

# Insurance clearance for cancer clinical trials participation: the Hopkins experience

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# SKCCC catchment area

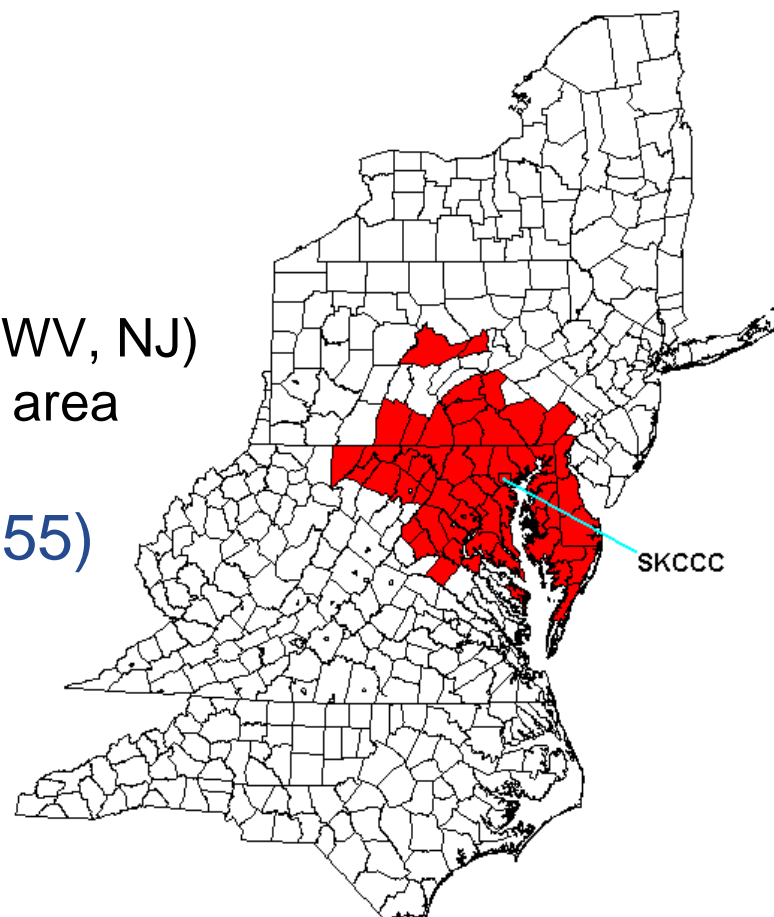
## SaTScan analysis

### Geographic area covered

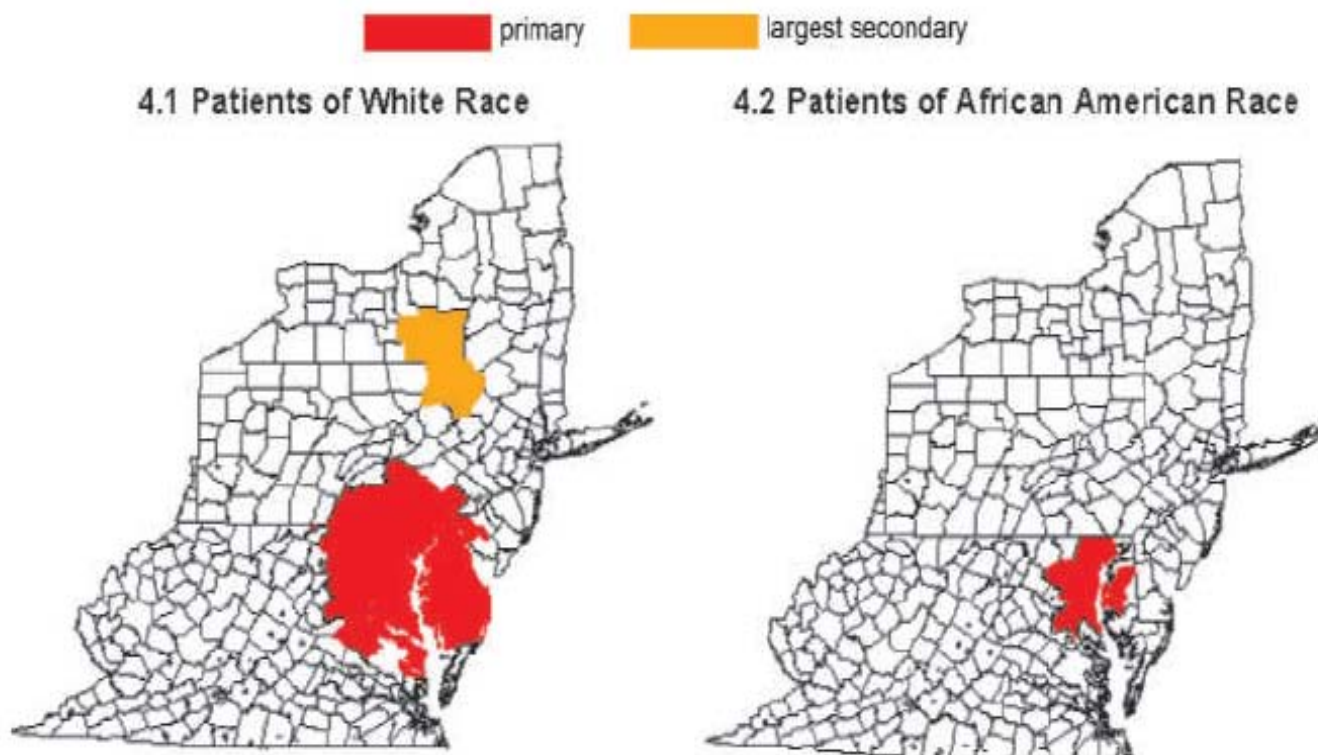
- 58 counties (MD, DE, DC, PA, VA, WV, NJ)
- Baltimore City is 18% of catchment area

