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Translational Research Leads to New Drugs

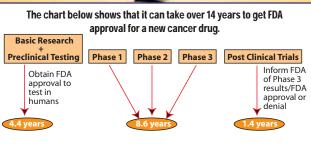
magine walking into a room filled with black countertops, test tubes shaking in their racks, incubators, unfamiliar chemical smells, culture plates, chemical bottles, and dedicated staff smartly dressed in their white lab coats hunched over their work. This is a picture of a typical research lab where the first step to finding a cure to cancer begins. Research scientists have devoted their lives to finding a cure for cancers and they often work long hours in comparison to the salary they receive. These scientists do this because they are passionate about their research.

In this issue of the NMCCA Community

Newsletter, we will focus on basic research performed in the laboratory which may lead to a new drug that can be given to a patient for the first time. This is often referred to as "bench-to-bedside" or translational research. Translational research refers to translating current research into new and effective treatments. This research includes basic science where the scientists test their theories in the laboratory. Once they prove that their theory looks promising in laboratory testing, preclinical studies on animals can start

In preclinical studies, scientists will test their theory for safety and biologic activity on animal models. If this research shows promising results, the scientists have to obtain approval





Average Number of Years for FDA approval for a New Drug = 14.4 years

Source: National Institute of Health National Cancer Institute Cancer Clinical Trials The Basic Workbook, 2002 National Institute of Health, National Cancer Institute Cancer Clinical Trials, The In-Depth Program, 2002

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PHASE I Finds the optimal dose, decides how the drug should be given,	PHASE 3 Compares new drugs with current standard treatment		
and observes how the drug affects the human body	PHASE 4 Further evaluates the long-term		
PHASE 2 Determines if the drug has a anticancer potential	safety and effectiveness of the new drug		

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from the Food and Drug Administration (FDA) to begin testing the drug through clinical trials on humans. A new drug will be tested on a human for the first time in a Phase I clinical trial. A Phase I clinical trial will test the drug to determine what dosage is safe, how the treatment should be given, and to see how it affects the human body. The trial is designed to increase the dose group by group in order to find the highest dose that does not cause unacceptable harmful side effects.

There are usually only 15-30 people who take part in a Phase I study. Cancer patients who have already tried several different

> treatment options or have no chances of a cure with current therapies are eligible for Phase I studies. Although the purpose of a Phase I study is to find the safest dose of the new drug, it is possible that the drug may have an effect on the cancer. Participants of Phase I studies may be the first to benefit, but they also may be the first to encounter the unknown side effects. Many participants in Phase I studies participate because they want to contribute to research and help others.

> Once the Phase I portion of the clinical trial is completed, Phase II and Phase III studies will commence before FDA approval of the drug can be obtained (we will discuss these trials in later newsletters).

GLANCE INSIDE A T A

Phase I and Phase II Clinical		Breast Cancer Re.
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Rolling the Dice By Ellen Reavis

Recently I had the opportunity to participate in a Phase 1 chemotherapy study. I had gotten my diagnosis of endometrial cancer with extensive metastasis just six months earlier. The good news about endometrial cancer is that most women learn they have it while it is still Stage 1 and confined to the uterus. I wasn't so lucky and the cancer had already spread to my lungs, liver, and brain.

The challenge created by the early cure most women have with their endometrial cancer is that very few researchers are looking at this cancer and most drug companies are uninterested in a cancer that has little likelihood of earning them buckets of money. I started in a Phase 3 study shortly after diagnosis. My role in the study was to receive the standard, currently accepted, chemotherapy treatment. It was successful in stopping the growth of my cancer for about five months and then my lymph nodes started to increase in size. That ended my involvement in the Phase 3 study.

Next, I was offered the chance to participate in a Phase 1 study. Phase 1 studies follow successful animal studies of a new drug or chemotherapy. Their purpose is to evaluate how a new drug should be given, how often, and what dose is safe. A Phase 1 trial usually enrolls only a small number of participants. They increase the dose with each new group of participants until they reach an effective dose. Usually participants in a Phase 1 study have 'advanced' cancer and few options.

When it comes to the possibility that I will die soon. I am not much of an altruist. I am interested in figuring out how to have both a good quality of life and a long life. My cancer cut short my career and I do not want it to cut short my life. So, I wasn't too impressed

at the prospect of trying out a Phase 1 study. I enjoy going to the casino as much as the average person but I set a clear limit on how much money I am willing to lose.





