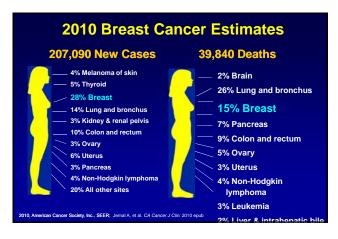
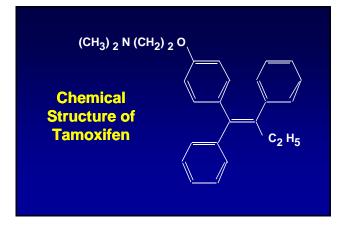
Latest Results of the STAR Breast Cancer Prevention Trial

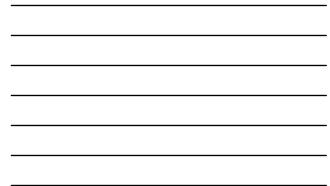
D Lawrence Wickerham, MD Associate Chairman NSABP

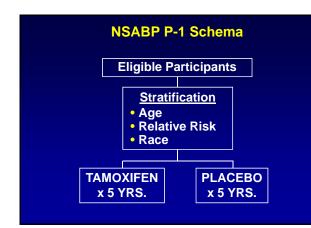


NSABP

National Surgical Adjuvant Breast and Bowel Project





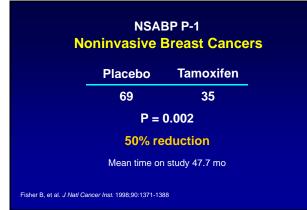


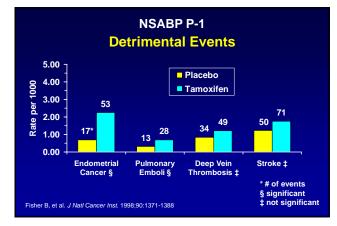


Gail Model Variables Used to Provide Composite Risk Assessment

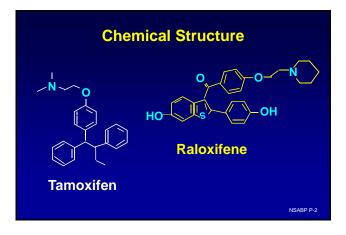
- No. 1st degree female relatives with breast cancer
- Nulliparity or age at 1st live birth
- No. of benign breast biopsies
- Atypical hyperplasia
- Age at menarche
- Race

	NSABP P-1 Invasive Breast Cancers			
	Placebo	Tamoxifen		
	175	89		
	P < 0.	00001		
	49% re	duction		
	Mean time on	study 47.7 mo		
Fisher B, et al. J A	atl Cancer Inst. 1998;90:1371-138	38		

