Recruitment and Retention in Cancer Prevention Trials

*The Community Clinical Oncology Programs*

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Division of Cancer Prevention

National Cancer Institute

Department of Health and Human Services
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
Community Clinical Oncology Program

- **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
  - MBCCOP 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
• 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

Cancer Centers  CCOPs  Cooperative Groups
Community Clinical Oncology Program

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

![Graph showing treatment credits from 1991 to 2003.](image-url)
Minority-Based Community Clinical Oncology Program

Cancer Prevention & Control Accrual Credits

<table>
<thead>
<tr>
<th>Year</th>
<th>1991</th>
<th>93</th>
<th>95</th>
<th>97</th>
<th>99</th>
<th>2001</th>
<th>2003 Proj</th>
</tr>
</thead>
<tbody>
<tr>
<td>Credits (in Hundreds)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>MBCCOPs</td>
<td>CCOPs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>---------</td>
<td>-------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>67%</td>
<td>10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer Control</td>
<td>60%</td>
<td>6%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment/CC</td>
<td>66%</td>
<td>9%</td>
<td></td>
<td></td>
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</tbody>
</table>
RALOXIFENE
60 mg/day
x 5 years

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

NSABP STAR Schema
Community Clinical Oncology Program

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

<table>
<thead>
<tr>
<th>RACE</th>
<th>Placebo %</th>
<th>Tamoxifen %</th>
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</thead>
<tbody>
<tr>
<td>White</td>
<td>96.4</td>
<td>96.5</td>
</tr>
<tr>
<td>Black</td>
<td>1.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Other</td>
<td>1.9</td>
<td>1.8</td>
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</table>
### Source of BCPT Participant's Accrual

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

<table>
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<tr>
<th></th>
<th>BCPT</th>
<th>BCPT ≥ 50</th>
<th>STAR</th>
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<tbody>
<tr>
<td>RAFs</td>
<td>83,698</td>
<td>39,992</td>
<td>112,290</td>
</tr>
<tr>
<td>Randomized</td>
<td>11,653</td>
<td>7,059</td>
<td>13,034</td>
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</table>
Comparison of the First 36 Months of Recruitment in the BCPT and STAR for African Americans

<table>
<thead>
<tr>
<th></th>
<th>BCPT</th>
<th>BCPT ≥ 50</th>
<th>STAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAFs</td>
<td>3,918</td>
<td>1,609</td>
<td>10,646</td>
</tr>
<tr>
<td>Randomized</td>
<td>162</td>
<td>98</td>
<td>291</td>
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</table>
Summary of Corporate Initiatives

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

- Prevention
- Treatment
- Total

Year of Med School Graduation:
- '52-'73
- '74-'80
- '81-'86
- '87-'98
- UNK
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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 risk/benefit counseling
• 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.