### Racial/ethnic diversity (N = 19,655)

- Black 18%
- White 79%
- Other 3%
- 1% Hispanic



## Catchment area by race



## Patient demographics 2005-07

		Catchment Area		Non-Catchment	All (%)
		Baltimore City (%)	Non-BC Catchment (%)	Area (%)	
		N=1,952	N=11,145	N=4,540	N=17,637
<b>Race</b>					
	White	839 (43.0)	9468 (85.0)	4159 (91.6)	14466 (82.0)
	Black	1082 (55.4)	1229 (11.0)	245 (5.4)	2556 (14.5)
	Other	31 (1.6)	448 (4.0)	136 (3.0)	615 (3.5)
<b>Sex</b>					
	Male	973 (49.8)	6519 (58.5)	3311 (72.9)	10803 (61.3)
	Female	979 (50.2)	4626 (41.5)	1229 (27.1)	6834 (38.7)
<b>County poverty quartile</b>					
	1 (least)	--	9760 (87.6)	1372 (30.2)	11132 (63.1)
	2	--	996 (8.9)	1072 (23.6)	2068 (11.7)
	3	--	52 (0.5)	917 (20.2)	969 (5.5)
	4 (most)	1952 (100.0)	337 (3.0)	438 (9.6)	2727 (15.5)
<b>Participation in therapeutic clinical trials, by location</b>					
		251 (12.8%)	2352 (21.1%)	666 (15.1%)	3269 (19%)

# Enrollment in clinical trials: 2005-07

## Poisson multivariate model

		Therapeutic		Nontherapeutic	
		ACR*	p-Value	ACR*	p-Value
<b>Age</b>	<20	0.96	0.64	1.37	0.009
	20-64	1.00	--	1.00	--
	>64	1.12	0.002	0.87	0.007
<b>Sex</b>	Male	1.00	--	1.00	--
	Female	1.33	<0.001	1.29	<0.001
<b>Race</b>	White	1.00	--	1.00	--
	Black	0.73	<0.001	0.86	0.05
	Others	0.99	0.90	0.70	0.02
<b>County poverty, %</b>	<16.2	1.00	--	1.00	--
	>16.2	1.14	0.10	0.88	0.31
<b>Place of Residence</b>					
	Catchment area, non-BC	1.00	--	1.00	--
	Baltimore City	0.64	<0.001	1.02	0.89
	Non-Catchment Area	0.76	<0.001	0.72	<0.001

\*accrual to case ratio

# Clinical trials participation: taking into account race and residence

	Therapeutic			Non Therapeutic		
	Baltimore City	Non-BC Catchment	Non-Catchment	Baltimore City	Non-BC Catchment	Non-Catchment
White	0.64 (0.52,0.79)	Reference	0.76 (0.70,0.84)	1.02 (0.76,1.38)	Reference	0.72 (0.63,0.81)
Black	0.47 (0.38,0.58)	0.73 (0.65,0.82)	0.56 (0.48,0.65)	0.88 (0.65,1.20)	0.86 (0.74,1.00)	0.62 (0.51,0.76)
Other races	0.64 (0.48,0.84)	0.99 (0.82,1.19)	0.75 (0.61,0.93)	0.71 (0.47,1.08)	0.70 (0.52,0.93)	0.50 (0.36,0.69)

Model includes age, sex, county poverty quartile and cancer site.

