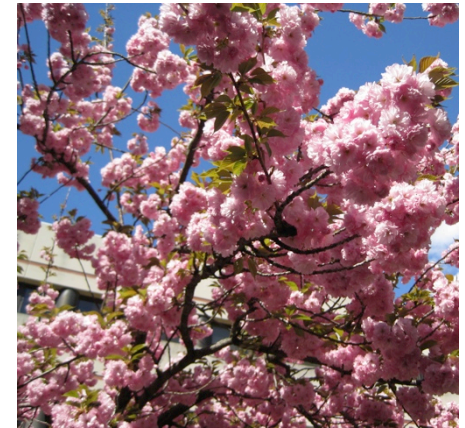
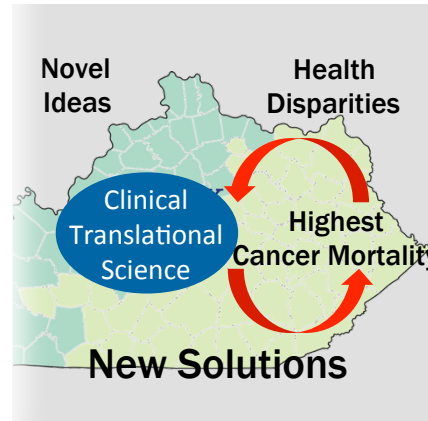


# Combating Lung Cancer in Kentucky



## Markey Cancer Center Research Network

Tim Mullett, MD  
Professor, Thoracic Surgery  
University of Kentucky



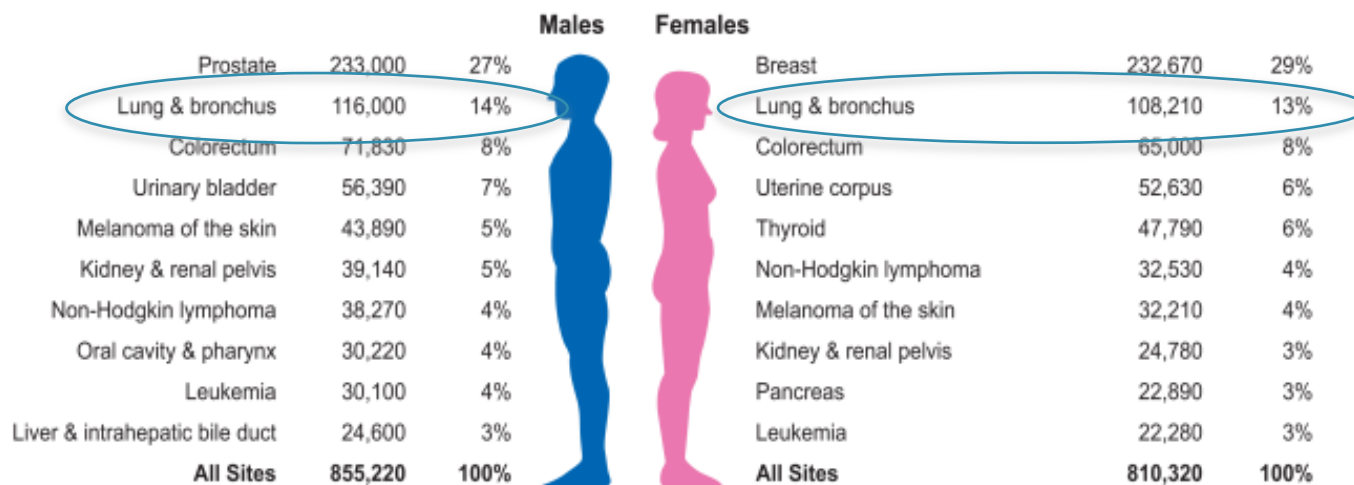
MARKEY CANCER CENTER

# Lung Cancer Screening Excellence Project

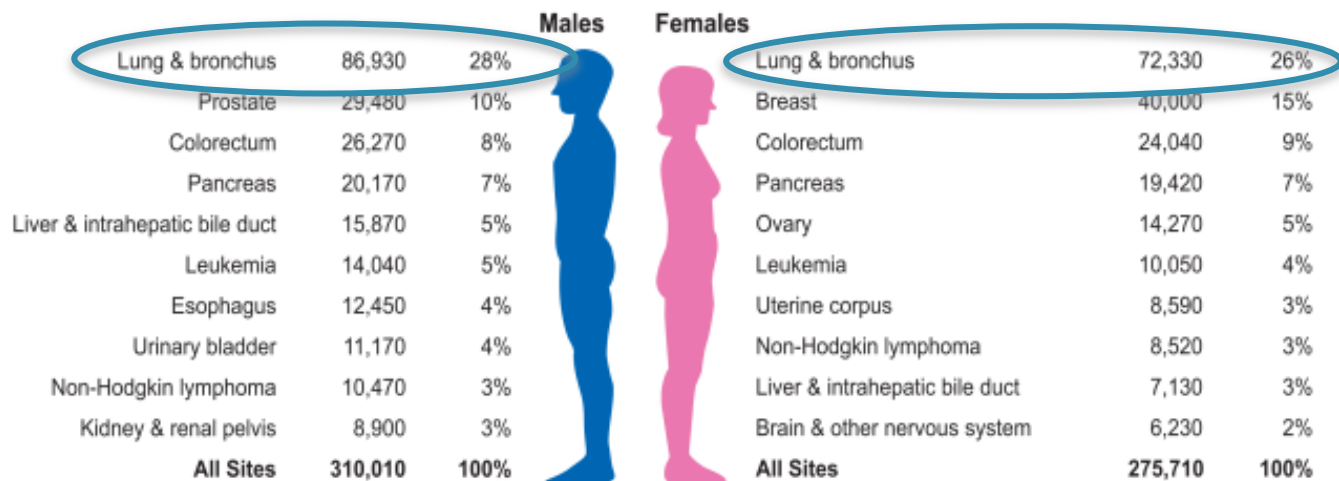
- Impact of Lung Cancer in Kentucky
  - What we are up against...
- Evidence regarding Lung Cancer Screening
  - Challenges in Kentucky/Ohio River Valley
- Development of a Kentucky-centric model for Lung Cancer Screening
- What's next? Implementation of Quality Lung Cancer Screening in Kentucky

