

# Comparative Effectiveness Research & NCI Designated Cancer Centers

November 30, 2009

NCAB Cancer Centers Subcommittee

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# Presentation Overview



- CER overview – definition
- CER activities at Cancer Centers
- Future CER priorities and funding opportunities
- On-going NCI efforts to conduct and support CER

# CER OVERVIEW



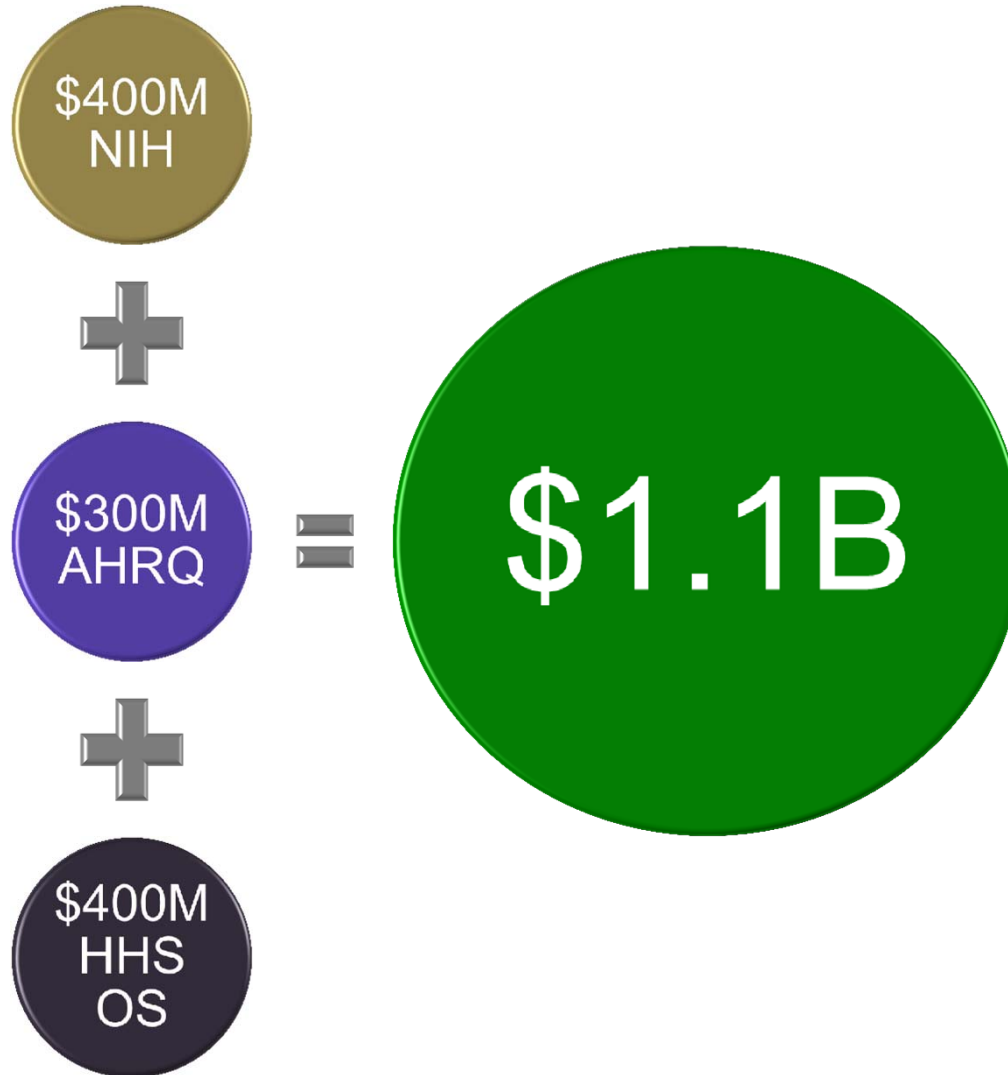
# CER Definition used at HHS



The conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

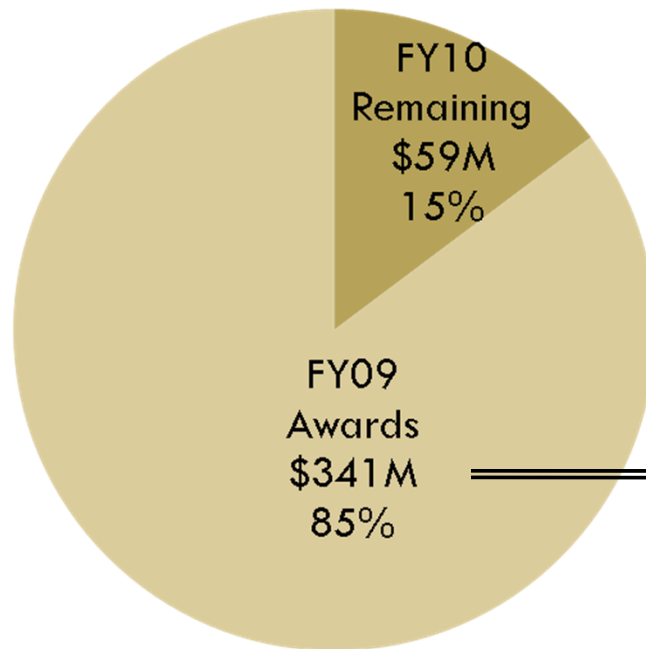
- To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and subgroups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.
- This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

