CCOP Clinical Trials
Contributions and Challenges

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NCI Community Clinical Oncology Program (CCOP) Mission

- Provide state-of-the-art cancer treatment, prevention and cancer control research to individuals in their own communities
- Involve community physicians and their patients in NCI-approved clinical trials
- Involve primary health care providers in research process
- Increase minority & underserved community clinical trial participation
Community Clinical Oncology Program

- 1983 Established and Funded by NCI
- Community Based Physicians and Hospitals to Accrue to NCI-Sponsored Cancer Prevention, Cancer Control and Treatment Clinical Trials
- Cooperative Groups and Cancer Centers to Design and Conduct Cancer Prevention and Cancer Control Clinical Trials
CCOP Organizational Relationships

Research Bases
(Groups/Centers)
- Develop Protocols
- Data Management & Analysis
- Quality Assurance

CCOPs & MB-CCOPs
- Accrual to Protocols
- Data Management
- Quality Control

Members and Affiliates
- Accrual to Prevention & Control Protocols
Community Clinical Oncology Program

- 49 Funded CCOPs
- 14 Funded Minority-Based CCOPs
- 34 States, DC, Puerto Rico
- Over 3500 participating physicians and over 430 participating hospitals
- 33% of Total Accrual to NCI Treatment and Prevention Trials
CCOP Contributions to CALGB

- 30% of accrual to CALGB studies
- CALGB Executive Committee and Board of Directors
- Committee members and study chairs
- Community perspective in trial design
- Quality clinical trial data and biospecimens
- Access to early stage patients
- Dissemination of best practices and evidence-based medicine
- Accrual diversity
Community Benefits from CCOP Participation

- Access to state of the art treatment and prevention/cancer control trials
- Access to new drugs
- Distinction of peer review
- Training of research staff
- Mentoring of investigators
- Opportunity for community physicians to design and participate in research studies
CCOP Contributions to NCI

- Provides NCI with a Core Group of Community Investigators for community perspective and rapid dissemination of new critical information.
- Community Physicians to participate in the national trials enterprise (Chair of CIRB, NIH Consensus Conferences, CTAC).
- National Network provides relocated patients a continuum of trial participation and care (Katrina).
## Overall Program Funding

<table>
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<th>FY 2007</th>
<th>$88.25 Million</th>
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<tr>
<td>CCOPs</td>
<td>$34.89 million</td>
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<tr>
<td>MBCCOPs</td>
<td>$6.25 million</td>
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<tr>
<td>Research Bases</td>
<td>$26.28 million</td>
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<tr>
<td>Large Prevention Trials</td>
<td></td>
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<tr>
<td>SELECT</td>
<td>$11.44 million</td>
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<tr>
<td>STAR</td>
<td>$8.13 million</td>
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<tr>
<td>PCPT</td>
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CCOP: 25 Years of Success
(through 2007)

- 132,270 CA Treatment Trial Accruals
- 88,610 CA Control and Prevention Accruals
- 13,000 Annual Accruals in 21st Century
- Soon to Surpass a Quarter Million Participants
- Breast, Prostate, Colon Cancer Prevention Trials Positive Results
DE Christiana Care CCOP

- Funded CCOP since 1987
- Main Member and 4 Affiliates (Tristate)
- Average over 400 NCI Treatment and Cancer Control Accruals Annually
- Over 5000 Participants in NCI Trials
- Members of 27 Cooperative Group Committees (CALGB, NSABP, RTOG)
- Study Chair / Co-Chair: 3
Delaware Christiana Care CCOP NCI Accrual

Participants

YEAR


CAControl Treatment Total
Research Accrual
Local versus National Accruals

Year

2001 2002 2003 2004 2005 2006

CCHS Accruals
National Accrual Average
NCI Community Cancer Centers Program (NCCCP)
NCI Community Cancer Centers Program (NCCCP)

- 3 year Pilot Program started July, 2007
- Ten Community Based Health Care Systems
- 16 Hospitals
- Goals:
  - Accrue More Patients to Clinical Trials in Community Based Settings and Increase Minority Accrual
  - Reduce Cancer Healthcare Disparities
  - Standardize Biospecimen Collection
  - Link Sites to CA Biomedical Informatics Grid (caBIG)
- NCI Community Cancer Centers Program (NCCCP)
What factors impact participation in clinical trials?
Clinical Trial Accrual Barriers

