

# UT CANCER INSTITUTE CLINICAL TRIALS

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## APRIL 2007

### BREAST

#### Node-neg

**PACCT-1** Program for the Assessment of Clinical Cancer Tests (PACCT-1): *Trial Assigning Individualized Options for Treatment*.  
**TAILORx** The TAILORx Trial (Coordinator – Shanna) **OPEN**

#### Eligibility:

- Operable histologically confirmed adenocarcinoma of the female breast with completed primary surgical treatment.
- ER and/or PR positive, Her2 negative
- Negative axillary nodes
- Tumor size 1.1 cm to 5 cm (or 5 mm-1 cm) plus unfavorable histology – poor nuclear grade, lymphovascular invasion)
- No prior chemo or RT for this malignancy
- Age range 18-75
- Does NOT have to be post-menopausal

#### Required Studies:

H&P, weight, height  
CBC, Leuk, Plts, creat., AST  
Oncotype DC Assay  
Biopspecimen submission

**CALGB 40302** Endocrine Therapy With or Without Inhibition of EGF and HER2 Growth Factor Receptors: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial for Postmenopausal Women with Estrogen-Receptor Positive Advanced Breast Cancer (Coordinator – Shanna) **OPEN**

#### Eligibility:

- Postmenopausal
- Stage IV breast cancer or locally advanced Stage III
- ER and/or PR positive
- HER2 positive (IHC 1+, 2+, 3+ or FISH positive)
- Measurable disease (bone)
- Must have had 1 or 2 prior treatments for breast cancer in either adjuvant or metastatic setting
- Must have received prior AI therapy
- Up to 1 prior chemo for stage IV breast cancer
- No prior Herceptin treatment for stage IV breast cancer. It is allowed in adj or neoadj setting.

#### Required Studies:

H&P, weight, height  
CBC, diff, plts, SGOT, SGPT  
Bili, INR  
CXR or CT  
Bone Scan (if met dz only in

**NSABP B42** A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer (Coordinator – Mary) **OPEN**

#### Eligibility:

- Must be postmenopausal
- Must be disease-free from time of initial diagnosis until randomization
- Stage I, II or IIIA IBC that is ER and/or PR positive
- Must have undergone lumpectomy with axillary node staging followed by RT or a total mastectomy with axillary node staging or sentinel node biopsy.
- 57-63 months from first dose of hormonal therapy which consisted of an AI or a combination of up to 3 years of tamoxifen followed by an AI.
- Must randomize within 6 mos following completion of 5 years of initial adj. hormonal therapy.
- NOTE:** There is an optional letrozole registration program and consent form for those who have not completed 5 years of hormonal therapy

#### Required Studies:

H&P, cardiac risk factors  
Fasting lipid panel (depending on cardiac risk factors)  
Mammogram and bone density (w/i 1 yr)

**NSABP-B36** A Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5-Fluorouracil, Epirubicin and Cyclophosphamide to Four Cycles of Adriamycin and Cyclophosphamide in Patients with Node-Negative Breast Cancer (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Life expectancy of at least 10 years, excluding diagnosis of breast cancer
- No more than 84 days between last surgery for breast cancer (lumpectomy, mastectomy, SLN biopsy, axillary surgery, or re-excision of margins) and randomization
- Invasive adenocarcinoma (no pure tubular or mucinous)
- T1-3 by clinical and pathologic evaluation
- Lymph node negative
- Must have undergone axillary node staging

**Required Studies:**

H&P, CBC, diff, plts, creat, bili, AST, Alk phos, chest image, MUGA or ECHO  
EKG  
Serum and/or tumor collection  
Menopausal status

**Node-pos**

**NSABP-B38**

A Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens in Women with Node-positive Breast Cancer: Docetaxel/Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel (DD AC→P); DD AC Followed by DD Paclitaxel Plus Gemcitabine (DD AC→PG) (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Interval between last surgery for breast cancer staging or treatment and randomization must be no more than 84 days
- Life expectancy of at least 10 years, PS status 0 or 1
- Tumor must be invasive carcinoma of the breast based on histologic exam
- T 1-3, ipsilateral nodes must be cN0, cN1, or cN2a by clinical eval, ipsilateral nodes must be pN1, pN2a, pN3a, pN3b by path eval.
- pN3b only if due to micro involvement of node by sentinel node dissection with ≥ 3 pos. axillary nodes.
- Must have had either a lumpectomy or total mastectomy