# CER ARRA Allocation

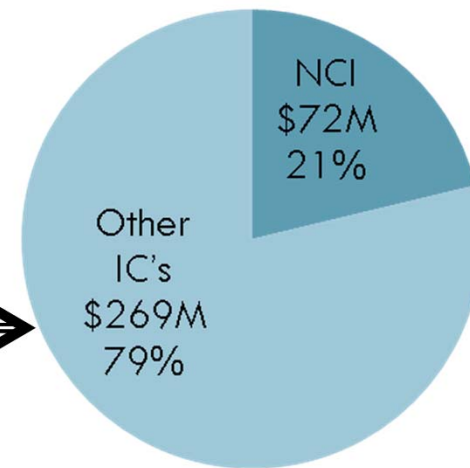


# NCI and CER ARRA Funds

In FY 2009, NIH  
Allocated 85% of the  
\$400M received for CER



NCI received  
over 20% of all  
funds awarded



# CER Research funded with NIH ARRA \$'s

<b>Funding Mechanism</b>	<b>Awarded by NIH*</b>	<b>Portion to NCI</b>	<b>% of Dollars Awarded to NCI</b>
Grand Opportunity Grants (RC2)	\$144.7	\$51.4	35.5%
Challenge Grants (RC1)	\$76.5	\$13.4	17.5%
Pay-line Expansions	\$35.8	\$16.6	46.4%
“Other”	\$58.5	\$0	0.0%
Competitive Revisions	\$7.3	\$3.4	35.6%
Administrative Supplements	\$19 .1	\$0.5	2.6%
<b>Total</b>	<b>\$341 .9</b>	<b>\$72.4</b>	<b>21.2%</b>

\*All dollars in millions and rounded.

“Other” category includes contracts and grants, for example NIH signature projects.

# CER ACTIVITIES AT CANCER CENTERS





# Examples of Challenge Grants Funded with ARRA CER Dollars



## Breast Cancer

- Role of Advanced Screening Technologies in Early Detection of Breast Cancer (Dana-Farber)

## Colon Cancer

- Comparative effectiveness of FIT vs. colonoscopy for colon cancer screening (University of Iowa)

## Prostate Cancer

- Comparative Analysis of Surgical Treatment Options for Localized Prostate Cancer (Sloan Kettering)

# Examples of Challenge Grants Funded with ARRA CER Dollars, cont.

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## Other Scientific Areas

- Interactive Exploration of Temporal Patterns in Electronic Health Records (University of Maryland)
- A Comprehensive Model to Assess the Cost-Effectiveness of Patient Navigation (MD Anderson)
- Improving the population-wide effectiveness of U.S. tobacco cessation quitlines (University of Wisconsin)

# Examples of GO Grants Funded with ARRA CER Dollars

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## In response to CER FOA in Genomic and Personalized Medicine

- Center for Comparative Effectiveness Research in **Cancer Genomics (CANCERGEN)** (Fred Hutchinson)
- Clinical validity and utility of genomic targeted chemoprevention of Pca (Wake Forest University Health Sciences)
- Programs in Clinical Effectiveness of Cancer Pharmacogenomics (Duke University)
- Comparative Effectiveness in Genomic Medicine (University of Pennsylvania)

# Examples of GO Grants Funded with ARRA CER Dollars

## In response to CER FOA in Cancer Prevention, Screening and Treatment

- Building CER Capacity: Aligning CRN, CMS, and State Resources to Map Cancer Care (Dana Farber)
- CYCORE: **Cyber**infrastructure for **C**omparative effectiveness **R**esearch (MD Anderson)
- **ADV**ancing **I**nnovative **C**omparative **E**ffectiveness research-cancer diagnostics (ADVANCE) (University of Washington)
- Comparative Effectiveness of Advanced Imaging in Cancer (Dartmouth)
- Developing Information Infrastructure Focused on Cancer Comparative Effectiveness (Lee Moffitt)

# Examples of Other Grants Funded with ARRA CER Dollars

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- Cancer Center Support Grant Supplement aimed at promoting cancer CER through targeted faculty support, pilot projects, shared resources, and technology methodology innovation (Dartmouth)
- Clinical Trial - Multicenter Selective Lymphadenectomy Trials, MSLT I and MSLT II (John Wayne Cancer Institute)

# Examples of non-ARRA CER activities

## Clinical Trials



### Clinical Trials Cooperative Groups Program

- Established in 1955 to develop and conduct phase III clinical trials
- 11 groups; more than 1,700 institutions
- Place more than 23,000 new patients into cancer treatment clinical trials each year
- Groups differ in structure and research focus
- Cooperative agreement grants (U10)


# Examples of other non-ARRA CER activities

## Clinical Trials

- Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial
- National Lung Screening Trial (NLST)
- Neurofibromatosis Type I Trials

**AND MANY MORE!**

# Examples of other non-ARRA CER grants



- Cost Effectiveness Analysis of Lung Cancer Screening (Stanford)
- Primary Prevention Versus Screening for Prostate Cancer (Fred Hutchinson)
- Cost-effectiveness of genetic screening for colon cancer (University of Michigan)



# CER in the spotlight: White House Office of Urban Affairs - Seattle Tour



- Seattle tour part of the WH *National Conversation on the Future of America's Cities and Metropolitan Areas*
- Highlighted success of Fred Hutchinson Cancer Research Center, UW Medicine and others in spurring scientific research efforts, including CER