Literature

- Physician Does Not Offer Trial
- No Available Protocol
- Performance Status Requirement
- Age
- Patient Desire for Standard Therapy
- Minority Accrual
Clinical Trial Accrual Barriers
DE CCOP

- 76% Not Eligible
  - 54% No Trial
  - 20% Poor Performance Status
  - 6% Prior Cancer History
  - 5% Abnormal Labs

- 24% Eligible
  - 38% Enrolled
  - 62% Declined: 2/3 Patient Choice, 1/3 Physician Choice
Clinical Trial Accrual Barriers
DE CCOP

Factors Against Enrollment
– Age (>70 years)
– Gender: Trend for Female (Except Breast)

No Difference Caucasian and Africa American
DE CCOP Accrual Barriers

- Dedicated Clinical Investigator Recruitment (medical and non-medical oncology)
- Infrastructure Resource Limits
  - Funding (1/3 From Hospital and “in kind” from Private Practice)
  - Regulatory Burden
  - Documentation Burden
  - CRA Retention
- Insurance Restrictions
DE CCOP Accrual Barriers

- Private Practice Limits
  - Physician Time Constraints
  - More Complex Trials & Consents
  - Increased Overhead
  - Cancer Care Reimbursement Issues
- Incorporating “non traditional” Physician Investigators (i.e. Radiology, Pathology)
- Pharmaceutical Competitive Trials
- The 80/20 Rule
What should be the clinical trials participation level?
ASCO Exemplary Clinical Trials
Site Attributes

- Clinical Trial Portfolio Diversification
- High Accrual (> 10%)
- Participation in Clinical Trial Process
- Formal Maintenance of High Education Standards
- Quality Assurance
- Multidisciplinary Care
- Clinical Trials Awareness (JCO 5/20/08)
How can these goals be reached?
CCOP “Wish” List

- Adequate Funding for CCOP Infrastructure
- Clinical Trial Development for “the silent majority”, the ineligible or no trial patient
- Adequate Third Party Reimbursement for Oncology Care and Clinical Trial Participation
- Ease Regulatory Burdens
- Simplify Consent Forms
CCOP “Wish” List

- Private Insurance and CMS recognition of Clinical Trial Value
- Education of Public
- Fellowship Tracts to train and encourage Community Clinical Investigators
- Mentoring of new and underachieving Community Research Sites
- Develop a cadre of Recognized & Credible Oncology Trial Specialists
DE CCOP Investigator Minimal Standards

- Minimum Annual Accrual of 4 to NCI Trials
- Cooperative Group or Cancer Control Research Base Meeting Attendance every 2 years.
- Successful Internal Audit Program Participation

(JCO 5/20/08)
What incentives will enhance physician participation?
Physician Incentives

- Oncologist Inquisitiveness and Altruism
- Positive Market Place Forces for Clinical Trials
  - Recognition of Clinical Trial Benefits
  - Recognition of NCI Clinical Investigator Specialist
  - Patient Demand
  - Third Party Payer Demand?
  - Improved Reimbursement
  - Ultimately Personalized Cancer Care
Delaware Cancer Clinical Trials
Benefit

✓ Contributions to Cancer Care Advancements

✓ Advanced State Cancer Control Program
  ✓ DE Cancer Consortium
  ✓ Access of all Delawareans to NCI Clinical Trials
  ✓ Statewide Colorectal Screening & funding of uninsured colonoscopy

✓ Funding for Uninsured 2 years Cancer Care

✓ Health Disparity Emphasis
Delaware Cancer Clinical Trials Benefit

- Raised Cancer Standard of Care
  - Quality Physician Recruitment
  - Disciplined Cancer Care

- Reduction Cancer Burden
  - State Cancer Mortality First to Sixteenth
  - Most Rapidly Declining State Annual Cancer Mortality Rate, Twice the U.S. Rate
CCOP Conclusion

- CCOP is an integral part of the nation’s clinical trial enterprise and should remain so.
- CCOPs produce high quality and quantity clinical research and are the vehicles that elevate community quality cancer care.
- The CCOP program is robust but under the same multiple pressures experienced by academia and private practice medicine.
CCOP Conclusions

Proper alignments in the health care system and the clinical trial enterprise will lead to cancer “personalized medicine” and the growth of clinical trial access and participation in our communities.