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CANCER RESEARCH Forum

SPRING 2006

CLINICAL RESEARCH STUDIES AT THE CANCER INSTITUTE OF NEW JERSEY AT COOPER

Cooper Participates in Breakthrough Breast Cancer Studies

Two clinical research studies of Herceptin® (trastuzumab), a drug used to treat some types of advanced breast cancer, recently showed benefits in early stage breast cancer. The results of these studies show that women with early stage breast cancer who received Herceptin along with chemotherapy had half the risk of the cancer returning compared to women treated only with chemotherapy. They also lived longer.

These results were so promising that the National Cancer Institute (NCI), the study's sponsor, stopped the research ahead of schedule to make the findings public. Researchers at The Cancer Institute of New Jersey at Cooper participated in these breakthrough studies.

"These results are truly exciting for women with early-stage breast cancer and will affect thousands of women in the United States each year," said Generosa Grana, MD, FACP, Director of The Cancer Institute of New Jersey at Cooper and an investigator on these studies. "Only through the

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Photo: Jim Graham

Generosa Grana, MD, FACP, was an investigator on two breakthrough breast cancer studies conducted at Cooper.

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Understanding Clinical Trials

Cancer clinical trials are research studies seeking better treatments for cancer or better ways to prevent, screen, or diagnose cancer. Many of today's most effective standard treatments for cancer are based on previous clinical trials. Many people who are treated for cancer are now living longer thanks to progress made through these research studies.

Promising new cancer treatments are often only available through clinical trials. "Clinical trials enable cancer programs to offer the most advanced treatments and approaches available to fight cancer," said Steven J. DiBiase, MD, Chief of Cooper's Department of Radiation Oncology, Director of the Radiation Therapy Clinical Trials Program within the Cancer Clinical Trials Center at The Cancer Institute of New Jersey at Cooper, and a Top Doc (*South Jersey Magazine*). Dr. DiBiase is an Associate

Professor of Radiation Oncology at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School.

*"It's been proven that **all** patients at cancer programs which offer clinical trials, not just those who participate in the trials, receive better care than those at programs which do not offer clinical trials."*

Robert A. Somer, MD, Medical Oncologist

Studies have shown that cancer programs that offer clinical trials—like The Cancer Institute of New Jersey at Cooper—provide the best care for all patients. "It's been proven that all patients at cancer programs which offer clinical trials, not just those who participate in the trials, receive

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A MESSAGE FROM THE CANCER CLINICAL TRIALS CENTER

Photo: Jonathan Kolbe



Welcome to the first issue of *Cancer Research Forum*, from the Cancer Clinical Trials Center at The Cancer Institute of New Jersey at Cooper. We developed this newsletter to keep you informed about the many clinical research studies (also called clinical trials) available at Cooper, and their important role in treating, preventing, screening, and diagnosing cancer.

The Cancer Institute of New Jersey at Cooper offers more clinical research

studies than any other hospital in South Jersey, in virtually all types of cancer. *Cancer Research Forum* highlights select research studies in breast, cervical, colon, endometrial (uterine), head and neck, lung, ovarian, prostate, renal (kidney), and bladder cancers, and leukemia and multiple myeloma. We hope that this newsletter demonstrates the depth and breadth of therapies available at The Cancer Institute of New Jersey at Cooper, and our commitment to providing patients with the best cancer care possible.

Sincerely,

Robert A. Somer, MD

Director, Hematology/Medical Oncology
Clinical Trials Program, Cancer Clinical Trials Center,
The Cancer Institute of New Jersey at Cooper

Select Clinical Trials at The Cancer Institute of New Jersey at Cooper

The following is a sample of clinical trials at The Cancer Institute of New Jersey at Cooper. Approximately 60 clinical trials are currently seeking participants. For descriptions of the sample studies, and a current listing of all open clinical trials and study descriptions, visit www.coopercancer.org (under Search Clinical Trials).