# CER in the spotlight: White House Office of Urban Affairs - Seattle Tour

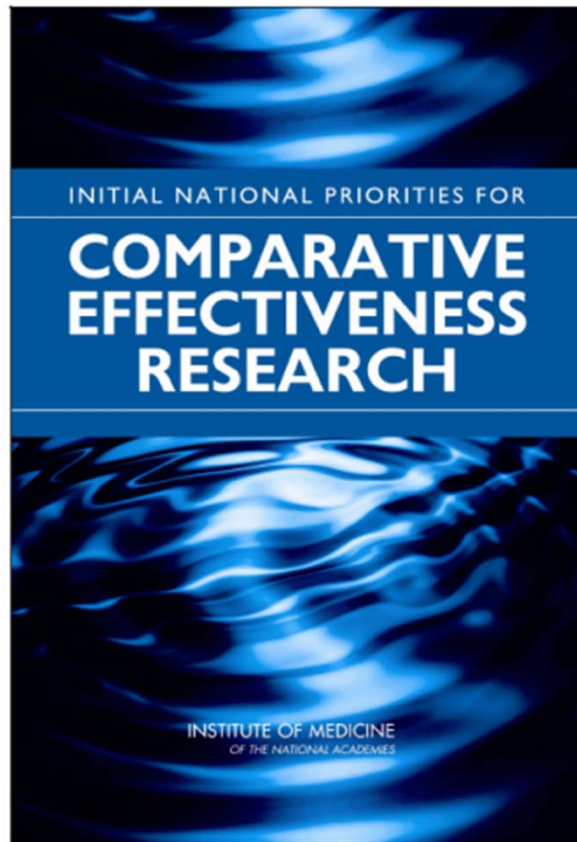
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- Seattle-based institutions Fred Hutchinson and Group Health Research Institute were extremely successful in obtaining funding for CER
- Key take-aways for Cancer Center leaders
  - The Obama Administration recognizes the importance of investing in CER
  - Cancer Centers should think strategically about how to engage in CER
  - Dissemination of CER information and encouraging adoption of best practices will be challenging

# FUTURE CER PRIORITIES AND FUNDING OPPORTUNITIES



# IOM CER Report

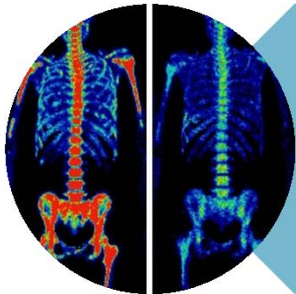


- Required under ARRA
- Released 6/30/09
- Lists 100 national priorities for CER
- Future efforts in CER will focus on addressing these priorities
- Informed by testimonials given by advocacy, industry, and other groups

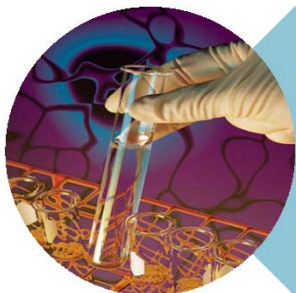
# IOM CER Report: Examples of Cancer Priorities



Compare management strategies for localized prostate cancer on survival, recurrence, side effects, quality of life, and costs



Compare imaging technologies in diagnosing, staging, and monitoring patients with cancer including PET, MRI, and CT



Compare genetic and biomarker testing and usual care in preventing and treating breast, colorectal, prostate, lung, and ovarian cancer, and possibly other clinical conditions

## IOM CER Report:

### Recommendations for long-term investment

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- Ensuring meaningful consumer, patient, and caregiver participation
- Building robust information systems and research methods
- Development and support of a highly skilled CER workforce
- Support efforts to translate CER knowledge into everyday clinical practice

# CTSA's and CER

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- NCRRT's Clinical and Translational Science Award (CTSA) program recently established a new Key Functional Committee (KFC) to focus on CER
- The KFC will begin meeting this December and will include a representative from NCI
- The CTSA program released a white paper on how they can facilitate CER for ICs, other federal agencies, outside stakeholders, and the healthcare system
- Related funding opportunities may follow

# NIH 2010 – ARRA CER Funding Opportunities

- Upcoming FOA's to support CER using ARRA \$'s
  - Institutional CER mentored career development award – K award
  - NIH Administrative Supplements for Comparative Effectiveness Research Workforce Development and Dissemination
  - Methodology Development in Comparative Effectiveness Research (RC4)
  - CER projects in targeted, high-priority areas (RC4)





# AHRQ Spending

- \$100M - Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE)
- \$48M - national patient registries
- \$29.5M - translation and dissemination grants
- \$20M - training and career development in CER
- \$9.5M - infrastructure to identify new/emerging issues for CER review investments
- \$10M - citizen's forum to formally engage stakeholders and expand public involvement
- \$80M - grants and contracts for evidence generation, synthesis and translation
- \$3M- staff

# Other Specific funding opportunities

## AHRQ

- Application Due Date: December 16, 2009
  - Innovative Adaptation and Dissemination of AHRQ Comparative Effectiveness Research Products (iADAPT)
  - AHRQ Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE)
- AHRQ may release other additional funding announcements in FY10
  - Visit <http://www.ahrq.gov/fund/grantix.htm> for updates



# HHS Spending Plan

- Plan closely aligns with the Office of the National Coordinator for HIT and the Department's HIT investments.
- AHRQ will largely be in charge of administering
- Two NIH proposals will be funded, with more to follow
  - Enhancing NLM and Clinical trials.gov (\$4M)
  - Behavioral Economics and Change (\$20M with AHRQ)
- NIH is able to use contracts and inter-agency agreements (IAAs) as well as grants for CER ARRAs awards.

