

**Recruitment and Retention in Cancer
Prevention Trials**
*The Community Clinical Oncology
Programs*

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Prevention Trials in the CCOPs

- Overview of the CCOPs
- Recruitment Strategies
- Impact of Prevention Trials in Special Populations

Community Clinical Oncology Program

What is a CCOP?

- **A Group of Community Hospitals and Physicians**
- **Funded by a Peer Reviewed Cooperative Agreement**
- **To Participate In NCI-approved Cancer Treatment, and Cancer Prevention and Control Clinical Trials**

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What is a Minority-Based CCOP (MB-CCOP)?

- **Hospitals and Physicians with > 40% New Cancer Patients from Minority Populations**
- **University Hospitals are Eligible to Apply**
- **Funded by a Peer-Reviewed Cooperative Agreement**
- **Participate in NCI-approved Cancer Treatment, and Cancer Prevention and Control Clinical Trials**

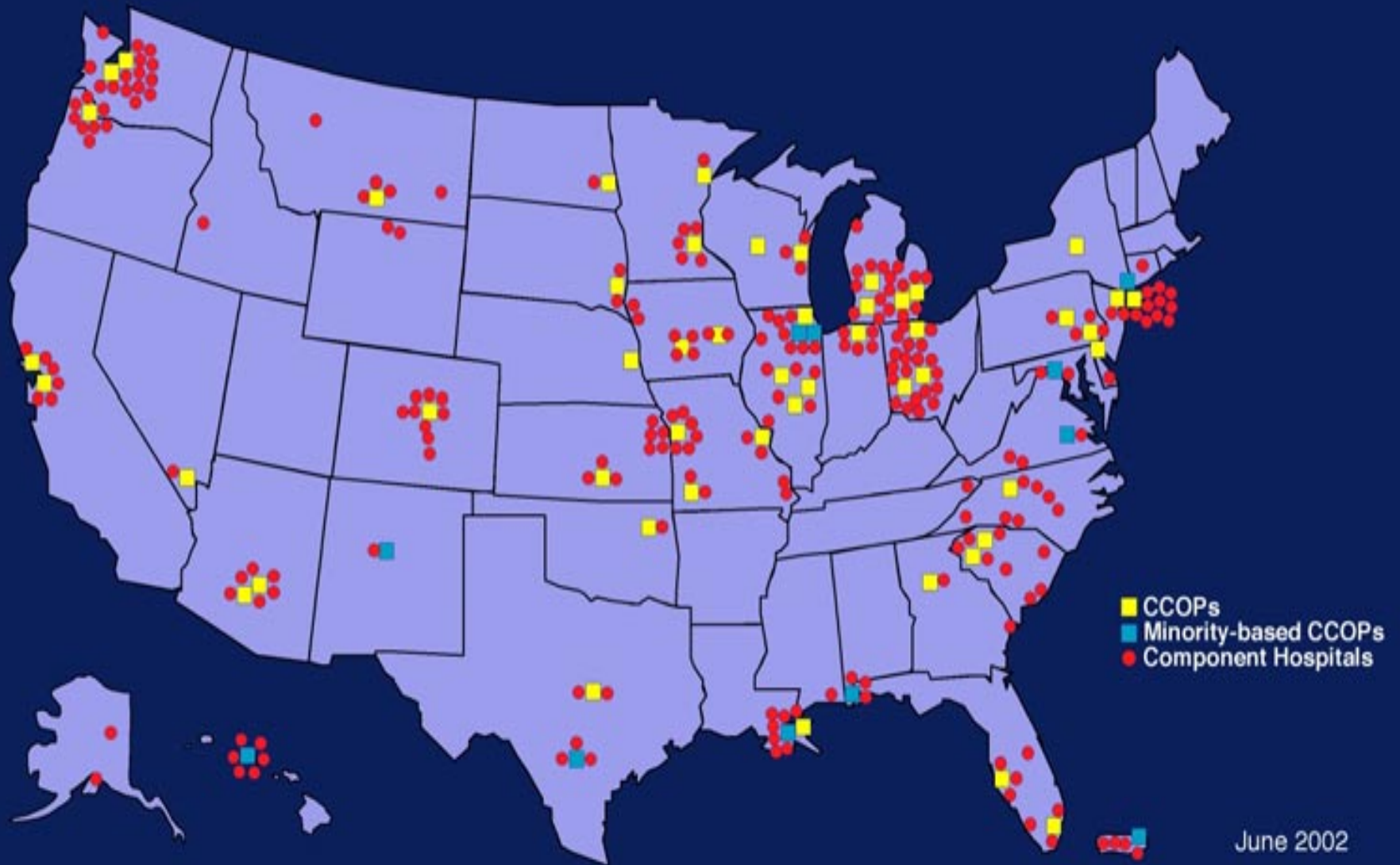
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- **1983: First CCOP Awards**
 - **Conduct Treatment, Build Network for Cancer Prevention and Control**
- **1987: Require Prevention/Control**
- **Research Bases Peer Reviewed**

