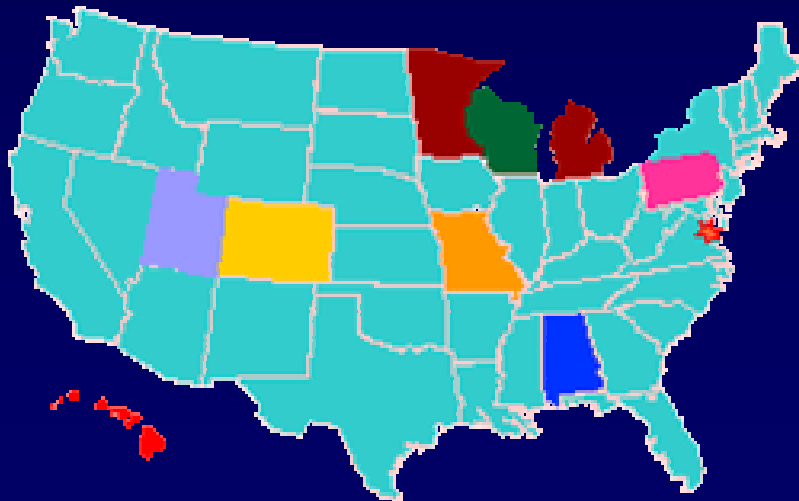


Flexible Sigmoidoscopy in the Prostate, Lung, Colorectal and Ovarian Cancer (PLCO) Screening Trial

Robert S. Bresalier, M.D.



PLCO Trial: Study Design

Screening Centers: 10

Coordinating Center

Participants: 155,000

Screening arm (6 years)

Prostate - PSA & DRE

Lung - x-ray

Colorectal - sigmoidoscopy

Ovarian – CA125 & TVU

Control arm: usual care

Gender 50:50

Age 55-74 years

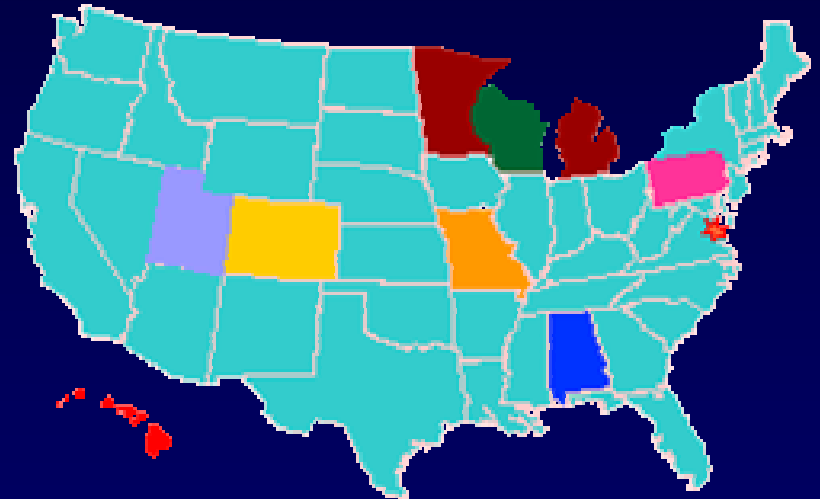
Recruitment: 1993-2001

Screening: 1993-2006

Follow-up to 2015

Annual surveys

Mortality searches



Materials collection in the PLCO Trial

<u>Exam Cycle</u>	<u>Risk Factors</u>	<u>Usual Diet</u>	<u>Serum</u>	<u>Plasma</u>	<u>RBC</u>	<u>DNA</u>	<u>Viable Cells</u>	<u>Tumor Sample</u>
Intervention Arm								
Baseline	X	X	X	X	X	X		
Year 1			X					
Year 2			X					
Year 3		X	X	X	X	X	X	
Year 4			X	X		X		
Year 5			X	X	X	X		
2004-2008	P							P
Non-intervention Arm								
	X	X				X		P

(X: in place; P: proposed)

Schedule of Collections in PLCO

	Subjects	Completion Year
General Questionnaire	154,951	2001
Diet Questionnaire 1	71,877	2001
Diet Questionnaire 2	154,951	2004
Baseline Blood	72,005	2001
Year 1 Blood	70,664	2002
Year 2 Blood	69,385	2003
Year 3 Blood	68,202	2004
Year 4 Blood	67,582	2005
Year 5 Blood	66,889	2006
BuccalCells (control arm)	77,483	2004

PLCO Flexible Sigmoidoscopy Baseline Screening Data

- 77,465 enrolled at 10 screening centers
- 64,658 (83.5%) underwent flexible sigmoidoscopy
- Polyp or mass in 15,150 (23.4%)

J Natl Cancer Instit, in press 2005

PLCO Flexible Sigmoidoscopy Baseline Screening Data

Yield per 1000 screened based on 5-yr age range:

	Women (50.5%)	Men (49.5%)
Advanced adenoma	18.0 to 30.4	36.1 to 49.1
Colorectal cancer	1.1 to 2.5	2.4 to 5.6
CRC or any adenoma	50.6 to 79.6	101.9 to 128.6

77% of 169 colorectal cancers were Stage I or II at diagnosis