Bladder Cancer

Pemetrexed Disodium and Gemcitabine in Treating Patients With Advanced Cancer of the Urothelium (ECOG-E4802), a phase II study sponsored by the National Cancer Institute

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Breast Cancer

Combination Chemotherapy in Treating Women who have Undergone Surgery for Node-Positive Breast Cancer (NSABP-B-38), a phase III study sponsored by the National Cancer Institute

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Comparison of Anastrozole (ZD1033, Arimidex)-Placebo to the Combination Anastrozole-ZD1839 (gefitinib, IRESSATM) in Postmenopausal Patients with Estrogen Receptor (ER) and/or Progesterone Receptor (PgR) Metastatic Breast Cancer (03-119), a phase II study sponsored by the pharmaceutical industry

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Cervical Cancer

Comparison of Four Combination Chemotherapy Regimens Using Cisplatin in Treating Patients with Stage IVB, Recurrent, or Persistent Cancer of the Cervix (GOG-0204), a phase III study sponsored by the National Cancer Institute

CONTACT: Maria DeFrancesco: (856) 325-6733 or
defrances-maria@cooperhealth.edu

Chemotherapy-Induced Neuropathy

Amifostine in Treating Peripheral Neuropathy in Patients who have Received Chemotherapy for Gynecologic Malignancy (GOG-0192), a phase III study sponsored by the National Cancer Institute

CONTACT: Maria DeFrancesco: (856) 325-6733 or
defrances-maria@cooperhealth.edu

Colon Cancer

Fluorouracil, Leucovorin, and Oxaliplatin with or without Bevacizumab in Treating Patients who have Undergone Surgery for Stage II or Stage III Colon Cancer (NSABP-C-08), a phase III study sponsored by the National Cancer Institute

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Chemotherapy and Bevacizumab with and without Panitumumab in Treating Metastatic Colorectal Cancer (RP 05-019), a phase III-B study sponsored by the pharmaceutical industry

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Endometrial Cancer

Trastuzumab in Treating Patients with Stage III, Stage IV, or Recurrent Endometrial Cancer (GOG-0181-B), a phase II study sponsored by the National Cancer Institute

CONTACT: Maria DeFrancesco: (856) 325-6733 or
defrances-maria@cooperhealth.edu

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PATIENT STORY

Deborah RoyRoberts

Like many people, Deborah RoyRoberts never thought that she would participate in a clinical trial. “I thought it was a risk,” said the 49-year-old homemaker from Malaga, NJ. Today, Deborah feels that she is fortunate to have participated in a breast cancer study of Herceptin® (trastuzumab) at The Cancer Institute of New Jersey at Cooper.

After being diagnosed with breast cancer in May 2004, Deborah came to Cooper for treatment. In June 2004, she had a mastectomy, which revealed that the cancer was HER-2 positive. HER-2 positive breast cancers tend to grow faster and are more likely to return after treatment than other breast cancers.

“Participating in a clinical trial gave me absolutely the best level of care. Study staff were very supportive and accommodating. They listened to my worries, and answered all of my questions. They also guided me in things that weren’t related to the study.”

Generosa Grana, MD, Deborah’s oncologist, recommended a clinical trial of Herceptin in combination with conventional chemotherapy as part of Deborah’s

treatment plan. Herceptin is a drug that was being used to effectively treat advanced breast cancer. The study was testing Herceptin in early stage breast cancer that was HER-2 positive and had first been treated with surgery. Dr. Grana, who is the Director of The Cancer Institute of New Jersey at Cooper, was an investigator on the study.

Deborah wanted to know more about the clinical trial. “Dr. Grana explained everything about the study to me, many times over, and answered all of my questions,” she said. “I also did a great deal of research on the Internet. In particular, after reading about the success of Herceptin for advanced breast cancer, I decided I wanted to participate.”