**Required Studies:**

H&P, CBC, diff, pts, creat, bili, AST  
Alk phos, chest image, MUGA or ECHO  
EKG  
Serum and/or tumor collection

**Adv/met.**

**SWOG S0500 :**

A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining Therapy for Metastatic Breast Cancer Patients who Have Elevated Circulating Tumor Cell Levels at First Follow-up Assessment (**Coordinator – Mary**) **OPEN**

**Eligibility:**

- Histologically or cytologically confirmed adenocarcinoma of the breast
- Must have measurable disease or bone-only disease. Those with non-measurable dz that does not include bone are ineligible.
- HER 2 negative.
- No prior chemo for met. disease
- Those with brain mets. Must have stable disease > 90 days after RT

**Required Studies:**

H&P, ECOG PS, vitals, height, weight  
CBC, diff, plts, hemoglobin, ALT, AST  
Bili, creatinine, HER2 status, HCG  
CT scan or MRI of chest/ab  
Bone scan (whole body)

**Genentech RIBBON 1 :**

A Multicenter, Phase III, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Bevacizumab in Combination with Chemotherapy Regimens in Subjects with Previously Untreated Metastatic Breast Cancer (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Histologically or cytologically confirmed adenocarcinoma of the breast, with measurable or non-measurable locally recurrent or metastatic disease
- For anthracycline cohort only: adequate left ventricular function at baseline by either MUGA or ECHO
- Cannot be HER2 positive.
- No prior chemo for locally recurrent or met. disease, hormonal therapy allowed if discontinued at least 3 wks prior.
- No RT within 3 weeks prior to study start.

**Required Studies:**

H&P, ECOG PS, vitals, height, weight  
WBC w/diff, hemo, plts, chemistries  
INR and PTT, Urine protein/creat ratio  
ECHO or MUGA  
CT or MRI (chest and ab)  
Bone scan

**Lilly 377:**

A Randomized Phase II Trial of Paclitaxel and Bevacizumab versus Gemcitabine, Paclitaxel, and Bevacizumab as First Line Treatment for Locally Advanced or Metastatic Breast Cancer (**Coordinator – Shanna**) **OPEN**

**Eligibility:**

- Histologically or cytologically confirmed carcinoma of the breast, w/ measurable metastatic dz outside a prev. RT area
- No prior cytotoxic agent for met. dz
- May have received chemo, endocrine therapy, RT in adj or neoadj setting
- No HER2 positivity

**Required Studies:**

H&P, ECOG PS, vitals, height, weight  
ECG  
CT scans and/or CXR for tumor assess  
Bone Scan (per doc discretion)  
CT or MRI of Brain

- No prior tx with Gemzar, Herceptin or Avastin in any setting

Chemistries, urine protein, CBC, diff, plts  
PT/INR (if clinically indicated)

**Genentech RIBBON 2:** A Multicenter, Phase III, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Bevacizumab in Combination with Chemotherapy Regimens in Subjects with Previously Treated Metastatic Breast Cancer  
(Coordinator – Shanna) **OPEN**

**Eligibility:**

- Histologically or cytologically confirmed carcinoma of the breast, w/ measurable or non-measurable metastatic dz that has progressed
- Progression during or following 1 chemo regimen (single agent or pre-specified combo or sequence of cytotoxic agents in 1<sup>st</sup> line setting)
- Subjects whose initial tx changed prior to progression in the 1<sup>st</sup>-line setting are not eligible unless change occurred within 30 days and was due to toxicity
- No prior hormonal therapy for met. breast cancer if it was used as the “sole” tx
- Cannot have more than 1 prior cytotoxic regimen for met. breast cancer

**Required Studies:**

H&P, ECOG PS, vitals, height, weight  
WBC w/ diff, hemo, plts, chemistries  
INR and PTT, Urine protein/creat ratio  
ECHO or MUGA  
CT or MRI (chest and ab), Bone scan

**Gastrointestinal: COLON, RECTAL, STOMACH**

**Adjuvant colon**

**CTSU E5202:** A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Tumor must be ≥12 cm from the anal verge on endoscopy, then the distal extent of the tumor must be ≥12 cm from the anal verge as determined by surgical examination.
- No history of metastases
- Must be stage II carcinoma, T3,4, N0, M0.
- Must have ≥ 8 lymph nodes evaluated
- No obstruction or perforation of the bowel upon presentation.
- No systemic or radiation therapy for this malignancy

