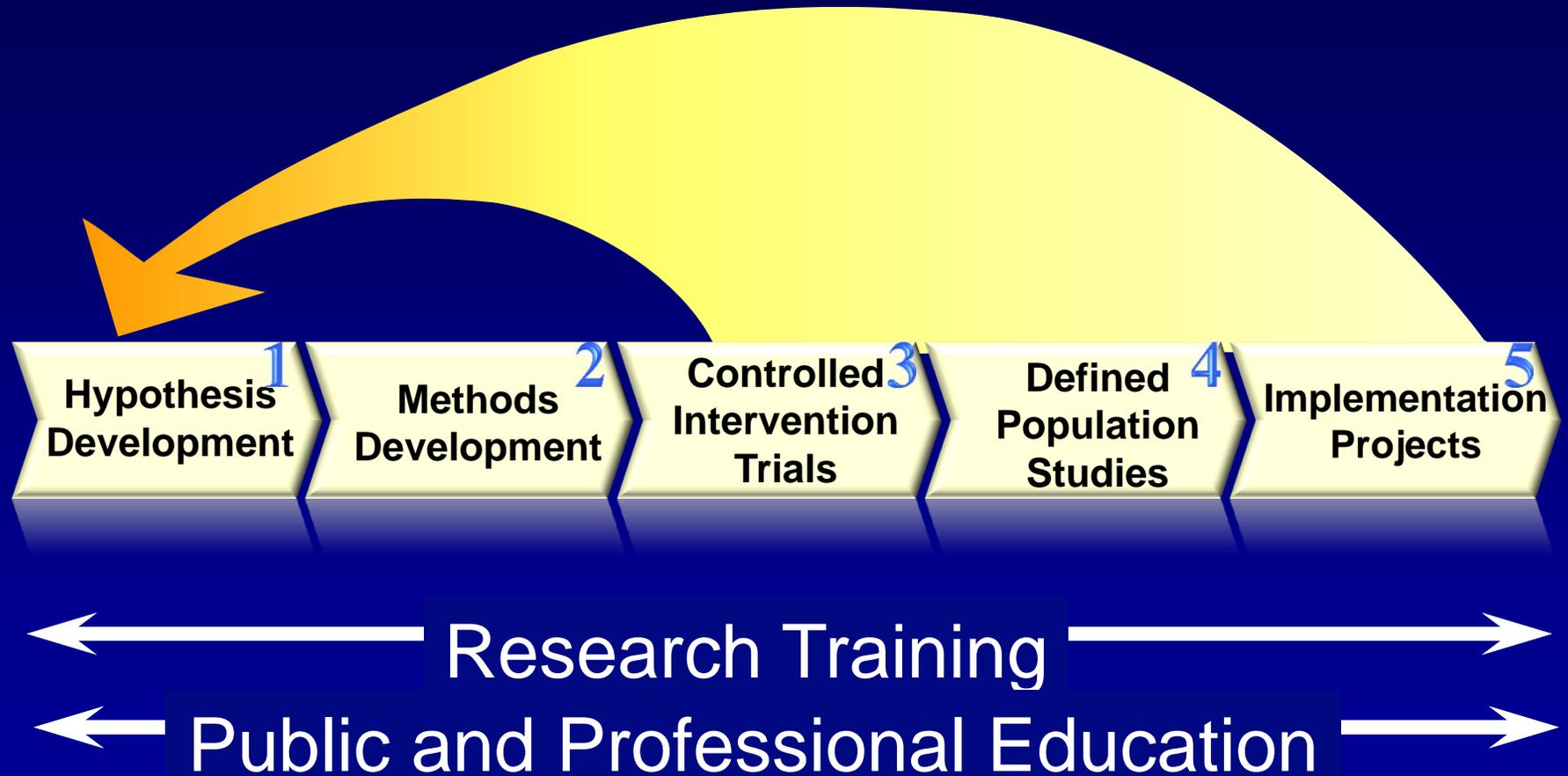


Current and Future Perspectives on Cancer Prevention Research

National Cancer Advisory Board
February 2012

Barry Kramer, M.D., M.P.H.
Director
Division of Cancer Prevention
National Cancer Institute