# Cancer statistics, 20??

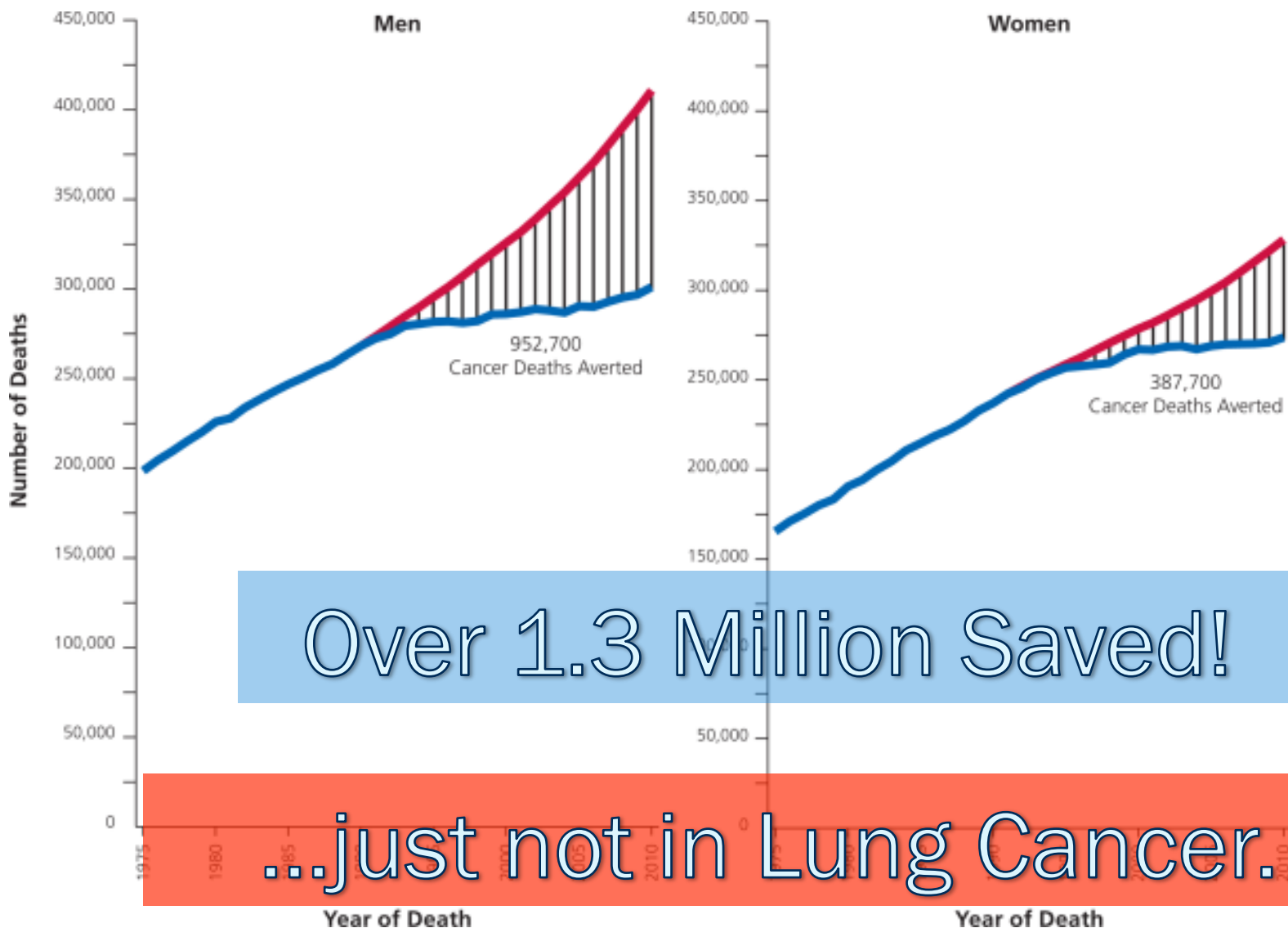
## Estimated New Cases\*



## Estimated Deaths



# Cancer statistics, 2014

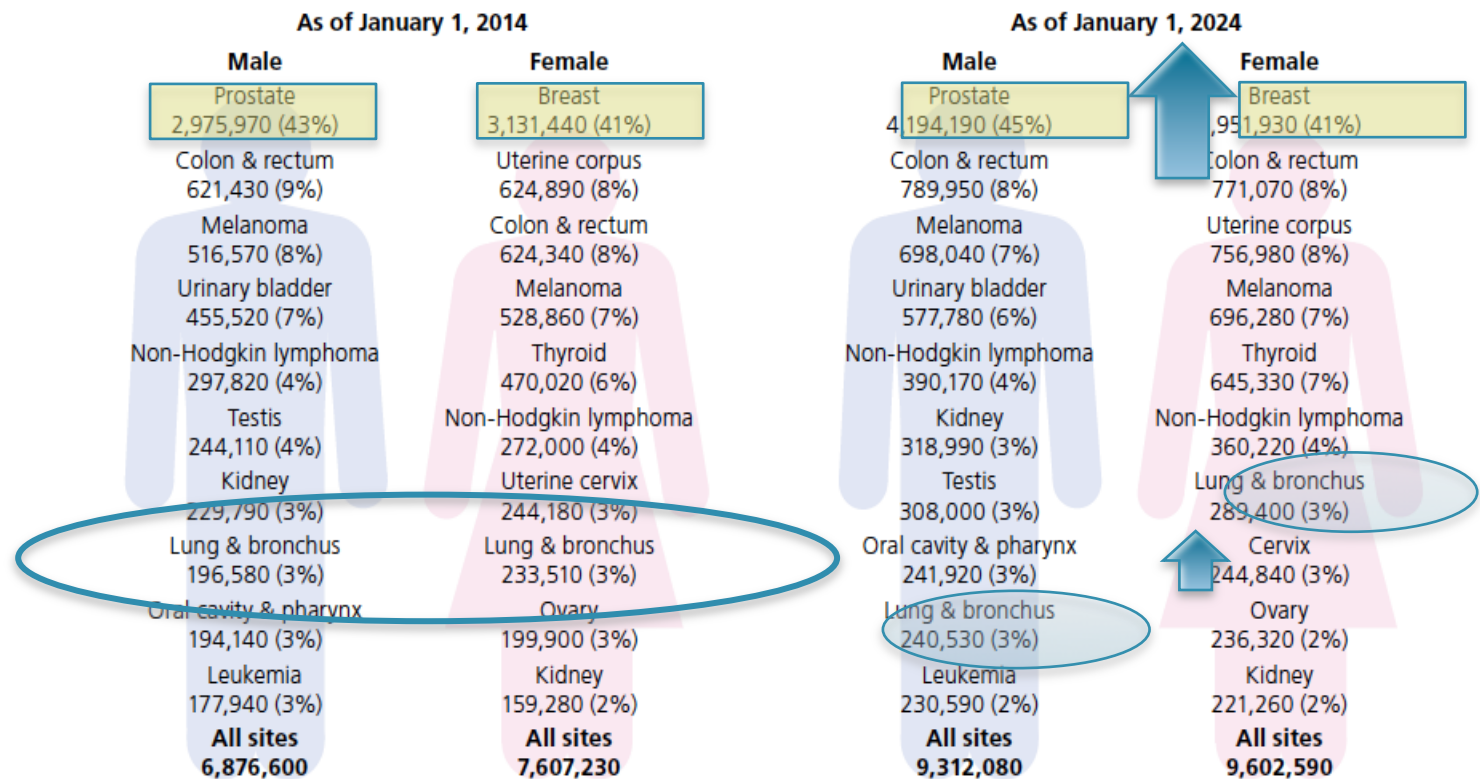


Over 1.3 Million Saved!

...just not in Lung Cancer.

# Survivorship

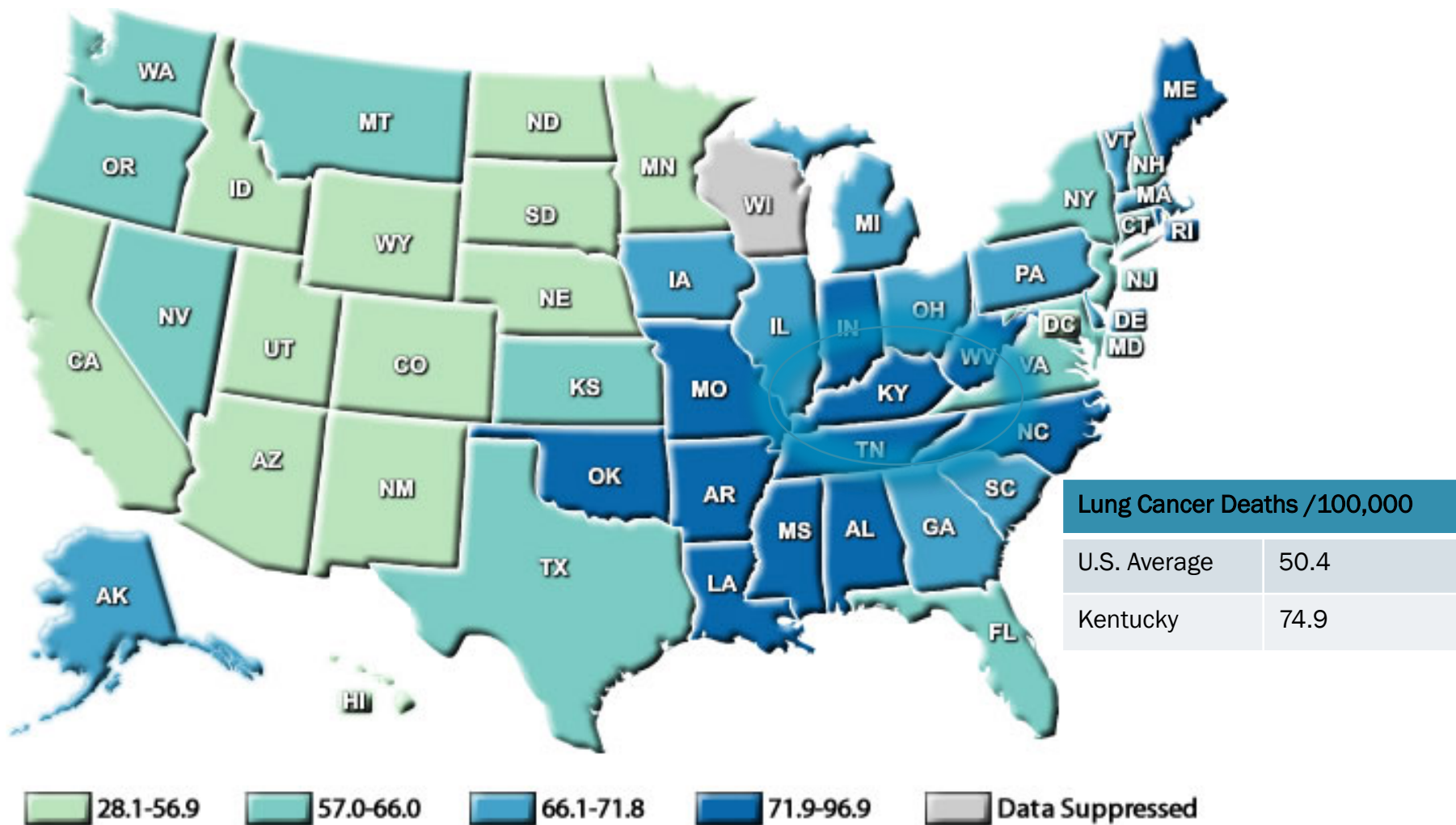
Figure 1. Estimated Numbers of US Cancer Survivors by Site



Source: Data Modeling Branch, Division of Cancer Control and Population Sciences, National Cancer Institute.

American Cancer Society, Surveillance and Health Services Research, 2014

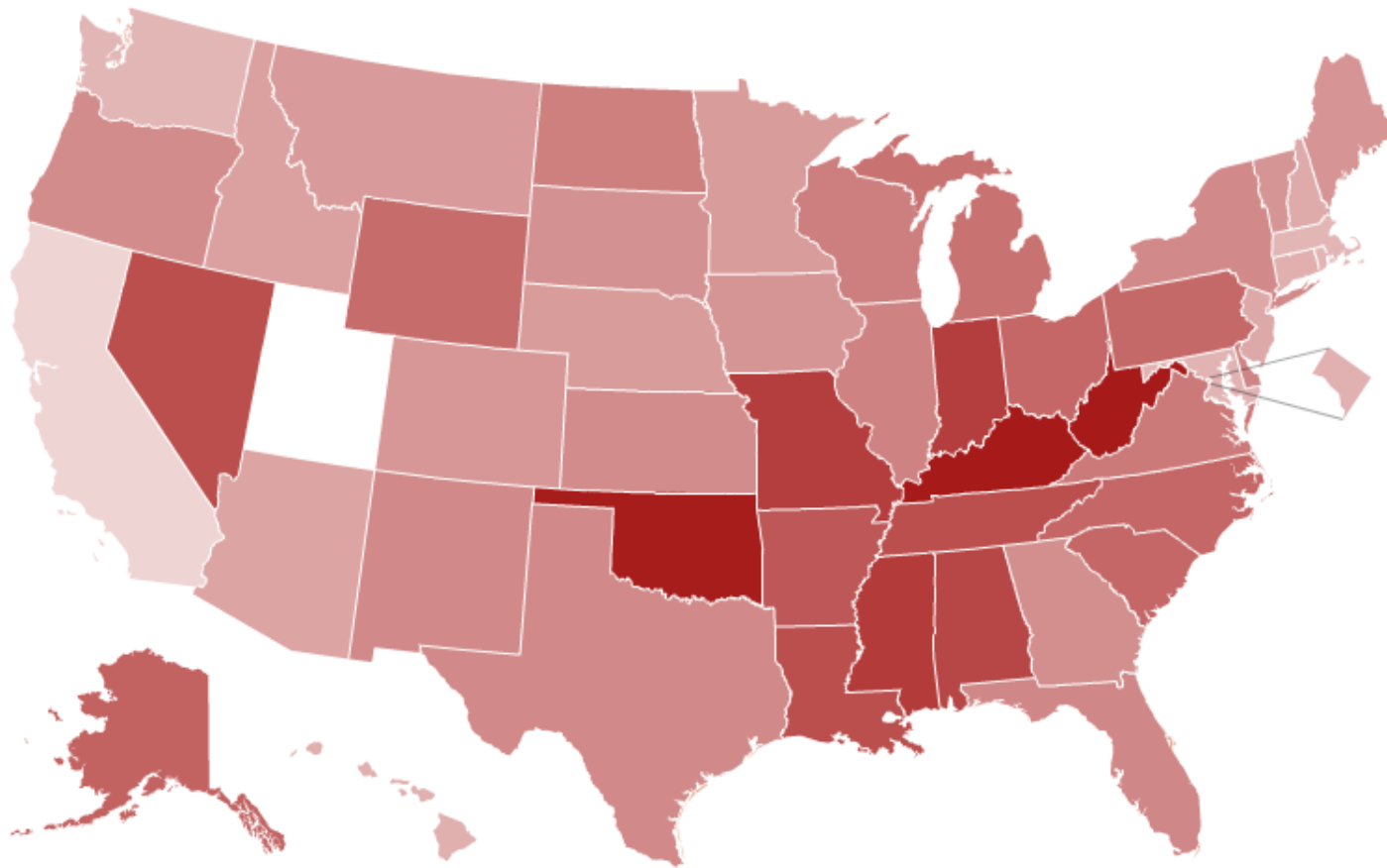
# Lung Cancer Age-Adjusted Incidence Rates by State, 2009



