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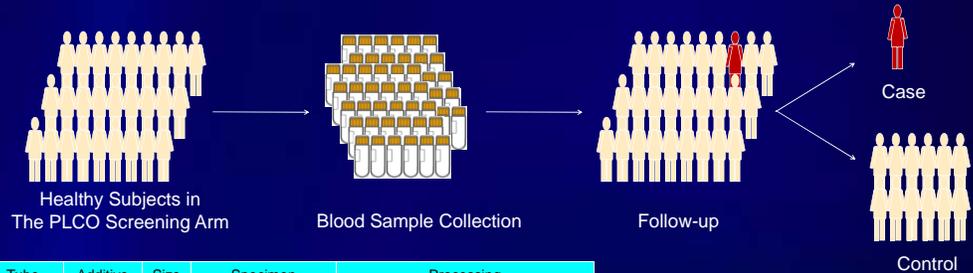
Abstract

The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial is a large scale, randomized controlled cancer screening trial. In addition to the primary goal of evaluating the effects of screening on cancer-related mortality, the trial also established a biorepository to facilitate ancillary studies of early detection biomarkers and etiologic factors within the PLCO cohort.

Current cancer biomarker research is often hampered by hidden biases hard-wired in the samples. These biases have resulted in numerous false positive results, leading to wasted downstream efforts and resources. One way to avoid these biases is to collect/select specimens that are inherently bias-free. In this presentation, we illustrate how PLCO biospecimens are a resource for unbiased samples. For researchers, we provide detailed information about the samples and how to access them. For biorepository managers, we provide information on the design and utilization strategies of this resource.

With approximately 2.5 million well-annotated biospecimens, PLCO biospecimens resource offers several distinctive advantages: 1) specimens were prospectively collected before diagnosis was known; 2) uniform collection, processing and storage protocols; 3) up to 6 annually collected serial samples from the same individuals available for longitudinal analysis; 4) detailed epidemiological and clinical data linked to the specimens. More information is available at: <http://www.parpco.org>; <http://plco.cancer.gov>.

Prospective specimens collection



Tube	Additive	Size	Specimen	Processing
Red/Gray	Clot Activator	6 ml	Serum	Allow clot at room temp. for 1 hr; centrifuge (15 min at 1200 x g or 6 min at 3900 g); aliquot and freeze within 2 hrs of draw; store at -70°C.
Red	None	10 ml	Serum	
Royal Blue	None	7 ml	Zinc-free Serum	Invert gently several times; keep at 2°C - 8°C; centrifuge; aliquot and freeze within 2 hrs of draw; store at -70°C.
Green	Sodium Heparin	10 ml	Plasma, Buffy Coat & RBC	
Lavender	Liquid EDTA	10 ml	Plasma, Buffy Coat & RBC	Invert gently several times; mixed with 10% DMSO; aliquot and freeze (rate controlled) within 35min; store at -157°C.
Yellow	Acid-citrate-dextrose	8.5 ml	Whole Blood	

Access to PLCO Biospecimen Resource



Summary of Data & Specimens Available

Year	DATA		BIOSPECIMENS					Tumor Sample
	Risk Factors	Usual Diet	Serum	Plasma	RBC	DNA Source	Viable Cells	
SCREENED ARM								
Baseline	X	X	X	X	X	X		
Year 1			X					
Year 2			X					
Year 3		X		X	X	X	X	
Year 4			X	X	X	X	X	
Year 5			X	X	X	X		
2005-2007	X							
2006-								X
CONTROL ARM								
Baseline	X							
1998-2000		X						
2000-2005						X		
2006-2007	X							
2006-								X

Cancer cases with specimens available

Cancer	Serum	Plasma	RBC	Buffy Coat	Whole Blood	Buccal Cell
Prostate	3345	3228	1570	2854	2518	1814
Lung	1102	1052	526	731	661	82
Colon	677	588	609	517	481	161
Ovarian	126	124	57	113	87	77
Bladder	454	433	263	375	351	61
Brain	106	103	55	73	55	44
Breast	1515	1449	800	1185	1334	840
Kidney	267	263	157	208	199	38
Liver	78	76	47	58	46	28
NHL	395	384	225	314	276	299
Pancreas	252	242	144	146	145	38

Data as of December, 2008; Updated information available at www.parpco.org

Some Criteria for Biomarker Studies

- Preliminary data showing acceptable performance characteristics (Sensitivity, Specificity, ROC)
- Parsimonious use of samples
- Study design considerations:
 - Pre-specified marker(s) and classification rule
 - Separate dataset for training and validation

Currently Research Portfolio