Ellen receiving care from her Phase I nurse, Valerie Parks

The Phase 1 study seemed to be a very uncertain roll of the dice. I didn't want to waste any of the now more precious than ever days of my life on something that seemed likely to be ineffective for me. However, just like when we go to the voting booth, sometimes we don't

any choices that we like. One

choice presented to me at that point in time was a standard chemotherapy with a high likelihood of noxious side effects and a low

likelihood of being effective in fighting my cancer.

The other choice was a specific Phase 1 study with an interesting scientific theory as to why it might work for my cancer. I was able to find out that previous participants (at lower doses) had not suffered side effects but had also not experienced control of their cancer. I was hopeful that the current dosage level would be high enough to be effective for me.

I rolled the dice, participated in six weeks (two cycles) of the investigational chemotherapy and came out the other end with no side effects but significant growth of the cancer in my lymph nodes and an increase in the number of lymph nodes involved. That ended my involvement with that study.

While it is possible that this treatment was not at a high enough dose for me or it was just not effective for endometrial cancer, I am still a strong proponent for ongoing research. I'm now receiving the standard chemotherapy and have been able to manage the side effects. My recent CT scan showed no significant growth or shrinkage of my measurable cancer and my blood shows an increase in my tumor markers. One plus and one minus - for me right now, that's pretty good news. I'll keep on making the best choices I can to work towards controlling this cancer and to have a good time in this beautiful world.

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Valerie Parks, RN, feels you should never be afraid to ask your physician if there is a clinical trial that fits your situation.

My name is Valerie Parks and I am an RN who has been working at the UNM Cancer & Research Treatment Center for the past 5 years as a Phase I research nurse. My journey working as a research nurse in the oncology field began like many other nurses: I had a family member affected and taken away by cancer. My uncle was offered participation in a clinical trial as his first treatment option and then again when his cancer returned. This was my first exposure to clinical trials in a personal sense.

As I read the consent and listened to the physician and nurse explain the goals of the research study, I advised my uncle to sign up. I

Research nurse, Valerie Parks, shares her experiences with Phase I Clinical Trials.

felt he should because the trial was offering him standard treatment plus the option of possibly something better (a new drug). After just 3 months on the job as a research nurse the option of working on Phase I trials became available. At the time I really did not understand the full concepts of Phase I trials, but was drawn to the challenge and the opportunity to be on the cutting edge of oncology research.

As you will learn in this newsletter the purpose of Phase I trials is to test the safety of a new drug or combination of drugs by looking at different doses, times of administration, and side effects. Over the next 6 months as I worked closely with the physicians I listened to how they introduced Phase I trials to their patients. I quickly learned that my initial assumption that Phase I studies are the last option for patient was incorrect. Although it is true that many times a Phase I trial is considered when a patient has already gone through the standard treatment for their particular cancer, there are many occasions that a Phase I trial may be the best first option for a patient.

Phase I trials can include other FDA approved drugs used in combination with the research drug. Working in research I consider my number

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one priority to be ensuring that every patient is making an informed decision about participating in a clinical trial. The informed consent process is very important for patients to take their time, discuss with family and friends, and never feel guilty about asking too many questions or taking the time they need to make their decision. Many times I am asked if it is hard or depressing to work in oncology Phase I trials because many of the patients I work with have "metastatic end stage disease." Nothing could be further from the truth because I have found working in oncology one of the most rewarding nursing fields. To me nursing is about helping people and I learned that most of the time that does not mean curing their cancer.

However if I can answer a question, hold a hand, schedule an appointment, help them through a side effect, make someone laugh, or just sit there with them for awhile to listen, then my job is rewarding. My initial steps into the oncology research field were because I wanted to be a part of solving the cancer crisis and help those trying to find the cure, but much to my surprise it turned out to be so much more than that.

Sharing Your Thoughts *Have you participated in a clinical trial?*

Would you like to share a few words about your experience?

If so, we'd love to include your thoughts in our newsletters.

Contact Debbie Putt at dputt@nmcca.org Or write to: NMCCA, 801 University Blvd. SE, Suite 102, Albuquerque, NM 87106.

Don't Miss Out!

Sign up to Receive the *NMCCA Community Newsletter* Today!

> Email Debbie Putt at dputt@nmcca.org if you'd like to request additional copies.