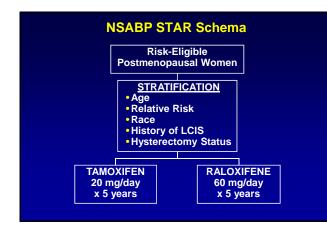




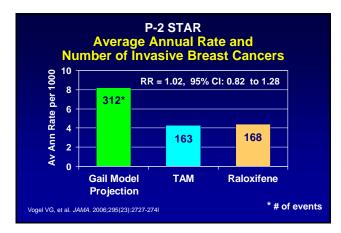




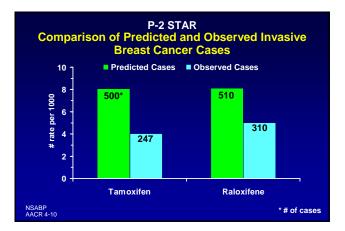




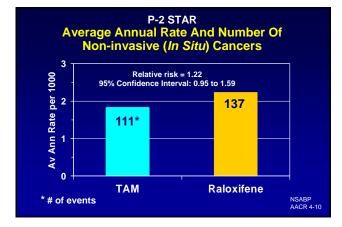


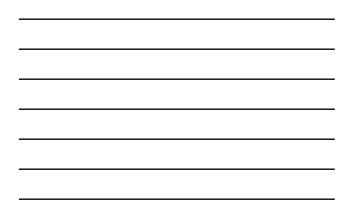


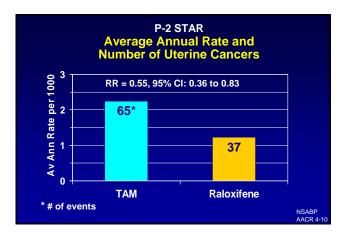








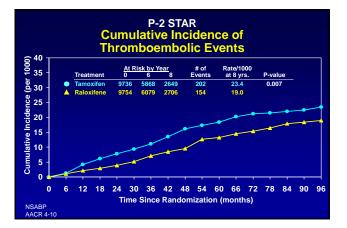




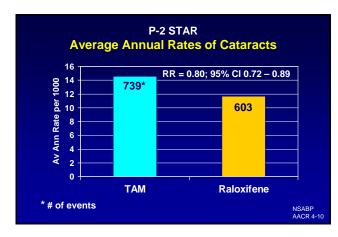


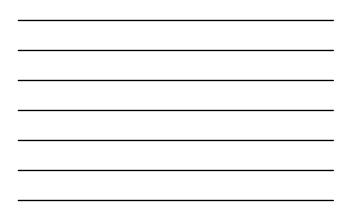
P-2 STAR							
Hysterectomy* and Endometrial Hyperplasia							

	No. of Events		Risk Ratio	RR 95% Confidence			
	Tam	Ral	(RR)	Interval			
Hysterectomy*	349	162	0.45	0.37 to 0.54			
Hyperplasia*	126	25	0.19	0.12 to 0.29			
With atypia*	22	4	0.17	0.04 to 0.51			
Without atypia*	104	21	0.19	0.11 to 0.31			
*Among women not diagnosed with uterine cancer							
				NSABP AACR 4-10			









P-2 STAR Conclusions

- With a median follow-up of 81 months

 Tamoxifen is more effective than Raloxifene in reducing the risk of both invasive and noninvasive breast cancer among postmenopausal women at increased risk
- Raloxifene retains 76-78% of Tamoxifen's chemoprevention benefits with significantly fewer
 - Endometrial cancers
 - Thromboembolic events and
 - Cataracts
- Raloxifene remains an important option for postmenopausal women who wish to reduce their risk of breast cancer

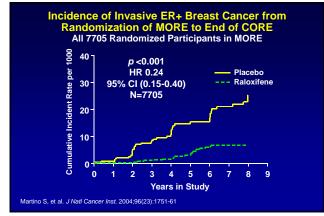




Table 5. Benefit/risk indices for tamoxifen and raloxifene chemoprevention by level of 5-year projected risk of invasive breast cancer among white women with a uterus, by age group en vs. Placebo (with uterus) Placebo (with uterus) Raloxifene vs. Placebo (with uterus) 50-59 60-69 70-79 30-39 40-49 50-59 60 bo (with uterus) Tai 30-39 40-49 1. 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 cted risk of ist cancer IBC Using P1 data and WHI b Combining RR from P1 and P2 using baseline rates 1 67%

iterus, by a	90 9.0	- P									
5-y projected risk of IBC, %	Та	Tamoxifen vs. Placebo (w/o uterus)					Raloxifene vs. Placebo (w/o uterus)				
	30-39	40-49	50-59	60-69	70-79	30-39	40-49	50-59	60-69	70-79	Strong Evidence
1.5											Benefits outweigh
2.0											risks
2.5											
3.0											Moderate
3.5											Evidence of Benefits
4.0											outweigh the risks
4.5											the Flores
5.0											
5.5											Benefits
6.0											do not outweight
6.5											he risks
7.0											

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P-2 Update 4-10 AACR-Wickerham

Profiles of Potential Candidates for Breast Cancer Chemoprevention

Women who are <u>ALREADY</u> taking raloxifene (Evista[®]) for their bones

Women with biopsy proven:

- Atypical hyperplasia of the breast OR
- Lobular carcinoma-in-situ (LCIS)

Post-menopausal women with osteoporosis <u>AND</u> risk factors for breast cancer