# ON-GOING NCI EFFORTS TO CONDUCT & SUPPORT CER



# SEER –Medicare Linkage

- Created by linking two population-based sources
  - ▣ cases from SEER and Medicare claims from CMS
  - ▣ Over 1.5 million persons with cancer
  - ▣ Can be used to examine health care before, during and after cancer diagnosis
- SEER data: detailed clinical, demographic and cause of death information for persons with cancer
- Medicare: longitudinal, claims for all covered health services from the time of eligibility to death
- Details at:  
<http://healthservices.cancer.gov/seermedicare/>

The linked data can be used for a number of analyses

that span the course of cancer control activities

Diagnosis/ Tx →	Survivorship →	Second Occurrence →	Terminal Care
Patterns of care	Late effects of treatment	Rates of recurrence/ second primaries	Use of hospice services
Peri-operative complications	Post-diagnostic surveillance	Relationship of second events to initial treatment and ongoing surveillance	Patterns of care during the last year of life
Volume outcomes studies	Treatment of prevalent cancers		
Extent of staging	Survival		
Comorbidities			

← Health disparities, quality of care and cost of treatment →

# CISNET - Cancer Intervention & Surveillance Modeling Network

- NCI Sponsored Collaborative Consortium (U01) of Modelers in Breast, Prostate, Colorectal and Lung Cancer
- Focused on bringing the most sophisticated evidence-based decision tools to:
  - Understand the impact of cancer control interventions (screening, treatment, prevention) on current and future trends in incidence and mortality
  - Extrapolate evidence from RCT's, epidemiologic, and observational studies to determine the most efficient and cost-effective strategies for implementing technologies in the population
  - Be responsive to challenges due to the increased pace of technology, by helping to determine which new technologies

# HMO Cancer Research Network (CRN)

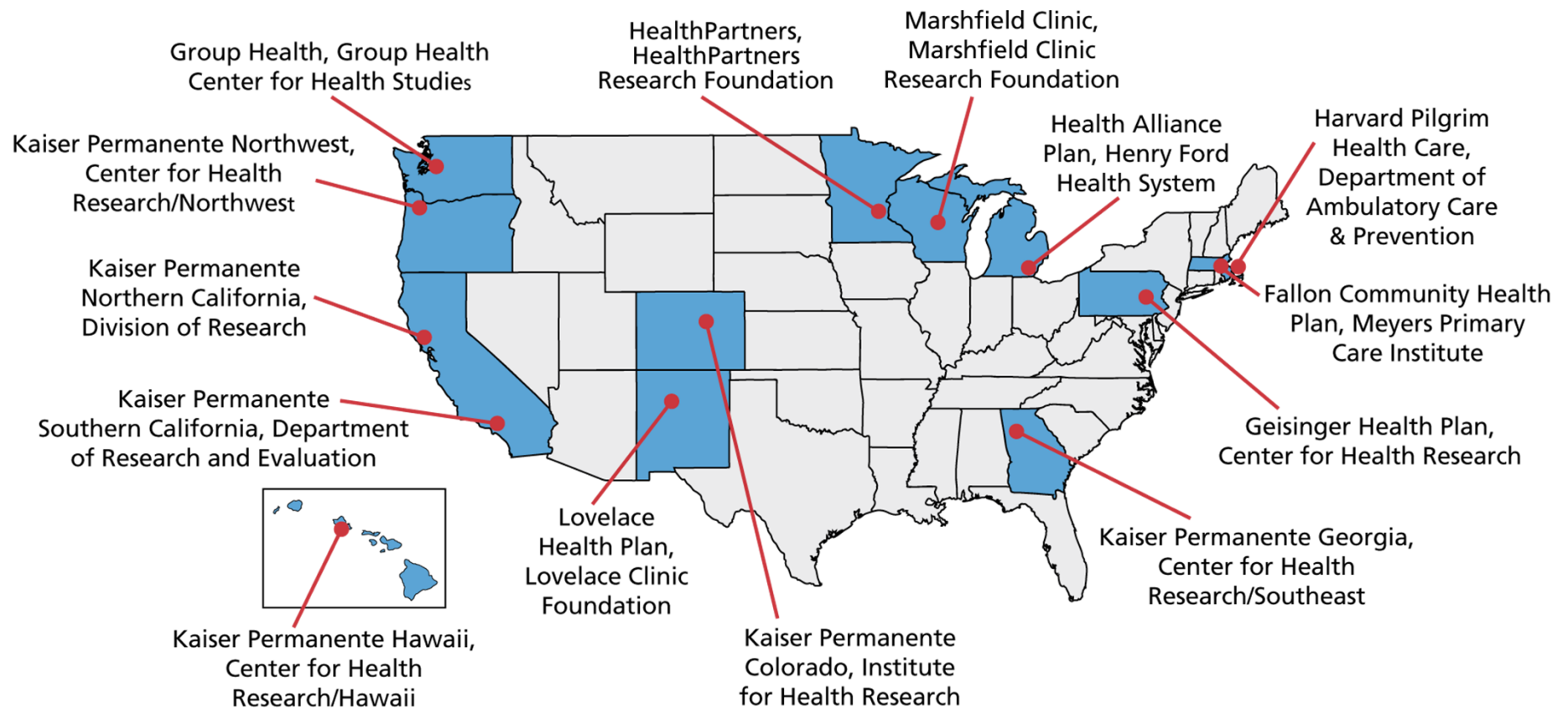


- Original RFA released by NCI in 1997
- 14 health care systems in HMORN participate
- Funded through a cooperative agreement grant and supplements
- Agency for Healthcare Research and Quality (AHRQ) is a co-sponsor
- [Crn.cancer.gov](http://Crn.cancer.gov)



# HMO Cancer Research Network (CRN)

## Cancer Research Network Sites



# Clinical Research Infrastructure



- Cancer Centers Program
- NCI Community Cancer Centers Program (NCCCP)
- SPORES
- Clinical Trials Cooperative Groups Program