Visit our website www.nmcca.org

Summer 2008

Phase I and Phase I/II trials become available in New Mexico

PHASE I

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INST 0712C: A Phase 1 Protocol of Hydralazine and Valproic Acid in Advanced Solid Tumor Malignancies

INST 0710C: A Phase I Protocol of 5-Azacytidine and Erlotinib in Advanced Solid Tumor Malignancies (lung cancers only)

EGF110557: An Open-Label, Two-Part, Single Sequence Study to Examine the Effects of Lapatinib on the Pharmacokinetics of Orally Administered Digoxin in Subjects with Metastatic ErbB2+ Positive Breast Cancer

11Y-MC-JFBA: A Phase I study of LY2523355 in patients with advanced cancer

SP0-0011A: Phase I Open Label, Multicenter, Dose Escalating, Clinical Study of Safety, Tolerability and Pharmacokinetic and Pharmacodynamic Profiles of SNS-314, a Novel Aurora Kinase Inhibitor, Administered to Patients with Advanced Solid Tumors

TPU S1111: A Phase I, Open-Label Study

Evaluating the Pharmacokinetics of Components of S-1 in Patients with Varying Degrees of Renal Function S1111

INST 0100C: Phase I Dose Finding Clinical Trial of Combination Paclitaxel, Carboplatin and Temozolomide for Subjects with Solid Tumor Malignancies.

INST 0529C: Phase I study of concurrent radiotherapy with weekly Topotecan for primary treatment of inoperable localized non-small cell lung cancer (NSCLC) (Stage I to IIIA).

PHARM 0530P: An open label, phase I study to evaluate the safety, tolerability, and pharmacokinetics of patupilone in patients with advanced solid tumors and varying degrees of hepatic function (CEPO906A2121)

Pharm CEPO906A2105: A phase Ib, multicenter, open-label, dose-finding study of patupilone administered intravenously every 3 weeks in combination with carboplatin AUC 6 in adult patients with advanced solid tumors

All Phase I studies are available at University of New Mexico Cancer Center

PHASE I/II

INST 0509C: Phase I/II Study of the Combination of Docetaxel, Gemcitabine, and Bevacizumab, in Patients with Advanced or Recurrent Soft Tissue Sarcoma (Available at University of NM Cancer Center, Hematology Oncology Associates, NM Cancer Care Associates, and St. Vincent Regional Medical Center)

NCI/Johns Hopkins J0658: A Phase I/ II Study of MS-275 in Combination with 5-Azacytidine in Patients with Recurrent Advanced Non-Small Cell Lung Cancer. This study is available at the UNM Cancer Center.

PHARM VIOQUEST 7059: A Phase I/IIa, Open-Label, Dose Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Sodium Stibogluconate in Combination with Interferon Alpha-2b for Patients with Advanced Malignancies. This study is available at the UNM Cancer Center.

STUDIES TO OPEN SOON:

GSK NKV103444: An Open Label, Repeat Dose , Randomized, Two Period, Crossover Study to Investigate the Potential Pharmacokinetic Interactions between Oral GW679769 and Intravenous Cyclophosphamide in Cancer Patients **SWOG S0727:** A Phase I and Randomized Phase II Trial of Gemcitabine + Erlotinib (NSC-718781) + IMC-A12 (NSC-742460) vs. Gemcitabine + Erlotinib as First-Line Treatment in Patients with Metastatic Pancreatic Cancer

GOG 9918: A Phase I Trial of Tailored Radiation Therapy with Concomitant Cetuximab (C225, NSC #714692) and Cisplatin(NSC #119875) in the Treatment of Patients with Cervical Cancer

President Signs Genetic Information Nondiscrimination Act (GINA) On May 21, 2008 the President signed into law the Genetic Information Nondiscrimination Act (GINA) that will protect Americans against discrimination based on their genetic information when it comes to health insurance and employment. GINA will pave the way to promote personalized medicine and the use of genetic information in healthcare without fear of discrimination.

Summer 2008

Tribal

2nd Annual New Mexico Native Women's Pink shawl Project



May 17, 2008 Anderson-Abruzzo Albuquerque International Balloon Museum

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The New Mexico Cancer Care Alliance combined efforts with People Living Through Cancer, New Mexico Department of Health Cervical and Breast Program, United Native Council, and the University of New Mexico Cancer Center to sponsor the Second Annual New Mexico Native Women's Pink Shawl Project. The Pink Shawl Project included educational programs, health fair, luncheon and Powwow.

On May 17, attendees at the Public Education Seminar listened to Nellie Sanoval, BS, MS, on "Breast Cancer: Honor Yourself," and Monique Giago on "Winyan Ta Oinajin Topa" - (Four Stages of a Woman's Life): A Traditional Lakota Healing Model. The Professional Medical Seminar speakers were Gayle Dine'Chacon, MD, speaking about "Patient Interactions in Cancer Diagnosis, Treatment, Prevention and Screening," Emily Haozous, RN, speaking on "Cancer Pain in Southwest American Indians," and Josephine Waconda, RN, on "The Nuance of Native American Traditional Behavior to Western Medicine."