Data Source: CDC

<http://www.cdc.gov/cancer/lung/statistics/state.htm>

# Smoking Demographics



## Smoking in... Kentucky

Percentage of smokers	25.6%
National rank	1st
Pack price	\$4.55
National rank	40th

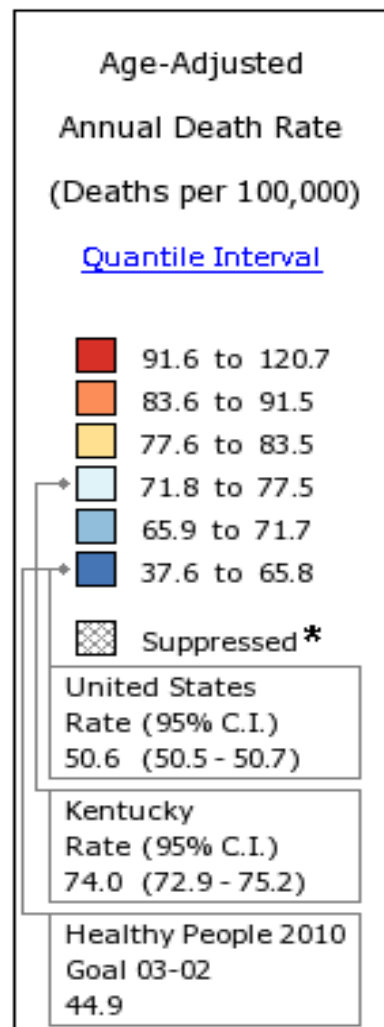
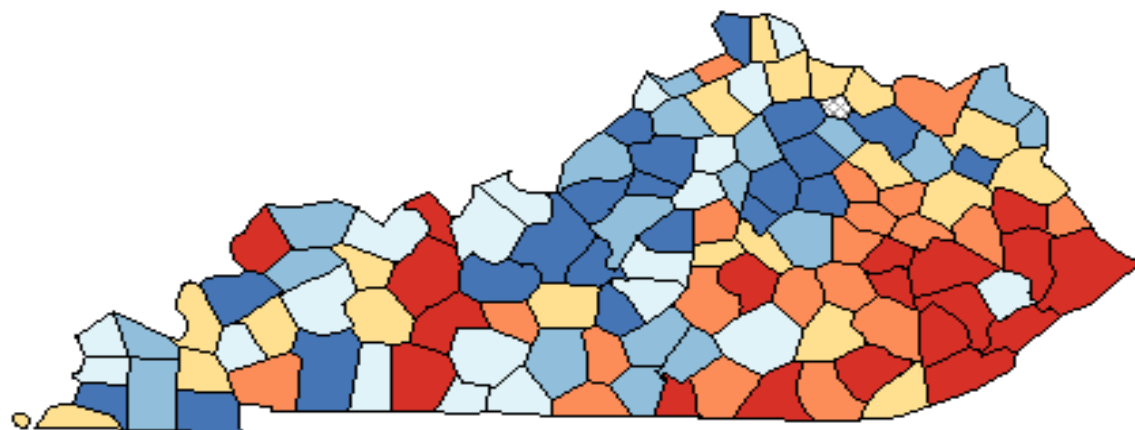
Percentage of  
adult population that smokes

Low  High

Data last updated: April 1, 2011

# A land of opportunity...

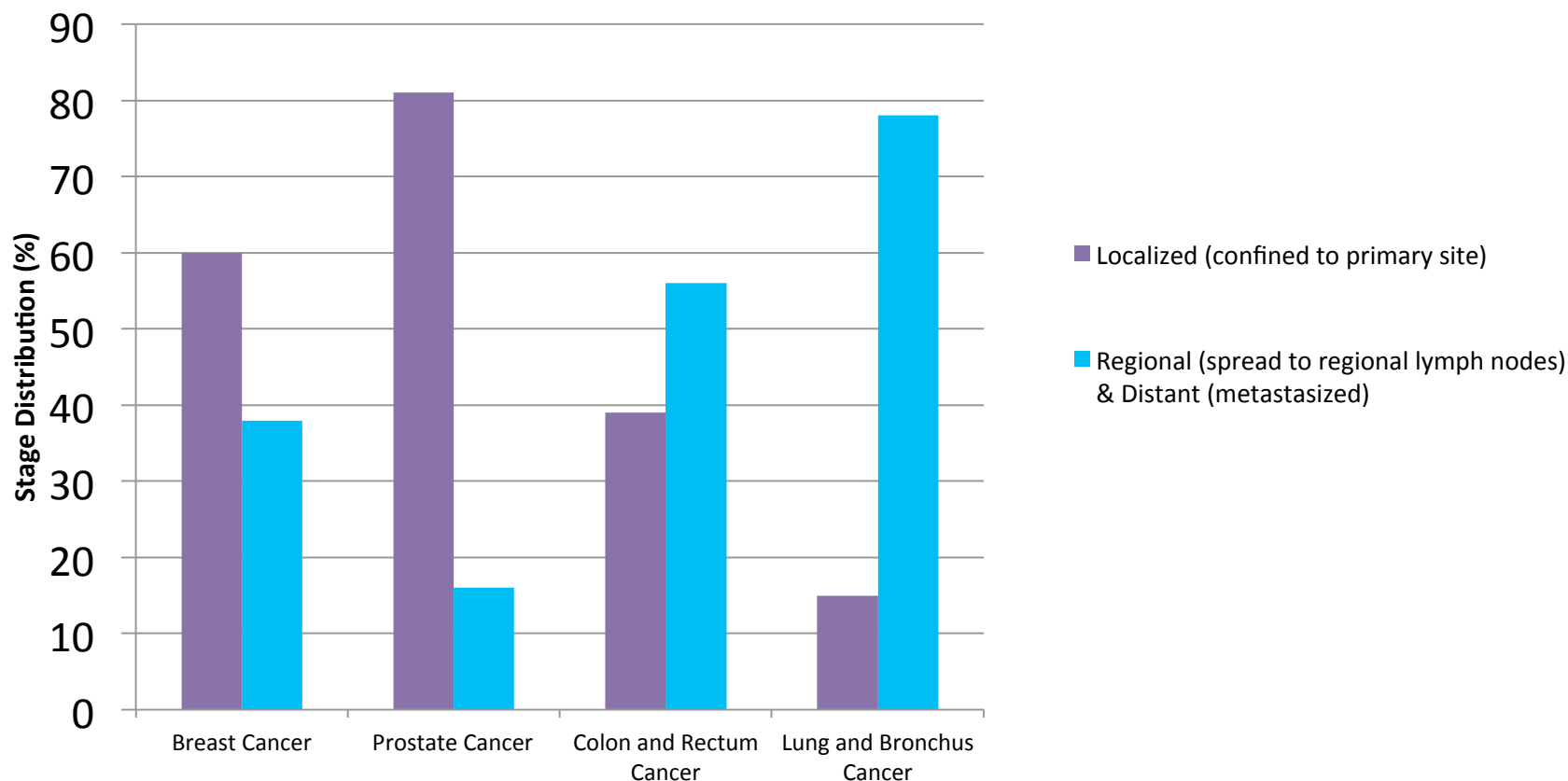
## Age-Adjusted Death Rates for Kentucky, 2005 - 2009 Lung & Bronchus All Races (includes Hispanic), Both Sexes, All Ages





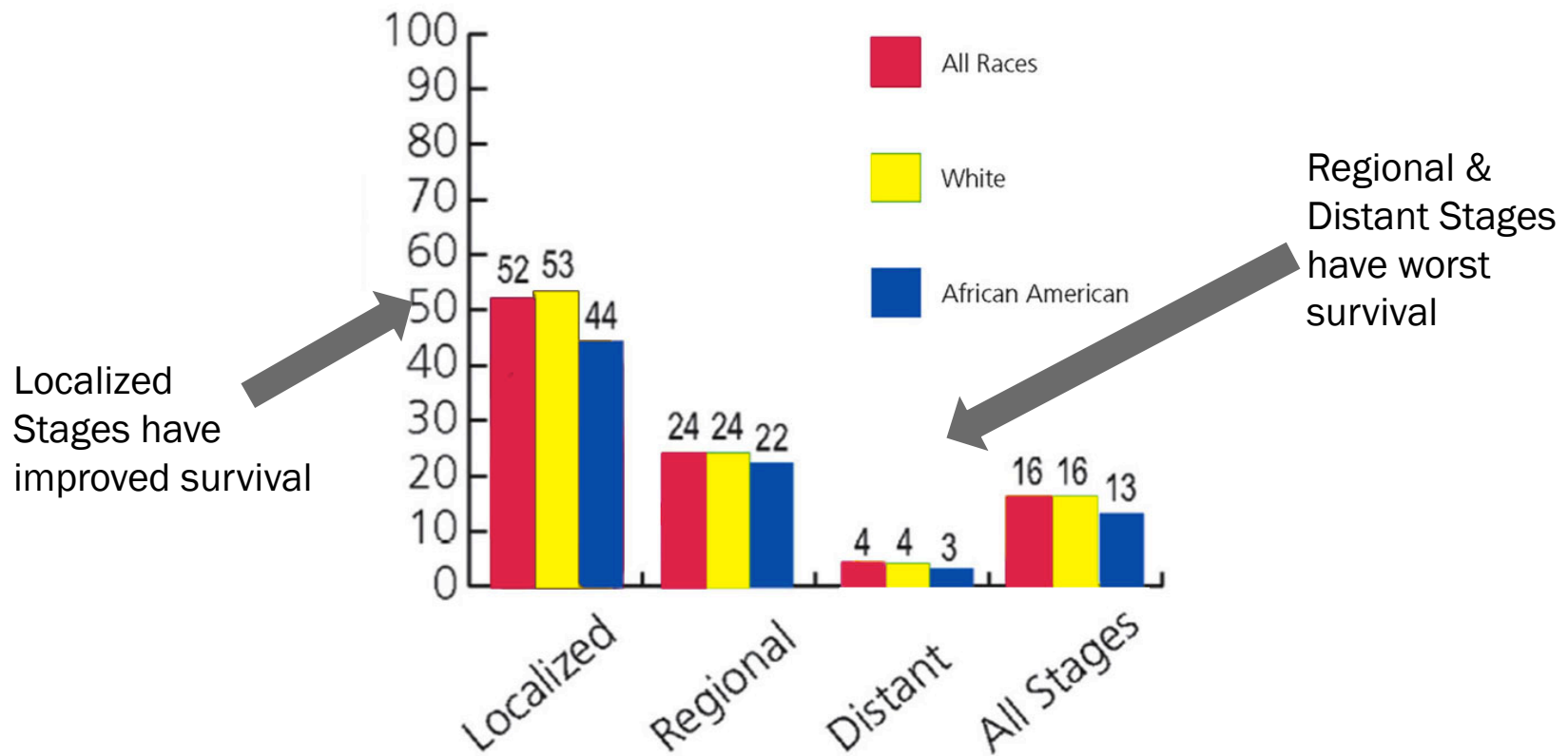
# More than 75% of lung cancers are diagnosed in advanced stages.