# Does *insurance clearance* contribute to disparities in clinical trials accrual?

- Johns Hopkins Hospital *Access Services*
  - Confirms coverage for participation prior to clinical trials enrollment
  - Process initiated in July 2003
- Examined database from 2005 -2007
  - 4,617 patients referred – all eligible for clinical trials
    - 490 cases denied
    - 138 cases without coverage for clinical trials
    - Total excluded from clinical trials = **628 cases**

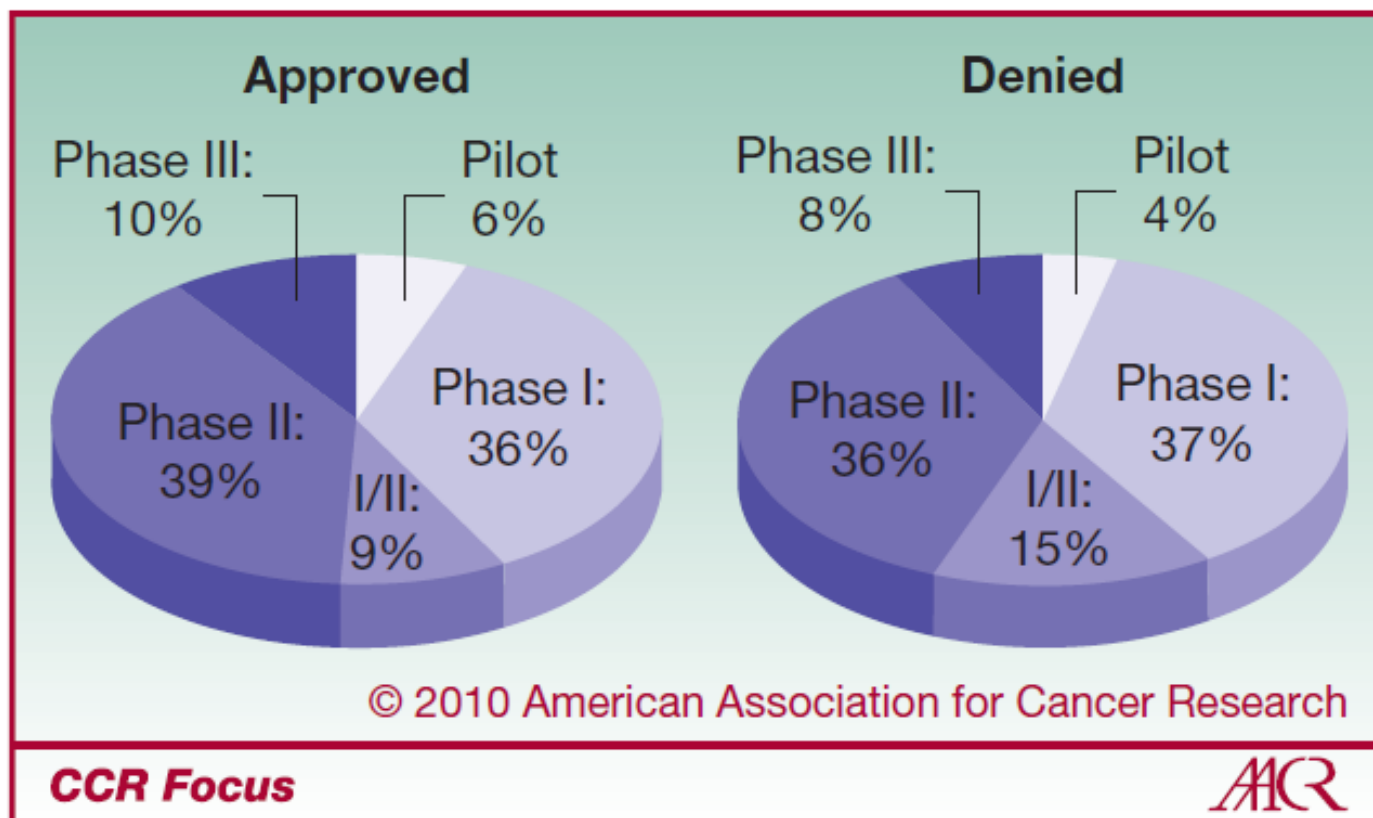
## Demographics: approved and denied

Characteristic		Insurance clearance outcome	
		Approved	Denied
Age	Median (yrs)	59.2	54.9
	95% CI	57.8 – 60.5	53.6 – 56.2
Sex	% female	42%	42%
Race	White	83%	81%
	Black	12%	13%
	Other	5%	6%