There were over 20 educational booths providing attendees with a wide-range of breast health information and resources.

The luncheon brought Native Americans and non-Natives together to learn about the history and significance of the Pink Shawl. A "Traditional Blessing of Shawls" honored the Breast Cancer Survivors, empowering them with the strength to continue their battle and to educate their communities on the significance of prevention.

The Pink Shawl Gourd Dance and Powwow included 10 drum groups for the Intertribal dances.

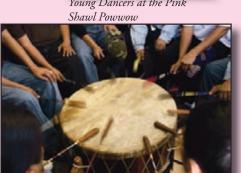
2008 Annual New Mexico Pink Shawl Project fulfilled its mission by bringing breast health information to Native Americans in a safe and culturally-relevant manner.



Young Dancers at the Pink



Carla Sakiestewa (left) and Linette Edaakie (right) enjoying the Powwow



Zuni Boyz Drum Group

Special Thanks to the Following Sponsors and Participants

- University of New Mexico **Cancer Center**
- **City of Albuquerque and Mayor Martin Chavez**
- Lance Armstrong Foundation
- McCune Charitable Foundation
- **Central New Mexico Affiliate of** Susan G. Komen for the Cure
- Petroglyph Pathology Services
- All Things Said/Relay New Mexico
- American Cancer Society, **Albuquerque and Phoenix**
- Cochiti Pueblo
- Construction Reporter
- **First Nations Community Healthsource**
- Genentech
- Guiding Eagles Health Coalition

- Isleta Casino and Resort
- Lovelace Women's Hospital
- Tom Mims
- MGI
- New Mexico Cancer Care Alliance
- New Mexico Dpt. of Health, Breast & Cervical Cancer Program
- Onyx Pharmaceuticals
- People Living Through Cancer
- Pfizer
- Presbyterian Healthcare Services
- Radiation Oncology Associates
- Sanofi Aventis
- United Native Council
- University of New Mexico Center for Native American Health
- William Johnson of Isleta Pueblo

Summer 2008





Breast Cancer Resource Center Connecting You

Providing a Life-Affirming Connection to the Women of New Mexico

Jahaan Martin, pictured left, and Nelly Taveras offer non-medical support, advocacy and assistance to women with breast cancer and their families.

Imagine a place where women can find comprehensive, non-medical help for breast cancer, including up-to-date information about risk reduction, emotional support, and personalized help in navigating the complexities of breast cancer resources and services. Fortunately, women in New Mexico no longer need to imagine this resource. It exists and is available to anyone seeking help with breast cancer.

The Breast Cancer Resource Center, an initiative of St. Joseph Community Health is designed to provide one-stop access to comprehensive help based on the individual needs and circumstances of each client, says Jahaan Martin, director of the Resource Center. "Every woman brings her own set of unique circumstances. We try to meet a woman's needs and connect her with services based on what's appropriate for her. Working in partnership with community organizations like the NMCCA enables the Resource Center staff to make these connections."

According to Martin, who is a breast cancer survivor, medical resources for breast cancer patients in New Mexico are excellent. "We are so fortunate; New Mexico is home to world class cancer treatment centers, renowned physicians and researchers." Unfortunately, it is often non-medical resources, such as child care and transportation that create barriers for cancer patients. "Perhaps a woman needs a ride to a medical appointment or financial assistance to offset the rising cost of gas. Maybe she and her family would like to learn more about clinical trials or would like to talk with others facing a similar situation."

Inspired by cancer survivors, non-profit organizations, and medical professionals, the Breast Cancer Resource Center offers a wide range of non-medical services, including:

- **Information.** An information clearinghouse that includes an extensive database of community resources, providers, treatment locations, counseling services, and more. Information on risk reduction and screening is also available.
- Advocacy. Assistance and support from specially-trained, culturally aware facilitators and staff who assess each individual's needs and connect women to services. Follow-up and monitoring services help identify existing gaps.
- **Comfort.** A home-like setting to provide a soothing and comfortable environment for women and their families.
- **Convenience.** Easily accessible via public transportation, the Breast Cancer Resource Center operates on a drop-in or scheduled appointment basis.
- **Community.** Life-affirming events and activities for cancer patients and their families.

The Breast Cancer Resource Center will be moving into its new location at 316 Central SE (just west of Standard Diner) and will be celebrating the grand opening of this new facility later this year. For more information about the Breast Cancer Resource Center, call **505-924-8100** or visit www.st.josephnm.org.