Stage Distribution 2002-2008,  
All Ages, Races, Both Sexes (SEER)



# Survival declines with Clinical Stage

**Lung & Bronchus**  
**5-year Survival % vs. Stage Distribution**



HOPE

# Stigmata of Lung Cancer

## ■ Nihilistic Approach

- Survival is poor in many patients
- Survival is better in early stage patients
- Should be a stimulus to shift stage to earlier disease

## ■ Self-Inflicted/Deserved

- Often perceived as a self-inflicted disease
- While smoking is a major risk factor in lung cancer it is not the only factor
- Heavy metals or other potential toxins are being defined for high risk areas (Appalachia)
- Although as many as 20% of patients never smoked

## ■ Difficult population to treat

- Older, more co-morbid factors that complicate treatment
  - Poor lung function, concomitant cardiac disease, etc.
- It is crucial that surgeons are involved in the treatment decisions and that assumptions are not being made with our potential patients

EARLY DETECTION  
LCA ADVOCACY EFFORTS

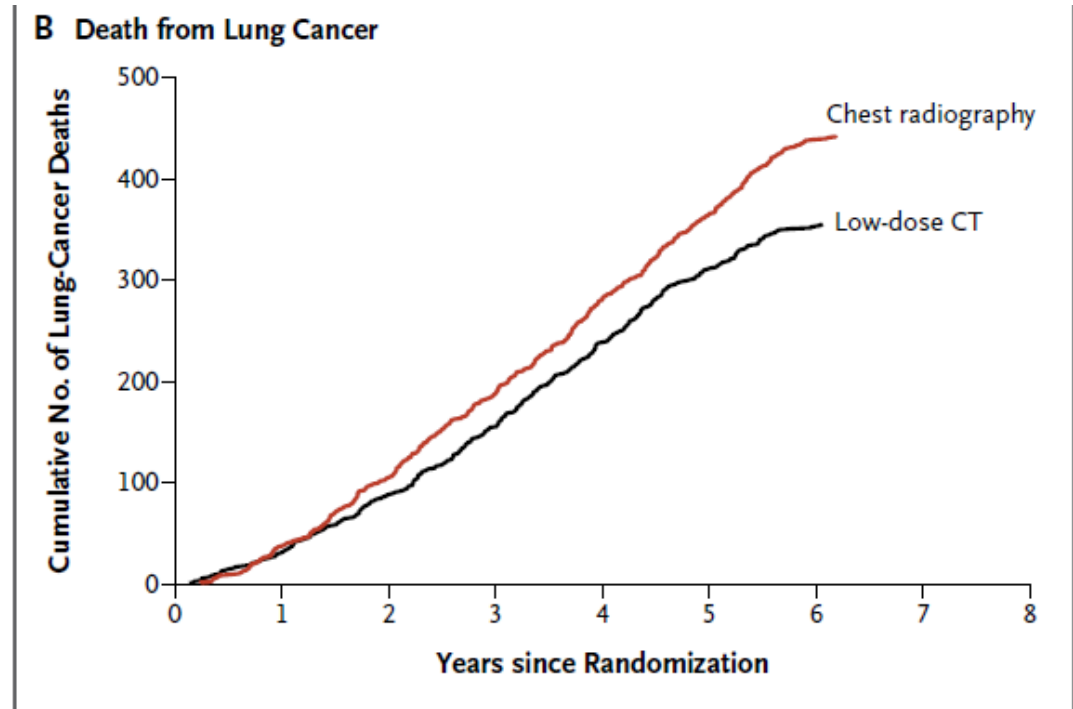
CONTROL RISKS  
AWARENESS

SURGEONS STAY INVOLVED  
EXPAND TARGETED THERAPY

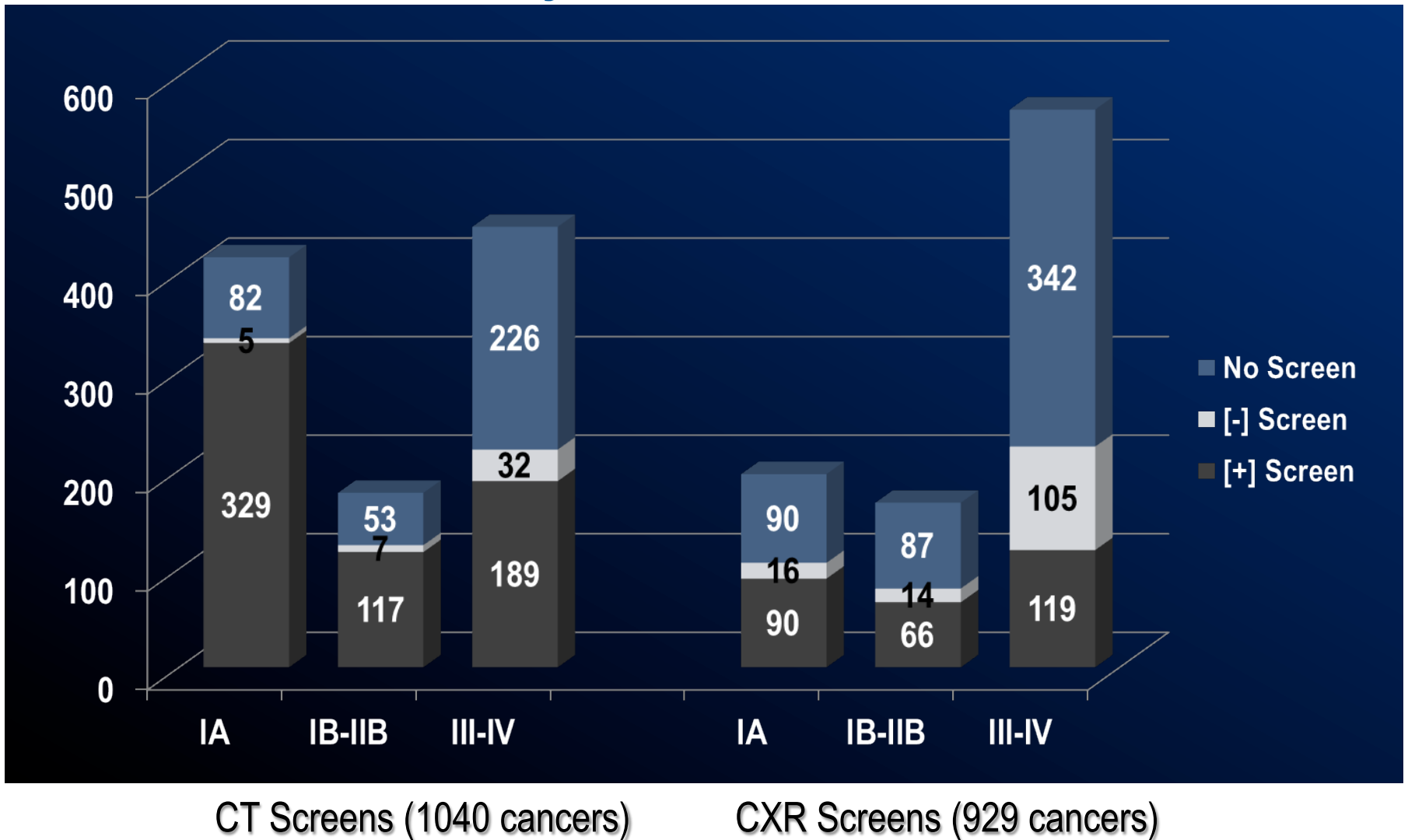
# The largest randomized lung cancer screening trial completed, indicates screening high-risk populations saves lives.

## ■ NLST:

- Screening High-Risk Populations = 20% Relative Reduction in Lung Cancer Mortality
- High Risk = current or former ( $\leq 15$  yrs quit) heavy smokers ( $\geq 30$  pk-yrs), aged 55-74
- 24% of CT scan group had a positive scan
- ( $> 4$  mm non-calcified nodule), of these 96% were false positives.



# Stage Distribution for Lung Cancers by Screen Status



# **The largest randomized lung cancer screening trial completed, indicates screening high-risk populations saves lives.**

- Population enrolled to NLST was ethnically diverse
- Applicability to other selected populations is not yet examined.
- Applicability of results to typical community based practice is mixed.
- Participating centers were comprised of NCI-designated cancer centers, large academic centers and handful of satellite centers of these institutions.
- It has not been evaluated if there is an association between the screening setting and outcomes; however, variability in rates of false-positive scans, additional imaging, and follow-up procedures suggest that this should be examined.

# NCCN Recommendations to Set Up a Screening Program.

- Screening Program Navigator
- Smoking cessation: patient education, counseling and pharmacotherapy options
- Establish well-defined guidelines for PCPs to identify / recommend high-risk patients
- Structured CT reports interpreted with expertise in Fleischner guidelines
- Board-certified Radiologist with expertise in screening scans.
- Comparison with prior chest CT images to evaluate change in size, morphology, and density of nodules; review of serial chest CT exams to detect slow growth
- Board-certified, Multidisciplinary physicians with expertise in diagnosis and treatment of lung cancer diagnosed in screening programs.
- Continuum of care, management of patients with pulmonary nodules for all abnormal scans and annual screening for negative scans.
- Standardized data collection management. Biospecimen repository

# USPSTF Guidelines for Lung Cancer Screening

The Task Force recommends *annual* screening for lung cancer using *low-dose computed tomography* (LDCT) in individuals at high risk for lung cancer based on *age* and *smoking history*.

