



Dr. Anthony Murgu

*Head, Early Clinical Trials
Development, Division of
Cancer Treatment and
Diagnosis, NCI*

(photo from NCI webpage)

FIRST ANNUAL CLINICAL TRIALS NETWORK RETREAT

Saturday, September 8, 2007

9:30am - 2:30pm

(with reception immediately following)

**Hollings Cancer Center,
Conference Room 120**

Keynote Speaker:

Anthony Murgu, MD, MS, FACP,
Head, Early Clinical Trials Development,
Division of Cancer Treatment and Diagnosis,
National Cancer Institute

The Clinical Trials Network Retreat is free to all investigators, health professionals, and research personnel. [Please register today!](#)

[Click here to view more details about the September 8th Event.](#)

[Register Now!](#)

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LABOR DAY CLOSURE

The HCC-CTO will be closed on **Monday, September 3** in observance of Labor Day. If you anticipate any drug orders or other protocol assistance during this time, please contact the Network Office to make prior arrangements.

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2nd ANNUAL LCACRP SYMPOSIUM: "CONTEMPORARY ISSUES IN CLINICAL RESEARCH"

The Low Country Chapter of the Association of Clinical Research Professionals (LCACRP) is sponsoring their 2nd Annual "Contemporary

Features:

Network Office News

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IIT Highlight, Regulatory Updates, Cooperative Group Info, and more

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Upcoming Events and a Listing of Resources Available for our Patients

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If you would like to share a news item or subscribe to the Newsletter, please email Arlene Felipe at felipe@musc.edu

Issues in Clinical Research" symposium in Charleston, SC.

This year's program is designed to examine issues relevant to clinical research including medical and device trials, recruitment and retention issues and research ethics.

Guest Speakers:

Glenda Guest, CCRA, RQAP-GCP

Judy Stone, MD

Mark Macedo, BS, RN

Christine Pierre, RN

Event Date & Time: Saturday, September 29, 8am - 4:30pm

Location: MUSC Gazes Thurmond Building, Solomon Conference Room, Rm. 125, 114 Doughty Street, Charleston, SC

Continuing Education Credits: 6.0 Contact hours are available to qualified participants (\$25.00 fee for Non-LCACRP members).

Contact: Christine Davis, Program Administrator, 843-792-2001 or davisct@musc.edu for more information.

LCACRP was founded in 2004 to increase communication, networking and developmental opportunities for clinical research professionals in the southeastern US. In an effort to accomplish this mission, LCACRP co-sponsors an array of educational programs with academic, non-profit, and various industry groups involved in clinical research.

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SWOG FALL 2007 GROUP MEETING

The Southwest Oncology Group invites you to attend the Fall 2007 Group Meeting.

Event Dates: Wednesday, October 3 - Sunday, October 7

Location: Hyatt Regency Huntington Beach Resort & Spa, Huntington Beach, CA

Registration Information: Registration is now open! [Click here to register for the Group Meeting](#). There you will be able to make your hotel reservations, review the schedule, plan your travel, and view details of the Group Meeting.

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HCC CLINICAL RESEARCH ASSOCIATE SERIES: LCACRP SEMINAR: ORGANIZING THE RESEARCH SITE

Guest Speaker: Sarah Hibbard

Event Date & Time: Thursday, November 15, 6:00 p.m.

Primary Location: MUSC Basic Science Building, Room 202, Charleston,

SC

Videoconference Location: Palmetto Health, Two Medical Park Conference Center, Columbia, SC.

*Please see below for more information

Continuing Education Credit: 2 hours. As a CTN Member, you can participate and obtain credit hours for this event at no charge.

More details are TBA.

**To find more info for the Videoconference Location in Columbia, please contact Rosemary Faile at 803.255.3462 or 2MP_CONFERENCE_ROOM@gw.mp.sc.edu.*

If you are interested in being an additional videoconferenece site, please call the Network Office (843.792.1753) with your request by Monday, September 17th.

For more information regarding this event in general or at MUSC, please contact Erica Ellington at 843.792.0299 or ellingte@musc.edu.

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Clinical Trial Updates: September 2007



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INVESTIGATOR-INITIATED STUDIES

Contact Information and Regulatory Updates within the month of August 2007.