In August 2004, Deborah enrolled in the study, which was sponsored by the National Cancer Institute. As part of the study, she received chemotherapy with doxorubicin and cyclophosphamide, followed by paclitaxel and Herceptin, and then Herceptin alone. She also had radiation therapy, which was not part of the study, but part of standard treatment.

“Participating in a clinical trial gave me absolutely the best level of care,” said Deborah. “Study staff were very supportive and accommodating. They listened to my worries, and answered all of my questions.



Photo: George Moore

Medical Oncologist Generosa Grana, MD, FACP, meets with clinical trial participant Deborah RoyRoberts.

They also guided me in things that weren’t related to the study.”

As the study progressed, Deborah became more comfortable about being a clinical trial participant. She began to tell other women with HER-2 positive breast cancer about her experience. “I met women who chose not to do the study because they were afraid of the risks or did not know enough about it,” she said. “They needed to talk to someone who was like them and who had gone through or was in the study. Some of them seriously reconsidered after I spoke to them.”

The study Deborah participated in was

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NCI Study for Women with Advanced Ovarian Epithelial or Peritoneal Cancer

Paclitaxel, Polyglutamate Paclitaxel (CT-2103) or Observation in Treating Patients in Remission from Stage III or Stage IV Ovarian Epithelial or Peritoneal Cancer (GOG-0212), a phase III study sponsored by the National Cancer Institute

Women with stage III or stage IV ovarian epithelial or peritoneal cancer who have recently been treated for their disease and who are now in remission may be eligible to participate in a study that will try to determine if continuing chemotherapy will keep their disease from returning sooner or not at all when compared to no additional treatment. A previous National Cancer Institute Gynecologic Oncology Group study showed an increase in the length of time of remission in patients who continued monthly paclitaxel for 12 months after receiving the standard regimen for treatment of stage III or stage IV ovarian or primary peritoneal cancer. However, the study was not continued long enough to

determine if overall length of survival was affected.

The current study compares two types of chemotherapy (paclitaxel or Xyotax™ [polyglutamate paclitaxel]) to observation alone. Participants will be randomly given 12 monthly treatments of paclitaxel or polyglutamate paclitaxel (a modified form of paclitaxel currently under investigation) or no treatment. All participants will be seen monthly for exams and tests. ●

For More Information

CONTACT: Maria DeFrancesco: (856) 325-6733 or
defrances-maria@cooperhealth.edu

Cancer Team Profile

David P. Warshal, MD, Director, Gynecologic Cancer Center

David P. Warshal, MD, became a gynecologic oncologist because of his interest in the biology of cancer and his desire to improve the care of women with gynecologic cancer (cancers of the ovaries, uterus, cervix, fallopian tubes, vulva, and vagina). “I felt that more could be done to help these patients,” said Dr. Warshal, who has helped build the largest and only comprehensive program for gynecologic cancer in South Jersey: the Gynecologic Cancer Center at The Cancer Institute of New Jersey at Cooper.

Dr. Warshal joined Cooper in 1997 and was named head of the Gynecologic Cancer Center in 2002. A Top Doc (*South Jersey Magazine*), he also received a Humanism in Medicine Award from The Healthcare Foundation of New Jersey. Dr. Warshal is an Assistant Professor of Obstetrics and Gynecology at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School.

Clinical trials are a key component of the Gynecologic Cancer Center. “Clinical trials enable us to move promising new drugs from the lab to the clinic, test their effectiveness in treating a variety of cancers, and ultimately, to establish the best of these drugs as part of the standard of care for the best treatments for patients,” said Dr. Warshal.

As the only full member of the National Cancer Institute’s Gynecologic Oncology Group in New Jersey, the Gynecologic Cancer Center offers patients more clinical trials than any other center in the state. About 40 gynecologic cancer studies are available at any time; the majority are available in South Jersey only at Cooper.

Cooperative groups like the Gynecologic Oncology Group identify important questions in cancer research and design clinical trials to answer those questions. “We are an integral part of the mechanism that drives the care of patients with gynecologic cancer forward,” said Dr. Warshal.

