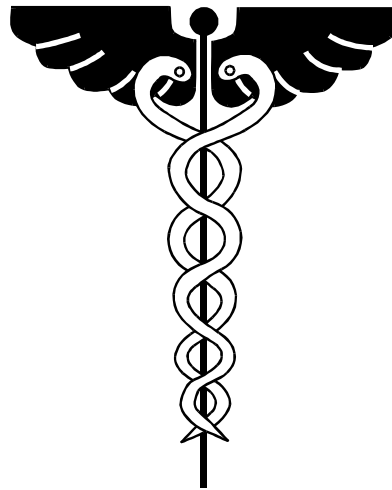


Louisiana State University Health Sciences Center

Stanley S. Scott Cancer Center

Minority- Based CCOP

Research Protocol List



Last Updated: 10/01/09

CLINICAL TRIALS CONTACTS

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Wey, Jane (surgical Onc)	

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Key, Evita	225-237-1673

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 Prellop, Perri B. “
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MB-CCOP PROGRAM MANAGER

Connelly, Alicia 504-568-3410

BRAIN		
TITLE	ELIGIBILITY	TREATMENT
No trial open currently		

BREAST		
TITLE	ELIGIBILITY	TREATMENT
IRB#6700: ECOG; PACCT-1: Program for the Assessment of Clinical Cancer Tests (PACCT-1) Trial Assigning Individualized Options for Treatment	<ul style="list-style-type: none"> • Operable histologically confirmed adenocarcinoma of the female breast with completed primary surgical treatment. • ER and/or PR positive, and Her2/neu negative. • Negative axillary nodes (assessed by sentinel lymph node biopsy, axillary dissection, or both). • Tumor size of 1.1cm to 5.0cm (or 5mm to 1.0cm plus unfavorable histological features) • Unfavorable features = intermediate or poor nuclear and/or histologic grade, or lymphovascular invasion. • Tissue specimen from primary tumor available for shipping in order to undergo Oncotype DX Assay. <ul style="list-style-type: none"> ○ Patients must not have had had this assay previously done, unless they received a Recurrence Score of 11-25. • Within 84 days from final surgical procedure; tumor must have been removed by either mastectomy or local excision plus an acceptable axillary procedure; margins must be free of invasive cancer or DCIS. (see Section 3.1.7.1.1 and .2). • No prior chemotherapy or radiation therapy for this malignancy. • Up to 8 weeks of a SERM or aromatase inhibitor for this malignancy; must not have developed breast cancer while on a hormonal therapy for breast cancer prevention, DCIS, or other indication. • Age range = 18-75 	<p>RS ≤ 10 (Secondary Study Group 1) <i>Arm A*</i>: Hormonal therapy (Appendix III) of the treating physician's choice RS 11-25 (Primary Study Group)</p> <p>Randomization: <i>Arm B*</i>: Hormonal therapy (Appendix III) of the treating physician's choice. <i>Versus</i> <i>Arm C*</i>: Chemotherapy (Appendix II) plus hormonal therapy (Appendix III) of the treating physician's choice.</p> <p>RS ≥ 26 (Secondary Study Group 2) <i>Arm D*</i>: Chemotherapy (Appendix II) plus hormonal therapy (Appendix III) of the treating physician's choice.</p> <p>* Patients may be enrolled on a separate CTSU trial if: (1) the patient is already registered on the TAILORx and, (2) the treatment option in the other trial is consistent with the TAILORx-specific treatment assignment (i.e., chemotherapy/ hormonal therapy or hormonal therapy alone)</p> <p>Treatment Note: Patients who had breast-conserving surgery will be treated with radiotherapy (see Section 5.2)</p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 5899: S0221, Phase III Trial of Continuous Schedule AC + G Vs. Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node Positive or High-Risk Node-Negative Breast Cancer</p> <p>Adjuvant</p> <p>Node positive or high risk node negative</p>	<ul style="list-style-type: none"> Histo confirmed dx of operable Stage I, II, or III invasive breast ca w/ known ER/PR status. Pts w/ bilat synchronous breast ca dx w/in 1 month of each other OK if the higher TNM stage primary tumor meets eligibility. Patients must be high risk by a) tumor > 2 cm at greatest diameter, b) tumor > 1 cm in diameter and either ER- and PgR- or ER+ or PgR+ with a Genomic Health Recurrence Score of ≥ 26, or c) at least one axillary or intramammary node involved by metastatic cancer Patients may have HER2+ tumors; they must be treated per Sec. 7.7. Patients must have had either a modified radical mastectomy or local excision of all tumors with an axillary LN dissection or sentinel LN resection prior to registration (see Sec. 5.5). At least 6 axillary or intramammary LNs must be sampled (unless SLN sampling showed no LNs involved by malignancy) (see Sec. 5.5). Patients must not have received prior RT except for PBI following lumpectomy, or RT for DCIS (see Sec. 5.8) Patients must not have received cytotoxic chemotherapy for this cancer, or had prior chemotherapy with an anthracycline, anthracenedione, or a taxane for any condition. 	<p>Arm 1 (AC + PEG-G f/b T + PEG-G): Doxorubicin 60mg/m² IV D1 q2wks x 6 cycles Cyclophosphamide 600mg/m² IV D1 q2wks x 6 cycles Pegfilgrastim 6mg SC D2 q2wks x 6 cycles <i>Followed by</i> Paclitaxel 175mg/m² IV D1 q2wks x 6 cycles Pegfilgrastim 6mg SC D2 q2wks x 6 cycles</p> <p>Arm 2 (AC + G f/b T + PEG-G): Doxorubicin 24mg/m² IV D1 qwk x 15wks Cyclophosphamide 60mg/m² PO qd x 15wks Filgrastim 5mcg/kg SC D2-7 qwk x 15wks Prophylactic Trimethoprim Sulfa <i>Followed by</i> Paclitaxel 175mg/m² IV D1 q2wks x 6 cycles Pegfilgrastim 6mg SC D2 q2wks x 6 cycles</p> <p>Arm 3 (AC + PEG-G f/b T): Doxorubicin 60mg/m² IV D1 q2wks x 6 cycles Cyclophosphamide 600mg/m² IV D1 q2wks x 6 cycles Pegfilgrastim 6mg SC D2 q2wks x 6 cycles <i>Followed by</i> Paclitaxel 80mg/m² IV qwk x 12 weeks</p> <p>Arm 4 (AC + G f/b T): Doxorubicin 24mg/m² IV D1 qwk x 15wks Cyclophosphamide 60mg/m² PO qd x 15wks Filgrastim 5mcg/kg SC D2-7 qwk x 15wks Prophylactic Trimethoprim Sulfa <i>Followed by</i> Paclitaxel 80mg/m² IV qwk x 12 weeks</p> <p>See Section 7.6 for information on hormonal therapy for ER+ or PR+ patients after chemotherapy.</p> <p>Note: GCSF provided by study.</p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 6389: NSABP B-39/RTOG 0413: A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Patients must have stage 0, I, or II breast cancer. If stage II, tumor size must be <3 cm. <input type="checkbox"/> On histological exam, tumor must be DCIS or invasive adenocarcinoma of the breast. <input type="checkbox"/> Surgical treatment must have been lumpectomy with clean margins (see Sec. 6.1.6). <input type="checkbox"/> Gross disease must be unifocal with pathologic tumor size <3 cm (see Sec. 6.1.7). <input type="checkbox"/> Invasive breast cancer requires axillary staging (see Sec 6.1.8). <input type="checkbox"/> No more than 3 histologically positive axillary nodes, and no positive non-axillary sentinel node(s) are allowed. <input type="checkbox"/> Must be randomized within 42 days following the last surgery for this breast cancer. <input type="checkbox"/> ER/PgR analysis must be performed on the primary tumor (see Sec. 6.1.10). <input type="checkbox"/> Target lumpectomy cavity must be delineated and target reference volume must be <30%. <input type="checkbox"/> Those with non-breast malignancies are eligible if disease-free for >5 years (see Sec. 6.1.14) <input type="checkbox"/> Age >18 years; Life expectancy >10 years. <input type="checkbox"/> All suspicious ipsilateral or contralateral axillary, supraclavicular, infraclavicular or internal mammary nodes, or microcalcifications, densities, or palpable abnormalities must be biopsy-proven negative (see Secs. 6.2.5 and 6.2.6). 	