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- **1989: BSC approved ongoing program**
- **MBCCCOP to focus on minority populations**
- **1991: Breast Cancer Prevention Trial**
 - **First Use of CCOP Network for Large Prevention Trial**
- **1998: Expanded Access**
 - **Use of Network to R01 Investigators**
- **2003:**
 - **Guidelines and Annual Program Announcement**

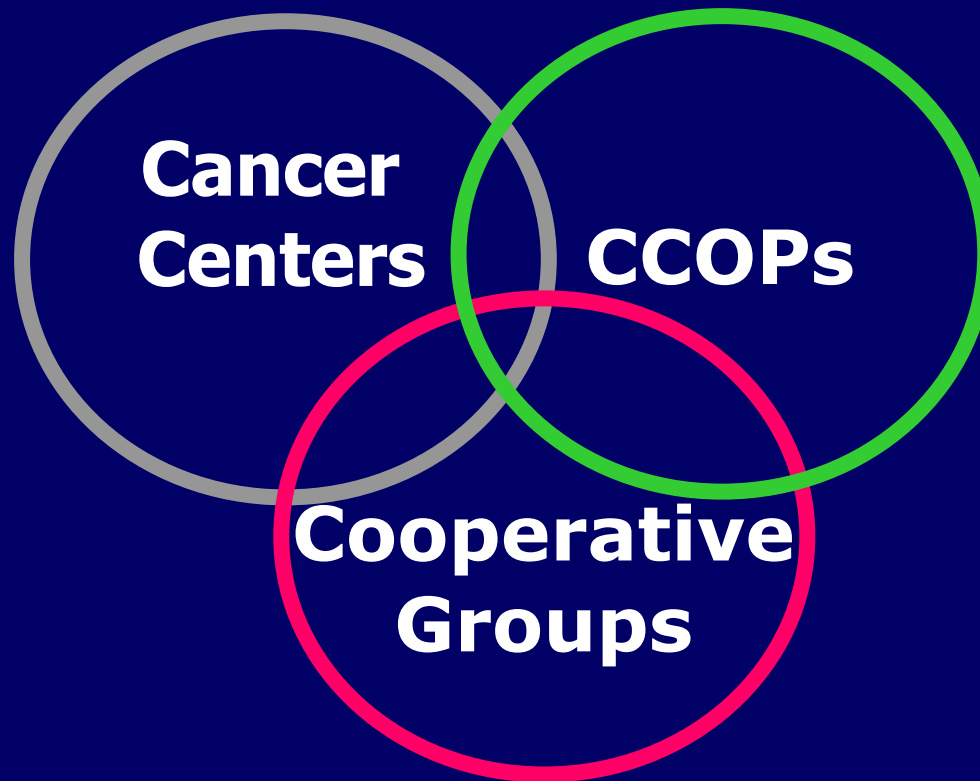
CCOPs and Minority CCOPs



- Gulf Coast – Mobile, AL
- D. C. United – Washington, D. C.
- Our Lady of Mercy, Bronx, NY
- U. of Illinois, Chicago, IL
- U. New Mexico, Albuquerque, NM
- U. Of Hawaii, Honolulu, HI
- San Juan , San Juan, PR
- South Texas Pediatric, San Antonio, TX
- Cook County Hospital, Chicago, IL
- Virginia Commonwealth U., Richmond, VA

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Integral to NCI Clinical Trials Network



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CCOP Research Bases: Cooperative Groups