**Grade B**



- **adults ages 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years.**
- **Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.**

(Posted 31 December 2013)

[www.uspreventiveservicestaskforce.org/uspstf/usp lung.htm](http://www.uspreventiveservicestaskforce.org/uspstf/usp lung.htm)

(Humphrey et al., 2013, Annals of Internal Medicine, online)  
<http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfact.pdf>



# USPSTF Recommendation of Grade B.

- **GRADE B:** *The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.*

USPSTF Recommendation Grades	
Grade	Definition
A	Recommended.
B	Recommended.
C	Recommendation depends on the patient's situation.
D	Not recommended.
I statement	There is not enough evidence to make a recommendation.

# Momentum is Building

- CMS/Payers are recognizing/reimbursing for LCS
- Multiple centers have initiated lung cancer screening
  - Most are centered around a CT Scan
  - Not patient Centric
- Governor Beshear Issues Kentucky Health Now Goals
  - 2 of the 9 goals are addressed by effective lung cancer screening
    - Reduce KY Smoking Rate by 10%
    - Reduce KY Cancer Mortality by 10%

# Medicare Reimbursement Levels for Lung Cancer Screening and Shared Decision Making in 2016

CPT Code	Description	Work RVUs	2016 Payment
G0296	Counseling visit to discuss need for lung cancer screening LDCT	0.52	\$54.10
G0297	LDCT for lung cancer screening	1.02	\$230.73

# Lung Cancer Screening Excellence Project

- Kentucky Lung Cancer Research Project and the Kentucky Clinical Trials Network established a focus on lung cancer early detection
  - Statewide network on lung cancer clinical trials and funded research projects
  - KDMC founding member site
  - Current portfolio guided with input from sites for trials on early detection, implementation and dissemination of lung cancer screening.
  - Future portfolio, continuation and expansion of examination of early detection.

James Graham Brown

Cancer Center

A proud member of  Health Care

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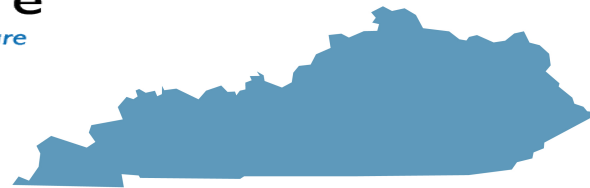


**Bridging Cancer Care**

*Community Awareness, Prevention and Care*



LUNG CANCER ALLIANCE



**KENTUCKY  
LEADS**  
COLLABORATIVE

**LUNG CANCER**  
EDUCATION • AWARENESS  
DETECTION • SURVIVORSHIP

**UKHealthCare®**

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**NCI·CC**

A Cancer Center Designated by the  
National Cancer Institute



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Markey Cancer Center

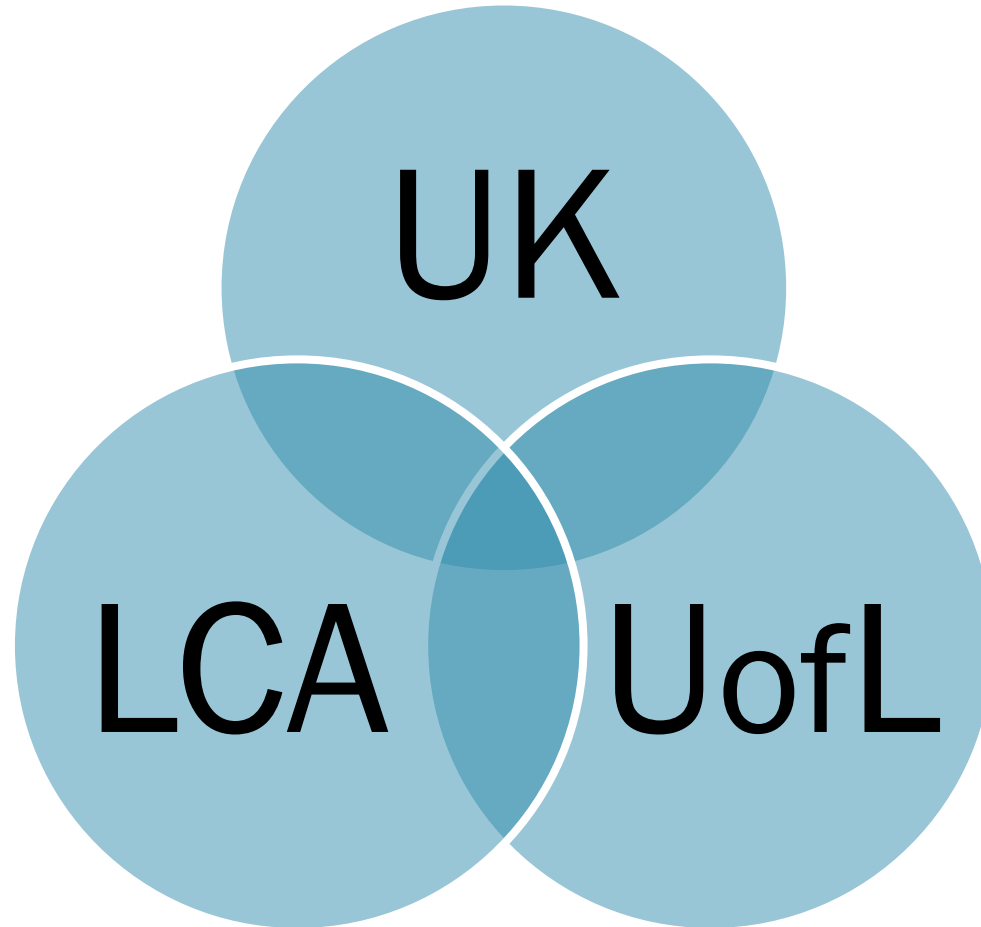
Research Network

 **Kentucky  
Clinical Trials Network**

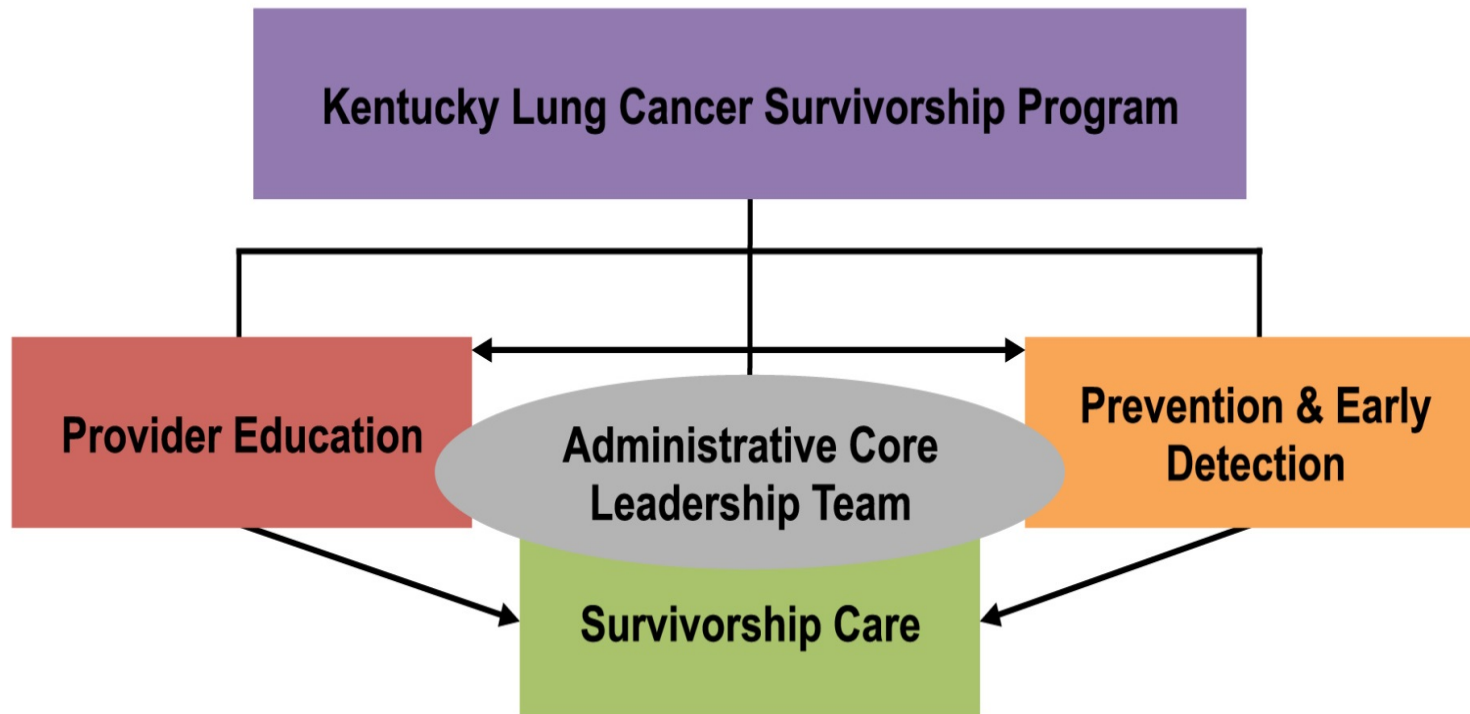
# Lung Cancer Survivorship in Kentucky

- Mission of the Lung Cancer Survivorship in Kentucky Collaborative: Reduce the burden of lung cancer in Kentucky through development, evaluation, and dissemination of novel, community-based interventions to promote provider education, survivorship care, and prevention and early detection of lung cancer.
- KDMC will participate in both the Survivorship Care and Screening studies.