Dr. Warshal has participated in dozens of studies, including some which have changed the standard of care for women



Photo: Ed Wheeler

Dr. Warshal, who helped build the only comprehensive program for gynecologic cancer in South Jersey at Cooper, reviews a study with Clinical Research Coordinator Maria DeFrancesco, CCRC.

“Clinical trials enable us to move promising new drugs from the lab to the clinic, test their effectiveness in treating a variety of cancers, and ultimately, to establish the best of these drugs as part of the standard of care for the best treatments for patients.”

with gynecologic cancer. For example, Dr. Warshal and his colleagues, James K. Aikins, MD, and Thomas F. Rocereto, MD, participated in studies which found that adding chemotherapy to radiation therapy improved outcomes in cervical cancer. Since then, the National Cancer Institute declared Cisplatin-based chemotherapy plus radiation therapy the new standard of care for non-operable forms of cervical cancer.

Dr. Warshal and his colleagues are currently participating in research that combines antibodies and standard chemotherapy in treating ovarian cancer. These antibodies are immune system-related proteins that bind to specific sites on cancer

cells to kill them. “Antibodies get down to the basics of how cancer cells grow, disrupting this process at the cellular level. We think that by combining standard chemotherapy with antibody therapy, we will do much better in treating cancer,” said Dr. Warshal.

As chair of one of the two committees that comprise Cooper’s Institutional Review Board (IRB), Dr. Warshal helps ensure that study participants are protected. The IRB includes scientists, doctors, clergy, and community representatives. Members review and must approve the action plan (protocol) for every clinical trial. They check to see that the trial is well designed, does not involve undue risks, and includes safeguards for patients. “We try to think about what it would be like to be a patient entering the study,” said Dr. Warshal. “We make sure that the circumstances for participation protect the patient, and studies are presented in a way that is understandable to the patient and in a context that gives the patient sufficient time to decide whether participation is appropriate.” ●

DAVID P. WARSHAL, MD

Board Certification

- Obstetrics and Gynecology
- Gynecologic Oncology

Medical Degree

- Pennsylvania State University College of Medicine

Internship

- Nassau County Medical Center

Residency

- University of Rochester School of Medicine and Dentistry

Fellowships

- Pelvic Surgery at Pennsylvania Hospital
- Gynecologic Oncology at the University of Rochester School of Medicine and Dentistry

New Leadership for Hematology/Medical Oncology Clinical Trials Program



Photo: Ed Wheeler

Susan Coakley, MHA, CCRP, recently joined The Cancer Institute of New Jersey at Cooper as Clinical Research Manager of the Hematology/Medical Oncology Clinical Trials Program. Coakley has more than 15 years of experience in managing cancer programs and is a certified clinical research professional (CCRP).

“Susan Coakley will be instrumental in helping us build our clinical research program, which will enable us to provide patients with access to more clinical trials,” said Robert A. Somer, MD, Director of the Hematology/Medical Oncology Clinical Trials Program.

Coakley will lead and direct clinical research staff and investigators (physicians who conduct studies). She will manage the administrative, regulatory, educational, and clinical aspects of hematology/medical oncology trials. “I look forward to being a part of the dynamic team of physicians and staff here at Cooper, as well as contributing to the growth of a dynamic research program,” said Coakley.

The current hematology/medical oncology research team has nine full-time physician investigators and three full-time research staff. Staff members are responsible for the regulatory, study coordination and data management aspects of research to ensure patient safety, protocol compliance, and data quality. They each

have several years of clinical research experience and are: Regulatory Specialist Juliette May and Clinical Research Associate Elta Field, CCRP. Coakley is in the process of recruiting additional staff, primarily two research nurses who will work with the research staff and physician investigators to coordinate care for study participants.

“Susan Coakley will be instrumental in helping us build our clinical research program, which will enable us to provide patients with access to more clinical trials.”

