Racial and Ethnic Minorities Accrual to NCI Clinical Trials

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National Cancer Institute/NIH
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ACOSOG - American College of Surgeons Oncology Group
CALGB - Cancer and Leukemia Group B
COG - Children's Oncology Group
ECOG - Eastern Cooperative Oncology Group
GOG - Gynecologic Oncology Group
EORTIC- European Organization for Research and Treatment of Cancer
NCI-CCTG - National Cancer Institute of Canada, Clinical Trials Group
NSABP - National Surgical Adjuvant Breast and Bowel Project
NCCTG - North Central Cancer Treatment Group
RTOG - Radiation Therapy Oncology Group
SWOG - Southwest Oncology Group
NCI Infrastructure to Support Clinical Trials

Clinical Trials and Translational Research Advisory Committee (CTAC)

*External oversight committee*

Advises on:
- NCI-supported national clinical trials
- Translational research enterprises

Clinical and Translational Research Operations Committee (CTROC)

*Internal advisory committee*

Responsible for review and prioritization of:
- Proposed NCI-supported clinical trials
- Correlative science programs
- Translational research
## NCI Resources for Providers/Researchers

### caBIG Clinical Trials Suite

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>• Recorded Demos</td>
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<td>• Presentations</td>
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<td>• Live Demo Environment</td>
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Product shortcuts for each tool provide access to:
- Recorded Demos
- Presentations
- Documentation and Training Materials
- Live Demo Environment

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<tbody>
<tr>
<td>NCI Center for Bioinformatics Application Support</td>
<td><a href="mailto:ncicb@pop.nci.nih.gov">ncicb@pop.nci.nih.gov</a></td>
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NCI Educational Resources for Patients/Providers/Communities

- Over 20 resources
  - Brochures, Workbooks, Web site, Slide shows, Videos, DVD, CD, and Booklets
  - Targeted education and outreach to patients/families, health professionals, and the community
Online tutorial with practical advice for healthcare professionals about incorporating clinical trials into their practices.

Accrual Net - Coming Soon!
Interactive online community for researchers to share information, challenges, and success in clinical trials accrual.
Who Participates in Cancer Clinical Trials?

Enrollment by Race and Ethnicity
National Cancer Institute, Publicly Funded Cancer Clinical Trials
(Phase I-III Treatment Studies)
January 1, 2003 – June 30, 2005

- RACE
  - White, 88.6%
  - Black/African American, 8.0%
  - Asian/Pacific Islander, 2.8%
  - Multiple, 0.1%

- ETHNICITY
  - Hispanic/Latino, 5.6%
  - Non-Hispanic/Latino, 94.4%

Barriers for Specific Populations

**LATINOS/HISPANICS**
- Fatalism
- Use of folk remedies
- Delays seeking health care
- Fear
- History of past abuses
- Family/Work responsibilities
- Poor MD/pt communication
- Language barriers (regional dialects)

**AFRICAN AMERICANS**
- Lack of CT awareness
- Mistrust of research and the medical system
- Fear
- Hopelessness, fatalism
- Lower priority
- Family and/or work responsibilities
- Perceived harms of participation
Barriers for Specific Populations

ASIAN AMERICANS

• Different Values
  – Decisions by consensus
  – Group welfare
  – Family centrality
• “Saving face”
• Degree of acculturation
• Language barriers

AMERICAN INDIANS

• Past Discrimination
• Tribal “taboo” – loss of body parts
• Different communication styles
• Traditional gender roles
• Language barriers
• Other co-morbidities

NATIVE HAWAIIANS/PACIFIC ISLANDERS

• Mistrust of research
• Past discrimination
• Language barriers
• Geographic isolation
NCI Programs Supporting Clinical Trials Accrual within Diverse Communities

Division of Cancer Prevention:
CCOP and MB-CCOP
Network connects academic centers with community physicians by conducting cancer prevention and treatment clinical trials

Minority Institution/Cancer Center Partnership
Enables minority-serving institutions and NCI Cancer Centers to train scientists from diverse backgrounds in cancer research

Patient Navigator Research Program
Aims to develop innovative patient navigation interventions and test their efficacy and cost-effectiveness

Community Networks Program
Aims to reduce and eliminate cancer disparities through community-based research, education, and training

NCI’s Community Cancer Centers Program
National network that expands cancer research and delivers most advanced cancer care to home communities
Minority-Based-CCOP (MB-CCOP)

The Community Clinical Oncology Program (CCOP) is a network for conducting cancer prevention and treatment clinical trials by community physicians. This network connects academic centers (Research Bases who design and conduct the trials) with community physicians (CCOP, MB-CCOP who accrue patients to those trials).

- A Minority-Based-CCOP (MB-CCOP) must meet the same criteria as a CCOP and also have 40% of their new cancer patients from minority populations.