FAST FACTS

- Breast cancer is the most frequently diagnosed cancer among women in New Mexico.
- Access to screening, treatment and other resources is even more difficult for underserved women.
- Breast cancer is the leading cause of cancer death in New Mexico for Hispanic, Native American and African American women, even though their incidence rate is lower than their Non-Hispanic White counterparts.
- Medical professionals, cancer survivors and community organizations in New Mexico have identified significant gaps in how women are connected to resources, despite research that indicates women live longer with better education support.

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of New Mexico Fall Family **Cancer Retreat**

September 12-14, 2008 Glorieta, NM

This free, three-day educational program will provide NM's adult cancer patients/ survivors and their love ones with tools and information to manage the treatment and recovery process.

> For more information, please call Mike Capeless at (505) 239-4239 or visit www.cancerservicesnm.ora. Reservations are required.



Lights of Life Celebration October 25, 2008

People Living through Cancer invites friends and family to honor their loved ones by tying pink ribbons on the "Tree of Life and Hope" that will be planted permanently in the city and purchasing luminaries.

Contact People Living through Cancer at 505-242-3263 for more information.



The Leukemia & Lymphoma Society Fighting Blood Cancers

Light the Night September 20, 2008 at the Albuquerque Civic Plaza

Light The Night Walk is The Leukemia & Lymphoma Society's nationwide evening Walk to build awareness of blood cancers and raise funds for cures. Walkers carry

Women's Hospital

illuminated balloons-white for survivors and red for supporters-to celebrate and commemorate lives touched by cancer.

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For additional information contact Janine Collins at (505) 872-0141 ext. 228 or Janine.collins@lls.org

Lovelace hope. health. healing. Save the Date

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Please join us Saturday, October 18th from 8:30am - 2pm for our 11th Annual Breast Care Symposium. Call 727.6933 for more information.

YOGA for Survivors Breast Health Education Classes Keynote Speaker Digital Mammography Seminar

Survivorship Panel Mock Tumor Board Free Food Vendors and much more!

E V E N T S

The 2008 Cowboys for **Cancer Research Dinner.** Dance and Roping

October 10, 11, & 12th Las Cruces, NM, Calhoun Arena. For additional information, please visit www.cowboysforcancerresearch.org or call 575-526-6028.

The 2008 "NMSU Aggies Are Tough Enough to Wear Pink"

October 18th, 2008 Against San Jose State! More information on this event is available at www.PinkAggie.com.



Brought to you by: The University of New Mexico Cancer Center,

Las Cruces and New Mexico State University

Hike for Discovery 8 Great Hikes in New Mexico

Whether you're a seasoned hiker or someone who just enjoys a good walk, there is a hike program for your ability and level of fitness.

For a 14-18 week period, your hike leader will provide training and clinics to prepare you for your grand "finale" hike weekend at a spectacular destination. Transportation, lodging, social events with your group and a one-year membership in the American Hiking Society are all part of the package!

As you train, you'll raise funds for vital research so blood cancer patients live longer, better lives.

Hike for Discovery Information Meeting August 6, 2008 at REI • 5:30 p.m.

Contact Kirsten Theisen 505-872-0140x235 or 888-286-7846 kirsten.theisen@lls.org

Spring 2008

Patient Education

Presbyterian Health Care Services Programs

July 31, 1:00-2:30 p.m. "Take Control - Cancer Basics, Side Effects of Treatment & Benefits of Exercise"

Ann Brooks, RC, OCN Presented by Presbyterian Cancer Rehabilitation Program September 18, 1:00-2:30 p.m. "Hospice Care and COPD" Chronic Obstructive Pulmonary Disease Presented by Presbyterian Cancer Rehabilitation Program Lydia Lawson, MD, Presbyterian Hospice

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September 4, 1:00-2:30 p.m. "Virtual Colonography" and "New Trends on Breast Imaging" Dr. Eugenio Rivera, Dr. Gary Wood, and RAA Imaging

All Presbyterian programs are Located at the Presbyterian Healthplex 6301 Forest Hills Drive NE • Registration is required, please call 823-8352

New Mexico Cancer Care Alliance and Genentech Inc. present:

RECRUITMENT STRATIGES

August 12, 2008 • 7:30 a.m.

Rotunda Conference Room 801 University Blvd. SE Albuquerque, NM Continental Breakfast

> For more information contact Debbie Putt at 505-272-7819 or dputt@nmcca.org

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801 University Blvd., SE Suite 102 Albuquerque, NM 87106