# Kentucky LEADS Collaborative



# Kentucky LEADS Collaborative



*Integrated & Interdisciplinary*



# Lung Cancer Survivorship in Kentucky

- Grant to examine a combination of efforts to increase quality lung cancer care and reduce the burden of lung cancer on patients, caregivers and providers.
- Led by Dr. Jamie Studts, UK, Markey Cancer Center in collaboration with the Brown Cancer Center and others

# Lung Cancer Survivorship in Kentucky

- “Kentucky LEADS Collaborative: Lung Cancer Education, Awareness, Detection, Survivorship” and consists of three distinct studies:
  1. **Primary Care Provider Education**, led by Dr. Goetz Kloecker at the University of Louisville, Brown Cancer Center and Connie Sorrel Kentucky Cancer Program West,
  2. **Survivorship Care**, led by Dr. Jamie Studts at the University of Kentucky, Markey Cancer Center,
  3. **Prevention and Early Detection (Screening)**, led by Dr. Tim Mullett and Dr. Jennifer Knight at the University of Kentucky, Markey Cancer Center.
- KCTN and MCCRN sites

# Lung Cancer Survivorship in Kentucky: Kentucky LEADS Collaborative Fundamental Principles

## ■ Community-Engaged

- Over 15 implementation sites throughout KY
- Over 20 additional community partners & organizations
- Integration of community and medical advisory boards

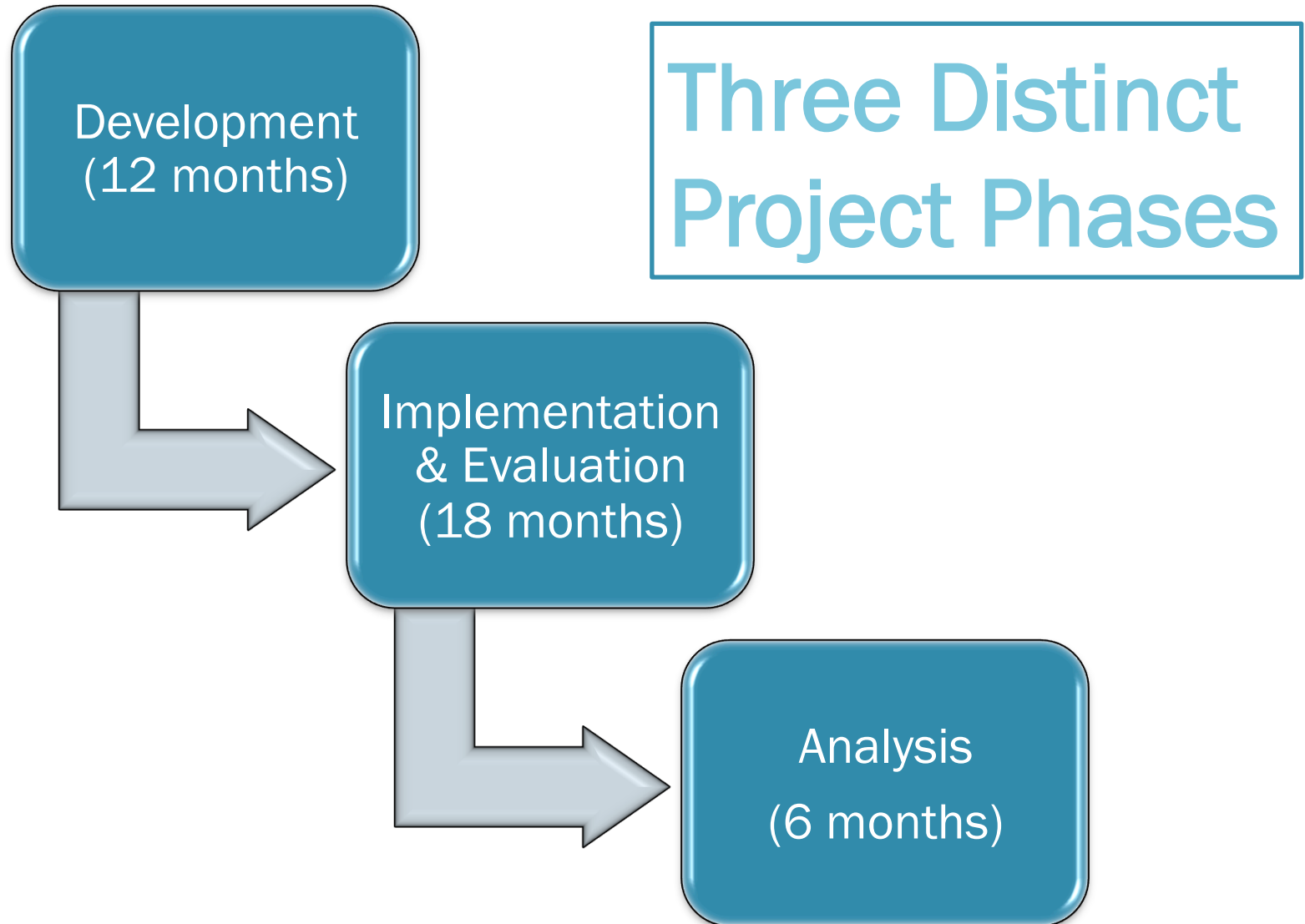
## ■ Interdisciplinary

- oncology, nursing, social work, palliative care, education, public health, communication, advocacy, psychology

## ■ Multi-level

- Providers
- Individuals diagnosed with LuCa and Caregivers
- Health Systems/Lung Cancer Screening Programs

# Project Plan and Timeline



# Provider Education (PE): C1

- Led by Goetz Kloecker, MD, Brown Cancer Center and Connie Sorrell, KCP West
- In the PE component, we hypothesize that continuing education programming will demonstrate...
  - 1) tremendous reach into the primary care community, including physicians, nurse practitioners, and physician's assistants.
  - 2) increased provider knowledge of evidence-based lung cancer care across the continuum (e.g., evidence-based treatments, innovative treatments including immunotherapies, survivorship care, screening guidelines, radon testing, and tobacco prevention and treatment).
  - 3) more favorable attitudes toward lung cancer care across the continuum.
  - 4) expanded referral patterns for quality lung cancer care across the continuum.

# Survivorship Care Overall Aims: C2

- Led by Jamie Studts, PhD, Markey Cancer Center
- Build a novel psychosocial survivorship care intervention for individuals diagnosed with lung cancer and their caregivers
- Build a companion training program to facilitate provider implementation
- Evaluate the intervention program in a community-based clinical/observational trial

# **Implementation of Quality Lung Cancer Screening in Kentucky**

# Prevention & Early Detection (PD): Implementation of Quality Lung Cancer Screening in Kentucky (C3)

- We hypothesize that the program will demonstrate greater implementation of quality indicators for lung cancer screening, including:
  - optimal referral patterns for evidence-based lung cancer care,
  - use of strong patient navigation,
  - integration of evidence-based tobacco treatment,
  - use of shared decision making,
  - established protocols for follow-up services and program retention.



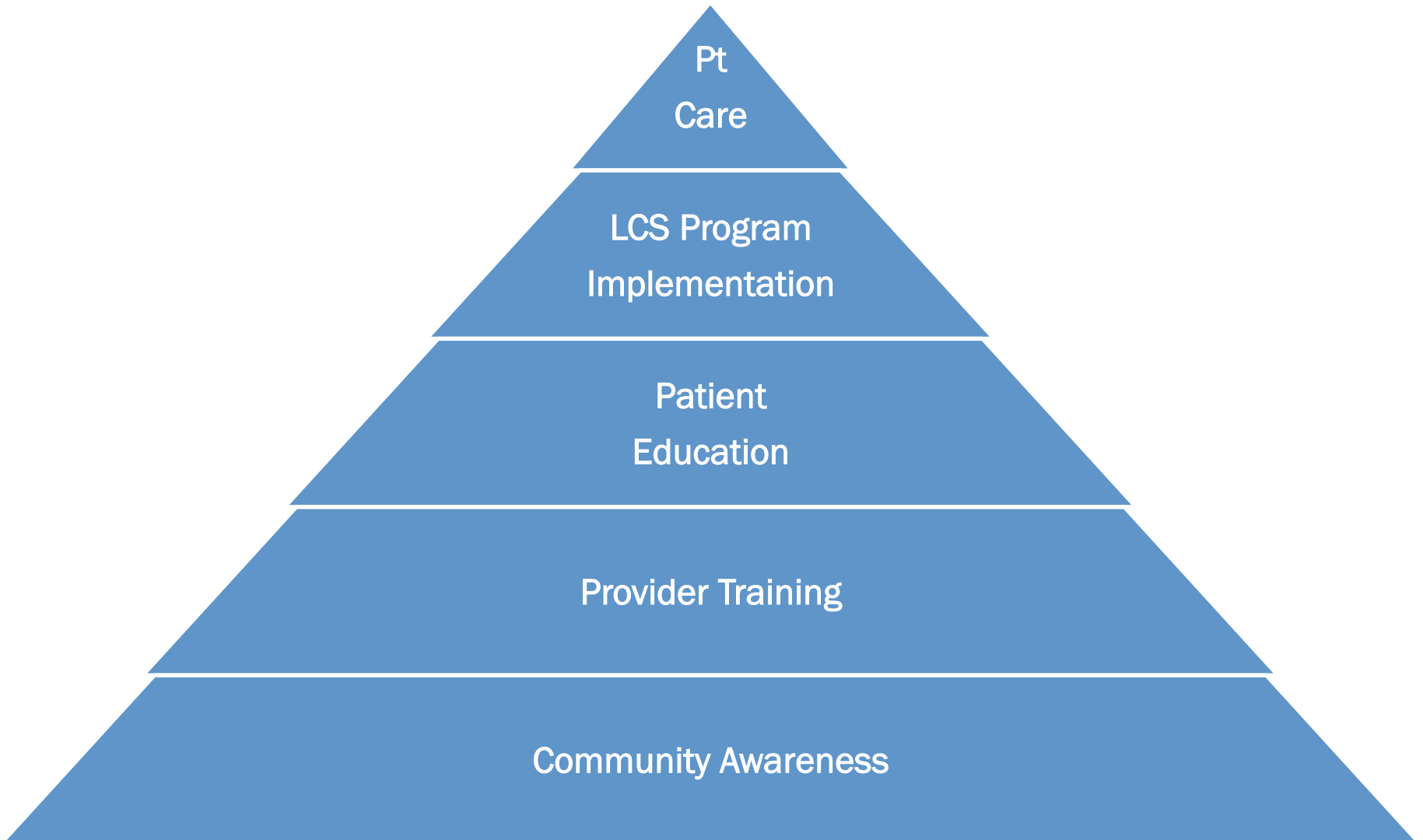
# It takes an average of 17 years for only 14% of research to translate into practice

- People may thus experience a significant delay in, or never be offered, interventions that have been proven to improve health. (Balas, 1998).
- Implementation Science:
  - study of methods that influence the integration of evidence-based interventions into practice settings.
  - addresses how health interventions can be delivered with efficacy and effectiveness within real-world public health and clinical service systems. (NCI, Implementation Science, part of NCI's Division of Cancer Control and Population Science)
  - enhances the extent to which intervention research is generalizable, representative, and comprehensive in order to increase public health impact

# Implementation of Quality Lung Cancer Screening in Kentucky

- Given the devastating burdens of lung cancer on Kentuckians, we must examine the barriers and facilitators that influence successful implementation of effective lung cancer screening intervention in Kentucky.
- Dissemination and implementation research is our first research step to ensure that high quality lung cancer screening programs are available throughout Kentucky, reaching our communities with the highest incidence and mortality rates of lung cancer in the country

# Implementation of Quality Lung Cancer Screening in Kentucky



# Implementation of Quality Lung Cancer Screening in Kentucky

- Study Goal: Facilitate lung cancer care through collaborative efforts with lung cancer screening programs/sites to implement best practices
- Best practices include the integration of key components into screening programs
- High Quality Screening
  - ✓ High-risk individuals
  - ✓ Screening protocols
  - ✓ Tobacco treatment
  - ✓ Shared decision making
  - ✓ Pathways to care coordination
  - ✓ patient navigation
  - ✓ Reduce exposure to second-hand smoke,
  - ✓ Radon prevention
- Share & Learn with Collaborative Sites
  - To help guide and refine best practices for Kentucky