→ ACTIVE STUDIES

Velcade (Bortezomib) for Injection Therapy for Early Relapsed Prostate Cancer

CTO: 100822

PI: Andrew S. Kraft, MD

Participating Network Members:

[Loma Linda University Cancer Institute](#)

[South Carolina Oncology Associates, PA](#)

[Spartanburg Regional Healthcare System](#)

[University of California at Irvine](#)

Phase II Study of Neo-Adjuvant Cisplatin, Gemcitabine and Bevacizumab, Followed by Radical Cystectomy for Patients with Muscle-Invasive, Resectable, Non-Metastatic Transitional Cell Carcinoma (TCC) of the Bladder

CTO: 100892

PI: Uzair Chaudhary, MD

Participating Network Member:

[Spartanburg Regional Healthcare System](#)

→ PENDING STUDIES

Phase II Study of Neoadjuvant Gemcitabine/Oxaliplatin and Cetuximab followed by Surgery or concurrent External Beam Radiation with Capecitabine for Patients with Locally Advanced Unresectable Nonmetastatic Pancreatic Cancer

CTO: 100918

PI: Uzair Chaudhary, MD

Network Member Reviewing Study:

[McLeod Regional Medical Center](#)

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Multicenter Randomized Phase II Study of Erlotinib, Cisplatin, and Radiotherapy versus Cisplatin and Radiotherapy in Patients with Stage III and IV Squamous Cell Carcinoma of the Head and Neck

CTO: 100949

PI: Anand Sharma, MD

Network Member Reviewing Study:

[McLeod Regional Medical Center](#)

Phase II Trial of Dasatinib [Sprycel (R)] in Subjects with Hormone-Refractory Prostate Cancer, Previously Treated with Chemotherapy

CTO: 101137

PI: Andrew Kraft, MD

Network Member Reviewing Study:

[McLeod Regional Medical Center](#)

→ **STUDY CLOSURES**

Phase II Study of Xelox in Locally Advanced or Metastatic Gastric Cancer

CTO: 100829

PI: Uzair Chaudhary, MD

Participating Network Members:

[South Carolina Oncology Associates, PA](#)

[Spartanburg Regional Healthcare System](#)

Regulatory Information:

-Study closed on July 18, 2007

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CTN PROTOCOL HIGHLIGHT

Phase I/II Trial of Bortezomib and Bevacizumab ("BB-mib-mab") in Patients with Advanced or Recurrent Renal Cell Cancer (RCC) with Assessment of Tissue Correlates of Response

CTO: 101098

PI: Harry A Drabkin, MD

Sponsor: University of Southern California: David I. Quinn, MD, PhD, FRACP

Primary Objective:

To determine the maximum tolerated dose (MTD) of this combination in patients with advanced RCC, within the dose limits of previously documented biological activity for each drug as a single agent.

Inclusion Criteria:

Patient must have

- Distant metastatic (TxNxM1)(1) or locally recurrent renal cell carcinoma not amenable to cure by surgical or other means
- Measurable or evaluable disease either on imaging scan or physical examination
- Pathological confirmation of the diagnosis of renal cell



Harry A. Drabkin, MD
Division Director,
Department of Hematology -
Oncology

carcinoma either at prior nephrectomy or by biopsy of a primary or metastatic lesion - provision of a paraffin-embedded tissue block to confirm the diagnosis and allow molecular correlate assessment is required

- ECOG performance status 0 or 1

Patient may have

- Been treated with interleukin and/or interferon but must not have had more than one line of prior cytotoxic chemotherapy
- Had up to one biologic therapy provided they have not had Bortezomib or Bevacizumab
- Had up to 2 prior vaccine therapies
- Been treated with radiation therapy, provided there are measurable or evaluable lesions outside the field of radiation, the patient has recovered from the side effects of the therapy (typically 2 weeks after final fraction) and less than 30% of the total bone marrow has been irradiated

Baseline Laboratory Values

Hemoglobin >9g/dl (transfusion permitted)	Platelets >100 000/fl
Neutrophils >1500/fl	Urine Protein/Creatinine Ratio <1.0
AST & ALT <2.5x ULN	Total Bilirubin <1.0xULN
Creatinine Clearance >30ml/min or Serum Creatinine <1.5xULN	

If interested in activating the trial, please download the study request form and fax the completed form to the Network Office, 843.876.1963.

[Click here to download the study request form for this clinical trial.](#)

If You Have a Potential Patient, Please Contact One of Our Participating Sites in South Carolina:

[Medical University of South Carolina](#)

Principal Investigator: Harry A. Drabkin, MD

Study Coordinator: Alan Brisendine, brisend@musc.edu

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COOPERATIVE GROUP STUDIES

Network Cooperative Group Studies

Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) vs. Partial Breast Irradiation (PBI) for Women with Stage 0, I, II Breast Cancer

MUSC Cooperative Group Affiliates
NSABP Carolina Regional Cancer

Protocol ID: NSABP B-39
Participating Network Members:
[Carolina Regional Cancer Center](#)
[Georgetown Hospital System](#)