<p>Group 1: Whole Breast Irradiation (WBI) 45-50 Gy in 25 (1.8-2.0 Gy) fractions to whole breast, followed by optional boost to > 60 Gy</p> <p>Group 2: Partial Breast Irradiation (PBI) 34 Gy in 3.4 Gy fractions using multi-catheter brachytherapy Or 34 Gy in 3.4 Gy fractions using MammoSite® balloon catheter Or 38.5 Gy in 3.85 Gy fractions using 3D conformal external beam radiation</p> <p>For all PBI techniques: RT given to index quadrant only, BID (with a fraction separation of at least 6 hours), for a total of 10 treatments given on 5 days over a period of 5-10 days) *****</p> <p>If chemotherapy is to be given (at the discretion of the patient's medical oncologist), it will be given prior to WBI (Group 1) or following PBI (Group 2). At least 2 weeks should separate the two modalities. If hormone therapy is to be given, it should begin between 3 and 12 weeks after the completion of any chemotherapy. In patients not receiving chemotherapy, hormones may begin before, during or after radiation.</p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 5636: CALGB 40101: Cyclophosphamide and Doxorubicin (CA)(4 vs. 6 cycles) vs. Paclitaxel (4 vs. 6 cycles) as Adjuvant Therapy for Breast Cancer in Women with 0-3 Positive Axillary Lymph Nodes: A 2X2 Factorial Phase III Randomized Study</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Histologically confirmed invasive carcinoma of the female breast with 0-3 positive axillary lymph nodes <input type="checkbox"/> If node-negative, must have high risk cancer that warrants chemotherapy <input type="checkbox"/> ER/PgR receptor pos, neg or unknown <input type="checkbox"/> HER2/neu pos, neg, or unknown <input type="checkbox"/> Tumor margins must be negative for invasive cancer & DCIS; LCIS is acceptable at the margin (see sec 5.1.5) <input type="checkbox"/> Multicentric breast cancer is allowed if resected with neg margins & axillary nodes neg (see sec 5.1.2 & 5.1.6) <input type="checkbox"/> Patients must be registered < 84 days from MRM or lumpectomy <input type="checkbox"/> No prior chemo, trastuzumab, or hormonal therapy except tamoxifen (see sec 5.10) <input type="checkbox"/> No locally advanced or inflammatory breast cancer (see sec 5.3) <input type="checkbox"/> > 18 yrs of age <input type="checkbox"/> CTC performance status 0-1 <input type="checkbox"/> No concomitant exogenous hormone therapy (see sec 5.9) 	<p>Standard Chemotherapy Arm:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cyclophosphamide 600mg/m2 IV Day 1 <input type="checkbox"/> Doxorubicin 60 mg/m2 IV Day 1 <input type="checkbox"/> Repeat every 14 days for 4 cycles <p>Single Agent Arm:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Paclitaxel 175 mg/m2 IV Day 1 <input type="checkbox"/> Repeat every 14 days for 4 cycles <p>Note: Administration of filgrastim, sargramostim or pegfilgrastim is recommended with all regimens (see Sections 8.2 & 8.3)</p> <p>Note: Trastuzumab should be given for all HER2-neu-positive patients (see Section 8.4)</p> <p>Note: Tamoxifen (or an aromatase inhibitor) should be given for all ER and/or PR-positive patients (see Section 8.5)</p> <p>Note: Radiation should be given when appropriate per Section 8.7.</p>
