NATIONAL CANCER INSTITUTE

# NCI Cancer Bulletin

Special Issue

*Eliminating the Suffering and Death Due to Cancer*

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*Director's Update*

## For More Than 20 Years, CCOPs Define Commitment, Success

There are many examples of successful National Cancer Institute (NCI) programs that span every part of our research enterprise. With this special issue of the *NCI Cancer Bulletin*, we are honoring a program that has come to represent the very definition of success: the Community Clinical Oncology Program (CCOP).

In 1982, a Request for Applications was issued soliciting participants for a unique program that would bring together community hospitals, the growing cadre of community oncologists, and other local health care providers into a nationwide network for conducting cancer clinical trials. Who could have imagined just how effective this program would become? But here we are, more than 20 years later, with CCOPs having enrolled more than 172,000 patients into cancer treatment and prevention trials.

From the beginning, there were those who doubted the program would work, who believed community providers could not stand up to the rigors of conducting large clinical trials. But time and again, these critics have been proven wrong. Analysis of CCOPs' performance over the years has consistently shown that they are not only skilled at recruiting patients,

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## Minorities Gaining Access to Clinical Trials

This past June, when the NCI Clinical Trials Working Group focused on the ongoing need to increase recruitment of minority populations to cancer clinical trials, a key element of their proposed solution was to fund more Minority-Based Community Clinical Oncology Programs (MB-CCOPs), and for good reason. Over the last decade, more than 5,500 minorities have enrolled in both treatment and prevention clinical trials sponsored by NCI through the MB-CCOP network.

The MB-CCOPs were launched in 1990 as part of the efforts of the CCOPs to deliver the best cancer care to patients, wherever they live. At least 40 percent of the local populations served by MB-CCOPs are minorities and the programs have had a disproportionately positive effect: In 2003, for instance, the MB-CCOPs accounted for less than 20 percent of

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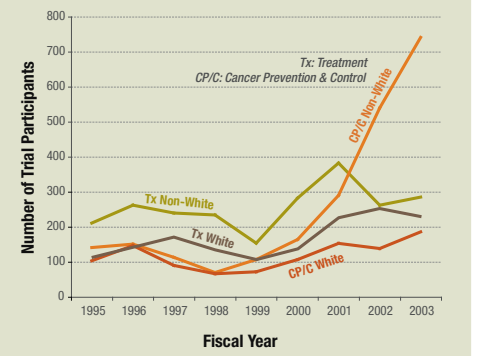
**MBCCOP Accruals to Cancer Treatment and Cancer Prevention and Control Clinical Trials by Race, FY 1995-2003**

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*(Director's Update continued from page 1)*
but also produce quality data and ensure the adoption of new standards of care by community providers.

The CCOPs' role in treatment trials has been critical. But under the inspired, excellent leadership of Dr. Peter Greenwald and his staff in the Division of Cancer Prevention (DCP)—including the program's current head, Dr. Lori Minasian, and its previous leader of 10 years, Dr. Leslie Ford—the cancer prevention and control arena is where the CCOPs have helped stake new ground. Indeed, the first drug ever approved for cancer prevention, tamoxifen, might never have been if the CCOP network had not conducted the Breast Cancer Prevention Trial, on which the approval was based.

From the beginning, the individuals and institutions participating in the CCOP network have had a remarkable commitment to its success. That commitment can be seen in the unselfish and cooperative manner in which they work with the NCI Cooperative Group and Cancer Centers, collectively known as the Research Bases. During a time when we are still working to more effectively integrate team science into cancer research, the CCOPs' collaboration with the Research Bases has been the epitome of teamwork.

A perhaps underappreciated component of the CCOPs is their participation in symptom management trials. These trials may not garner as many headlines as treatment and prevention trials, but their importance in developing interventions to reduce side effects such as nausea and mucositis is undeniable.

Finally, there is no greater indicator of success than imitation, which is why two institutes at the National Institutes of Health (NIH) have followed the CCOP model in developing community-based clinical trial networks to test new treatments for HIV and drug abuse.

In many respects, the success of the CCOPs is not a surprise. The genesis of the term "cancer community" is rooted in the unwavering commitment displayed by so many individuals in this country to defeating this disease. So it should come as no shock that, more than 20 years ago, when NCI reached out to communities to play a new role in advancing cancer research, they exceeded every expectation—and continue to do so. ◆

*Dr. Andrew C. von Eschenbach*
*Director, National Cancer Institute*

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*(Minority Communities continued from page 1)*
the CCOP network but enrolled half of the minority patients in the studies. (See August 2 *NCI Cancer Bulletin* and August 2 *Journal of Clinical Oncology*.)