Phases of the Cancer Prevention Research Continuum



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**Gastrointestinal &
Other Cancer**
Asad Umar, DVM,
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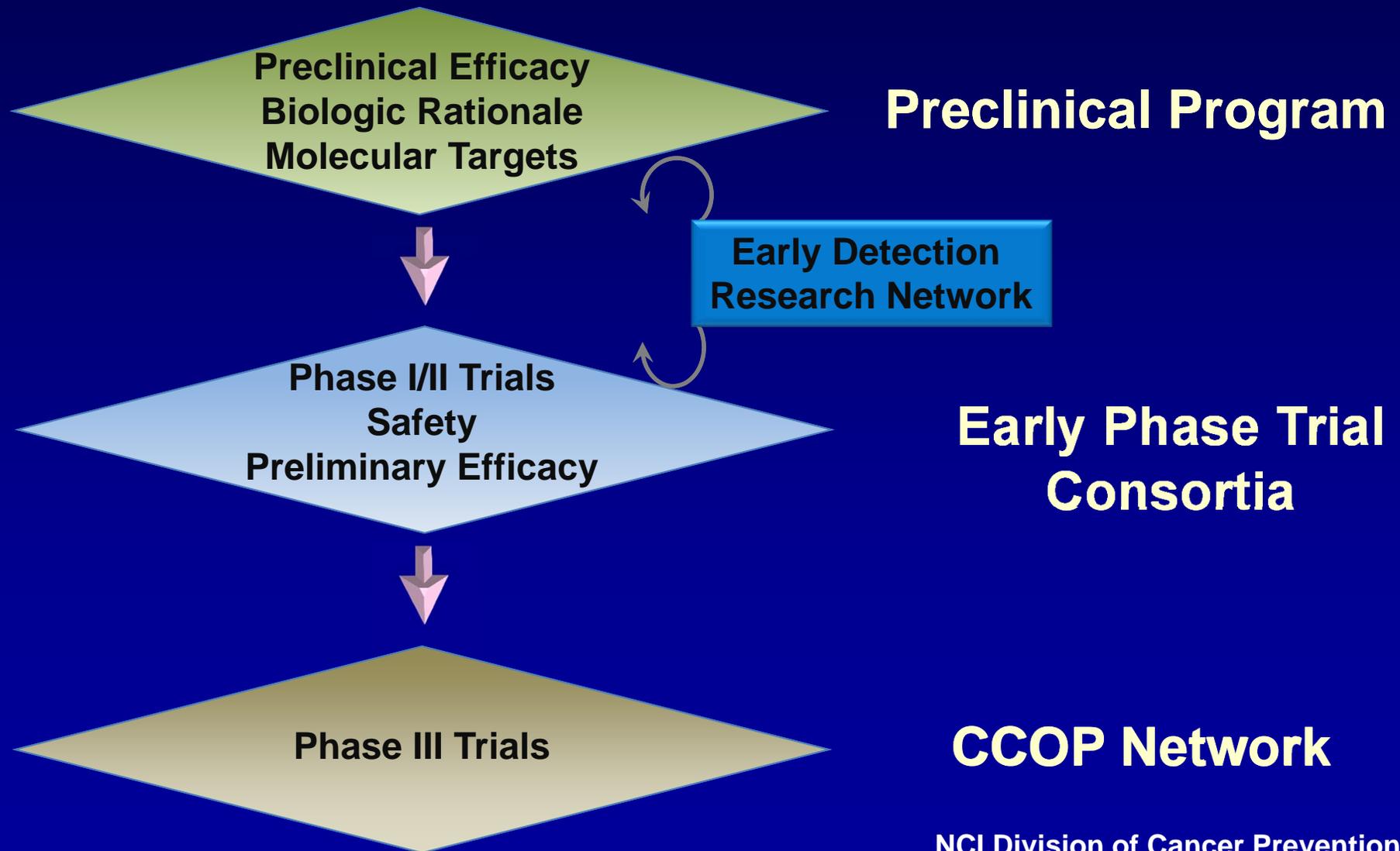
**Cancer Prevention
Fellowship Program**

David Nelson, MD
Chief

**Lung & Upper
Aerodigestive
Cancer**
Eva Szabo, MD
Chief

**Prostate & Urologic
Cancer**
Howard Parnes, MD
Chief

Example of the Cancer Prevention Continuum



Major Accomplishments

- **Breast Cancer Prevention**
 - Breast Cancer Prevention Trial (tamoxifen) (BCPT)
 - Study of Tamoxifen and Raloxifene (STAR)
- **Prostate Cancer Prevention**
 - Prostate Cancer Prevention Trial (finasteride) (PCPT)
 - Selenium and Vitamin E Cancer Prevention Trial (SELECT)
- **Cancer Screening Trials**
 - Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO)
 - National Lung Screening Trial (NLST)

All have biorepositories in use for hypothesis testing.