Phase III Randomized Study of Hypofractionated 3D-CRT/IMRT vs. Conventionally Fractionated 3D-CRT/IMRT in Patient Treated for Favorable-Risk Prostate Cancer
Protocol ID: RTOG 0415
Participating Network Member:
[Carolina Regional Cancer Center](#)

Phase III Randomized Trial of Anastrozole vs. Anastrozole and Fulvestrant as First Line Therapy for Post-Menopausal Women with Metastatic Breast Cancer
Protocol ID: SWOG 0226
Participating Network Member:
[The Regional Medical Center of Orangeburg and Calhoun Counties](#)

→ **STUDY CLOSURES**

Phase III Comparison of Prophylactic Cranial Irradiation vs. Observation in Patients with Locally Advanced Non-Small Lung Cancer
Protocol ID: RTOG 0214
Participating Network Members:
[Carolina Regional Cancer Center](#)
[Lexington Medical Center](#)
Regulatory Information:
-Study closed on August 30, 2007

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COOPERATIVE GROUP TRIAL ACTIVATIONS

Below is a listing of newly activated cooperative group trials activated between **July 15, 2007** and **August 1, 2007**. If you would like to review any of the protocols listed below, please view the information on the cooperative group websites or contact the Network Office.

[ACOSOG](#)

No newly activated studies.

[CTSU](#)

No newly activated studies.

[GOG](#)

No newly activated studies.

[NSABP](#)

No newly activated studies.

Center

Georgetown Hospital System

The Regional Medical Center of Orangeburg and Calhoun Counties

SWOG

Lexington Medical Center

The Regional Medical Center of Orangeburg and Calhoun Counties

Cooperative Group Information:

Sites that have affiliate cooperative group memberships through HCC may access all available studies as offered by their affiliated cooperative group or through CTSU.

If you would like to review any of these protocols, please review the information on the cooperative group

RTOG

No newly activated studies.

SWOG

E1697

Re-Activation: 08/01/2007

Phase III Randomized Study of Four Weeks of High Dose IFN-alpha2b in Stage T3-T4 or N1 (microscopic) Melanoma

S0438

Activation: 08/01/2007

Randomized Phase II Trial of BAY 43-9006 (Sorafenib; NSC-724772) with Either CCT-779 (Temsirrolimus; NSC-683864) or R115777 (Tipifarnib; NSC-702818) in Metastatic Melanoma and Assessment of the Role of PET Imaging for Evaluation as an Early Indicator of Response

websites or contact the
Network Office at
843.792.1753 or
hcccrnet@musc.edu.

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MUSC Health Audio Podcasts
Hosted by various MUSC faculty, physicians and special guests. MUSC patients, physicians, and staff discuss current health topics, health news and what's new at MUSC.

**MUSC HEALTH AUDIO PODCASTS:
"CLINICAL TRIALS -
WHAT A PATIENT SHOULD EXPECT"**

The MUSC Digestive Disease Clinical Trials Coordinator, Rebekah Whichard, walks through the entire process from beginning to end for a patient that will participate in a clinical trial, covering the patient's eligibility for a trial, enrollment, review of the consent form and what to expect during the trial period.

 [Click here to listen and find more information about this podcast.](#)

Other Clinical Trials-related podcasts include:

[An Overview Explaining Clinical Trials](#)
[Digestive Disease Clinical Trials](#)
www.muschealth.com/podcast

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CURE INITIATIVE: ITEMS FOR CTN PATIENTS

As a part of the **CURE** Initiative (Clinical Trials, Understanding, Research, Education), HCC has launched tokens of appreciation for clinical trials patients.

Patient journals, memo pads, highlighters, and pens are among the items available to our patients.

 [Click here to view the goals of the CURE initiative as well as](#)

Features:

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[more detailed descriptions and list of our items.](#)

The Clinical Trials Awareness video includes five testimonies from former Clinical Trials patients. The video may be customized for your site and include contact information, logo, and photos of your facility and staff members.

 [Click here to view the Clinical Trials Awareness Video.](#)

CURE Patient Items
Thanks to you Bag, Certificate,
Bumper Sticker, Document
Holder, Stress Star, Pill Box,
Pin, and Flashlight.

For more information regarding orders and pricing, please contact the Network Office.

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FREE PATIENT EDUCATION MATERIALS

[ACS: American Cancer Society](#)

Examples of Materials: Brochure for Patients: Is a Clinical Trial the Right Choice for Me?; Brochure for Physicians: Referring Your Patient to a Clinical Trial.

Contact Inf Charleston Office: 843.744.1922, Columbia Office: 803.750.1693 and HCC Network Office 843.792.1753. To find your local ACS chapter, visit cancer.org.