- **Children's Oncology Group**
- **Cancer and Leukemia Group B**
- **Eastern Cooperative Oncology Group**
- **North Central Cancer Treatment Group**
- **Radiation Therapy Oncology Group**
- **Southwest Oncology Group**
- **National Surgical Adjuvant Breast & Bowel Project**

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CCOP Research Bases: Cancer Centers

- **H. Lee Moffitt Cancer Center**
- **M.D. Anderson Cancer Center**
- **University of Michigan Cancer Center**
- **University of Rochester Cancer Center**
- **Wake Forest University Cancer Center**

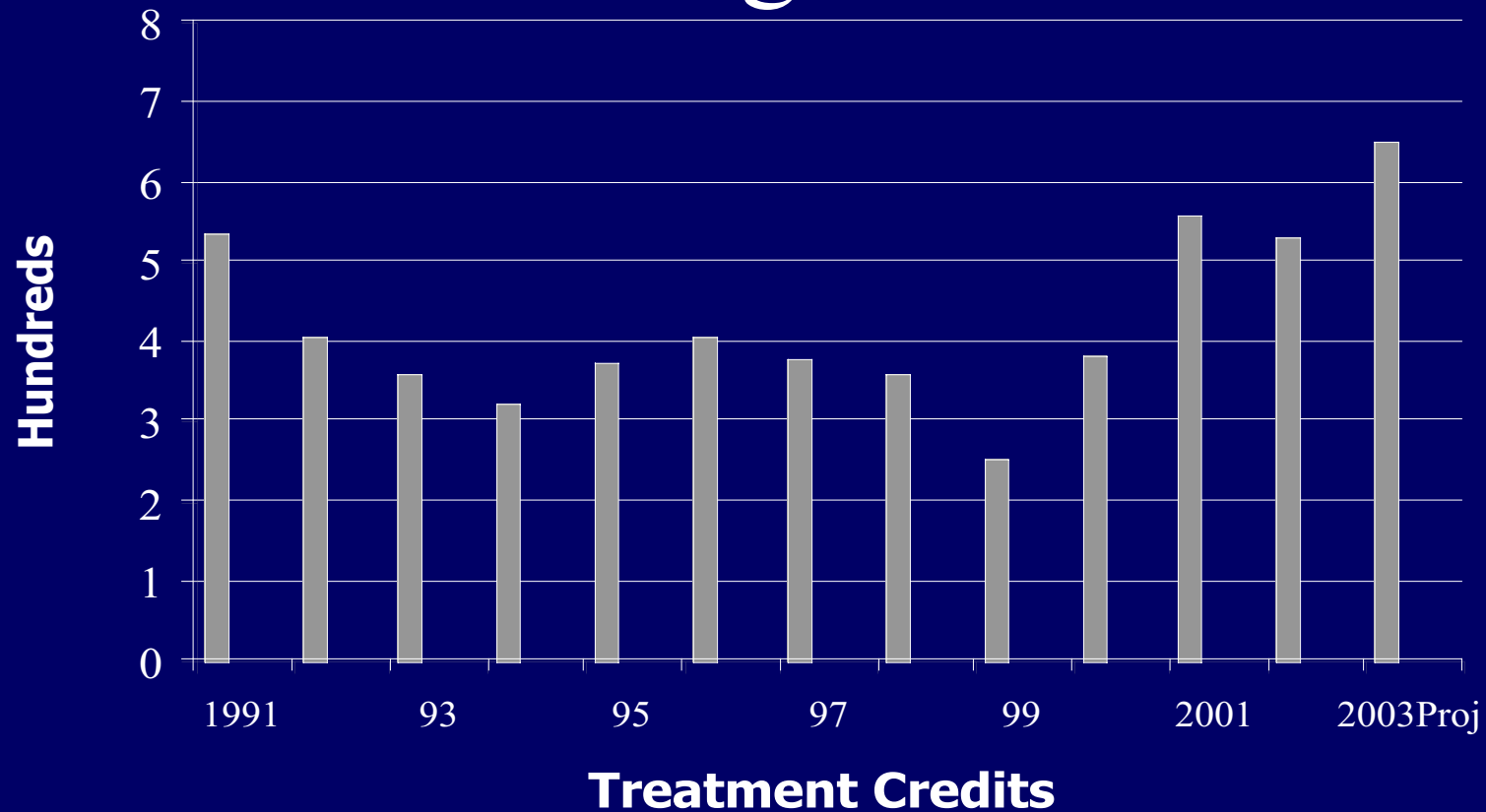
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Participating Physicians (4,115)