*Dr. McCaskill-Stevens*

"Despite the recruitment challenges remaining, and any new barriers that may arise, the MB-CCOPs have shown that they can use their infrastructure to engage community health care providers and successfully recruit minorities into prevention trials," says Dr. Worta McCaskill-Stevens, the MB-CCOP program director in NCI's DCP.

Minority communities experience an unequal burden of cancer, and the professionals who work with them face challenges in recruiting for trials. In some African American communities, for example, earning the trust of patients and their families is essential.

"We address the issue of trust immediately, and we focus on educating people about the clinical trials that are available," says Dr. Lucile Adams-Campbell of the Howard University Cancer Center in Washington, D.C., who directs the District's MB-CCOP.

MB-CCOPs also benefit the communities they serve. In Puerto Rico, for example, the program targets cancer patients who cannot afford the drugs and treatments being evaluated. This was the case in trials that recently led to the new standard of care for HER-2 positive breast cancer. "This program offers patients hope and state-of-the-art therapies in their own communities from people who know their language and their culture," says the director, Dr. Luis Baez of the University of San Juan.

Dr. McCaskill-Stevens feels that MB-CCOPs also are in a unique position to address issues critical to minority populations and cancer, including mentoring investigators, sharing recruitment strategies with other institutions, identifying trends in cancer incidence in their local communities, and contributing to trial designs that account for competing minority health issues.

Dr. McCaskill-Stevens is optimistic about the increasing access that minorities will have to cancer trials, whether for prevention or treatment. "The future of minority participation in cancer trials rests with the burgeoning potential of this network," she says. "Their early successes will continue to bring quality health care delivery to diverse groups for years to come." ◆

*By Edward R. Winstead*

# Community Clinical Oncology Programs (CCOPs)

For a more detailed table of CCOPs, go to http://www.cancer.gov/ncicancerbulletin/NCI_Cancer_Bulletin_091305/page4.
The most recent list of CCOPs can also be found at http://www3.cancer.gov/prevention/ccop/aboutccop.html.

| Mid-Atlantic | | |
|---|---|---|
| Christiana Care Health Services | Newark, DE | 302-733-6227 |
| Northern New Jersey CCOP | Hackensack, NJ | 201-996-5834 |
| North Shore CCOP | Manhasset, NY | 516-562-8914 |
| Geisinger Health System | Danville, PA | 570-271-7854 |
| Main Line Health CCOP | Wynnewood, PA | 610-645-2649 |
| Hematology-Oncology Associates of Central New York | East Syracuse, NY | 315-472-7504 x 1735 |
| **Minority-Based CCOPs** | | |
| DC United MB-CCOP | Washington, DC | 202-806-9122 |
| Our Lady of Mercy Comprehensive Cancer Center MB-CCOP | Bronx, NY | 718-920-1100 |

| South | | |
|---|---|---|
| Florida Pediatric CCOP | Tampa, FL | 813-396-9528 |
| Mount Sinai CCOP | Miami Beach, FL | 305-574-2625 |
| Atlanta Regional CCOP | Atlanta, GA | 404-851-7115 |
| Ochsner CCOP | New Orleans, LA | 504-842-3708 |
| Southeast Cancer Control Consortium, Inc., CCOP | Winston-Salem, NC | 336-777-3036 |
| Oklahoma CCOP | Tulsa, OK | 918-494-2531 |
| Upstate Carolina CCOP | Spartanburg, SC | 864-560-6812 |
| Greenville CCOP | Greenville, SC | 864-241-6251 |
| Scott & White Center for Cancer Prevention and Care | Temple, TX | 254-724-1106 |
| **Minority-Based CCOPs** | | |
| The Gulf Coast MB-CCOP | Mobile, AL | 251-435-3214 |
| Medical College of Georgia | Augusta, GA | 706-721-6136 |
| LSU Health Sciences Center Stanley S. Scott Cancer Center MB-CCOP | New Orleans, LA | 504-568-5136 |
| San Juan MB-CCOP | San Juan, PR | 787-763-1296 |
| Meharry Medical College | Nashville, TN | 615-341-4513 |
| South Texas Pediatric MB-CCOP | San Antonio, TX | 210-704-2028 |
| Virginia Commonwealth University MB-CCOP | Richmond, VA | 804-628-1939 |