# Implementation of Quality Lung Cancer Screening in Kentucky

- Study Design: Examine implementation of lung cancer screening as well as case data of screening participants at up to ten participating sites across Kentucky. No minimum or maximum number of screening participants.
- Specific Aims:
- Integrate recommendations from evidence-based standards and guidelines to establish programmatic elements of high quality lung cancer screening in Kentucky
- Deliver implementation strategies (i.e., resources, training, feedback) to facilitate adoption and implementation of lung cancer screening programs in diverse settings throughout Kentucky
- Evaluate implementation outcomes and factors that influence

# Components Necessary for High-Quality Lung Cancer Screening

## The National Consensus

1. Who is Offered Lung Cancer Screening
2. How often and How Long to Screen
3. How the Scan is Performed
4. Lung Nodule Identification
5. Structured Reporting
6. Lung Nodule Management Algorithms
7. Smoking Cessation
8. Patient and Provider Education
9. Data Collection

Mazzone, P., Powell, C.A. (2014). Components necessary for High Quality Lung Cancer Screening: American College of Chest Physicians and American Thoracic Society Policy Statement. *Chest*,

# Kentucky Components of LCS

- Modified Lung RADS
  - Accommodate the high incidence of PET Positive benign nodules
- Emphasized *Certified* Tobacco Treatment Specialists
  - Tobacco control within the program
  - Radon and Second Hand Smoke Assessments
- Training modules for radiologists and multidisciplinary team
  - Specific reading of LDCT
- Enhanced emphasis on administrative support
  - Navigator
  - Data collection
  - Retention of subjects

# Implementation of Quality Lung Cancer Screening in Kentucky

## Site Selection:

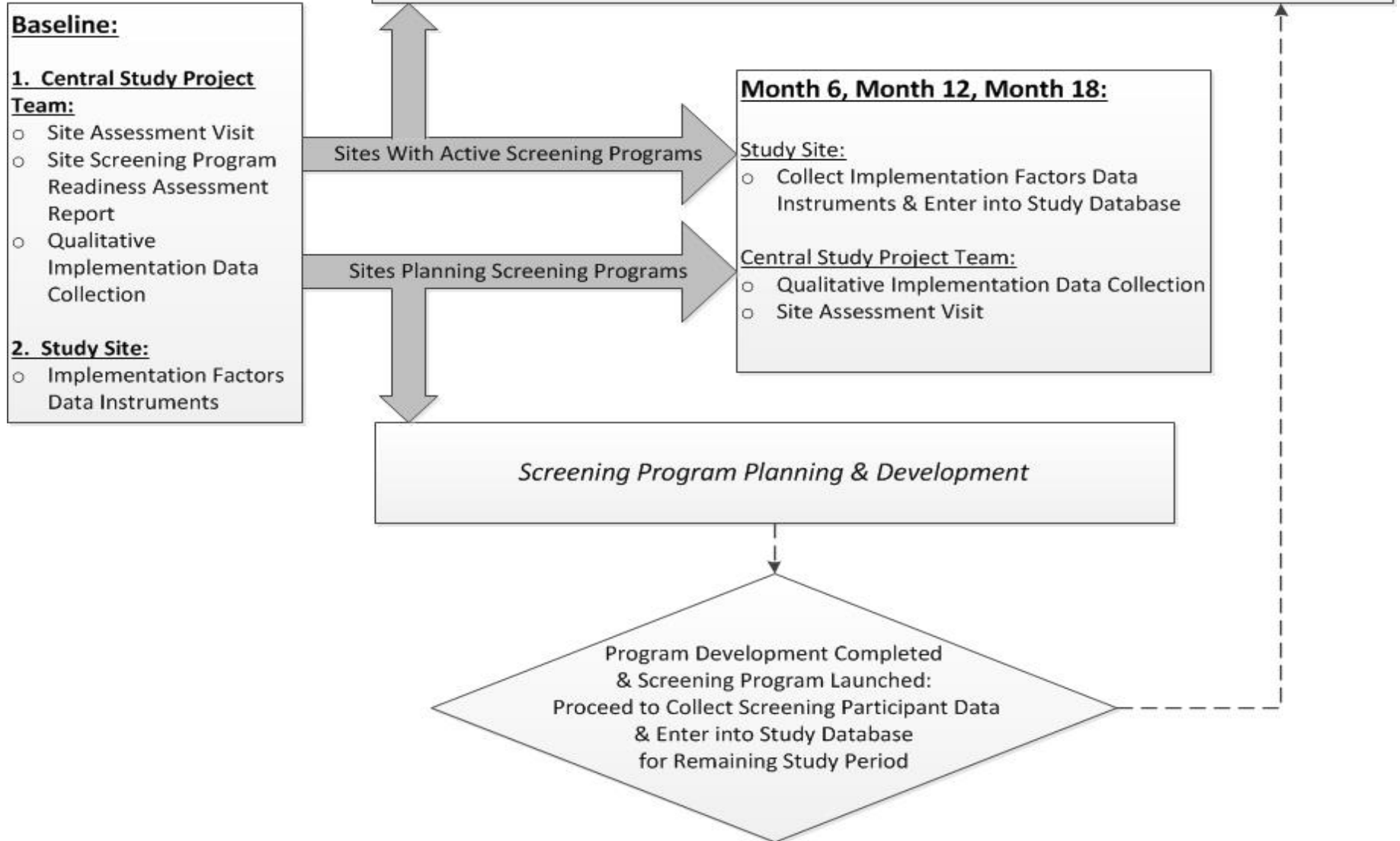
- Collaborative Research Sites throughout Kentucky committed to high quality lung cancer prevention and screening.
  - ✓ Committed to reducing the burden of lung cancer in Kentucky
  - ✓ Committed to working across organizations and institutions to focus on patient care and developing best practices and standards in diverse settings
  - ✓ Committed to providing broad access for patients to lung cancer prevention and screening within a reasonable travel distance



# Implementation of Quality Lung Cancer Screening in Kentucky

- Study Goals:
  - ✓ Quality Research, Compliant Research
  - ✓ Assure Human Subjects Protection
  - ✓ Assure Data Integrity
  - ✓ Evaluable Data collected and suitable for evaluation of endpoints
  - ✓ Submission for publication

# Study Schema:



# Implementation of Quality Lung Cancer Screening in Kentucky

## ■ Eligibility Criteria:

### ■ Inclusion:

- Site must be willing to follow evidence-based guidelines to establish and manage a lung cancer screening program.
- Participants must meet criteria of high-risk
- Participants must have capacity and provide consent

### ■ Exclusion:

- Site does not have commitment or capacity to follow evidence-based guidelines to establish and manage a lung cancer screening program.
- Participants that do not meet criteria of high-risk
- Participants unable or unwilling to provide consent

# Implementation of Quality Lung Cancer Screening in Kentucky

- **Study Resource Portal:** includes training modules and a library of screening program resources
  - Hosted on central CME website
  - Up to 8 CME / CE credits
  
- Training Modules include:
  1. Screening Program Team & Quality Elements
  2. Overview of Lung Cancer Screening for Radiologists
  3. Mechanics of Lung Cancer Screening for Radiologists
  4. Screening Program Navigation & Management
  5. Treatment of Tobacco Addiction
  6. Shared-Decision Making
  7. Multidisciplinary Evaluation/Work-Up & Care
  8. Radon Prevention & Second-Hand Smoke

# Implementation of Quality Lung Cancer Screening in Kentucky

## Study Calendar:

	<u>Baseline:</u>	<u>Month 6:</u>	<u>Month 12:</u>	<u>Month 18:</u>
Study Training/Screening Program Modules	X			
Screening Program Assessment	X	X <sup>B</sup>	X <sup>B</sup>	X <sup>B</sup>
Implementation Factors Data Instruments:	X	X	X	X
Site Receives Program Quality Metrics Report from Study Chair Project Team	X	X	X	X
<u>Site Visit by Study Chair Project Team:</u> 1. Implementation Qualitative Data Collection via discussion with site screening program team or planning team and site leadership or screening program leadership.	X	X	X	X
Screening Participant Data <sup>C</sup>			X	

<sup>A</sup> All Sites will complete study start-up and screening program assessment. Sites that have launched LDCT lung cancer screening programs will begin submitting screening participant data to the study database. Sites that have not launched a LDCT lung cancer screening program will proceed with development activities to establish a LDCT lung cancer screening program at their facility.

<sup>B</sup> Sites that have not initiated LDCT lung cancer screening programs will be assessed during program planning and development by the Study Chair Project Team, until they begin screening participants.

<sup>C</sup> Central Study Project Team will complete a Screening Readiness Assessment visit prior to sites beginning data entry of participant screening data. Sites will enter screening participant data into the study database for the duration of the study in which they are performing LDCT lung cancer screening.

# Implementation of Quality Lung Cancer Screening in Kentucky

- Screening Program Implementation Workbook/Toolkit:
- Materials include resources to plan, develop, manage and operate lung cancer screening programs, including:
  - background literature
  - guidelines and recommendations
  - screening program operational level resources (sample workflows, operations templates, intake and follow-up template, shared-decision making aids, structured scan report template, patient education materials, marketing and presentation templates)

# Implementation of Quality Lung Cancer Screening in Kentucky

- Study Start-Up:
  - Traditional Regulatory Start-Up Documents & Process
  - Site Screening Readiness Visit / Implementation Readiness:
    - Site Assessment Visit by Central Study Project Team
    - Site Screening Program Readiness Assessment Report
    - ACR Designated Lung Cancer Screening Program application
  
- Based on assessment of status, sites will proceed on one of the following paths:
  - Screening will collect and submit data for the duration of the study.
  - Sites that have not initiated LCS program will proceed with development activities to establish a LDCT lung cancer screening program at their facility. Upon advancement to status of active screening program, site will proceed to collect and submit participant data for the remaining study period.

# Implementation of Quality Lung Cancer Screening in Kentucky

- Data Collection:
- Implementation Data will be collected at Baseline, Month 6, Month 12 and Month 18
  - We are looking at factors that influence implementation and outcomes:
    - Satisfaction and engagement of clinicians, institutions
    - Fidelity, quality, presence of programmatic elements
    - Access and retention of participants
    - Perceptions of clinicians and institution
- Participant data will be collected for the duration study that site is screening
- Study database. Custom reports
- MCC CRI SRF and Data Manager provide technical assistance
- Participant level data, harmonized with CMS data reporting requirements, and ACR dataset. Optional: Support with transmission to ACR



# Site Implementation

- 10 participating sites.
- Sites provide lung cancer screening, tobacco treatment secondhand smoke and radon prevention education.
- Establish screening “champions” based on practice patterns.
- Track “lessons learned” from Sites.
- Site visits with each participating site.
- Provide technical assistance to sites.
- Promote utilization of Study Resource Portal
  - Evaluate outcomes of CME/CE modules.