Future Scientific Directions

- **Agent Development and Decision Making**
- **Overdiagnosis and Precancerous Lesions**
- **Cancer Immunoprevention**
- **Role of Microbiota**
- **New Approaches to Clinical Prevention Studies**

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Agent Development and Decision-Making (1)

- **Development of Promising Agents Based on Clinical Need**
- **Transparent Agent Review & Prioritization Process**
PREVENT Cancer Program, modeled after DCTD's NExT Program
 - External Steering Panel (Leaders from Academia and Pharma)
 - External Special Emphasis Panel (Review)
 - Management & Administration Committee (DCP & DCTD experts)
- **Preclinical Drug Development**
 - Predetermined Decision Gates (Go/No-Go)
 - Hand-off to Early Phase Clinical Development

Agent Development and Decision-Making (2): Making Better Decisions About Agents

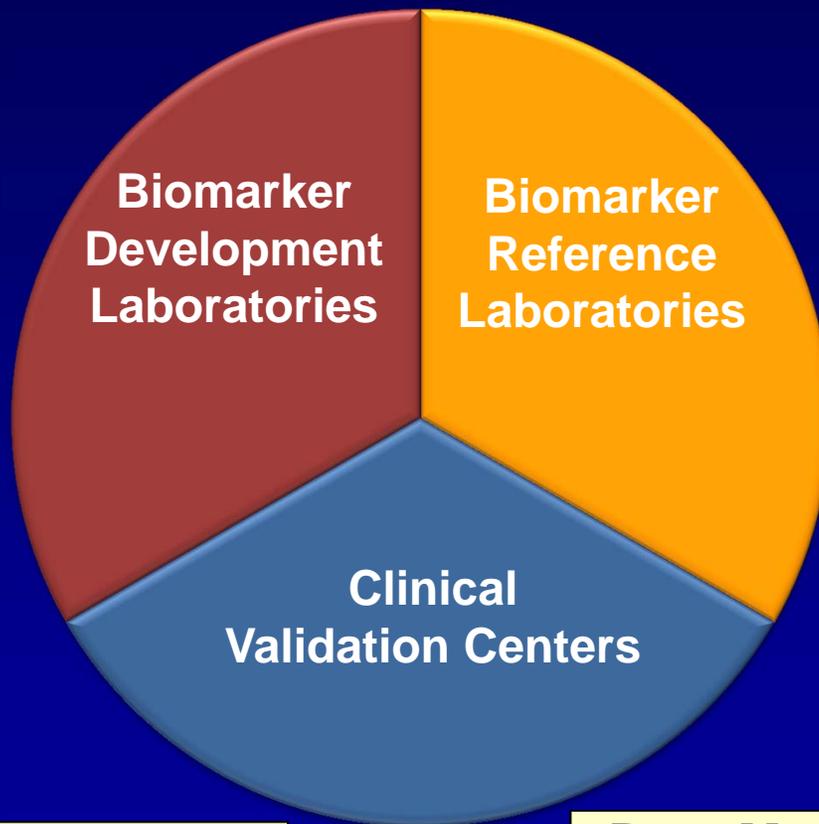
- **Determine Which Preclinical Models Predict Clinical Outcome (Positive & Negative Predictive Values)**
 - **Evaluate Efficacy of Cancer Preventive Agent Development in Preclinical Models in Relation to Clinical Data**
- **Back Validate Successful Clinical Trials in Collaboration with DCB's Mouse Models for Human Cancers Consortium (MMHCC)**
 - **DCP participates in MMHCC Prevention Subcommittee (DCB)**

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Overdiagnosis and Precancerous Lesions (1): Early Detection Research Network

Network Consulting Team



**Steering
Committee**



**Data Management
& Coordinating
Center**

- ◆ Biomarkers developed & tested for pancreatic, lung, prostate, ovary & liver cancers (>300)
- ◆ 8 Validation studies in progress; 4 FDA-approved markers
- ◆ Standard Reference Samples (serum & plasma) to test emerging biomarkers
- ◆ Collaborations
- ◆ Biomarker Database
- ◆ Biomarker plus Imaging Studies (DCTD)