**Required Studies:**

H&P, weight, height, BP, ECOG PS  
CBC, diff, plts, serum creat, bili, AST,  
CEA, PT, PTT  
Colonoscopy prior to surgery  
Urine protein/creat. ratio

**Adv/met. colon or rectum**

**CALGB 80405:** A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab, or Cetuximab (C225), or with Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Histologically or cytologically locally adv. or met. colorectal cancer
- No prior tx for adv. or met. colorectal cancer
- No prior RT to >25% of bone marrow
- Must be at least 4 weeks out since surgery
- No evidence of Gilbert’s syndrome for FOLFIRI patients and no grade 2+ sensory peripheral neuropathy for FOLFOX patients

**Required Studies:**

H&P, weight, height, vitals, PS  
CBC, diff, plts, creat, BUN, AST, ALT  
Electrolytes, Alk Phos, Bili, Albumin,  
LDH, Magnesium, PT/INR, Urinalysis  
Chest x-ray  
CT scan or MRI

**Genitourinary**

Deleted: 1

**Bladder**

**SWOG S0353:** Phase II Study of Intravesical Gemcitabine in Patients with Superficial Bladder Cancer Who Have Progressed Despite Intravesical BCG (Coordinator – Mary) **OPEN**

**Eligibility:**

- Recurrent superficial transitional cell carcinoma of the bladder
- Must have received at least two previous courses of intravesical BCG
- May have received one course of chemo more than one year ago
- No prior gemcitabine, intravesical interferon alpha is allowed**
- Must have had TURBT or bladder biopsy for staging and grade**
- No prior pelvis RT**
- Negative upper tract imaging study within 2 yrs of enrollment**
- No evidence of urethral or renal pelvis TCC**

**Required Studies: Within 56 days**

H&P, vitals, height, weight, PS  
UA (microhematuria is acceptable.  
Gross hematuria, leuk esterase +3 or  
**Nitrate +3 should have neg. urine culture prior to treatment**  
**ANC >1500 and Plts > 100,000**

**RTOG 0524:** A Phase I/II Trial of a Combination of Paclitaxel and Trastuzumab with Daily Irradiation or Paclitaxel Alone With Daily Irradiation Following Transurethral Surgery for Non-Cystectomy Candidates with Muscle-Invasive Bladder Cancer

**Adjuvant Renal**

**ECOG E2805** A Randomized Double-Blind Phase III Trial of Adjuvant Sunitinib versus Sorafenib versus Placebo in Patients with Resected Renal Cell Carcinoma (Coordinator – Mary) **OPEN**

**Eligibility:**

- Tumors must be > 4 cm and/or macroscopic, surgically resectable
- Must have RCC T1B, T2, T3, T4 with N0-2 with resection
- No history of distant mets.
- No prior anti-cancer therapy in either adj. or neoadj. setting
- Must be between 3-10 weeks from surgery at randomization

**Required Studies:**

H&P, vitals, height, weight, PS  
 CBC, chemistries, AGC, plts, creat  
 Bili, SGOT, SGPT, PT/PTT/INR, UA  
 Urine for DNA methylation (3wks prior to  
 or at resection)

**BETA HCG, EKG,  
 CT chest/ab/pelvis w/ contrast  
 Bone Scan, MUGA scan**

**Met. Renal**

**Genentech** A Multicenter, Phase II, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Sutent With or Without Bevacizumab in First Line Patients with Metastatic Renal Cancer (Coordinator – Shanna) *Pending*

**HEAD & NECK**

**Adv. Esophageal**

**SWOG S0414** Cetuximab Plus Cisplatin, Irinotecan and Thoracic Radiotherapy (TRT) for Locally Advanced (Non-Metastatic), Clinically Unresectable Esophageal Cancer (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Biopsy proven, non-recurrent, primary squamous cell or adenocarcinoma
- of the thoracic esophagus (20 or more cm from incisors) or GE junction.
- Disease confined to esophagus and peri-esophageal soft tissue
- Tumor at GE junction no greater than 2 cm into the gastric cardia
- T4M0 or surgically unresectable or have medically unresectable disease
- Required to submit specimens for mandatory correlative studies
- If primary esophageal cancer is <26 cm fro incisors, must have bronchoscopy and negative cytology