- 2,685 Physicians Accrue Trial Participants
- 1,430 Physicians Refer Trial Participants
- 113 Minority Investigators in MBCCOPs

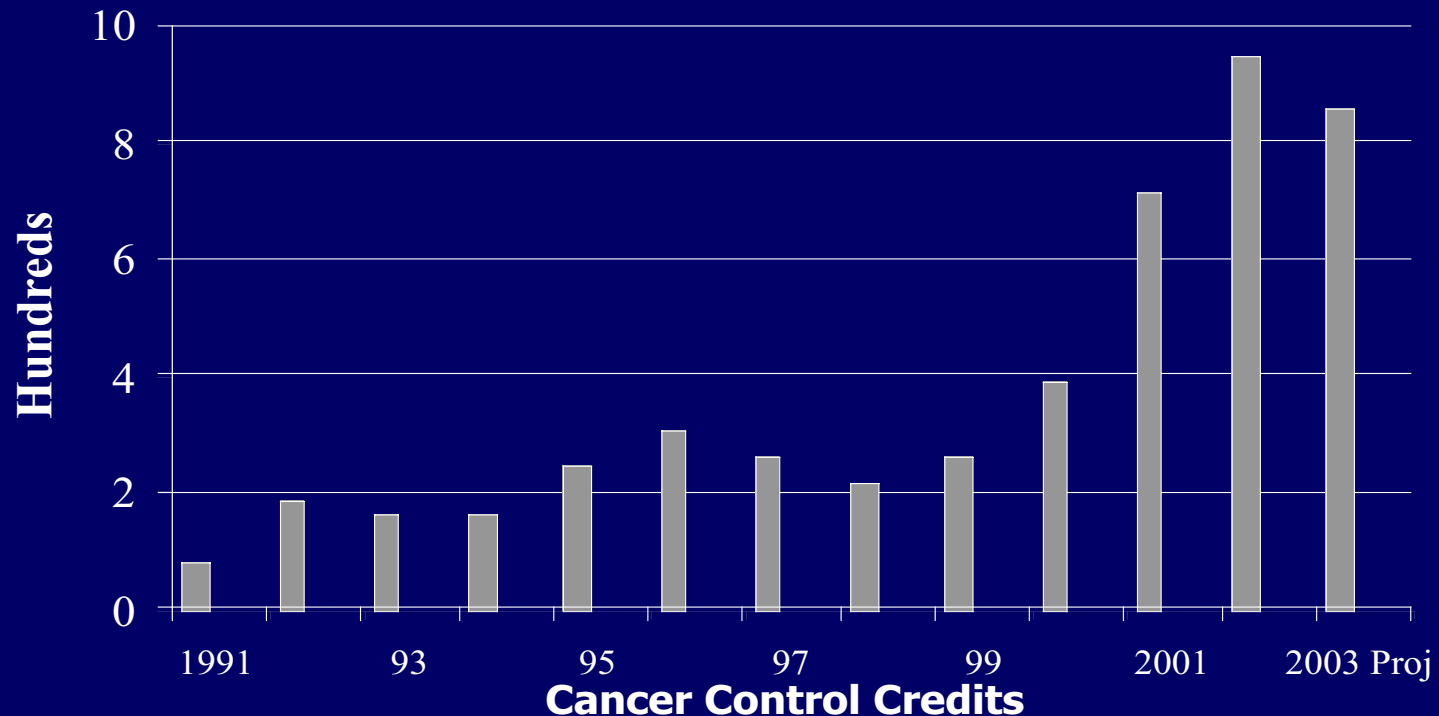
Participating Hospitals (410)

Minority-Based Community Clinical Oncology Program



Minority-Based Community Clinical Oncology Program

Cancer Prevention & Control Accrual Credits



	MBCCOps	CCOPs
Treatment	67%	10%
Cancer Control	60%	6%
Treatment/CC	66%	9%

NSABP STAR Schema

**RISK-ELIGIBLE
POST MENOPAUSAL WOMEN**

STRATIFICATION

- Age
- Relative Risk
- Race
- History of LCIS

TAMOXIFEN
20 mg/day
x 5 years

RALOXIFENE
60 mg/day
x 5 years NSABP P-2

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Study of Tamoxifen and Raloxifene (STAR)