<p>IRB# 7233C: CALGB 70301: Quality of Life, Employment and Informal Care Cost Analysis in Women Receiving Adjuvant Chemotherapy for Breast Cancer with 0-3 Positive Axillary Lymph Nodes</p>	<ul style="list-style-type: none"> • ANCILLARY STUDY TO 40101 	<p>n/a</p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 6733; 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</p>	<ul style="list-style-type: none"> • Histologic, pathologic or cytologic diagnosis of primary or metastatic stage IV breast cancer or locally advanced stage III breast cancer not amenable to curative therapy. • No active CNS metastasis (see section 4.1.2). • Tumors that are ER and/or PgR positive. • Tumors must have known HER2 status. • At least 1 measurable lesion or bone metastasis. • Prior therapy with one or two endocrine treatments (not including ovarian suppression) in either adjuvant or metastatic setting. • Tumors potentially sensitive to endocrine therapy. • Prior therapy with a third-generation aromatase inhibitor in either adjuvant or metastatic setting. • 0 or 1 prior chemotherapy regimens for advanced breast cancer. • Prior trastuzumab therapy for Stage IV cancer is permitted, in combination with up to one chemo and/or endocrine therapy regimen. • No prior therapy with fulvestrant or EGFR inhibitors. • Patients may have initiated biophosphonate therapy prior to study entry • Concurrent endocrine treatment is not allowed. • ≥ 18 years of age and postmenopausal • ECOG PS 0-2, and adequate general health 	<p>Fulvestrant + Lapatinib <u>Cycle 1:</u> Day 1- Fulvestrant 500 mg IM x 1; Day 15- Fulvestrant 250 mg IM x 1. + Day 1-28- Lapatinib- 1500 mg PO QD</p> <p><u>Cycle 2</u>, and each cycle thereafter: Day 1- Fulvestrant 250 mg IM x 1. + Day 1-28- Lapatinib- 1500 mg PO QD</p> <p>Versus</p> <p>Fulvestrant + Placebo <u>Cycle 1:</u> Day 1- Fulvestrant 500 mg IM x 1; Day 15- Fulvestrant 250 mg IM x 1. + Day 1-28- Placebo– PO QD <u>Cycle 2</u>, and each cycle thereafter: Day 1- Fulvestrant 250 mg IM x 1. + Day 1-28- Placebo– PO QD One cycle = 28 days</p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB#6943C: E1105: A Randomized Phase III Double-Blind Placebo-Controlled Trial of First-Line Chemotherapy and Trastuzumab with or without Bevacizumab for Patients with HER-2/NEU Over-Expressing Metastatic Breast Cancer</p>	<ul style="list-style-type: none"> • Patients with histologically confirmed breast cancer that overexpresses HER-2 with evidence of metastatic disease and/or chest wall recurrence prior to randomization. HER-2 overexpression is defined as 3+ HER-2 positivity by IHC (Herceptest) or HER-2 gene amplification via FISH. • Evaluable (measurable and non-measurable) disease is allowed if confirmed within 4 weeks prior to randomization. • Prior endocrine therapy in the adjuvant or metastatic setting is allowed; last dose must have been > 2 weeks prior to randomization. • Prior chemotherapy, trastuzumab, or bevacizumab for metastatic breast cancer is not allowed. • Patients must not have had > 360 mg/m² of doxorubicin or > 640 mg/m² of epirubicin in the adjuvant or neo-adjuvant setting at any time (cumulative doses). • No radiation for ≥ 3 weeks prior to randomization; no adjuvant trastuzumab or adjuvant/neo-adjuvant taxane for ≥ 12 months prior to diagnosis of recurrence; no adjuvant/neo-adjuvant lapatinib for ≥ 4 weeks prior to diagnosis of recurrence. • Patients must not have a history of grade 2-4 neuropathy. • Patients must not have a history or radiological evidence of CNS disease. • Patients must not have clinically significant cardiovascular disease. • Patients must not be taking drugs that inhibit platelet activity. 	