**Required Studies:**

H&P, weight  
 w/i 28 d –bronch (if <26 cm incisors)  
 w/i 28 days – x-rays, scans  
 ANC, WBC, plts, hemoglobin, albumin  
 Bili, BUN, alk phos, SGOT, SGPT  
 EKG, PET/CT or MRI w/i 42 days  
 Biopsy  
 EUS or EGD

**Met. H&N**

**SWOG S0618** Phase II Evaluation of E7389 in Patients with Metastatic or Recurrent Squamous Cell Carcinoma of the Head and Neck (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Histologically or cytologically confirmed squamous cell carcinoma of the head and neck that is either metastatic at dx or has persisted, metastasized or recurrent following definitive surgery and/or RT that is not surgically resectable. Patients with newly dx non-met dz are not eligible.
- Must have measurable disease.
- No active or prior CNS metastasis.
- No prior chemo for recurrent or newly diagnosed metastatic disease.
- Prior radiation therapy and/or surgery must have been completed at least 28 days prior to study start.
- Patients must not be planning to receive any other concurrent therapy while they are receiving protocol treatment.
- Tumor at GE junction no greater than 2 cm into the gastric cardia

**Required Studies:**

H&P, weight, vitals, PS  
 CT scan or MRI  
 CBC, diff, plts, bili, SGOT, SGPT, creat  
 Electrolytes

**LEUKEMIA**

**SWOG E1905** A Randomized Phase II Trial of Azacitidine with or without the Histone Deacetylase Inhibitor MS-275 for the Treatment of Myelodysplastic Syndrome, Chronic Myelomonocytic Leukemia ( dysplastic type ), and Acute Myeloid Leukemia with Multilineage Dysplasia (Coordinator – Shanna) **OPEN**

**Eligibility:**

- AML based on bone Myelodysplastic Syndromes
- Chronic Myelomonocytic Leukemia (Dysplastic subtype)
- Acute myeloid leukemia with multilineage dysplasia
- No prior treatment with Azacitidine, decitabine or MS-275.
- No AML induction chemo or stem cell transplant.
- No clinical evidence of CNS or pulmonary leukostasis, disseminated

**Required Studies:**

H&P, PS, CBC, diff, plts, reticulocytes  
 Electrolytes, calcium, phosphorus  
 BUN, creat, protein, albumin, bili, AST  
 ALT, Alk Phos  
 Chest CXR or CT, EKG  
 Bone marrow aspirate and biopsy

- intravascular coagulation, or CNS leukemia.
- Patients who have therapy-induced MDS or AML-TLD are excluded.
- **NOTE:** patients must be registered on SWOG-9007

**SWOG S0605** A Phase II Study of Lenalidomide (Revlimid) for Previously Untreated Non-M3 Deletion 5Q Acute Myeloid Leukemia (AML) in Patients Age 60 or Older Who Decline Remission Induction Chemotherapy (Coordinator – Shanna) **OPEN**

**Eligibility:**

- AML based on bone marrow aspiration and biopsy
- Patients must have declined standard AML cytotoxic chemo regimens
- Must have cytogenetic evidence of 5q deletion
- Must be 60 years or older
- No prior systemic chemo for acute leukemia with the exception of hydroxyurea
- Can have had prior myelodysplastic syndrome
- After induction, patients can be registered to maintenance therapy as long as they do not have progressive disease

**Required Studies:**

H&P, weight, PS  
 CXR, HIV test  
 CBC, diff, plts, bili, AST, ALT, creat

**CTSU E2902:** A Phase III Randomized Study of Farnesyl Transferase Inhibitor R115777 in Acute Myeloid Leukemia (AML) Patients in Second or Subsequent Remission or in Remission after Primary Induction Failure (Coordinator – Shanna) **OPEN**

**Eligibility:**

- AML patients in first remission following primary induction failure must have received at least two chemo induction regimens
- AML patients in second or subsequent complete remission
- CR by blood counts and bone marrow studies
- Acute promyelocytic leukemia not eligible
- Consolidation chemo is ok
- Autologous stem cell transplant is ok
- Must not have received any form of post-remission therapy
- Allogeneic BMT in current remission not eligible

**Required Studies:**

H&P, weight, vitals, PS  
 CBC, diff, plts, ANC, potassium, creat  
 Alk phos, bili, AST, ALT  
 Bone marrow biopsy and aspirate