Ordering Inf Contact your local Materials Coordinator. 100 of each publication will be sent at a time. No minimum charges apply.

Shipping Inf Free shipping!

[CCCG: Coalition of Cancer Cooperative Groups](#)

Examples of Materials: Knowledge is Power: featuring Lance Armstrong, Cokie Roberts; Myths and Facts about Clinical Trials Brochure.

Contact Inf Call 877.520.4457, visit cancertrialshelp.org, or contact Arlene Felipe at 843.792.6394 or felipe@musc.edu.

Ordering Inf Place orders over internet or phone. No minimum charges apply.

Shipping Inf Free shipping!

[NCI: National Cancer Institute](#)

Examples of Materials: Clinical Trials workbooks, notebooks, booklets, videos with discussion guides, and slide programs (also available in Spanish).

Contact Inf Call 800.4.CANCER, visit cancer.gov/publications, or contact Arlene Felipe at 843.792.6394 or felipe@musc.edu.

Ordering Inf Place orders over internet, phone, fax, or mail. \$8 min. charge

Shipping Inf 15 cents/ copy for bulk orders beyond 20 copies.

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CANCER CARE SERIES

A listing of featured programs is available by calling 888.337.7533 or logging on to cancercares.org. Register by calling Cancer Care at 800.813.HOPE or logging on to cancercares.org.

Coping with Nausea and Vomiting from Chemotherapy

When: Thursday, September 6, 1:30 p - 2:30 p EST

Free Telephone Workshop Will Include: review of nausea and vomiting, their causes, practical tips for symptom management, clinical trials, quality-of-life considerations, keeping a log, communicating with your health care team, questions for our panel of experts.

Caring for Your Bones when You have Prostate Cancer

When: Wednesday, September 19, 1:30 p - 2:30 p EST

Free Telephone Workshop Will Include: an overview of Prostate Cancer, managing bone health and bone metastases, treatment choices, pain and side-effect management, dental care during treatment, doctor-patient communication, quality-of-life considerations and questions for our panel of experts.

Medical Update on Metastatic Breast Cancer

When: Thursday, September 20, 3 p - 4 p EST

Free Telephone Workshop Will Include: Overview of metastatic breast cancer, treatment choices, the role of clinical trials, managing side effects and pain, quality-of-life considerations, doctor-patient communication, questions for our panel of experts.

Medical Update on Ovarian Cancer

When: Thursday, September 27, 1:30 p - 2:30 p EST

Free Telephone Workshop Will Include: Overview of ovarian cancer, staging, current standard of care, new treatment approaches, clinical trials, controlling symptoms and pain, communicating with your health care team, quality-of-life considerations and questions for our panel of experts.

Moving Forward: Breast Cancer Survivorship

When: Wednesday, October 3, 1:30 p - 2:30 p EST

Free Telephone Workshop Will Include: Current standard of care, weight gain and other side effects, sticking with your treatment, nutrition and exercise guidelines, body image and intimacy, the importance of a support network, and questions for our panel of experts.

The Importance of Taking Your Pills Everyday

When: Friday, October 19, 1:30 p - 2:30 p EST

Free Telephone Workshop Will Include: overview of compliance: taking your pills on schedule, the important role of compliance in the management of cancer, barriers to taking your pills, practical tips to overcome these barriers, planning ahead for traveling, refills and weekends, communicating with your health care team, the importance of a support network, resources for finding help, and questions for our panel of experts.

Caring for Your Bones when You have Breast Cancer

When: Friday, October 26, 1:30 p - 2:30 p EST

Free Telephone Workshop Will Include: Screening for bone health and risk factors, prescription medication to promote bone health, the role of nutrition, exercise, and calcium supplements, breast cancer and bone metastases, clinical trials, controlling pain and discomfort, doctor-patient communication, and questions for our panel of experts.

For Caregivers: Coping with a Loved One's Cancer During the Holiday

When: Wednesday, November 14, 1:30 p - 2:30 p EST

Free Telephone Workshop Will Include: Definition of a Caregiver, taking on this role, caring for the person with cancer, coping with caregiving during the holidays, managing family, friends, partners, and traditions, long-distance caregiving, tips for taking care of yourself and questions for our panel of experts.

The Latest Developments Reported at the 30th Annual San Antonio Breast Cancer Symposium

When: Wednesday, December 19, 1:30 p - 2:30 p EST

Free Telephone Workshop Will Include: An overview of breast cancer, new treatment approaches reported at the symposium, the role of systemic adjuvant therapies, how clinical research affects your care, symptom management, quality-of-life issues and questions for our panel of experts.

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