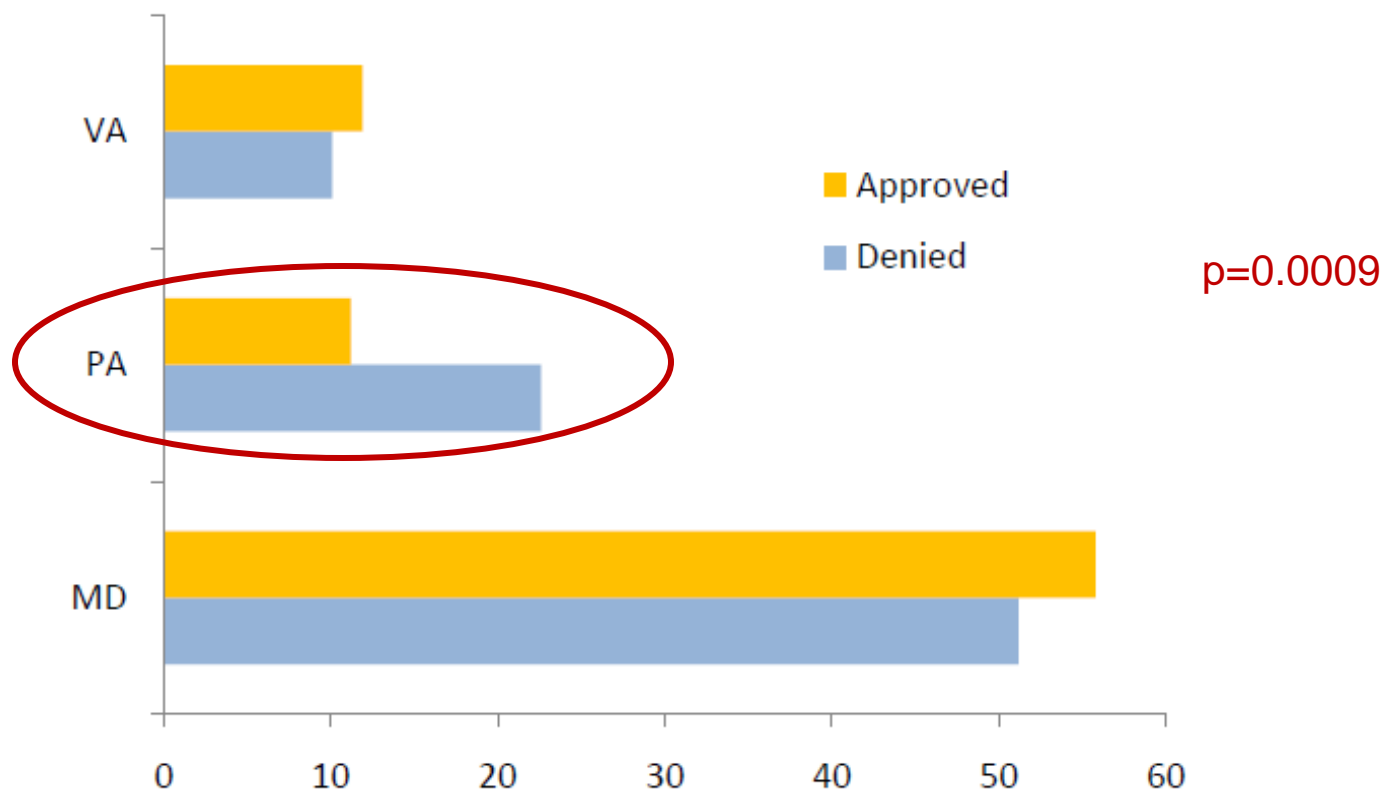
# Time to coverage decision by outcome and by race

Time to initial coverage decision (business days)		95% CI
Decision outcome		
Approved	5.51	4.93 – 6.09
Denied	5.98	5.28 – 6.67
Race		
White	5.8	5.34 – 6.39
Black	5.18	4.22 – 6.14
Other	5.29	3.76 – 6.83