**Genzyme** A Phase III Randomized, Double-Blind, Controlled Study Comparing Clofarabine and Cytarabine versus Cytarabine Alone in Adult Patients ≥ 60 Years Old with Acute Myelogenous Leukemia (AML) who have Relapsed or are Refractory after Receiving up to Two Prior Induction Regimens (Coordinator – Shanna) **OPEN**

**Eligibility:**

- AML patients who have not received more than 2 prior induction regimens
- Refractory or relapsed and at least 60 years old
- No prev. tx with clofarabine
- No intermediate or high dose cytarabine
- No grade 2 or higher GvHD
- No moderate or severe limited chronic GvHD or extensive chronic GvHD of any severity

**Required Studies:**

H&P, weight, height, BSA, vitals, PS  
 ECG  
 CBC, diff, plts, creat, chemistries, UA  
 Bone marrow biopsy and aspirate  
 Cytogenetics, and imaging studies

**LYMPHOMA**

**NHL**

**Pharmatech:** A Multicenter, Open-Label Study of Nipent, Cytoxan, and Rituxan in the Treatment of Previously Untreated and Treated, Stage III or IV, Low-Grade B-Cell Non-Hodgkin's Lymphoma or Bulky Stage II Lymphoma (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Stage III or IV low-grade B cell NHL
- CT or MRI scan confirming measurable tumor size or physical exam is acceptable if palpable.
- Positive expression of CD20
- Up to 1 prior chemo or immuno therapy allowed for B-cell NHL
- Negative HBV and HCV Infection

**Required Studies:**

H&P, weight, vitals, PS  
 CBC, diff, plts  
 HBV and HCV screen  
 CD20 status biopsy or peripheral blood w/i 28 d (radiologic tumor assessment)  
 Bone marrow aspirate and biopsy

**Brachytherapy**

**ACOSOG Z4032** A Randomized Phase III Study of Sublobar Resection versus Sublobar Resection plus Brachytherapy in High Risk Patients with Non-Small Cell Lung Cancer (NSCLC), 3 cm or smaller (Coordinator – Mary) **OPEN**

**Eligibility:**

- Suspicious lung nodule for clinical stage I NSCLC
- Mass less than or equal to 3 cm max diameter by CT size estimate: clinical stage Iaa or selected Ibb
- Must meet one major criteria or at least two minor criteria as described below:
  - Major: FEV%  $\leq$  50%, DLCO  $\leq$  50%
  - Minor: Age  $\geq$  75
    - FEV1 51-60% predicted
    - DLCO 51-60% predicted
    - Pulmonary hypertension as estimated by echocardiography or right heart catheterization
    - Poor left ventricular function
    - Resting or Exercise Arterial pO<sub>2</sub>  $\leq$  55 mmHg or SpO<sub>2</sub>  $\leq$  88%
    - pCO<sub>2</sub> > 45 mmHg
    - Dyspnea Scale  $\geq$  3

**Required Studies:**

H&P, ECOG PS  
Pulmonary function (incl. DLCO)  
CT chest and ab

**Radiation**

**RTOG 0214/CTSU** A Phase III Comparison of Prophylactic Cranial Irradiation Versus Observation in Patients with Locally Advanced Non-Small Cell Lung Cancer (Coordinator – Mary) **OPEN**

**Eligibility:**

- Newly diagnosed Stage IIIA or IIIB NSCLC having completed locoregional therapy (with surgery and/or RT, with or w/o chemo), w/ complete response, partial response, or stable dz after therapy
- Must be restaged and enrolled within 16 weeks of completing previous therapy with toxicities resolved
- No evidence of progressive disease at time of study entry
- MRI or CT show no suspicion for met. disease within 6 weeks of study entry
- No evidence of extracranial distant metastatic disease
- No prior cranial irradiation

**Required Studies:**

H&P, PS  
CT of chest, liver, adrenal glands  
Brain MRI or CT  
CBC, calcium, liver function tests,  
Alk phos  
Bone scan (if elevated alk phos)

**Adv/met. NSCLC**

**SWOG S0536:** A Phase II trial of Combination Carboplatin, Paclitaxel, Cetuximab and Bevacizumab Followed by Cetuximab and Bevacizumab in Patients with Advanced Non-Small Cell Lung Cancer (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Patients must have historically or cytologically proven newly dx Stage IIIB(T4 lesion due to malignant pleural effusion) or Stage IV
- Patients may have measurable or non-measurable disease
- Patients must not have received any prior systemic chemotherapy or biologic therapy for non-small cell lung cancer.
- Patients must not have received any adjuvant therapy for NSCLC
- Prior radiation is permitted
- Patients must be willing to provide prior smoking history