<p>Induction</p> <p>Arm A:</p> <ul style="list-style-type: none"> • Trastuzumab 2 mg/kg* IV q week x 6 4-week cycles (24 doses) • Placebo 10 mg/kg IV q 2 weeks x 6 4-week cycles • Chemotherapy** x 6 4-week cycles <p>Arm B:</p> <ul style="list-style-type: none"> • Trastuzumab 2 mg/kg* IV q week x 6 4-week cycles (24 doses) • Bevacizumab 10 mg/kg IV q 2 weeks x 6 4-week cycles • Chemotherapy** x 6 4-week cycles • <p>Maintenance (one week after completion of induction)</p> <p>Arm A:</p> <ul style="list-style-type: none"> • Trastuzumab 6 mg/kg IV q 3 weeks • Placebo 15 mg/kg IV q 3 weeks • Continue until disease progression, unacceptable toxicity, or death <p>Arm B:</p> <ul style="list-style-type: none"> • Trastuzumab 6 mg/kg IV q 3 weeks • Bevacizumab 15 mg/kg IV q 3 weeks • Continue until disease progression, unacceptable toxicity, or death <p>* Trastuzumab loading dose 4 mg/kg Week 1 only **Paclitaxel 80 mg/m² IV q week, three weeks on, one week off Carboplatin AUC 2 IV q week, three weeks on, one week off or Paclitaxel 90 mg/m² IV q week, three weeks on, one week off</p> <p><i>Bevacizumab will be provided by Genentech free of charge</i></p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 6823: S0307: Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer"</p>	<ul style="list-style-type: none"> • Women with histologically confirmed primary invasive adenocarcinoma of the breast (Stage I, II, III) with no evidence of metastatic disease. • Primary disease within the breast must be resected, and axillary node evaluation done per institutional standards. • Patients must receive standard (systemic) adjuvant therapy; chemotherapy or HT or combination chemotherapy/HT. Patients can also receive biologic agents and local RT; but those receiving only biologics and/or RT without adjuvant chemo and/or HT are not eligible. • Patients can be enrolled on a locoregional or systemic therapy breast cancer study (as permitted by the other protocol, and as long as the other protocol does not have bone density as an endpoint). • Patients must be enrolled within 12 weeks after the final surgical procedure if not receiving adjuvant chemo, or within 8 weeks after the completion of adjuvant post-operative chemotherapy. • Patients already taking bisphosphonates for bone density must discontinue the therapy at registration. • Patients must not have a history of esophageal stricture of motility disorders.. 	<p>Arm 1: Zoledronic acid 4 mg IV q 4 weeks x 6 months then q 3 months x 2½ years</p> <p>Arm 2: Clodronate 1600 mg PO q day x 3 years</p> <p>Arm 3: Ibandronate 50 mg PO q day x 3 years</p> <p>Note: Bisphosphonate therapy should be started as soon as possible after surgery (within 84 days). Protocol registration and bisphosphonate treatment can begin prior to, simultaneously, or after systemic therapy begins.