<table>
<thead>
<tr>
<th>Institution</th>
<th>Location</th>
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<tr>
<td>Downstate Medical Center, NY</td>
<td>John Stroger Cook Co., IL</td>
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<tr>
<td>Louisiana State University, LA</td>
<td>Louisiana State University, LA</td>
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<tr>
<td>Meharry Medical, TN</td>
<td>Medical College of Georgia, GA</td>
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<tr>
<td>South Texas Pediatrics, TX</td>
<td>Sacred Heart, AL</td>
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<tr>
<td>University of Hawaii, HI</td>
<td>San Juan, PR</td>
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<tr>
<td>University of Medicine and Dentistry of New Jersey, NJ</td>
<td>University of Illinois, IL</td>
</tr>
<tr>
<td>Va. Commonwealth University, VA</td>
<td>University of New Mexico, NM</td>
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MB-CCOPs Help Communities Increase Clinical Trials Accrual

- Significant contributors to minority representation in CCOP Network to NCI Trials 1995-2008

- Clinical trials laboratory for identifying preclinical, clinical and behavioral issues related to health disparities and accrual

- Fill research gaps in clinical trials
  ⇒ Howard University published their experience with the CARE Model which improved risk assessment among African American women and tested this model outside the clinical trial setting
MI/CCP and MB-CCOP: Partnership in Action

Meharry-Vanderbilt Cancer Partnership synergizes with MB-CCOP grant to facilitate accrual on clinical trials

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<tr>
<th>Screen relevant Clinical Trials</th>
<th>Defines and prioritizes clinical trials that are relevant to African American patient base</th>
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| Navigate cultural roadblocks   | • Employs patient navigation program
                                 | • Invites minorities and makes them feel welcome
                                 | • Communicates clearly what research is in a culturally sensitive way
                                 | • Earns trust
                                 | • Ensure true access
Involving Communities to Increase African American Accrual in NC CNP

**Community Bridges to Cancer Clinical Trials**
- Culturally and linguistically appropriate education materials developed
- Community organizations partner with Researchers and advocates to develop and test materials

**NC Cancer Clinical Trials Community Advisory Board**
- State-wide Advisory Board established to improve access to local clinical trials
- Partners with 5 State, 21 Cancer Center Clinical Trials Consortium

- Improve diversity in local clinical trials participation
- Increase awareness and education of clinical trials
- Meaningful participation of community and advocates
Using Patient Navigators to Increase Accrual

Increase enrollment of high risk Hispanic/Latino pediatric patients into hematology/oncology Clinical Trials in south Texas County with increased rates of leukemia

- Trained Spanish-speaking Patient Navigators
- Community outreach and education provider
- Enrollment tracking tool and medicine facilitated calendar

Increase enrollment of minority/underserved adults into symptom outcomes and CAM Clinical Trials in urban Massachusetts city (Boston)

- Trained CT Nurse Navigator
- Provider outreach and education
- Screen and prioritize Clinical Trials relevant to minority and underserved population

Increase enrollment of minority/underserved adults in urban Colorado city (Denver)

- Trained Patient Navigator
- 3 Clinical site Consortium Model
- Community/Provider Outreach and Education
NCCCP Supports Community Hospital Clinical Trials Accrual

NCCCP

Disparities

Quality of Care

CaBIG (IT)

Cancer Continuum

Prevention Screening Treatment Palliative Care Follow-up Survivor Support End-of-life Care
ARRA funding has allowed the Centers to hire and retain faculty and staff, purchase equipment for new and existing labs, increase their investment in information technology, and initiate developmental projects focused on clinical trials, personalized medicine, and health disparities, among other areas.

The Nation’s Investment in Cancer Research
An Annual Plan and Budget Proposal Fiscal Year 2011
National Outreach Network

ARRA Supplements
- CNP
- MI/CCP
- PNRP
- 2009

Administrative Supplements
- MB-CCOP, NCI Cancer Centers, and other NCI cancer health disparities programs
- 2010

Community Outreach Core
- CNP, MI/CCP, PNRP, MB-CCOP, NCCCP, NCI Cancer Centers
- 2011
What is Needed?
- Promising Strategies for Increasing Minority/Underserved for Clinical Trials Accrual -

**Patient/Family**
- Culturally/linguistically appropriate education, resources and outreach
- Encouraging a welcoming and trust-building approach to patient recruitment

**Community**
- Include community members as part of the IRB
- Meaningful engagement of community in Clinical Research Advisory Boards

**Provider**
- Utilize clinical trials navigators

**System**
- Three “R”s: Recruitment, Retention, Reporting back
- Reduce literacy levels of informed consents
- System to identify and match newly diagnosed patients with available clinical trials