



Wake Forest University Baptist
MEDICAL CENTER[®]
 Comprehensive Cancer Center

Mile Stones

CCCWFU CCOP Research Base

Medical Center Boulevard
 Winston Salem, NC 27157
 336.716.0891

www.wfubmc.edu/cancer/researchbase

Inside Mile Stones:

- Research Base Receives Competing Renewal Funding
- Soy EffexorXR™ Study Opens
- New Updates to Protocols
- Spotlight on Louise Brady, Delaware CCOP

Out and About with June *continued from page 1*

- Michigan Cancer Research Consortium CCOP; Ann Arbor, MI:
Phillip J. Stella, MD (PI), Beth LaVasseur, RN, MS (Administrator)
- Northern Indiana Cancer Research Consortium; South Bend, IN:
Rafat Ansari, MD (PI) Mary Jean Wasielewski, RN, OCN, CCRP (Administrator)
- Our Lady Of Mercy Comprehensive Cancer Center MB-CCOP; Bronx, NY:
Peter H. Wiernik (PI) Natalie Fuentes (Administrator)
- Ozarks Regional CCOP; Springfield, MO:
J. Wendall Goodwin, MD (PI) Marilyn Bauer, BSN, Med, MHA (Administrator)
- Washington Metropolitan MB-CCOP; Washington, DC:
Lucile Adams-Campbell, PhD (PI) Joan Pearson (Administrator)

As always, I'm happy to schedule a site visit to meet with you and your staff to provide any protocol specific training, to answer any questions that you may have regarding our protocols or to just assist you with becoming more familiar with our protocols/regulatory rules. Just give me a call when you are ready to schedule a visit and I will get it on my calendar. (336) 716-6733 See you soon!

June Fletcher-Sheeh

Online Survey



**What topics
 would you like to
 discuss at the
 next annual
 meeting?**

**Tell us what you think at
www.wfubmc.edu/cancer/researchbase**

**7th Annual Meeting
 September 27- 29
 Asheville, NC**



Information online at
www.wfubmc.edu/cancer/researchbase

Mile Stones

CCCWFU CCOP RESEARCH BASE

A Semi-annual Newsletter
 March 2007 Volume 4 Issue 1

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Soy/ Venlafaxine (EffexorXR™) Study Opens

Hot flashes occur in approximately two thirds of men who undergo androgen deprivation for treatment of prostate cancer. These hot flashes have been shown to greatly affect their quality of life. Researchers have previously reported reductions in the severity of the hot flashes in men by at least half when given venlafaxine and have attributed the beneficial action to the ability of this medication to inhibit serotonin reuptake. Soy is a strategy that has been used for the treatment of hot flashes in women, but to date, no studies have been conducted to evaluate if soy can reduce hot flashes in men. Isoflavones in soy protein bind to estrogen receptors. Data from clinical trials in breast cancer patients have been mixed, though some results have shown that soy protein consumption does reduce hot flashes. Although the individual effects of venlafaxine and soy protein may not be as powerful as the effects reported for estrogen replacement therapy, perhaps taking both therapies concomitantly will provide additional symptom relief. The objective of this study is to assess the effect of soy, venlafaxine (EffexorXR™), and the combination of the two on hot flash symptom severity score in 176 androgen-deprived men with prostate cancer. This is a double-blind, placebo controlled study and the time on study includes a 7 day pre-screening symptom recording and 12 weeks on "treatment". During the study period, participants will take one pill (venlafaxine or placebo) and consume one packet of powder (soy or casein protein) each day.

Visit the CCCWFU CCOP Research Base website to learn more about this study. www.wfubmc.edu/cancer/researchbase. If you have questions regarding this study, please contact the study PI, Mara Vitolins at (336) 716-2886 or mvitols@wfubmc.edu.

Mara Vitolins, RD, PhD

CCCWFU CCOP Research Base Grant Renewed!

The CCCWFU CCOP Research Base is proud to announce that our competing renewal was recommended for another 5 years of funding. We recently received our summary statement from the National Cancer Institute with many positive comments. We look forward to providing high quality cancer control studies to our participating CCOPs through 2012 (and hopefully beyond!).