| Pacific | | |
|---|---|---|
| Bay Area Tumor Institute CCOP | Oakland, CA | 510-465-8502 |
| Santa Rosa Memorial Hospital CCOP | Santa Rosa, CA | 707-521-3830 |
| Southern Nevada Cancer Research Foundation CCOP | Las Vegas, NV | 702-384-0013 |
| Columbia River Oncology Program | Portland, OR | 503-216-6260 |
| Virginia Mason CCOP | Seattle, WA | 206-341-0446 |
| Northwest CCOP | Tacoma, WA | 253-403-1461 |
| **Minority-Based CCOP** | | |
| Cancer Research Center of Hawaii MB-CCOP | Honolulu, HI | 808-586-2979 |

| Midwest | | |
|---|---|---|
| Iowa Oncology Research Association | Des Moines, IA | 515-244-7586 |
| Cedar Rapids Oncology Project CCOP | Cedar Rapids, IA | 319-363-2690 |
| Illinois Oncology Research Association CCOP | Peoria, IL | 309-243-3605 |
| Carle Cancer Center | Urbana, IL | 217-383-4083 |
| Evanston Northwestern Healthcare | Evanston, IL | 847-570-1381 |
| Central Illinois CCOP | Decatur, IL | 217-876-6618 |
| Northern Indiana Cancer Research Consortium | South Bend, IN | 574-647-7370 |
| Wichita CCOP | Wichita, KS | 316-268-5784 |
| Grand Rapids Clinical Oncology Program | Grand Grapids, MI | 616-391-1230 |
| Kalamazoo CCOP | Kalamazoo, MI | 269-373-7458 |
| Michigan Cancer Research Consortium CCOP | Ann Arbor, MI | 737-712-5658 |
| Beaumont CCOP | Royal Oak, MI | 248-551-7695 |
| Metro-Minnesota CCOP | St. Louis Park, MN | 952-993-1516 |
| Duluth CCOP | Duluth, MN | 218-786-3308 |
| St. Louis-Cape Girardeau CCOP | St. Louis, MO | 314-251-6573 |
| Kansas City Clinical Oncology Program | Kansas City, MO | 816-823-0555 |
| Cancer Research for the Ozarks | Springfield, MO | 417-269-4520 |
| Heartland Cancer Research CCOP | St. Louis, MO | 314-996-5569 |
| MeritCare Hospital CCOP | Fargo, ND | 701-234-6292 |
| Missouri Valley Cancer Consortium | Omaha, NE | 402-991-8070 |
| Dayton Clinical Oncology Program | Dayton, OH | 937-395-8678 |
| Columbus CCOP | Columbus, OH | 614-488-2118 |
| Toledo Community Hospital Oncology Program | Toledo, OH | 419-843-6147 |
| Sioux Community Cancer Consortium | Sioux Falls, SD | 605-328-8044 |
| Marshfield CCOP | Marshfield, WI | 715-389-4457 |
| St. Vincent Regional Cancer Center CCOP | Green Bay, WI | 920-433-8889 |
| **Minority-Based CCOPs** | | |
| University of Illinois at Chicago MB-CCOP | Chicago, IL | 312-996-1581 |
| John H. Stroger, Jr., Hospital of Cook County MB-CCOP | Chicago, IL | 312-864-5204 |

| Rocky Mountain | | |
|---|---|---|
| Western Regional CCOP | Phoenix, AZ | 602-239-2413 |
| Colorado Cancer Research Program | Denver, CO | 303-777-2663 |
| Montana Cancer Consortium CCOP | Billings, MT | 406-259-2245 |
| **Minority-Based CCOP** | | |
| University of New Mexico Cancer Research & Treatment Center | Albuquerque, NM | 505-272-6972 |