– Target Accrual	19,000
– Accrual by June 30,2003	16,359
– CCOP Accrual	5,364 (32%)
– CCOPs nonwhite	38%

- 394 African Americans (MBCCOP –172)
- 301 Latina/Hispanics
- 150 Oriental
- 50 Native Americans
- 54 Filipino
- 13 Native Hawaiians
- 49 Other

NSABP P-1

Breast Cancer Prevention Trial Results

- 49% reduction in invasive breast cancer (P=0.00001)
- 70 % reduction in estrogen receptor positive breast cancer
- 50 % reduction in non-invasive breast cancer
- First randomized trial to demonstrate that the incidence of breast cancer can be reduced
- 7% were BRCA1/2 mutation carriers

BCPT Participant Characteristics

	Placebo %	Tamoxifen %
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RACE

White	96.4	96.5
Black	1.7	1.7
Other	1.9	1.8

Source of BCPT Participant's Accrual

Source of Learning	African Am. N=276	Hispanics N=167	Whites N= 12,688
M. D./Nurse	42	44	31
Friend	2	4	5
Radio	2	7	4
Magazine	2	3	3
Brochure	4	7	4
Family	6	5	9
Television	22	14	20
Newspaper	16	16	32
Other	14	15	10

Most Difficult Factors to Overcome in Establishing Recruitment Program

- Educating physicians
- Preference for HRT
- Pro Estrogen physicians
- Internal and Local Politics
- Available Time/Staffing

BCPT

Most Common Ineffective Minority Recruitment Strategies

- Health Fairs
- Brochures
- Churches

Most Effective Minority Recruitment Strategy

- Outreach Coordinators
- Minority Advisory Board
- Focus Groups

BCPT RISK ASSESSMENT PROFILE

RISK FACTORS

MENARCHE: 12 yrs.

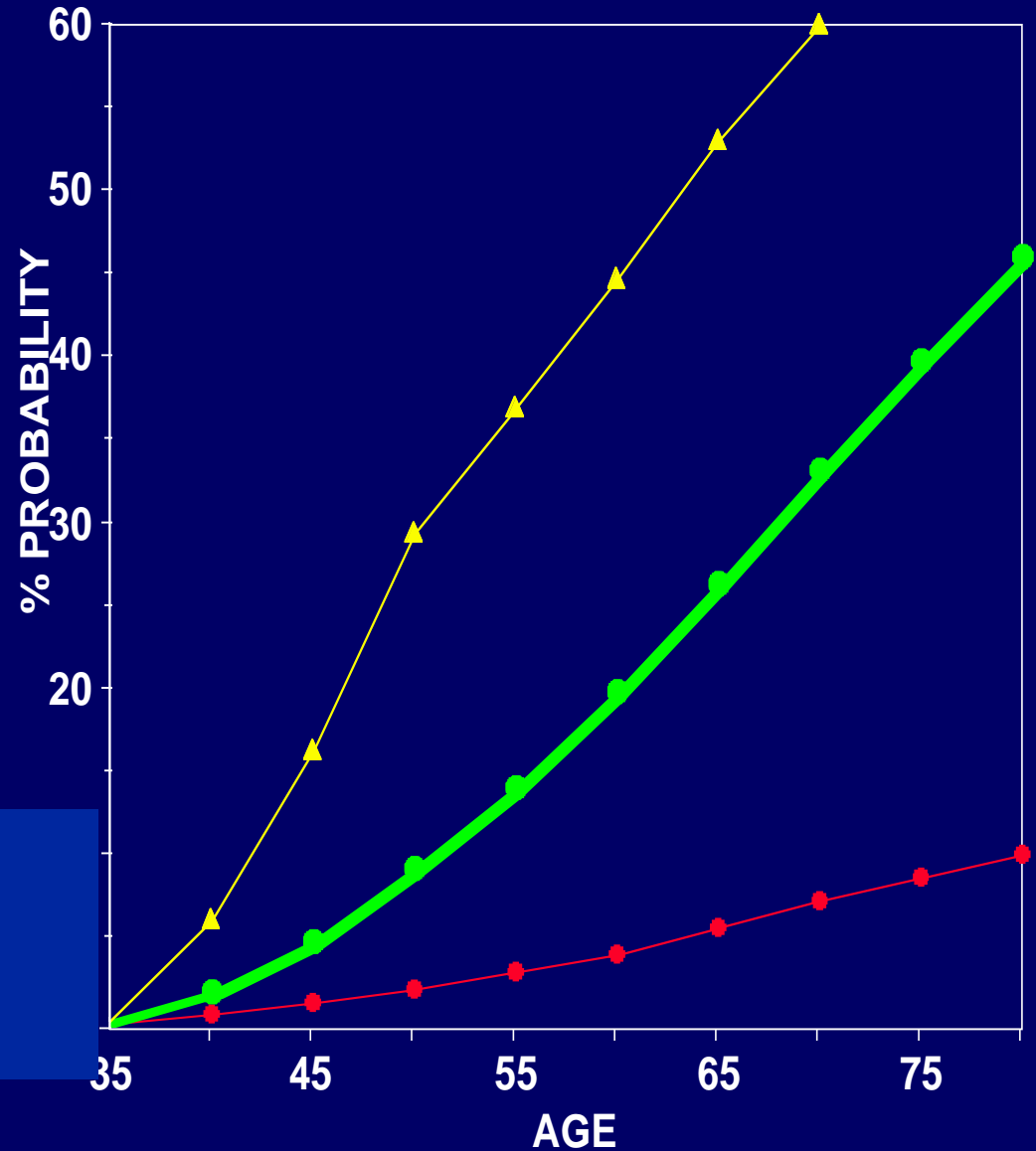
1st LIVE BIRTH: 22 yrs.