# Physician Surveys: Examples

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- Physician Survey on Cancer Susceptibility Testing
- National Surveys of Colorectal Cancer Screening Policies & Practices
- Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS)
- National Survey of Energy Balance-related Care among Primary Care Physicians
- National Survey of Primary Care Physicians' Recommendations & Practice for Breast, Cervical, Colorectal, & Lung Cancer Screening
- <http://appliedresearch.cancer.gov/>

# Survey Collaborations



- With CDC
  - ▣ National Health Interview Survey (NHIS)
  - ▣ National Health & Nutrition Examination Survey (NHANES)
  - ▣ Behavioral Risk Factor Surveillance System (BRFSS)
- California Health Interview Survey (CHIS)
- With Census
  - ▣ Current Population Survey (CPS) for the Bureau of Labor Statistics

# Health Information National Trends Survey



- U.S. population sample survey
- Assesses sources of information and cancer-related beliefs
- Used to understand how adults seek, understand and utilize health information and information technology
- <http://hints.cancer.gov/>



## Breast Cancer Surveillance Consortium

- Assesses the delivery and quality of breast cancer screening and related patient outcomes in U.S.
- Links to pathology and/or tumor registries
- Database of over 7.5M screening mammographic examinations of over 2M women
- 86,700 breast cancer cases
- Examines variation in radiologists' interpretative performance
- Co-funded by American Cancer Society
- <http://breastscreening.cancer.gov/>

# Cancer Care Outcomes Research and Surveillance Consortium (CanCORS)

- Goal: Understand variation in care delivered to 5,000 patients with lung cancer and 5,000 with colorectal cancer
- Evaluates how characteristics of physicians, patients, caregivers, and delivery systems affect quality of care and outcomes
- <http://healthservices.cancer.gov/cancors>