Robert A. Somer, MD,
Director, Hematology/Medical Oncology
Clinical Trials Program



Photo: Ed Wheeler

Regulatory Specialist Juliette May reviews study documents with Susan Coakley, MHA, CCRP.

Coakley joined Cooper from The Children’s Hospital of Philadelphia, where she managed research staff in the Clinical Trials Office. Before that, she spent seven years at Fox Chase Cancer Center as Director of the Protocol Management Office. Coakley was also a manager in the oncology programs at Memorial Hospital of Burlington County and Rancocas-Zurbrugg Hospital. She has a Master’s of Health Administration from Arcadia University. ●

Study for People with Advanced Non-Small Cell Lung Cancer

Bevacizumab (Avastin) plus Pemetrexed (Alimta) and Carboplatin in Previously Untreated Advanced Non-Small Cell Lung Cancer (AVF3158s), *an investigator-initiated phase II study sponsored by the pharmaceutical industry*

People with advanced lung cancer that cannot be cured with surgery, radiation therapy, or chemotherapy may be eligible to participate in a study of a new combination of three drugs: bevacizumab, pemetrexed, and carboplatin. Bevacizumab (Avastin®) has been approved by the Food and Drug Administration (FDA) for the treatment of metastatic colorectal cancer. It has not been approved for use in the treatment of lung cancer but was recently shown to improve the effectiveness of chemotherapy when added to standard chemotherapy treatments for patients with certain types of advanced lung cancer. Avastin works by blocking blood vessels from forming to provide a blood supply to tumors.

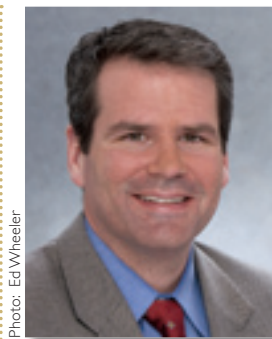


Photo: Ed Wheeler

James Stevenson, MD, is an investigator on this study, which is combining three drugs in advanced non-small cell lung cancer.

Blood supply is needed in order for tumors to grow.

Pemetrexed (Alimta®) has been approved by the FDA for use in lung cancer which has recurred or progressed after an initial treatment with another regimen. It has

not been approved for initial use in the treatment of non-small cell lung cancer. Carboplatin has been approved by the FDA for initial treatment of advanced non-small cell lung cancer.

The purpose of this study is to find out how well bevacizumab, pemetrexed, and carboplatin control the progression of advanced non-small cell lung cancer. Researchers will also study how well the disease responds to the investigational treatment, overall survival, and side effects. ●

For More Information

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Study for People with Brain Cancer

Study of Therapy with TransMID™ Compared to Best Standard of Care in Patients with Glioblastoma Multiforme (RP 05-057), a phase III study sponsored by the pharmaceutical industry

People with a type of brain cancer called glioblastoma multiforme may be eligible to participate in a study of a new approach and new drug called TransMID™. Cooper is 1 of 21 sites in North America participating in this study.

Glioblastoma multiforme tumors are usually treated with surgery followed by radiotherapy and chemotherapy. Unfortunately, this type of brain tumor may continue to grow or come back (recur) despite treatment.

This trial will compare TransMID with the best standard treatment. TransMID is a combination of a protein called transferrin and an inactivated form of diphtheria toxin. Cancer cells need iron in order to continue

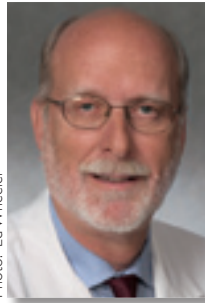


Photo: Ed Wheeler

H. Warren Goldman, MD, PhD, is an investigator on this study.

to grow. They need more iron than normal cells. Transferrin helps cells to take up available iron. Once the cancer cells are attached to the transferrin in TransMID, the diphtheria poison can work to kill them. The aim of this treatment is to kill the cancer cells while not affecting the normal brain cells. This treatment for brain tumors may have fewer side effects than other treatments because it targets cancer cells.