# Therapeutic clinical trial coverage, by trial type

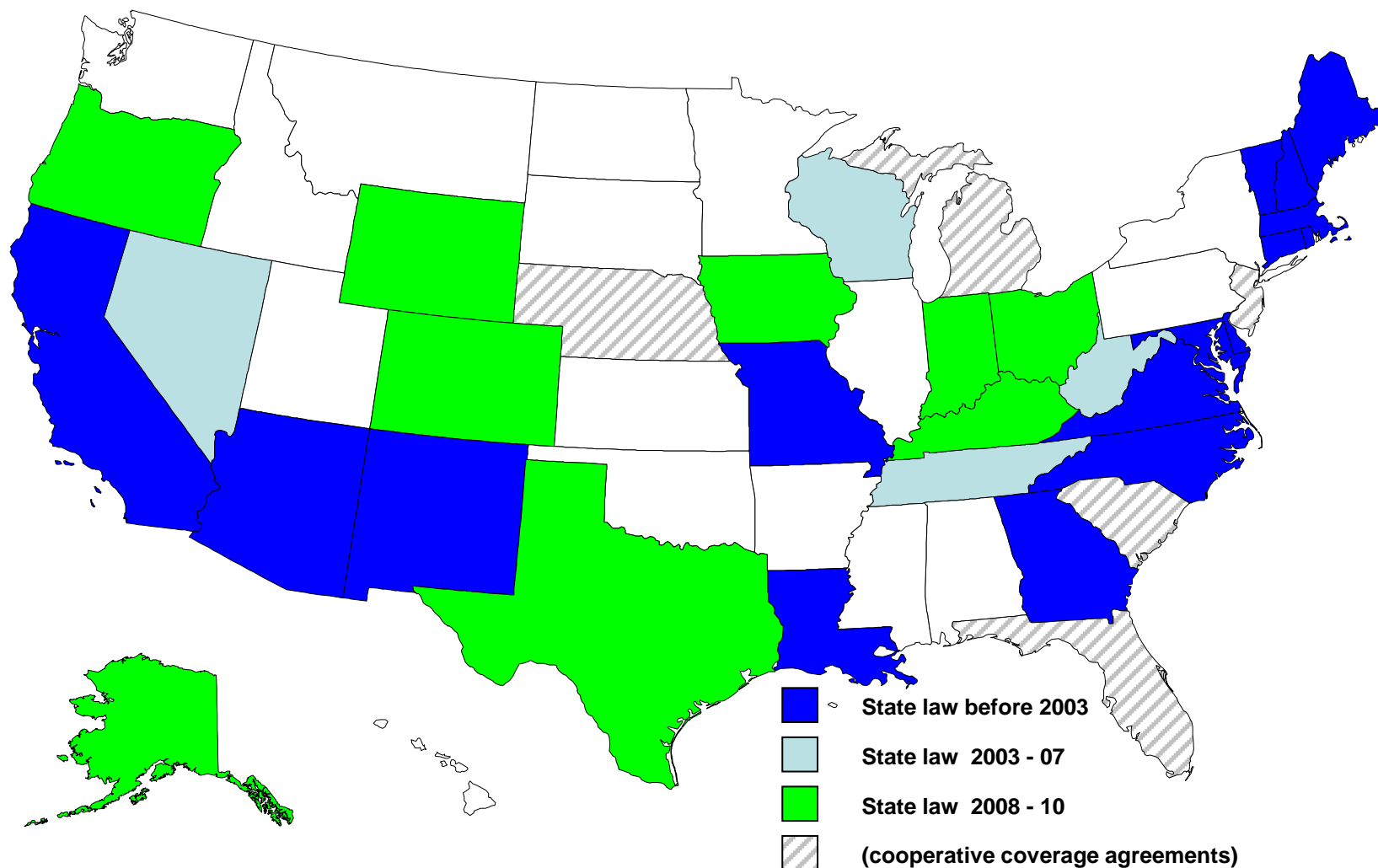


# Clinical trial coverage decision by state residency



- PA (unlike MD and VA) has no state law requiring insurance carriers to cover standard care costs associated with clinical trials

## Clinical trial coverage – state laws



## Rates of approval by insurance provider

Insurance provider*	Cases reviewed (N)	Final approval rate	Business days to complete review	
			Average	SD
Medicare only	137	100%	2.8	2.6
Medicare & secondary	769	100%	5.5	5.8
Medicare & supplement	444	100%	3.3	2.5
Johns Hopkins EHP	73	100%	6.1	4.0
Aetna	278	98%	6.5	7.7
United Healthcare	193	94%	6.1	5.4
BC/BS DC	273	93%	6.7	4.7
BC/BS Maryland	287	88%	4.3	3.7
Cigna	110	86%	7.2	7.1
Tricare	120	83%	7.0	4.5
UHC Mamsi	239	82%	7.5	5.0
Kaiser	74	81%	11.2	7.2
Out-of-state BC/BS (not DC)	529	76%	7.6	7.3
BC/BS NASCO	79	64%	4.2	2.4
Other PPO	259	55%	7.8	7.1
BC/BS Federal	250	46%	3.3	3.0

\* only companies reviewing over 70 cases are listed

Klamerus et al., *Clin Cancer Res* 2010