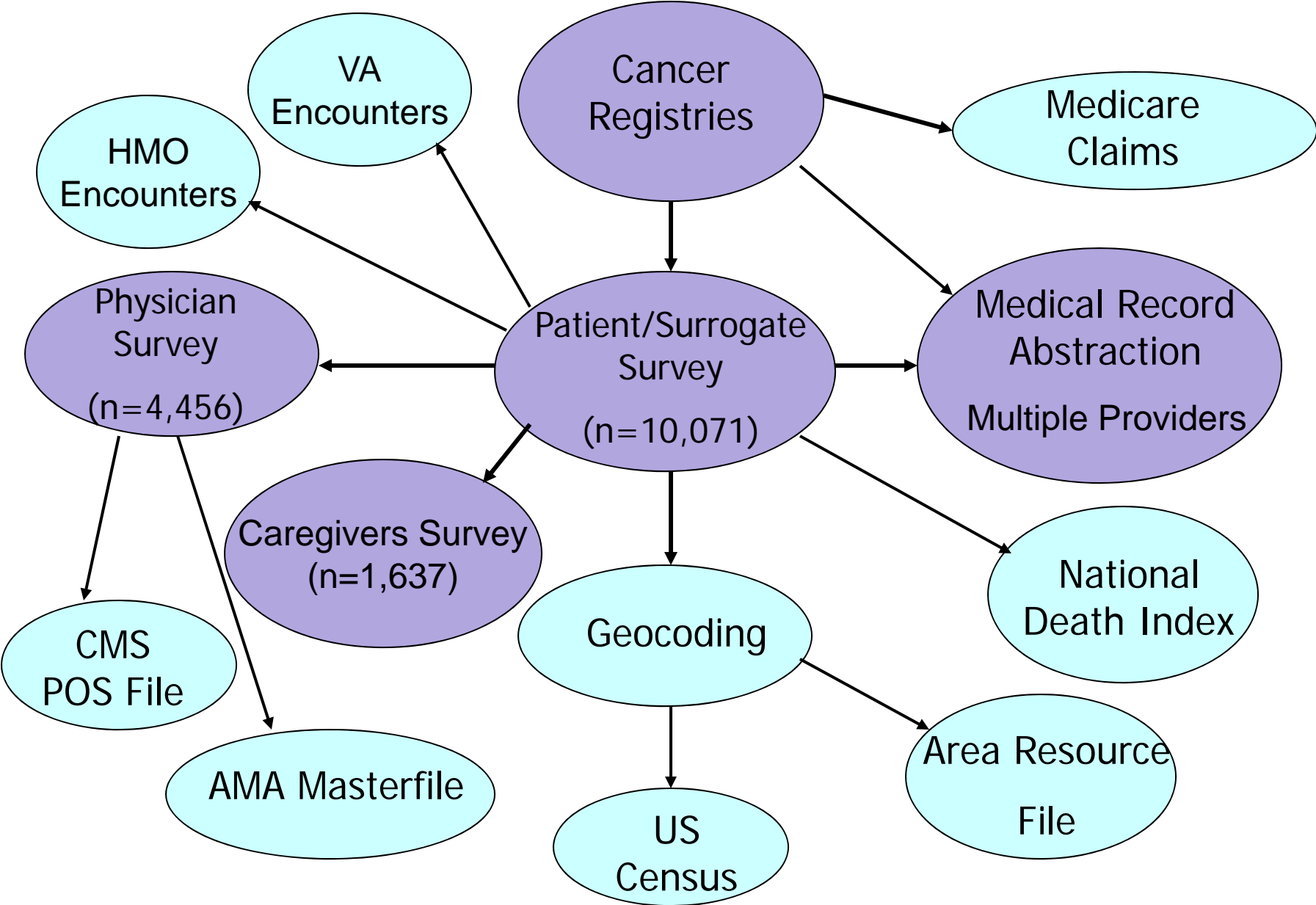
# CanCORS Sites



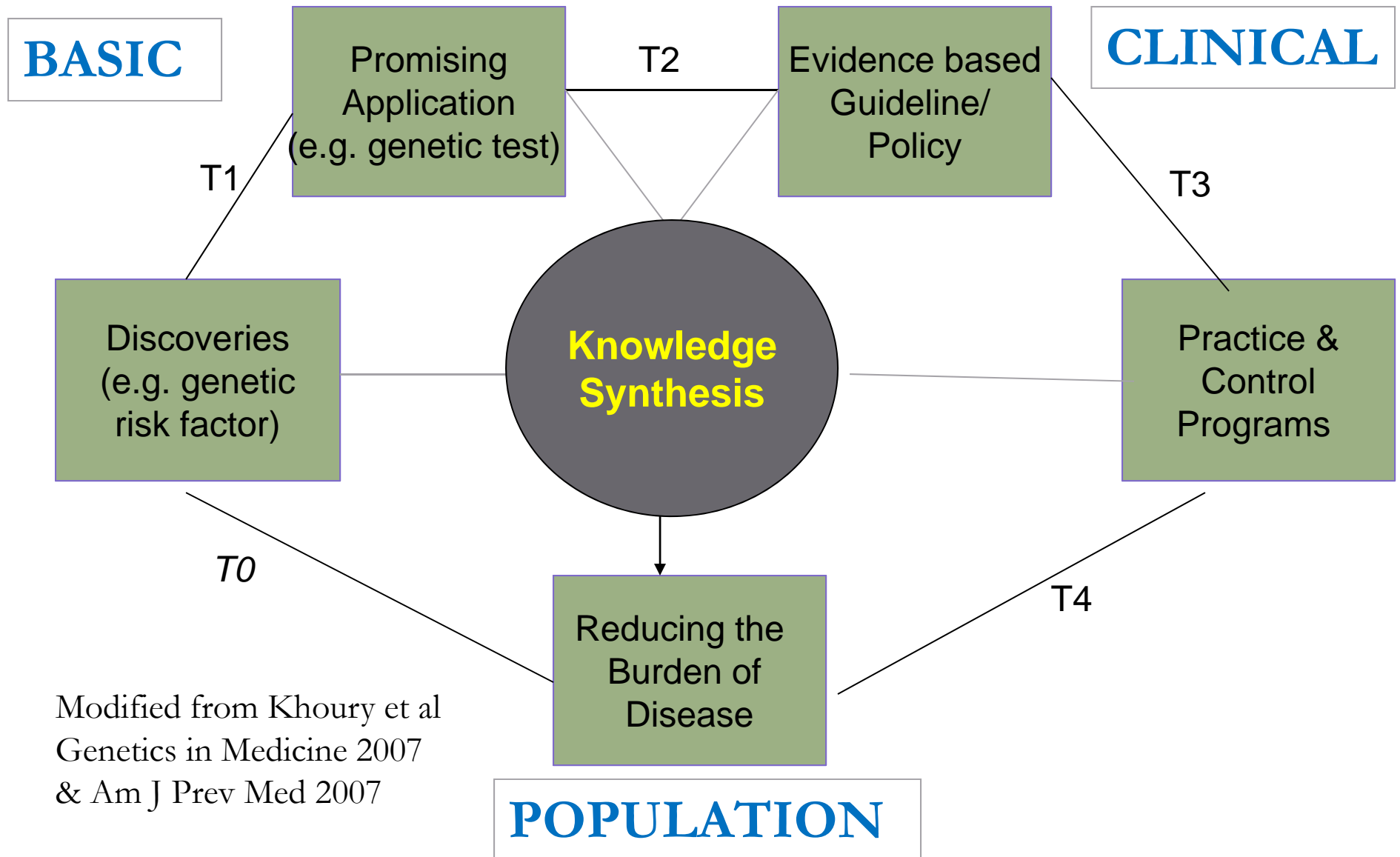
- Patients from population-based cohorts in geographic areas
- Patients from integrated health-care delivery systems
- Patients at Veterans Health Administration hospitals