Out and About with June

In 2006, the Research Base experienced a bit of a growth spurt. We have had several groups join the CCCWFU CCOP Research Base. I would like to take this opportunity to officially welcome the newest members to our group:



- Beaumont CCOP; Royal Oak, MI:
David Decker, MD (PI)
Jeanne Archer, PhD (Administrator)
- Metro Minnesota CCOP; St. Louis Park, MN:
Patrick Flynn, MD (PI)
Marilee Rose, MS, BSN (Administrator)

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The Learning Curve

98301 Phase II Study of St. John's Wort for the Treatment of Hot Flushes in Women with a History of Breast Cancer

New changes are in store for patient's that are not on Tamoxifen and do not need to have Tamoxifen levels drawn at the 2 and 4 week visits.

Sites may provide patients with POM's and SF-12 forms at the baseline visit (end of run-in) for the patient to mail them with completed calendars back to site at 2 and 4 weeks instead of coming into the clinic. The site will be required to do a phone interview with the patient to assess compliance, toxicities and any medication changes at the 2 and 4 week intervals.

The protocol will not change for patients taking Tamoxifen. These patients are still required to come into the clinic at the 2 and 4 week interval to have Tamoxifen levels drawn, complete the POM and SF-12 forms, return completed calendars, and have assessment for compliance, toxicities and medication changes recorded.

All patients will continue to be seen at screening, baseline, and the 6 week visits.

60A02 A Phase II Randomized Placebo Controlled, Double Blinded Trial to Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients

There have been a lot of debates over whether the Juice Plus capsules should be opened if patients are unable to swallow them. The final answer is:

It is recommended that the patient swallow the capsules. If the patient is unable to swallow, the capsules may be opened and contents (a fine powder) sprinkled over food (e.g., apple sauce or pudding). The patient needs to consume *all* of the food containing the contents of the capsules. Juice Plus capsules should not be opened and put down PEG tubes. The powder adhere to the tube, reducing the likelihood that the patient will the full contents, and the tube may become clogged.

Eligibility / Registration forms:

Sites have the ability to browse through their registered patients in CCRBIS (Cancer Center Research Base Information System). A link to CCRBIS can be found on the Research Base home page. After eligibility/registration forms have been submitted and the confirmation sheet has been printed, a site can view the patient's on-line registration and print a copy for the chart.

Robin Rosdhal RN, OCN



Data Management: Data Quality Checklist Reminders

- Complete headers on every form.
- The PID (Patient ID#) must be on every sheet of paper that you send to us.
- We must have CTC grades on all toxicities (MedWatch & Flowsheet).
- Complete all medication diaries with month, visit, start & stop dates, and patient's signature.
- Please check our website for the most up-to-date forms.
- Please call us anytime with your questions.

Open Protocols

Cancer Control and Prevention

97102 A Phase III Randomized Study Comparing the Effects of Oxandrolone (Oxandrin®) and Megestrol Acetate (Megace®) On Lean Body Mass, Weight, Body Fat, and Quality Of Life in Patients with Solid Tumors and Weight Loss Receiving Chemotherapy

Glenn Lesser, MD, PI

97202 A Phase III Randomized Double-Blind Placebo-Controlled Study of Oral Coenzyme Q10 to Relieve Self-Reported Cancer Treatment Related Fatigue in Breast Cancer Patients

Glenn Lesser, MD, PI

60A02 A Phase II Randomized Placebo Controlled, Double Blinded Trial to Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients

Steve Akman, MD, PI

98301 Phase II Study of St. John's Wort for the Treatment of Hot Flushes in Women with a History of Breast Cancer

Michelle Naughton, PhD, PI

97405 Phase III Study of Soy, Venlafaxine (EffexorXR™), and Soy + Venlafaxine on Hot Flush Symptoms in Men with Prostate Cancer

Mara Vitolins, RD, PhD, PI

Soon-to-Open Studies

Cancer Control and Prevention

91105 Phase III Study of Donepezil vs. Placebo in Irradiated Brain Tumor Patients

Steven Rapp, PhD, PI

97106 Phase III Double Blind Placebo Controlled Study to Determine Whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors

Kathryn Greven, MD and Brigitte Miller, MD, coPIs

Seventh Annual Meeting

The CCCWFU CCOP Research Base is pleased to announce it will host its Seventh Annual Meeting September 27 -29, 2007 in Asheville, NC.