# Community Clinical Oncology Programs (CCOPs)

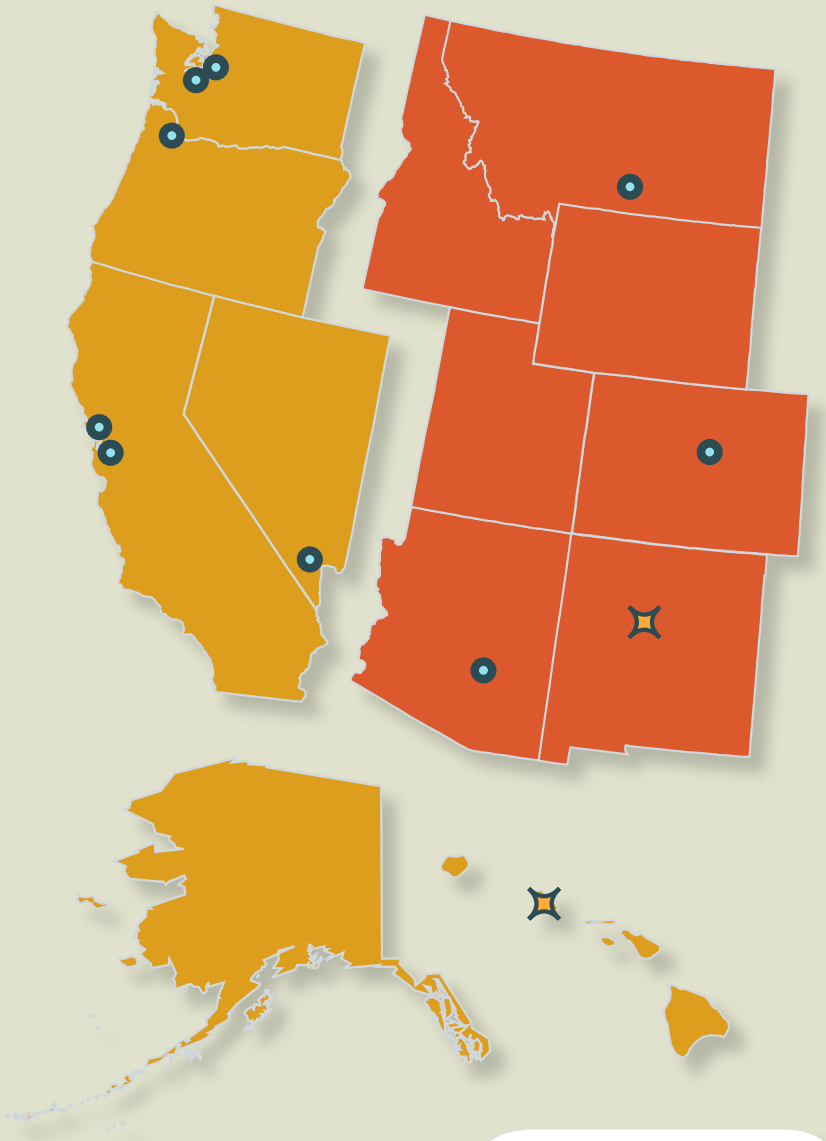
There are 415 hospitals participating in the CCOPs, ranging from 1 to 23 per program.

There are 3,675 physicians in the CCOPs, ranging from 2 to 132 per program.

There are 68 active prevention and control trials and 283 active treatment trials in the CCOPs network.

The Study of Tamoxifen and Raloxifene (STAR), one of the largest breast cancer prevention studies ever conducted, completed recruitment in October 2004 with 19,747 women, 6,579 at CCOP sites (33 percent). The Southeast Cancer Control Consortium CCOP was the top accruer to STAR.

Although Minority-Based CCOPs make up less than 20 percent of CCOP grantees, they contribute 33 percent of the network's minority accruals and 7 percent of minority patients on all cooperative group trials.



CCOPs (50)

Minority-Based CCOPs (13)