Overdiagnosis and Precancerous Lesions (2): Molecular Characterization of Preclinical Lesions

- **Molecular Characterization of Overdiagnosis & True Interval Cancers from Existing Screening Programs**
- **Overdiagnosis & Interval Cancers Think Tank**
- **Barrett's Esophagus Translational Research Network (BETRNet) (DCB)**
- **Proposed: The Genome Atlas for preCancers (TGAC) (DCB)**
 - **Risk Stratification**
 - **Driver Mutations**

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Cancer Immunoprevention

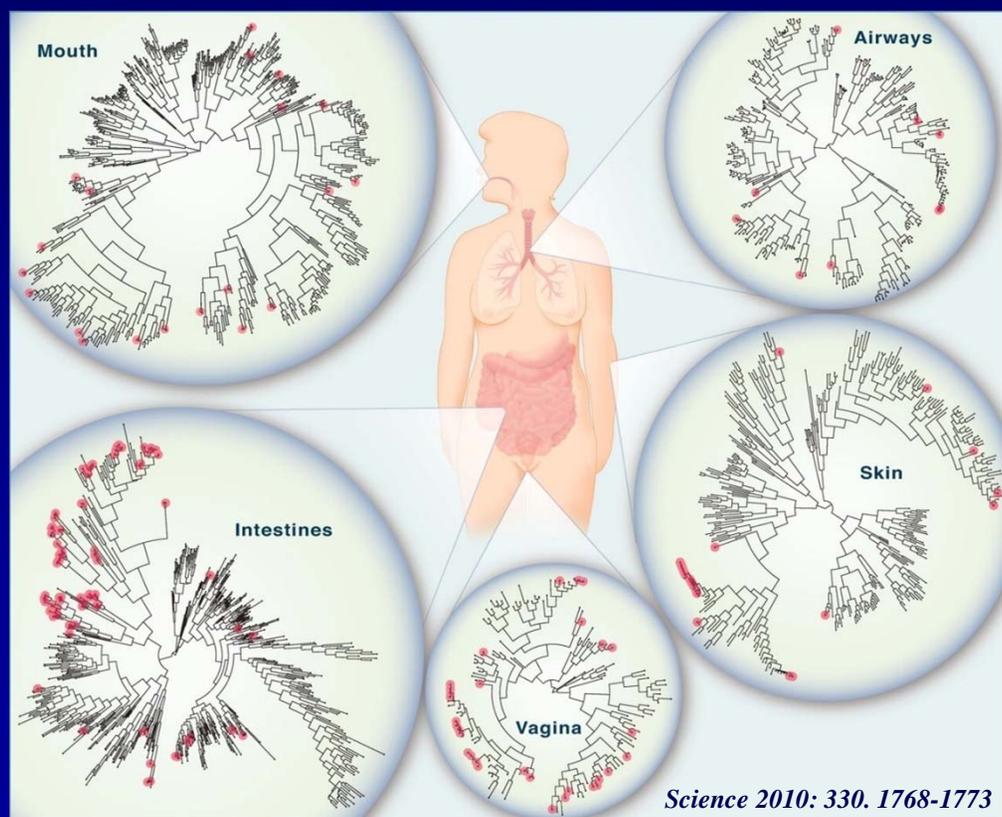
- **Infectious Causes of Cancer**
 - **Human Papilloma Virus, Hepatitis C Virus, etc.**
(NCI Center for Global Health, DCB, DCEG and NIAID)
- **Non-Infectious Tumor Antigens**
 - **Carcinoembryonic Antigen (CEA), Mucin 1 (Muc1), Human Epidermal Growth Factor Receptor 2 (Her2/neu) etc.**
(CCR, DCB)

Future Scientific Directions

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- Cancer Immunoprevention
- **Role of Microbiota**
- New Approaches to Clinical Prevention Studies

Role of Microbiota

- Study prevention interventions (agents, vaccines, diet) as modifiers of the balance of microorganisms in the body
 - Energy Exchange
 - Inflammation & Immunity
 - Dietary Choices



Future Scientific Directions

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- **New Approaches to Clinical Prevention Studies**