# CanCORS Data Sources and Linkages



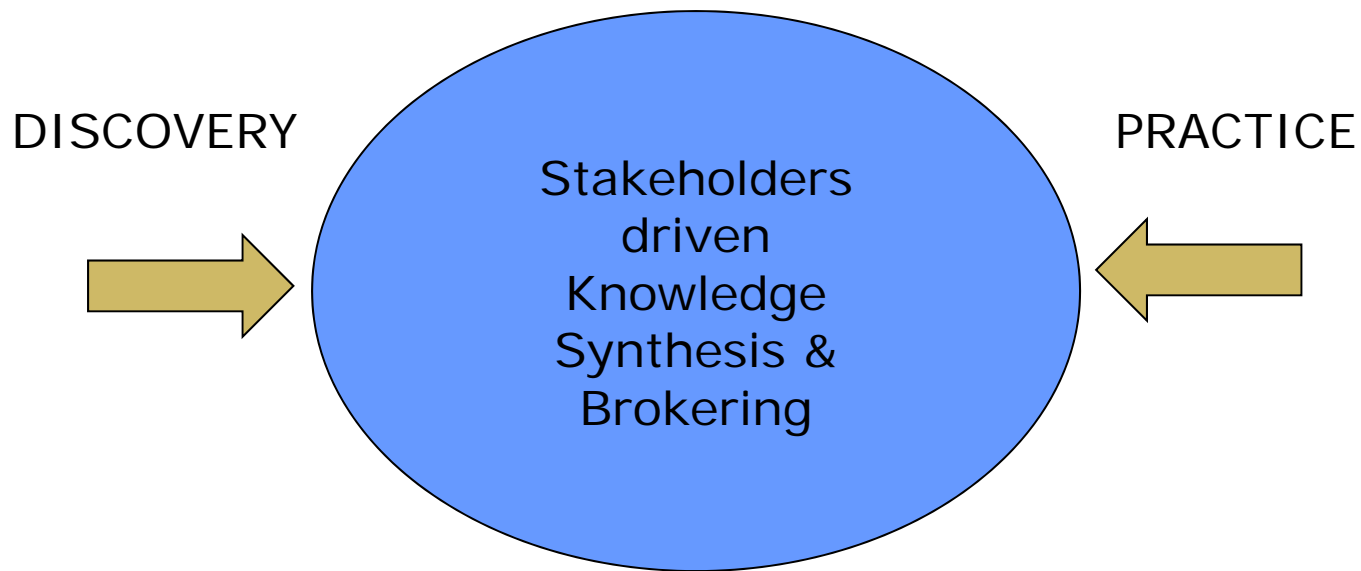
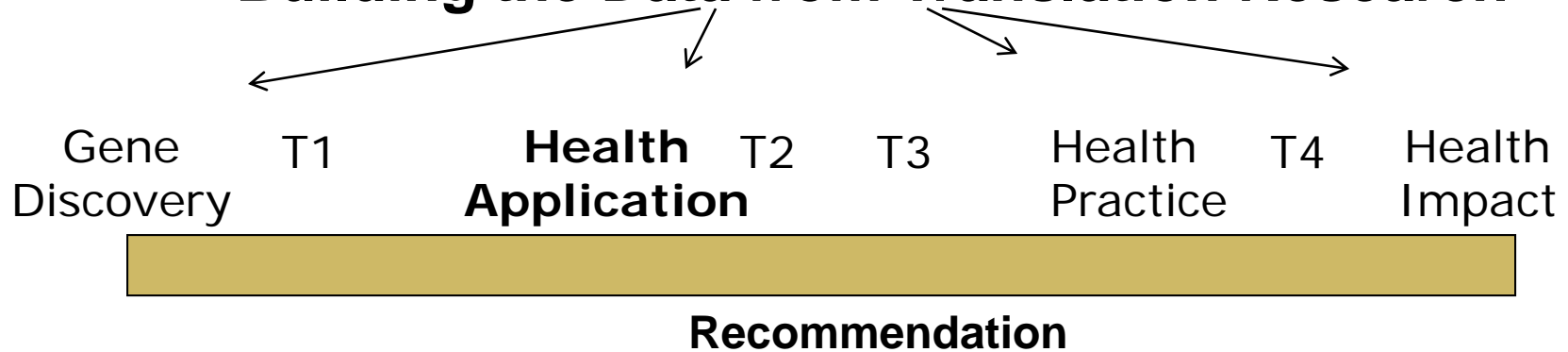
# Public Health Genomics Focus on the Full Translation Continuum



# GAPPNet

“Putting Stakeholders in the Same Room and let them drive and be influenced by translation data

## Building the Data from Translation Research



# The GAPPNet Initiative

REVIEW

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## The Genomic Applications in Practice and Prevention Network

*Muin J. Khoury, MD, PhD<sup>1</sup>, W. Gregory Feero, MD, PhD<sup>2</sup>, Michele Reyes, PhD<sup>1</sup>, Toby Citrin, JD<sup>3</sup>, Andrew Freedman, PhD<sup>4</sup>, Debra Leonard, PhD<sup>5</sup>; and the GAPPNet Planning Group: Wylie Burke, MD, PhD<sup>6</sup>, Ralph Coates, PhD<sup>1</sup>, Robert Croyle, PhD<sup>3</sup>, Karen Edwards, PhD<sup>7</sup>, Sharon Kardia, PhD<sup>2</sup>, Colleen McBride, PhD<sup>2</sup>, Teri Manolio, MD, PhD<sup>2</sup>, Gurbaneet Randhawa, MD<sup>8</sup>, Rebekah Rasooly, MD<sup>9</sup>, Jeannette St. Pierre, MPH<sup>1</sup>, and Sharon Terry, MS<sup>10</sup>*

**Abstract:** The authors describe the rationale and initial development of a new collaborative initiative, the Genomic Applications in Practice and Prevention Network. The network convened by the Centers for Disease Control and Prevention and the National Institutes of Health includes multiple stakeholders from academia, government, health care, public health, industry and consumers. The premise of Genomic Applications in Practice and Prevention Network is that there is an unaddressed chasm between gene discoveries and demonstration of their clinical validity and utility. This chasm is due to the lack of readily accessible information about the utility of most genomic applications and the lack

ered factors and clinical outcomes (clinical validity), and the costs, benefits, and harms of genome-based technologies in real world settings (clinical utility).<sup>4</sup> Furthermore, the process should facilitate the development of evidence-based guidelines for the use of genomic applications<sup>5</sup>; and appropriate implementation of these applications in practice, including protection of individuals and communities against discrimination based on genetic information.<sup>6</sup> Importantly, advances in genomics should be considered in the context of the larger forces affecting health care delivery in the United States, including escalating costs, differential access to quality health care, and a growing number