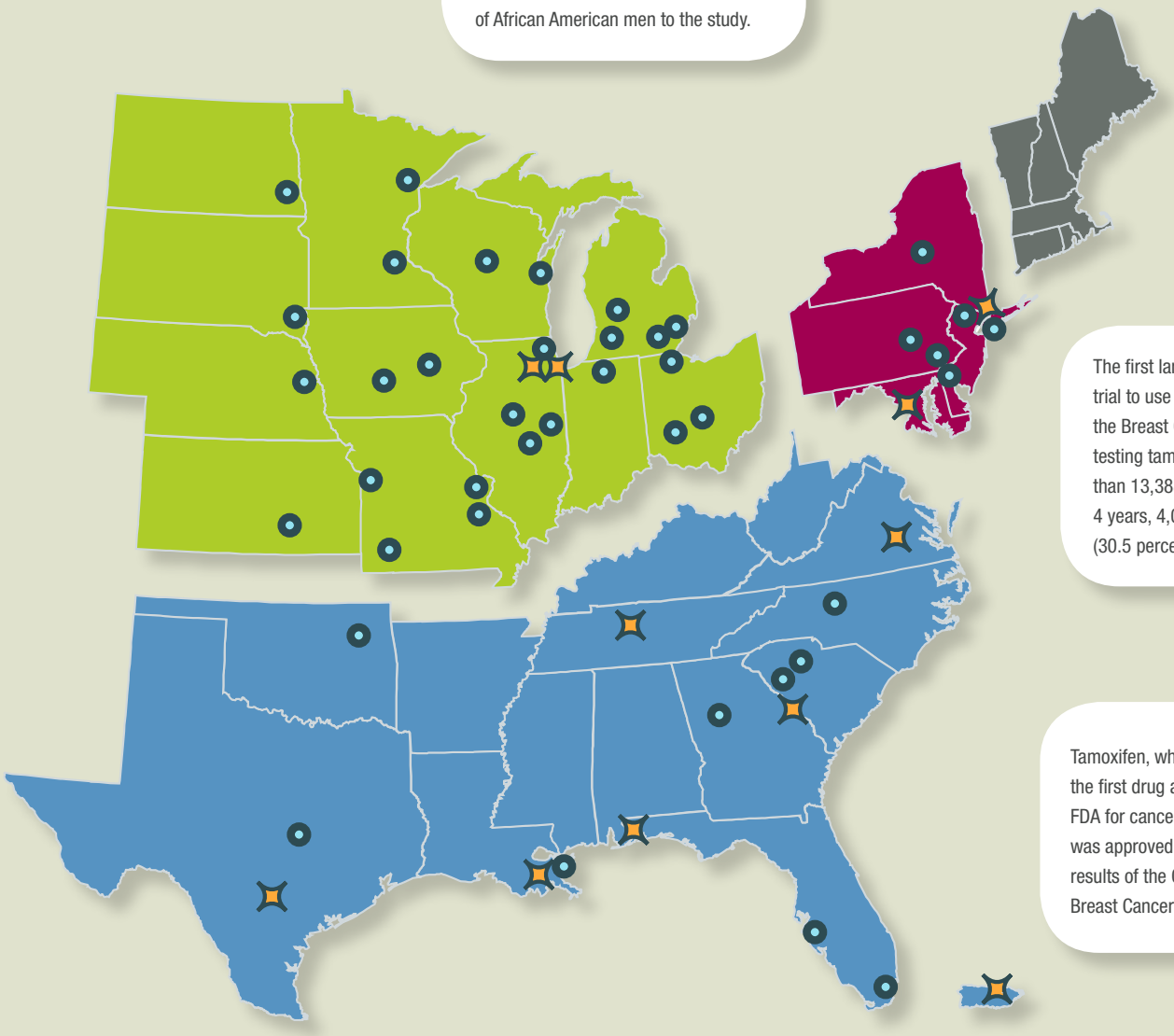
The most common symptoms addressed in CCOP symptom-management trials are pain, anorexia, mucositis, neuropathy, and hot flashes.

The primary NCI mechanism for conducting phase III clinical trials in symptom management, palliative care, and other cancer control issues is the CCOP network.

Since 1982, CCOPs have enrolled 104,160 patients—approximately 1/3 of all NCI treatment trial participants—to NCI-sponsored treatment clinical trials.

The Selenium and Vitamin E Cancer Prevention Trial (SELECT), an ongoing study of dietary supplements in prostate cancer prevention, enrolled 35,534 men in 3 years; 10,270 (29 percent) of these at CCOP sites. The Upstate Carolina CCOP was the second top accruer overall to SELECT and the University of Illinois at Chicago MB-CCOP was the top accruer of African American men to the study.

Since 1990, prevention clinical trials conducted by the CCOP program have enrolled 92,300 people at risk for cancer.



The first large-scale prevention trial to use the CCOP network was the Breast Cancer Prevention Trial testing tamoxifen in 1992. More than 13,388 women joined in just 4 years, 4,087 of them at CCOPs (30.5 percent).

Tamoxifen, which in 1998 was the first drug approved by the FDA for cancer risk reduction, was approved based on the results of the CCOP-conducted Breast Cancer Prevention Trial.

One of the first clinical trials to show cancer-preventive effects of aspirin was the CCOP-conducted Colorectal Adenoma Prevention Study in 2003, after several epidemiologic studies linked such non-steroidal anti-inflammatory drugs to lower rates of colorectal adenomas (polyps).

