

# Mile Stones

CCCWFU CCOP RESEARCH BASE

A Semi-annual Newsletter  
Volume 8 Issue 1 - 2011

## Smoking Cessation Study Opening Soon

by Kate Weaver, PhD, MPH

### A quitline based smoking cessation intervention for non-metastatic lung cancer patients in the outpatient oncology set-

This new study, with an estimated opening date of August 2011, will test the efficacy of a smoking cessation intervention that combines telephone counseling, nicotine replacement therapy, and a brief counseling session with an oncology nurse in comparison with usual care. This study is part of the Wake Forest CCOP Research Base's efforts to develop smoking cessation studies for oncology patients. A substantial number (10-40%) of oncology patients continue to smoke after their cancer diagnosis. Continued smoking is associated with increased likelihood of treatment complications, poorer quality of life, cancer recurrence, second primary cancers, and mortality. The study was designed to test a smoking cessation intervention that could be implemented in oncology practices throughout the country with minimal additional training or staff.

146 participants will be enrolled: 97 in the intervention group and 49 in usual care. Participants will complete 4 assessments: baseline, 6, 12, & 24 weeks and provide a saliva sample for cotinine to biochemically confirm their smoking status.

#### Basic Eligibility Criteria:

- AJCC stage I-III A/B non-small cell lung cancer or limited stage small cell lung cancer
- Smoked any amount in the past 7 days

**WE NEED YOU.** We will be training research nurses at each site to deliver the brief in-person counseling session, which will focus on enhancing patient motivation and providing education about the benefits of quitting after a cancer diagnosis using motivational interviewing techniques. We will provide two opportunities to get trained: one in late summer for "early adopter" sites and a second training session at the research base annual meeting. We hope providing this counseling training will give you the opportunity to really make a difference in the lives of the patients you work with.

Please contact Kate Weaver, PhD, MPH at [keweaver@wakehealth.edu](mailto:keweaver@wakehealth.edu) to learn more about this protocol.



## Mark your calendars! 11th Annual Meeting

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The CCCWFU CCOP Research Base  
 11<sup>th</sup> Annual Meeting  
 Greenville, SC  
 Hyatt Regency Hotel

**October 20-22, 2011**



The agenda for this year's Annual Meeting is packed with educational opportunities. Dr. Sebastian Kaplan of Wake Forest Baptist Health will be leading a motivational training session related to smoking cessation. Dr. Wortia McCaskill-Stevens, Acting Chief, Community Oncology and Prevention Trials Research Group with NCI and Dr. Bettina Beech of Wake Forest Baptist Health will be leading a session focusing on minority recruitment and retention to clinical trials. Dr. Ed Shaw will speak on preventing oncology healthcare provider burnout. In addition, closed study results will be discussed, and protocols both open and in development will be reviewed. This meeting promises to be one of the most informative yet. Registration for the meeting will open in early summer; keep an eye on your inbox for notifications. If you have any questions, suggestions or need additional information regarding the meeting, contact Lisa Autry at 336-716-0891 or [laury@wakehealth.edu](mailto:laury@wakehealth.edu).

### New Look , New Address

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You may have noticed that our website looks a bit different in format, logo, and name. Wake Forest Baptist Health (formerly Wake Forest University Baptist Medical Center) has undergone a branding change. These changes have altered the way the CCCWFU CCOP Research Base website appears, but the functionality and content remain the same.

- New web address: [www.wakehealth.edu/cancer/researchbase](http://www.wakehealth.edu/cancer/researchbase) (Our former url will continue to redirect you to this address.)
- New email addresses: All Wake Forest Baptist Health staff email addresses will change to [example@wakehealth.edu](mailto:example@wakehealth.edu). (Our former email addresses will continue to operate.)

No action is required on sites' part since our website and email addresses will continue to function as they have in the past. Please be aware that you will be receiving emails and links with a new look and name. If you have any questions about these changes, please contact Sarah Hahne at [shahne@wakehealth.edu](mailto:shahne@wakehealth.edu)

## The Learning Curve

by Robin Rosdhal RN, OCN



Want to learn new information associated with our most recently opened protocols?