# Cancer Pharmacogenomics:

Setting a Research Agenda to Accelerate Translation

Bethesda, MD | July 21, 2009

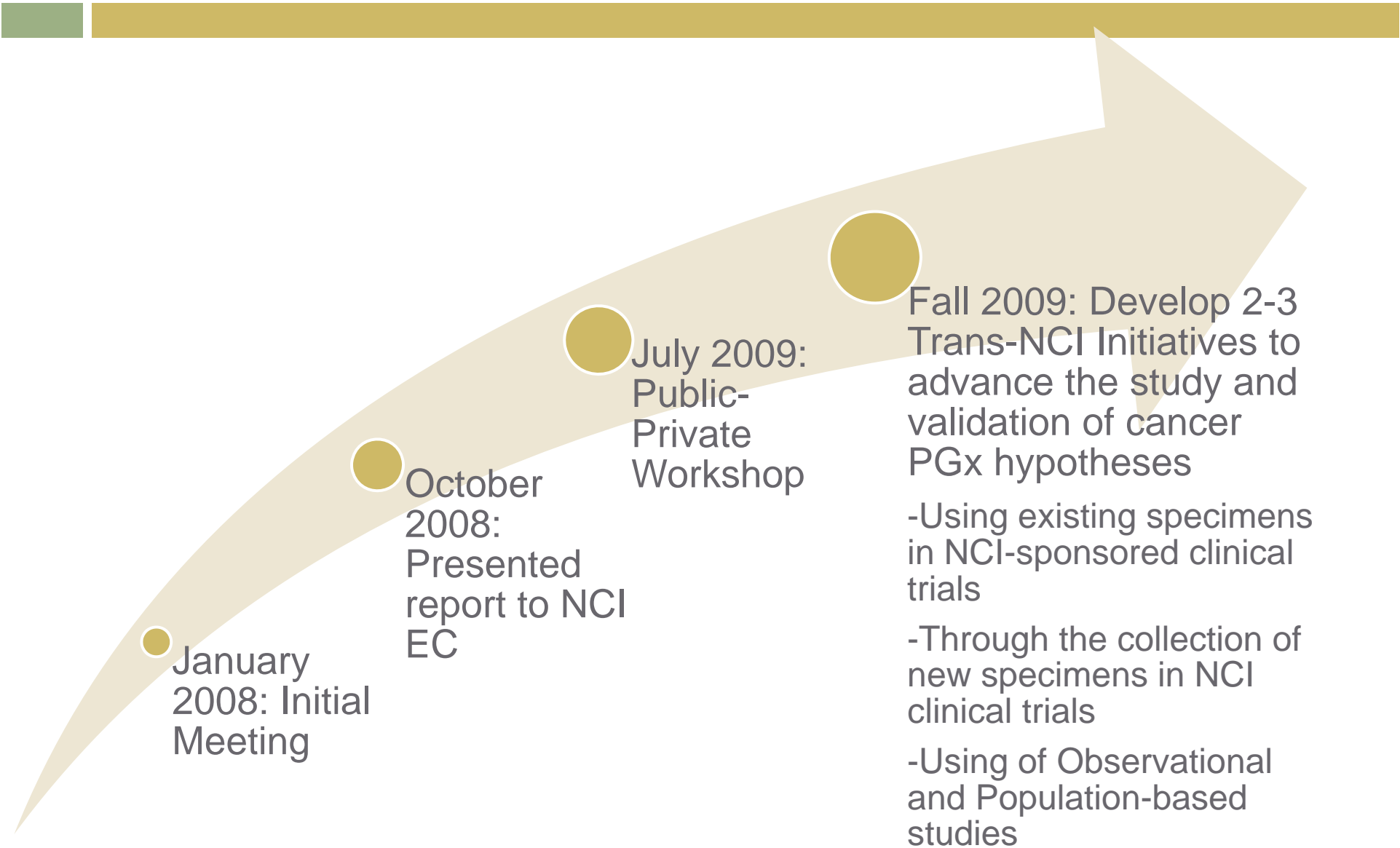


## Goal: To evaluate and Revise Trans-NCI PPWG recommendations

### Participants

- NCI: DCTD, DCB, DCEG, DCCPS, DCP, CCR, CRCHD
- NIH: NIGMS, NHLBI, NHGRI, OD, NCCR
- HHS: FDA, CDC, AHRQ, CMS
- Research Networks: Cooperative Groups, PGRN, HMO-CRN, SEER, Cohort and Case-Control Consortia
- DOD and VA
- Industry
- Pharmacy Benefit Providers
- Academic Medical Institutions
- Comprehensive Cancer Centers
- Health Maintenance Organizations
- Advocates

# Trans-NCI PPWG



# Practical Take-Home Messages

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- Multidisciplinary staff expertise essential
- Adopt a long-term perspective
- Piggy-back whenever possible
- Collaborate with other ICs, agencies early
- Engage public/advocates/patients early
- Invest in measurement and data standards
- Practice must inform research
- CER is here to stay!

# Additional Resources

- NCI CER Website

<http://cancercontrol.cancer.gov/cer/index.html>

- Physician Survey's – NCI's Applied Research Program

<http://appliedresearch.cancer.gov/>

- NCI Cancer Bulletin Spotlight on CER

<http://www.cancer.gov/ncicancerbulletin/051909/page6/print?page=&keyword>

- Federal Coordinating Committee report on CER

<http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>

- IOM report with recommendations on the priority areas that HHS should address with its CER funding

<http://www.iom.edu/?ID=71025>



# Additional Resources

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- Friends of Cancer Research report calling for a “new paradigm” on CER and offering cancer care as a case study

<http://www.focr.org/comparative-effectiveness>

- Academy Health – Cost of CER in the U.S., June 2009

<http://www.academyhealth.org/>

- Brookings hosted a CER Workshop which included speakers: Carolyn Clancy, Peter Orszag, Mark McCellan, Robert Rubin and Max Baucus

- [http://www.brookings.edu/events/2009/0609\\_health\\_care\\_cer.aspx](http://www.brookings.edu/events/2009/0609_health_care_cer.aspx)