The CCOP-conducted Prostate Cancer Prevention Trial (PCPT) enrolled 18,882 participants—7,312 from CCOP sites (38.7 percent). The drug studied, finasteride, is the first drug found to reduce the risk of prostate cancer.

# Moments in Community Clinical Oncology Program History

**July 1982 –** NCI launches the Community Clinical Oncology Program (CCOP) to establish a cancer control effort combining the expertise of community oncologists with NCI clinical research programs, and brings the advantages of clinical research to cancer patients in their communities.

**September 1983 –** The original 63 CCOPs, located in 34 states, are funded.

**1987 –** First evaluation of CCOP finds the program effective in enrolling patients in clinical trials and getting physicians to adopt trial results as standards of care.

**1989 –** Minority-Based CCOPs are established to focus on access to minority populations. Universities, as the primary health care providers for minorities, are permitted to apply to the program.

**April 1998 –** BCPT results are announced: Women taking tamoxifen had 45 percent fewer breast cancer diagnoses than women on the placebo, proving that breast cancer can be prevented.

**October 1993 –** The Prostate Cancer Prevention Trial (PCPT) begins. PCPT evaluates finasteride as a prostate cancer prevention drug, and is coordinated by the Southwest Oncology Group.

**June 1993 –** The Colorectal Adenoma Prevention Study (CAPS) is begun under the direction of the Cancer and Leukemia Group B, using the CCOP network. The trial evaluates whether aspirin will reduce the development of adenomas in people who have already had early-stage colorectal cancer.

**April 1992 –** The CCOP network is used for the first time to conduct a large prevention trial to evaluate the efficacy of tamoxifen to prevent breast cancer in women at increased risk of the disease. The National Surgical Adjuvant Breast and Bowel Project coordinates the Breast Cancer Prevention Trial (BCPT).

**1998 –** An Institute of Medicine report recommends that the National Institute on Drug Abuse and the Center for Substance Abuse Treatment use the NCI CCOP model to conduct community-based trials of drug and alcohol treatments.

**May 2002 –** CAPS results are presented at the American Society of Clinical Oncology meeting: Daily aspirin use reduced the development of adenomas by 35 percent in patients with previous colorectal cancers.

**June 2003 –** PCPT results are released: Men taking finasteride had 25 percent fewer prostate cancer diagnoses than men on the placebo, proving that prostate cancer can be prevented.

**2005 –** NCI funds 50 CCOPs across 30 states;13 MB-CCOPs in 10 states, Puerto Rico, and Washington, D.C.; and 14 Research Bases.

## A Conversation With…Dr. Lori Minasian

*Dr. Minasian has been chief of the Community Oncology and Prevention Trials Research Group, which administers the CCOPs, since 1997.*

### What do you think are the CCOPs' most important contributions to cancer research and prevention?

The first major accomplishment is that we've proven community physicians can be significant contributors (in terms of both quality and quantity) to clinical trials that set the national standards for quality care in cancer. Next, CCOPs have shown that cancer prevention and cancer control trials can be done in the community setting. And finally, the results of the landmark prevention trials themselves are a major contribution—the proof of principle that an agent can reduce a person's risk for developing cancer.

### Why are the CCOPs so successful at recruiting patients?

The program succeeds because CCOP physicians and their staffs are motivated to succeed. They believe that clinical trials allow them to offer state-of-the-art care for cancer patients and people at risk for cancer. These trials are carried out in the community setting, not as an exception to everyday care, but rather as part of excellent delivery of cancer care. The program lets stable resources get into the hands of the community physicians who have demonstrated their ability to accrue to clinical trials and provides them with significant, ongoing support so they can continue to do so.

### CCOP physicians receive training and support from NCI. What have the CCOPs taught NCI about community oncology?

These physicians, nurses, and support staff are incredibly committed to their patients, as well as to clinical trials. They have taught me that community physicians can integrate clinical research into their very busy practices when they have sufficient resources. ◆

## Why CCOP Physicians Participate in Prevention

**By Dr. James L. Wade III, Principal Investigator, Central Illinois CCOP, Decatur, Illinois**

CCOPs initially arose as mechanisms that would enable community oncologists to participate in cooperative groups' cancer treatment studies. Often such protocols would include the investigation of a new drug. Some studies would redefine the standard of care for a particular disease.