</p> <p><i>Investigational drugs and zoledronic acid are provided free of charge</i></p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB #6942C: E5103: A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node-Positive and High-Risk Lymph Node-Negative Breast Cancer</p>	<ul style="list-style-type: none"> • Patients with histologically confirmed adenocarcinoma of the breast at significant risk of distant recurrence based on at least one of the following criteria: • <input type="checkbox"/> involvement of at least 1 axillary LN on routine histologic exam (if + on IHC only, must also meet one of the other criteria) • <input type="checkbox"/> ER negative tumor ≥ 1 cm • <input type="checkbox"/> ER+ tumor ≥ 5 cm regardless of recurrence score • <input type="checkbox"/> ER+ tumor ≥ 1 cm but < 5 cm with recurrence score of ≥ 11 (may be enrolled in TAILORx trial) • <input type="checkbox"/> Must have completed definitive breast surgery. Margins must be histologically free of invasive breast cancer and DCIS (LCIS is allowed). • <input type="checkbox"/> Interval between last surgery for breast cancer and Day 1 of treatment must be > 28 days and ≤ 84 days. • <input type="checkbox"/> The following must receive appropriate radiation therapy: patients who have undergone breast conserving therapy (see Section 3.1.7) and postmastectomy patients with primary tumor ≥ 5 cm or ≥ 4 positive LNs (see Section 3.1.8). • <input type="checkbox"/> Patients must not have HER2+ breast cancer. • <input type="checkbox"/> Patients must not have clinical evidence of inflammatory disease or fixed axillary LNs at diagnosis. • <input type="checkbox"/> Patients must not have received prior cytotoxic chemotherapy or hormonal therapy for this breast cancer. Prior treatment with an anthracycline, anthracenedione, or taxane for any condition is not allowed. • <input type="checkbox"/> Prior use of tamoxifen (for prevention) and raloxifene must be discontinued at study entry. 	<p>Step 1 (Cycles 1-8)</p> <p>Arm A:</p> <ul style="list-style-type: none"> <input type="checkbox"/> AC (classic or DD) x 4 cycles along with <input type="checkbox"/> Placebo q 14 or 21 days* x 4 cycles <p>Followed by</p> <ul style="list-style-type: none"> <input type="checkbox"/> Paclitaxel q week x 12 doses along with <input type="checkbox"/> Placebo q 21 days x 4 cycles <p>Arm B:</p> <ul style="list-style-type: none"> <input type="checkbox"/> AC (classic or DD) x 4 cycles along with <input type="checkbox"/> Bevacizumab q 14 or 21 days* x 4 cycles <p>Followed by</p> <ul style="list-style-type: none"> <input type="checkbox"/> Paclitaxel q week x 12 doses along with <input type="checkbox"/> Bevacizumab q 21 days x 4 cycles <p>Arm C:</p> <ul style="list-style-type: none"> <input type="checkbox"/> AC (classic or DD) x 4 cycles along with <input type="checkbox"/> Bevacizumab q 14 or 21 days* x 4 cycles <p>Followed by</p> <ul style="list-style-type: none"> <input type="checkbox"/> Paclitaxel q week x 12 doses along with <input type="checkbox"/> Bevacizumab q 21 days x 4 cycles <p>All patients (Arms A, B, and C) are unblinded on Day 1 of Cycle 8 and then continue to receive assigned treatment for Cycle 8. Only those patients found to be on Arm C are eligible to move on to Step 2 (Arm D)</p> <p>Step 2 (cycles 9-18) [Prior Arm C patients only]</p> <p>Arm D:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bevacizumab q 21 days x 10 cycles <p>*Depends upon AC scheduling</p> <p>Bevacizumab (NSC 704865) and matching placebo will be provided free of charge by Genentech</p>