Participants in the study will be randomized to one of two groups. The first group will receive two TransMID treatments four to six weeks apart. The TransMID treatments are given via two tubes (catheters) inserted into the tumor. The drug is then delivered through these tubes over four to seven days. The catheters are removed following the treatment. The second group will receive the standard treatment for glioblastoma multiforme. ●

For More Information

CONTACT: Janet Scanlon, RN, MSN:
(856) 342-3416 or
Scanlon-Janet@cooperhealth.edu

(continued from page 2) **Select Clinical Trials at The Cancer Institute of New Jersey at Cooper**

Head and Neck Cancer

Oral Mucositis Treatment in Advanced Head and Neck Cancer (RP#04-123), a phase II study

CONTACT: Kavita Khatod: (856) 963-3952 or
khatod-kavita@cooperhealth.edu

Leukemia, Chronic Myelogenous

Imatinib at Standard or Increased Doses for Previously Untreated Patients with Chronic Myelogenous Leukemia (CML) in the Chronic Phase (CALGB 10303), a phase IIB study sponsored by the National Cancer Institute

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Lung Cancer

Docetaxel or Pemetrexed with or without Cetuximab in Patients with Recurrent or Progressive Non-Small Cell Lung Cancer (RP#04-124), a phase II study sponsored by the pharmaceutical industry

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Multiple Myeloma

Comparison of Thalidomide plus Dexamethasone versus DOXIL® plus Thalidomide in Patients with Newly Diagnosed Multiple Myeloma (RP# 04-141), a phase III study sponsored by the pharmaceutical industry

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Ovarian Cancer

A Study to Evaluate Pertuzumab (rhuMab 2C4) and Gemcitabine in Subjects with Ovarian, Primary Peritoneal, or Fallopian Tube Cancer (TOC3258g), a phase II study sponsored by the pharmaceutical industry

CONTACT: Maria DeFrancesco: (856) 325-6733 or
defrances-maria@cooperhealth.edu

PNH (Paroxysmal Nocturnal Hemoglobinuria)

SHEPHERD: Safety in Hemolytic PNH Patients Treated with Eculizumab: A Multi-Center Open Label Research Design Study (RP#05-055), a phase III study sponsored by the pharmaceutical industry

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Prostate Cancer

Ixabepilone in Treating Patients with Metastatic Prostate Cancer (ECOG-E3803), a phase II study sponsored by the National Cancer Institute

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu

Multi-Modality Approach for Treatment of High-Risk Non-Metastatic Prostate Cancer (RP# 03-049), a phase II study

CONTACT: Kavita Khatod: (856) 963-3952 or
khatod-kavita@cooperhealth.edu

Renal (Kidney) Cancer

Two Dose Levels of IMOxine® (IMO-2055 for Injection) in Patients with Metastatic or Locally Recurrent Clear Cell Renal Carcinoma (RP# 05-007), a phase II study sponsored by the pharmaceutical industry

CONTACT: Sue Coakley: (856) 325-6757 or
coakley-susan@cooperhealth.edu ●

(continued from page 1) **Understanding Clinical Trials**

better care than those at programs which do not offer clinical trials,” said Robert A. Somer, MD, a Medical Oncologist, Director of the Hematology/Medical Oncology Clinical Trials Program, and a Top Physician in America (Consumer’s Research Council of America). Dr. Somer is an Assistant Professor of Medicine at the Robert Wood Johnson Medical School.

Clinical trial participants, who are volunteers, receive regular and careful medical attention from researchers (doctors, study nurses, and other health professionals). In cancer treatment research studies, participants receive either the new treatment being tested or the best available standard treatment for their cancer.

Benefits of Participating in Cancer Clinical Trials

Participating in clinical trials has many advantages, yet, only 3% of adult cancer patients do so. “Most patients are completely unaware of clinical trials, and few understand the benefits of participating in a clinical trial,” said Dr. Somer. These benefits include:

- Access to promising new cancer treatments
- The best cancer care available

- Regular and careful medical attention
- The opportunity to help other people with cancer.