# Marketing

- Develop and implement media plans, including press releases, media events, that focus on :
  - enrollment at sites and communities as well as the project overall
  - outcomes achieved at these sites and communities as well as the project overall
  - Public service ads on risk and screening in partnership with sites in key markets.
  - Provide technical support to Kentucky Cancer Program Regional Cancer Control Specialists in promoting this effort to their District Cancer Councils.
  - Other efforts as guided by sites

# Expectations

- Lung Cancer Screening has been proven to be effective
- Application of LCS in the Community Setting has been challenged
- Will evaluate the effectiveness of implementation of a lung cancer screening program
- Monitor the evolution to high-quality, ethical delivery of lung cancer screening
- Effectively reduce mortality from lung cancer by impacting both incidence and stage of detection

# Implementation of Quality Lung Cancer Screening in Kentucky

## Summary

- The aim is to reduce the burden of lung cancer in Kentucky, employing a range of novel set of multi-level interventions
- Design for dissemination/implementation
- Scalable for broader application
- Consider future opportunities with BMS-F and NCI for testing our interventions

# Lung Cancer Screening Excellence Project Portfolio

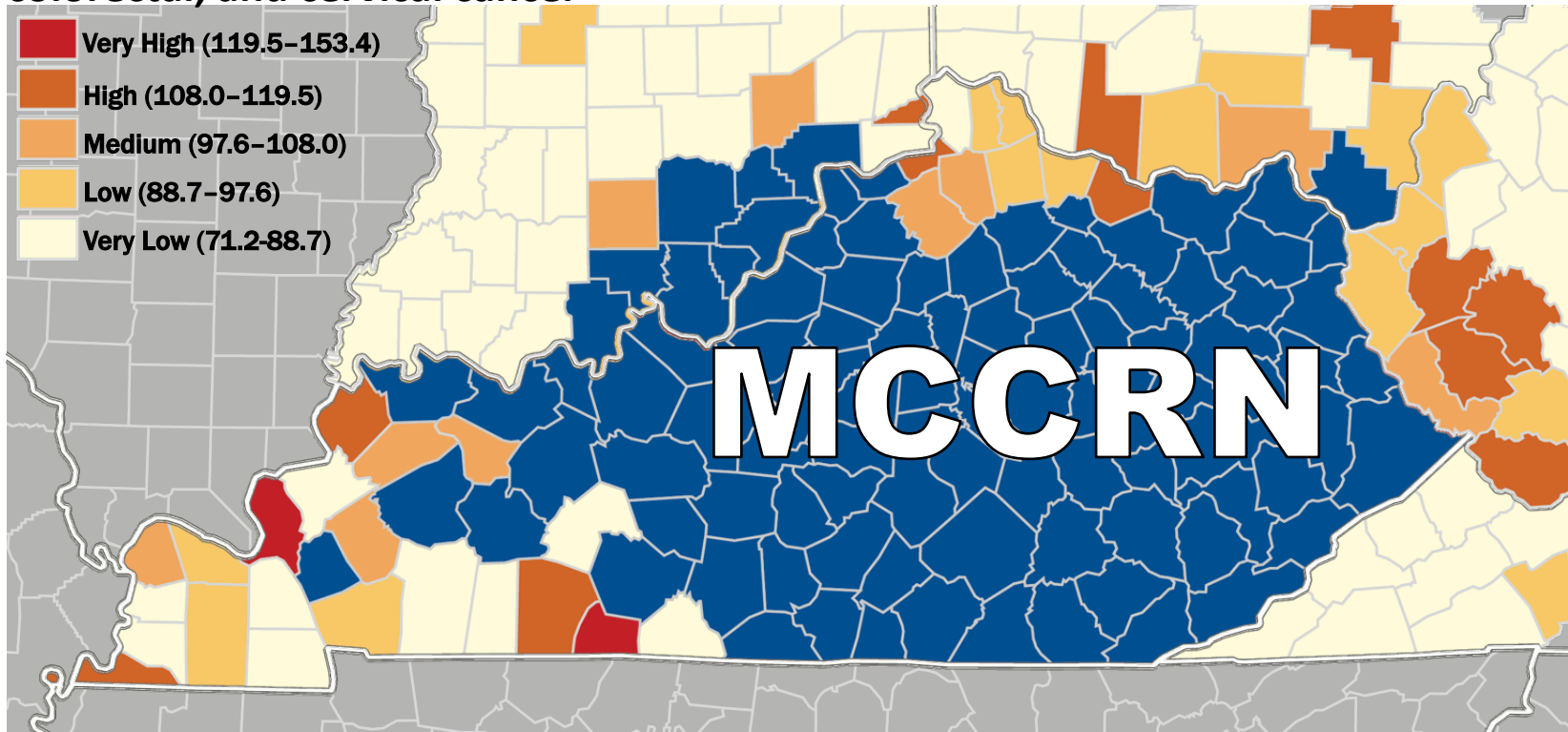
## ■ Future Research:

1. We hope that the data from this study will support the expansion of the database into a registry of Kentucky-wide data of all screening participants, similar to the Kentucky Cancer Registry.
2. A goal of this study is to establish a consortium of centers delivering high quality lung cancer screening that will have opportunities to conduct a portfolio of lung cancer studies linked to screening programs.

# Collaborations Focus on Significant Burden of Cancer

- **1<sup>st</sup>** in the nation in overall cancer mortality rate
- **Highest** incidence rate for all cancer sites

Cancer incidence and mortality are highest in Appalachia, especially for lung, colorectal, and cervical cancer



# Study Organization

- Project Team:
  - Study Chair: Tim Mullett  
[timothy.mullett@uky.edu](mailto:timothy.mullett@uky.edu)
  - Study Chair: Jennifer Redmond Knight  
[jredknight@kycancerc.org](mailto:jredknight@kycancerc.org)
  - KCTN Director:  
MCCRN Director Kris Damron  
[kris.damron@uky.edu](mailto:kris.damron@uky.edu)
  - Data Manager: Lara Sutherland  
[lara.sutherland@uky.edu](mailto:lara.sutherland@uky.edu)
  - KCTN Research Project Manager: Trey Alexander  
[joseph.alexander@uky.edu](mailto:joseph.alexander@uky.edu)
- Collaborators: University of Kentucky, Participating Sites, University of Louisville, Kentucky Cancer Consortium, Lung Cancer Alliance
- Study Funded by: Bristol Myers Squibb Foundation (BMSF)
- Resources: Kentucky Clinical Trials Network, Markey Cancer Center Research Network, Markey Cancer Center Shared Resource Facilities

# Implementation of Quality Lung Cancer Screening in Kentucky

## ■ Medical Advisory Board:

- Clinical and subject matter experts. Will review, advise and provide technical support. Convene 2 times/year.
- Responds to specific medical/screening/prevention issues within sites
  - Doug Adams                      Owensboro Health, Mitchell Memorial Cancer Center
  - Eric Bensadoun                      University of Kentucky, Markey Cancer Center
  - Michael Brooks                      University of Kentucky, Markey Cancer Center
  - Roberto Cardarelli                      University of Kentucky, Kentucky Ambulatory Network
  - Ellen Hahn                      University of Kentucky, Kentucky Center for Smoke-free Policy and Clean Indoor Air Partnership
  - Goetz Kloecker                      University of Louisville, Brown Cancer Center, Study Chair C1: Provider Education



# Implementation of Quality Lung Cancer Screening in Kentucky:

## ■ Community Advisory Board:


- Kentucky Cancer Consortium (KCC) Lung Cancer Prevention and Early Detection Network
  - Provides feedback
  - Supports education, outreach and dissemination of study results
  - Builds partnerships and encourages community participation

## ■ Consultants

- Nationally renowned experts in lung cancer prevention and early detection who will provide subject matter expertise, review and feedback for the project

**UKHealthCare®**  
Markey Cancer Center

**UKHealthCare®**  
Markey Cancer Center  
Research Network

Bristol-Myers Squibb Foundation  
  
**Bridging Cancer Care**  
*Community Awareness, Prevention and Care*

 Kentucky  
**Clinical Trials Network**



Bristol-Myers Squibb  
Foundation

  
**Kentucky**  
Cancer Consortium  
*A partnership for life.*

  
**LUNG CANCER ALLIANCE**

# Kentucky Lung Cancer Survivorship Program

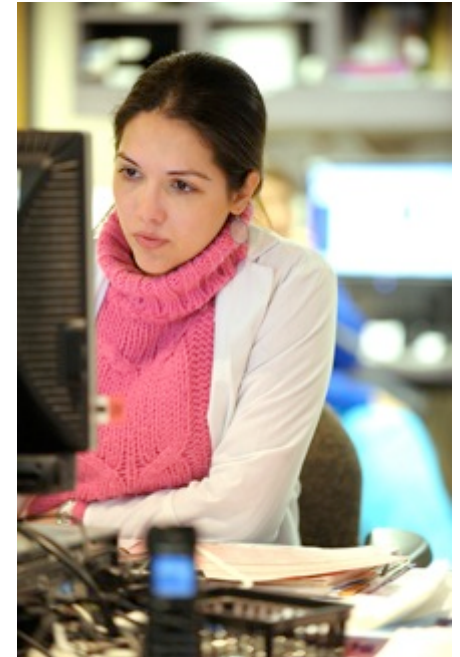
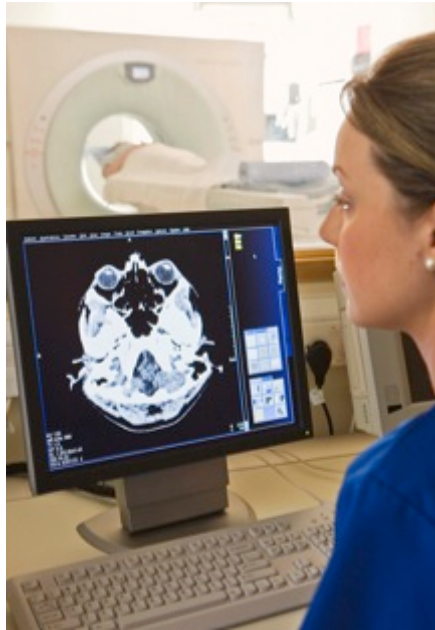
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