BIOPSIES: 2

#1st DEGREE REL.: 2

ATYPICAL HYPERPLASIA: +

- WOMEN WITH AV. RISK (1)
- MIN. ELIGIBILITY RR (5.07)
- ▲ CANDIDATE'S RR (18.3)



Comparison of the First 36 Months of Recruitment in the BCPT and STAR

	<u>BCPT</u>	<u>BCPT \geq 50</u>	<u>STAR</u>
RAFs	83,698	39,992	112,290
Randomized	11,653	7,059	13,034

Comparison of the First 36 Months of Recruitment in the BCPT and STAR for African Americans

	<u>BCPT</u>	<u>BCPT \geq 50</u>	<u>STAR</u>
RAFs	3,918	1,609	10,646
Randomized	162	98	291

Summary of Corporate Initiatives

	General Motors	Ford
Mailing	133,000	105,000
Risk Assessments	9,530 (7%)	3,006 (3%)
Risk Eligible	3,701 (39%)	1,051 (35%)
Risk/Menopausal Eligible	3,398 (92%)	951 (90%)
Interested in STAR	2,179 (64%)	711 (75%)
Enrolled	93	42

SELECT Trial

- Target accrual 32,000 men
- Current Enrollment 14% African American
target 20 percent

Lessons: urologist/primary care/trial/error,
intervention

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- **2624 Type A Physicians**
- **1137 Physicians (43%) Accrued**

(1999-2001)

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- **“Can COPTRG determine if there is a correlation between age of the investigator and accrual of participants to clinical trials?”**