How Clinical Trials Work

Clinical research is conducted according to strict scientific and ethical principles. Researchers must follow the study’s protocol (an action plan for conducting the trial). An Institutional Review Board (IRB) at each participating hospital or study site must approve the protocol before the study can start. The IRB, which includes consumers, clergy, and health professionals, ensures that the study will be conducted fairly and that participants are not likely to be harmed. The IRB also conducts ongoing review of the study.

Researchers explain the study thoroughly to patients, through the informed consent process. They provide the key facts about a clinical trial (including the study’s purpose, tests and other procedures, and possible risks and benefits) and answer the patient’s questions to help him/her decide whether to participate. The informed consent process continues throughout the study. For example, if new information on benefits, risks, or side effects becomes available during the study, researchers inform the participants immediately. Participants can leave a study at any time. ●

(continued from page 3) **Patient Story: Deborah RoyRoberts**

one of two Herceptin trials in early stage HER-2 positive breast cancer. In April 2005, the National Cancer Institute released findings from both studies early: Women on Herceptin in combination with chemotherapy had a 52% decrease in risk for breast cancer recurrence compared with women who received the same chemotherapy without Herceptin. Survival from breast cancer also increased.

Deborah’s participation in the study ended in November 2005, although she continues to be monitored long-term as part of the study. “I feel good and I look good. I feel very fortunate that I was able to participate in this trial,” she said.

Deborah believes that other cancer patients should strongly consider participating in a clinical trial. “Do the research and ask a lot of questions,” she said. “Then make the decision yourself, and make sure that you feel good about your decision.” ●

RESOURCES FOR PATIENTS

- **Cooper University Hospital:**
Search for clinical trials by disease, department, or keyword, and learn more about clinical trials.
cooperhealth.org/content/Research.asp (or www.cooper.org, click Healthcare Services, then Research Institute). Or call 1-800-8-COOPER.
- **National Cancer Institute:**
Search for clinical trials by type of cancer, type of trial, and more. Learn about clinical trials, cancer research results, and recent developments in cancer clinical research.
<http://www.nci.nih.gov/clinicaltrials>. Or call the NCI Cancer Information Service: 1-800-4-CANCER.
- **American Cancer Society:**
Access educational materials about clinical trials, a worksheet with questions to ask when deciding whether to participate in a clinical trial, and a clinical trials matching service.
http://www.cancer.org/docroot/ETO/ETO_6.asp. Or call the ACS’s Cancer Specialists at 1-800-ACS-2345.
- **New Jersey Cancer Trial Connect:**
Access this clinical trials matching service.
<http://www.njctc.org>. Or call (866) 788-3929.

PHASES OF CLINICAL TRIALS

Clinical trials are conducted in four phases:

- **Phase I studies** test a new drug or treatment for the first time in people to evaluate its safety, determine a safe dosage range, and identify side effects. Phase I studies include 20-80 people.
- **Phase II studies** focus on learning whether the new treatment has an anticancer effect (e.g., shrinking the tumor or improving blood test results). These studies involve 100-300 people.
- **Phase III studies** compare the results of people taking the new treatment with results of people taking the standard treatment. Participants are assigned by chance (randomized) to separate groups that compare different treatments; neither the researchers nor the participants can choose which group. Using chance to assign people to groups means that the groups will be similar and the treatments they receive can be compared objectively. At the time of the trial, no one knows which treatment is best. Phase III studies include 1,000-3,000 people.
- **Phase IV studies** collect more information on a drug or treatment after its approval in the United States, including on the best way to use it and its risks and benefits.