The meeting will include a Thursday September 27 afternoon training workshop on Cognitive Function for certification for the Donepezil Trial expected to open this spring. Friday morning opens with a session of Principal Investigator overviews of all open Research Base clinical trials and clinical trials in development. During lunch, enjoy a presentation by the world renown scientist Dr. Ski Chilton from the Wake Forest University School of Medicine (and author of the New York Times bestseller "Inflammation Nation"). He will be speaking on "The Effect of the Modern Western Diet on the Prevention and Treatment of Chronic Human Diseases Including Cancer".

Saturday morning, after a breakfast buffet business meeting, Dr. Kevin High will be speaking on "Preventing Infection In Cancer Patients", followed immediately by the opening of the round table session. At the conclusion of Saturday's events will be a short closing presentation of awards and announcement of the next meeting location.



All sessions are designed with research nurses, clinical research professionals and physicians (medical, radiation, and surgical oncologists) in mind. The three objectives are to provide protocol specific training, to review protocol specific issues for open Research Base cancer control studies and discuss new approaches to control and/or prevention in various cancers.

The meeting will be held at The Renaissance Hotel, located in the heart of downtown Asheville. It offers spectacular mountain views, and overlooks hundreds of shops, galleries and

restaurants. It is adjacent to the Thomas Wolfe Memorial and is located only three miles from Biltmore Estate & Winery. It is convenient to interstates, the Asheville Regional Airport and the Blue Ridge Parkway.

A block of rooms has been reserved until August 22, 2007. The rate for a single or double room is \$184 per night, including unlimited internet access, and local phone service. Space is limited and is on a first come basis. For reservations call 1-800-468-3571 and request the CCCWFU CCOP Research Base group rate.

For further information about the meeting and the Asheville area, see the Annual Meeting Page on the Research Base website. www.wfubmc.edu/cancer/researchbase/annual+meeting



Spotlight on: Louise Brady

I have been a nurse in Cancer Research for Christiana Care Health Services/Delaware CCOP for seven years. I was a Hospital Staff Nurse in Oncology for 14 years prior to joining the research program.

My present responsibilities include, screening potential study participants, reviewing the protocols with these participants, answering any questions or concerns that they might have as well as obtaining informed consent. I coordinate the scheduling of tests and procedures that must be completed prior to and while on the study. My responsibilities also include obtaining and processing specimens required by the study. I assist in interpreting the details of the study as well as correct dose modifications when required by the protocol to assure accurate study adherence. I complete and submit data regarding drug toxicity and treatment response while the patient is on active treatment. Basically, my responsibilities include whatever it takes to get the job done right!

It is easiest for me to write about my hobbies and interests because I enjoy many things. Dealing with people that have the diagnosis of cancer makes me feel that every moment of my life is a gift and I do not take my time here lightly. We really do not know what tomorrow will bring so make today count! I enjoy a variety of activities including morning aerobic exercise which on a work day gets me up a little after 4:00AM, long distance cycling, walking (after work), reading (always have a book going), gardening, and anything outdoors. I spend time with my 2 dogs Lucky and LT (that's when the walking comes in), and my husband and I have owned a pet sitting business for 10 years.

The key to successful recruitment and retention to clinical trials at Christiana Care are many. Our program has changed as the needs of the physicians have changed. Research Nurses are based in the private physician practices that accrue the majority of patients to clinical trials. There is a monthly research newsletter and Protocol Meeting to review protocol changes, updates and review new studies. This meeting is used to answer questions and solve problems that Doctors and Nurses have encountered with particular studies. A dynamic PI, Director of Cancer Research and Cancer Center Director have helped us tremendously with issues that impede successful and increased clinical trial accrual. The research nurses have a hard working support staff to help with time consuming work that would take us away from our research nurse responsibilities. Our program in Delaware has grown by leaps and bounds over the past several years and I believe we have made a difference.



Louise Brady, RN, BSN, OCN
Christiana Care Health Services
Delaware CCOP

Louise Brady, RN, BSN, OCN