### Protocol 98110 (Arginmax for Erectile Dysfunction)

- The new registration form has a place to

check if the radiation treatment was external beam or seed implants, both of which are allowed.

- Patients that received cryotherapy in addition to radiation are eligible.
- History of prior cancer is allowed if currently disease free.
- Prior vasectomy is allowed.
- Patients that are currently using or have used nitroglycerin within the last 6 months are excluded. If nitroglycerin is listed as a medication, ask the patient when they last took it. Many patients may have a prescription for nitroglycerin but have not taken it for 2-3 years.
- Patients taking  $\leq 325$ mg aspirin daily are eligible.
- Plavix, Disalcid, Persantine, Heparin, Lovenox, Warfarin, ginkgo biloba and other blood-thinning medications have been added to exclusion medications.
- Standard of care for patients that have received LHRH agonists or anti-androgen or estrogenic agents for suppression in the past have routinely required a normal testosterone level before going on study. They will be required on 98110 as well. The testosterone level and date performed will be required at registration. There is no outer time frame for how long it has been since level was drawn.

- Patients that have not received LHRH agonists or anti-androgen or estrogenic agents for suppression in the past do not require a testosterone level. However, if available (optional), please enter the testosterone level and date drawn.

- A sexual attempt at least once a week with a partner is required per protocol.

- Provide patients with several of the SEP forms. These are to be completed after every sexual attempt. The patient should enter the date of the sexual encounter on the form. When SEP form is returned have the patient sign/initial and date the bottom of the form. Keep this for use as source documentation.

- Herbal products for erectile dysfunction are not permitted while on study.

- The PI clarified Saw Palmetto is allowed since it is used for BPH and flow, not ED.

### Protocol 97509 (Armodafinil for Brain Radiation-Induced Fatigue)

- Sites WITHIN North Carolina need to provide the patient's name, address and date of birth on the Armodafinil/Placebo prescription to comply with regulations. The Dr.'s DEA # should be included.

- Biologics will call staff 2 weeks after study medication has been started inquiring if 2nd bottle of study medication should be shipped.

- These patients receive a varying number of radiation fractions; you may need to call Biologics to request 3rd bottle of study medication while patient is receiving radiation. Study medication should be provided to patient to ensure they have an adequate supply until 4 week return appointment.

- Sites OUTSIDE North Carolina do not need to fax a prescription. No patient specific information

(Continued on page 4)

## Learning Curve *continued*

(name, DOB, address) is needed to process an order. The site does need to fax their IRB approval letter for participating on the study, DEA license for their site with the exact address where study medication should be shipped, and the CV and current medical license for the investigator at their site.

- Cephalon needs this information faxed only once on each doctor that writes a prescription at a site. It is recommended this information be faxed to Coleen Myers at 610-883-5566 before a patient is registered to help expedite processing.
- Sites will need the kit number from the registration confirmation to verify what patient a shipment of study medication is being received for.

Cephalon will now include the patient's protocol identification # on bottles of study medication and packaging slip to assist with proper patient identification.

All patients:

- Patients will need to be given study medication when completing radiation. They will not be scheduled to return until 4 weeks after radiation is completed.
- If a patient is completing the neurocognitive testing at a fast pace, stop and let the patient fill in the QOL's. This will allow for the proper amount of time (20 minutes) to pass before completing the HVLTL (Part B & C).

## Open Protocols

**91105** Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients  
**Stephen Rapp, PhD, PI**

**97309** Yoga or Wellness Education during Breast Cancer Treatment: Establishing Community-Based Partnerships  
**Suzanne Danhauer, PhD, PI**

**97509** A Feasibility Study of Armodafinil for Brain Radiation-Induced Fatigue  
**Ed Shaw, MD, PI**

**98110** A Randomized Phase II Dose Finding Study of ArginMax with or without Phosphodiesterase-5 Inhibitors for Its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy  
**Jim Urbanic, MD, PI**

## Electronic Data Submission

In the coming months, the CCCWFU CCOP Research Base will be investigating implementation of a new electronic data submission system. This new method of collecting data from patients will begin in a protocol slated to open this summer. More information will be sent to sites in the weekly broadcast email when details are available.