**Required Studies:**

H&P, PS  
ANC, plts, Hgb, creat, calc creat clear  
<14 days, UPC, bili, SGOT or SGPT  
Alk phos, INR  
<28 days, CT/MRI/CXR, EKG  
<42 days, Brain CT or MRI

**Pfizer:**

A Multicenter, Randomized, Double-Blind, Controlled Phase 3, Efficacy and Safety Study of Erlotinib With or Without Sunitinib in the Treatment of Advanced/Metastatic NSCLC (Coordinator – Mary) *Pending*

**Point PTH305:** A Phase 3, Randomized, Double-Blind, Multicenter Study of Talabostat and Pemetrexed versus Pemetrexed and Placebo in Patients with Advanced (Stage IIIB/IV) Non-Small Cell Lung Cancer after Failure of Platinum-Based Chemotherapy (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Histologic or cytologically-confirmed NSCLC, recurrent, locally adv. or met inoperable Stage IIIB/IV. Failed or relapsed after platinum for adv NSCLC
- Measurable disease by CT
- No more than 2 prior chemo regimens
- No progression of disease on prior Alimta tx

**Required Studies:**

H&P, vitals, weight, height, PS  
ECG, CT (w/contrast) chest and ab  
CBC, diff, plts, reticulocyte count  
Chemistries, electrolytes, LDH, creat  
BUN, CPK, PT, PTT, INR, UA

**Pharmion:** A Phase II Trial of Single-Agent Amrubicin in Patients with Extensive Disease Small Cell Lung Cancer that is Refractory or Progressive within 90 Days of Completion of First-Line Platinum-based Chemotherapy (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Histological or cytological dz of SCLC
- Refractory to 1<sup>st</sup> line platinum-based chemo
- Measurable disease (at least one measurable lesion)
- No RT within 30 days
- No prior anthracycline tx

**Required Studies:**

H&P, vitals, weight, height, ECOG PS  
NQ01 genotyping  
MUGA or Echo  
CBC, diff, plts, chemistries  
CT or MRI within 28 days  
Serum preg. Tst, and UA

**Prevention**

**SWOG-E5597** Phase III Chemoprevention Trial of Selenium Supplementation in Persons with Resected Stage I Non Small Cell Lung Cancer (Coordinator – Mary) **OPEN**

**Eligibility:**

- Pts must have undergone complete resection of Stage 1A (pT1N0) NSCLC (except carcinoid) and be currently free of dz
- To be pathologic Stage N0, at least one mediastinal lymph node must have been sampled at resection.
- Pts must be 6-36 mos from date of surgical resection.
- Path material from initial diagnosis must be available for review if recurrence occurs.
- Pts must not have rec'd or currently be rec'g chemo or RT for lung cancer.
- Chest x-ray ≤ 8 wks prior to randomization must show no sign of new or recurrent lung cancer.
- Pt must not have any concurrent cancers or any prior ca hx within the past 5 yrs except localized skin cancer.
- Pts must have no synchronous lesions or mets even if resectable.
- Pt must have no history of greater than one lung cancer primary at any time.

**Required Studies:**

H&P, PS  
CBC w plts, bili, SGOT, SGPT  
CXR or chest CT  
QA assessment

**PET**

**UTMCK** Early, Prospective Rediction of Response to Chemotherapy in Non-Small Cell Lung Cancer (NSCLC) Patients Using FDG PET/CT (Coordinator – Shanna) **OPEN**

**Case Study**

**SWOG S0424** Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men (Coordinator –Mary) **OPEN**

**Eligibility:**

- Newly diagnosed, primary, Stage I, II, IIIA or IIIB NSCLC  
Cytology dz alone not sufficient
- Must be registered within 120 days of diagnosis.
- No malignant pleural effusion
- No prior systemic chemo or RT for lung cancer
- No pericardial effusions
- Patients must be willing to provide prior smoking history and complete questionnaire

**Required Studies:**

<120 days of dx-registration  
<42 days before registration-staging  
<7 days after registration-questionnaire  
<14 days after registration-submit blood  
<30 days after registration-blocks/slides