Although these programs focused on treatment trials have been quite successful, community oncologists have come to recognize that the greatest reduction in the cancer burden will only come from disease prevention. All of the advances in prolonging survival and reducing relapse pale in comparison to cancer prevention. CCOP investigators have learned this from their patients, their patients' families, and their communities. CCOPs now view themselves as the best medium for chemoprevention studies at the local level.

Indeed, CCOPs are the ideal platform for such prevention studies because they align the principal investigator's recognition that chemoprevention holds great promise with his or her local community's desire to participate in the research process..

The successes of such cancer awareness events as the "Race for the Cure" and the "Walk for Life" are clues to how important local communities feel about doing their part to help. CCOPs then take this local interest and desire to participate to a higher level by enrolling at-risk individuals into studies designed to reduce cancer incidence.

The cooperative groups have a responsibility to harness their considerable expertise to design a national prevention program for all malignancies that are candidates for prevention strategies. When armed with good national large-scale prevention programs, the CCOPs can fulfill their initial promise of truly reducing the cancer burden. ◆

# Why I Am a CCOP Physician

**By Dr. Richard L. Deming, Medical Director, Mercy Therapeutic Radiology Associates, Des Moines, Iowa**

Cancer treatment is an evolving process. The knowledge we gain from the results of clinical trials ultimately determines what the standard treatment for a particular type and stage of cancer will be.

During our residencies at academic medical centers we learned the value of evidence-based medicine. We studied the landmark clinical trials that influenced our current recommendations and we participated in new trials destined to influence future standards.

When we completed our residencies, we chose whether to stay in the academic world or to join the ranks of community physicians. Many of us struggled with this decision because we enjoyed the stimulation of the university setting, and felt the good that comes from working to advance the treatment.

Those of us who go into private practice don't give up our intellectual curiosity or our desire to help advance the knowledge of cancer treatment. Participation in clinical trials through the CCOPs allows us to continue contributing to our profession and helping to improve the quality of patient care.

For me, participation in the North Central Cancer Treatment Group, a CCOP Research Base, provides a framework for ongoing collaboration with my academic colleagues, an occasion to attend semiannual group meetings, and the opportunity to stay informed about new developments in oncology.

**Why do I participate?**

1. I want to help improve cancer care.
2. I want to be able to offer my patients the most up-to-date treatment possible.
3. I want to be part of a collaborative process with academic physicians to continue my professional development and learn about new developments in oncology. ◆

# Hurricane Katrina Update

Three CCOPs were directly affected by Hurricane Katrina: the Louisiana State University MB-CCOP and the Ochsner CCOP, both in New Orleans, and the Gulf Coast MB-CCOP in Mobile, Alabama. Of these three, only the Gulf Coast MB-CCOP has been able to reopen to treat cancer patients. In response to the overwhelming need of people displaced by the hurricane, CCOPs across the country have opened their doors to patients from the Gulf Coast area to help them continue cancer treatment, including patients who were on clinical trials with experimental drugs. NCI has a list of resources available to help patients and physicians after this national disaster at http://www.cancer.gov/katrina. ◆

**Coming Soon: CCOP Network Profiles**

Now that you've learned about the "why" and "how" of the CCOP network, look forward to learning about "who" the members are who make up this network through a new *Bulletin* feature, CCOP Profiles.

These profiles will run approximately every 6 weeks and provide an overview of each CCOP, with information about its history, clinical specialties, research activities, and new programs of interest to patients, investigators, and health care professionals.

**Upcoming profiles:**

- Wichita Community Clinical Oncology Program
- John H. Stroger, Jr., Hospital of Cook County MB-CCOP
- Southeast Cancer Control Consortium, Inc., CCOP
- San Juan MB-CCOP
- Upstate Carolina CCOP
- Columbia River Oncology Program
- Christiana Care Health Services

For more information about the CCOPs network, go to http://www3.cancer.gov/prevention/ccop/. ◆

The *NCI Cancer Bulletin* is produced by the National Cancer Institute (NCI). NCI, which was established in 1937, leads the national effort to eliminate the suffering and death due to cancer. Through basic, clinical, and population-based biomedical research and training, NCI conducts and supports research that will lead to a future in which we can identify the environmental and genetic causes of cancer, prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

For more information on cancer, call 1-800-4-CANCER or visit http://www.cancer.gov. *NCI Cancer Bulletin* staff can be reached at ncicancerbulletin@mail.nih.gov.