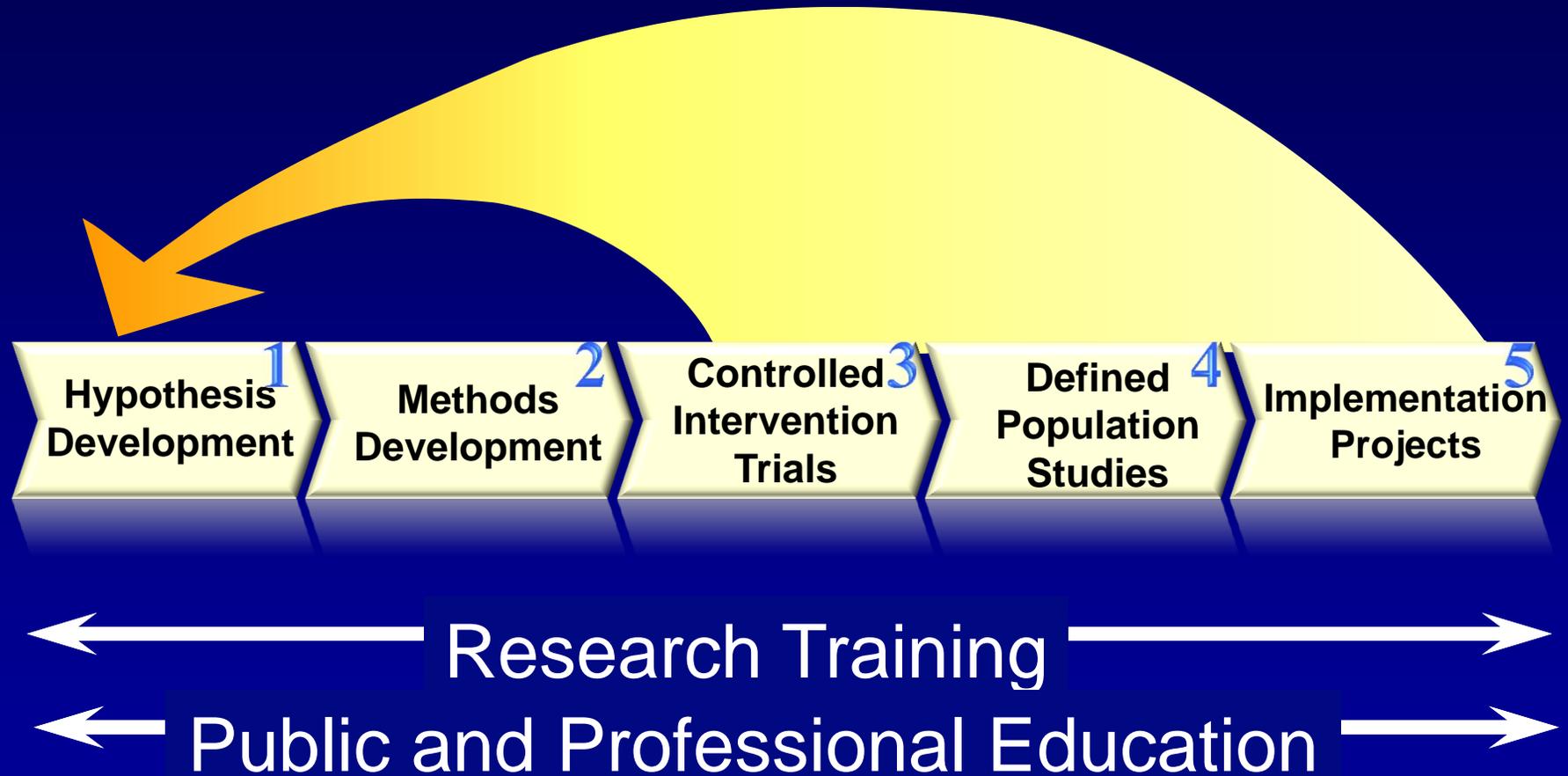
New Approaches to Clinical Prevention Studies

- **Repurposing Commonly Used Drugs For Cancer Prevention**
 - NSAIDs (including aspirin), statins
- **Using Non-cancer Disease Trials To Detect Cancer Prevention Signals**
 - Metformin studies at NIDDK
 - Lutein/omega-3 fatty acid study at NEI
- **Reciprocal Control Trials With Other Institutes/Centers**
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- **National Clinical Trials Network and CCOP Network Continue as Effector Arm for Implementing Large Trials**

Phases of the Cancer Prevention Research Continuum





DCP Controlled Funding FY 2011