**PANCREATIC**

**Adjuvant**

**CTSU E2204:** An Intergroup Randomized Phase II Study of Bevacizumab or Cetuximab in Combination with Gemcitabine and in Combination with Chemoradiation (Capecitabine and Radiation) in Patients with Completely-Resected Pancreatic Carcinoma (Coordinator – Shanna) **OPEN**

**Eligibility:**

- Histologically or cytologically confirmed pancreatic cancer (submission of tumor block required)
- Must have had all gross dz resected. Patients undergoing R2 resection are NOT eligible
- Between 4 wks and 8 wks post-surgery at time of registration
- No prior chemo or RT for pancreatic cancer
- No prior EGFR/VEGF inhibition and not receiving any other investigational agents
- No known mets

**Required Studies:**

H&P, CBC/diff, leukocytes, ANC, plts  
bili, AST/ALT <4 wks  
Creatinine clearance <4 wks  
CA19-9, EKG <2 wks  
CT or MRI for dz eval. <10 wks

**PROSTATE**

**UTMCK** Prostate Cancer CyberKnife Consortium-PC3: A Multi-Institutional Phase I Feasibility Study (Coordinator – Mary) **Pending**

**HRPC**

**CALGB 90401** A Randomized Double-Blinded Placebo Controlled Phase III Trial Comparing Docetaxel and Prednisone With and Without Bevacizumab in Men with Hormone Refractory Prostate Cancer (Coordinator – Mary) **OPEN**

**Eligibility:**

- Histologically documented adenocarcinoma of the prostate w/ progressive systematic disease despite maintained castrate levels of testosterone due to orchiectomy or LHRH agonist.
- Patients must have evidence of progressive metastatic disease, either a) measurable dz (any level of PSA) or b) non-measurable dz w/ PSA >5 ng/ml
- Patients must have demonstrated evidence of progressive disease since the most recent change in therapy defined as a) measurable disease progression, b) bone scan progression, or c) PSA progression
- Progression must be despite standard androgen deprivation therapy.
- Stop flutamide and megace >4 wks prior to registration, and bicalutamide and nilutamide >6 wks prior to registration.
- Progression must be evidenced after any improvement following antiandrogen withdrawal.
- Primary testicular androgen suppression should not be discontinued.
- No prior cytotoxic chemo, including estramustane or suramin, or anti-angiogenesis agents, like thalidomide or Avastin
- At least 4 weeks must have passed since any major surgery or prior radiation or other hormonal therapy.
- At least 8 weeks must have passed since the last dose of Strontium-89 or Samarium.
- Patients receiving bisphosphonates must be on a stable dose and must have started the bisphosphonate at least 4 weeks prior to initiating protocol treatment.

**Required Studies:**

H&P, vitals, height, weight, PS  
Tumor measurements and EKG  
CBC, diff, plts, creat, PSA, AST, bili  
Alk phos, LDH, testosterone, Albumin  
C-reactive protein, spot urine for protein  
CXR, Bone Scan, CT or MRI of ab/pelvis

**MISCELLANEOUS**

**S0000B** Prevention of Cataract and Age-Related Macular Degeneration With Vitamin E and Selenium - SELECT Eye Endpoints (SEE), Phase III Ancillary to S0000 – SELECT (Coordinator – Mary) **OPEN**

**Eligibility:**

- Subject must be a SELECT S0000 participant at the time of registration to this study
- Must report a diagnosis of age-related macular degeneration at baseline or at follow up, or a diagnosis of cataract or a cataract extraction at follow up

**Repositories**

**SWOG 9910:** Leukemia centralized reference laboratories and tissue repositories – consent to perform cellular and molecular studies in leukemia patients (**In conjunction with SWOG-0432**) (Coordinator – Shanna) **OPEN**

**SWOG 9007:** Cytogenetic Studies in Leukemia Patients (**In conjunction with SWOG-0432**) (Coordinator – Shanna) **OPEN**

**SWOG-9925** Lung Cancer Specimen Repository Protocol, Ancillary (Coordinator – Mary) **OPEN**

**Eligibility:**

- For patients enrolled and eligible for SWOG lung ca tx protocols
- Patients must submit specimens for this study as defined for the respective treatment study

**QUESTIONS REGARDING PROTOCOLS**

Call the **Clinical Trials Office** at (865) 544-9773

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