THE CANCER CLINICAL TRIALS CENTER

The Cancer Clinical Trials Center at The Cancer Institute of New Jersey at Cooper offers more cancer clinical trials than any other hospital in South Jersey. Each year, the center offers more than 100 phase II, III, and IV research studies (clinical trials) in virtually all types of cancer. Many of these studies are only available in South Jersey—and sometimes the Delaware Valley—at Cooper. These studies cover: cancer treatment, cancer prevention, the genetics of cancer, cancer control, and supportive care.

Cancer studies at Cooper are sponsored by the National Cancer Institute (NCI) and pharmaceutical companies. The NCI, part of the National Institutes of Health, sponsors, conducts, and oversees clinical trials and other cancer research and provides research-based information to health care professionals, patients, and the public.

Study visits and procedures are available at Voorhees, Camden, and Stratford, depending upon the study. In general, the costs of clinical trials are covered by health insurance or the trial sponsor.

The Cancer Institute of New Jersey at Cooper

The Cancer Institute of New Jersey at Cooper is an affiliate of The Cancer Institute of New Jersey, an NCI-designated Comprehensive Cancer Center. Comprehensive Cancer Centers are leaders in cancer treatment, research, and education. The Cancer Institute of New Jersey at Cooper is also the only cancer program in South Jersey designated by the American College of Surgeons as a Teaching Hospital Cancer Program.

Within The Cancer Institute of New Jersey at Cooper, teams of doctors—medical oncologists, radiation oncologists, and surgeons—work together to provide the best possible care for cancer patients. Each center also has a nurse coordinator who supports, educates, and assists patients and their families, serving as a link to their doctors and supportive services. The Cancer Institute of New Jersey at Cooper has six specialized centers: breast cancer, gastrointestinal cancer, genitourinary cancer, gynecologic cancer, leukemia/lymphoma, and lung cancer. Supportive services include complementary medicine, support groups, nutritional and psychological counseling, pain management, and social services.

For More Information

- For more information about cancer clinical trials at Cooper, visit www.coopercancer.org (Search Clinical Trials). Studies in other medical specialties are also listed.
- For more information about The Cancer Institute of New Jersey at Cooper, visit www.coopercancer.org.
- To schedule an appointment with a Cooper physician, call 1-800-8-COOPER. ●

(continued from page 1) Breakthrough Breast Cancer Studies

participation of eligible individuals in such trials can we hope to continue to make inroads into this and other cancers. We are grateful to the women in Southern New Jersey who participated in these trials. They should feel incredibly proud to know that they have dramatically changed the course for many women with this disease.” Dr. Grana is an Associate Professor of Medicine at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, and a Top Doc (*South Jersey Magazine* and *Philadelphia Magazine*).

Even though Herceptin works in only 20% to 30% of breast cancers, these results are dramatic. Herceptin targets a specific protein called HER-2/neu, and works only against breast cancers that have too much of it (HER-2 positive cancers). These cancers tend to grow faster and are more likely to return after treatment than cancers that don't have too much of the protein, thus, placing women at risk for recurrence.

The drug has been approved since 1998

to treat advanced (metastatic) breast cancers that are HER-2-positive. It has been shown to improve survival for women in this situation when given with chemotherapy.

The current findings come from a preliminary analysis of more than 3,300 women (out of more than 5,000) enrolled in the two studies. All the women had early stage, HER-2-positive breast cancer that had first been treated with surgery. After surgery some women received chemotherapy with doxorubicin and cyclophosphamide, followed by paclitaxel; others received the same chemotherapy regimen plus Herceptin. Women on Herceptin had a 52% decrease in cancer recurrence compared to women who only had chemotherapy. Most importantly, survival from breast cancer was also increased. Longer follow-up is needed to follow the potential long-term side effects from treatment.

The results of this research have had a profound effect on the treatment of early-stage breast cancer. This drug will now be incorporated into the treatment of appropriate women with early-stage breast cancer across the country. ●

CANCER RESEARCH Forum

is published by

The Cancer Institute of New Jersey
at Cooper

900 Centennial Boulevard
Voorhees, NJ 08043

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