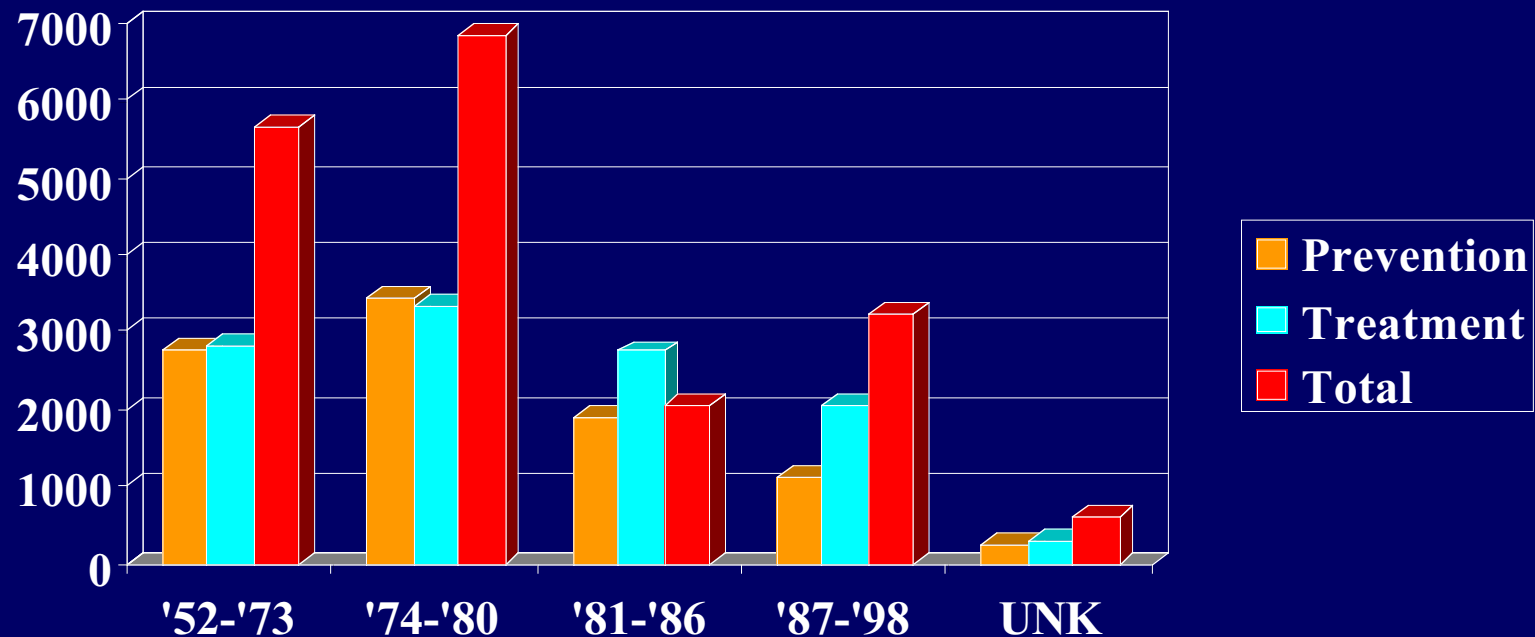
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Accruing Physicians (1137) by Med. School Grad. Date

- 1952-1973 275
- 1974-1980 287
- 1981-1986 296
- 1987-1998 250
- Unknown 29

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Accrual by Year of Med School Graduation



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Impact in Prevention:

- **Over 65,000 Persons at Risk for Cancer on Prevention Clinical Trials**
- **CCOP Network Is the Vehicle to Conduct Phase III Cancer Prevention Trials**
- **Community Physicians Practices Are the Forefront for Cancer Prevention**

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Impact in Cancer Control:

- **All Cooperative Group Symptom Management, Palliative Care Clinical Trials**
- **Broad Portfolio of Trials Developed and Ongoing**

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Research Accomplishments: **Cancer Control**

- **Anorexia - Megace (+)**
- **Hot flashes - Venlafaxine (+)**
- **Hot flashes - Soy (-)**
- **Xerostomia - Pilocarpine (+)**
- **Smoking Cessation - Bupropion**
- **Survey of Oncologists Pain Management Practices**

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Cancer Control Research: Ongoing Trials

- **Diarrhea - Octreotide**
- **Fatigue - Modafinil, Erythropoietin, Co-Q**
- **Cognitive Function - Ginkgo, Donepezil**
- **Bone Loss - Bisphosphonates**
- **Anorexia - TNF Antibody**
- **Peripheral Neuropathy-Gabapentin**

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Accomplishments:

- **Successful Involvement of Community Oncologists as Equal Partners in Research**
- **Establishment of Research Network that Extends Beyond Medical Oncologists**
- **Successful Mechanism for Implementing Landmark Prevention Trials**
- **Extension of Scientific Purview of Research Bases to Cancer Prevention and Control**

- Change public opinion about clinical trials
- **Educate** the public about prevention
- Educate physicians about **risk/benefit** counseling
- Promote the **science** of clinical trials promote academic recognition clinical trial recruitment and retention
- **Fund** recruitment
- Improve **national promotion** of cancer prevention to complement local and regional efforts
- Continue to seek better **identification** of high risk individuals and less toxic agents.