<p>IRB#6901: NSABP B-40: A Randomized Phase III Trial of Neoadjuvant Therapy in Patients with Palpable and Operable Breast Cancer Evaluating the Effect on Pathologic Complete Response (pCR) of Adding Capecitabine or Gemcitabine to Docetaxel when Administered Before AC with or without Bevacizumab and Correlative Science Studies Attempting to Identify Predictors of High Likelihood for pCR with Each of the Regimens</p>	<ul style="list-style-type: none"> • Females with invasive/adenocarcinoma of the breast that was diagnosed by core needle biopsy • Primary tumors must be palpable and measure ≥ 2.0 cm • Tumors must not be strongly HER2-positive (see Section 5.3.1) • No excisional or incisional biopsy of this primary breast cancer • No surgical axillary staging prior to study entry (see Section 5.3.3 for exceptions) • Tumors must not be clinically staged as T4 • No definitive clinical or radiological evidence of mets • No ipsilateral cN2b or cN3 disease • No synchronous bilateral breast cancer (invasive or DCIS) • No prior history of breast cancer, including DCIS • No prior treatment with radiation therapy, chemotherapy, biotherapy, and/or hormonal therapy for the current breast cancer (see Section 5.3.8 for exceptions related to hormonal therapy) • Hormonal agents such as OCP, ovarian HRT, raloxifene, tamoxifen, and other SERMS must be discontinued prior to randomization. • No prior treatment with anthracyclines, taxanes, capecitabine, 5-FU, gemcitabine, or bevacizumab for any malignancy. 	<p><u>Group 1A:</u> Docetaxel 100 mg/m² IV Day 1 q 21 days x 4 cycles <i>Three weeks later</i> AC q 21 days x 4 cycles Breast surgery</p> <p><u>Group 1B:</u> Same as 1A, but bevacizumab* is added during all four cycles of docetaxel, again during the first two cycles of AC, and is given again for ten cycles following surgery.</p> <p><u>Group 2A:</u> Docetaxel 75 mg/m² Day 1 q 21 days x 4 cycles Capecitabine 825 mg/m² PO BID Days 1-14 q 21 days x 4 cycles <i>Three weeks later</i> AC q 21 days x 4 cycles Breast Surgery</p> <p><u>Group 2B:</u> Same as 2A, but bevacizumab* is added during all four cycles of docetaxel /capecitabine, again during the first two cycles of AC, and is given again for ten cycles following surgery</p> <p><u>Group 3A:</u> Docetaxel 75 mg/m² Day 1 q 21 days x 4 cycles Gemcitabine 1000 mg/m² Days 1 and 8 q 21 days x 4 cycles <i>Three weeks later</i> AC q 21 days x 4 cycles Breast Surgery</p> <p><u>Group 3B:</u> Same as 3A, but bevacizumab* is added during all four cycles of docetaxel /gemcitabine, again during the first two cycles of AC, and is given again for ten cycles following surgery *Bevacizumab 15 mg/kg IV Day 1 q 21 days <u>Gemcitabine, capecitabine, and bevacizumab will be provided free of charge</u></p>
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BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>B42: NSABP B-42: 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 Cancer</p>	<ul style="list-style-type: none"> ☐ Female patients with histologically confirmed invasive carcinoma of the breast documented by core needle biopsy or by final pathologic evaluation of the surgical specimen. ☐ Primary tumor was ER- and/or PgR-positive. ☐ Patients must have undergone either lumpectomy with axillary nodal staging followed by breast RT or a total mastectomy with axillary nodal staging. SN biopsy alone is acceptable if SNs were negative on H&E staining. ☐ Patients must be postmenopausal at time of randomization (see Section 4.2.4). ☐ Patients who received neoadjuvant chemo must have been clinical Stage I, II, or IIIA. For patients who received adjuvant chemo, the primary tumor must have been T1-3 on pathological evaluation and ipsilateral nodes must have been pN0, pN1 (pN1mi, pN1a, pN1b, pN1c), pN2a, pN3a, or pN3b. ☐ Patients must have remained disease-free from the time of initial breast cancer diagnosis until the time of randomization. ☐ Patients must have received hormonal therapy following diagnosis for a duration of 57-63 months from the first dose regardless of number of missed doses. Hormonal therapy must have consisted of an AI or a combination of up to 3 years of tamoxifen followed by an AI. ☐ Patients must be randomized within 6 months of completing initial adjuvant hormonal therapy. ☐ Patients must not be taking sex hormonal therapy, e.g., HRT or oral contraceptives, or hormonal agents such as raloxifene for management of osteoporosis. Patients are eligible if these treatments are discontinued prior to randomization. 	<p style="text-align: center;">Double-Blind Randomization</p> <ul style="list-style-type: none"> ☐ Letrozole 2.5 mg/placebo PO QD x 5 years (5 years from the date of the first dose regardless of any missed doses) ☐ Osteoporosis Management <ul style="list-style-type: none"> - Calcium supplement 500-600 mg PO BID recommended for all patients. - Vitamin D 800-1000 IU PO QD recommended for all patients. - Bisphosphonate therapy recommended for all patients meeting criteria in Section 7.2.2. <p><u>Letrozole is provided free of charge</u></p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>NSABP B-43: A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy</p>	<ul style="list-style-type: none"> • Only patients who had a lumpectomy are eligible. Re-excision(s) to achieve tumor-free margins are permitted, but mastectomy is not. • Pre-entry central HER2 testing (see Sections 6.1 and 6.2 and Appendix C) is required for all patients. • Patients must have an ECOG performance status of 0 or 1 • On histologic examination, the tumor must be ductal carcinoma in situ (DCIS). (Patients with mixed DCIS and lobular carcinoma in situ [LCIS] are eligible.) The DCIS must be HER2-positive as determined by central testing • Estrogen and/or progesterone receptor status must be determined prior to randomization. (Patients with DCIS that is hormone receptor positive or negative are eligible.) • All DCIS must have been resected by lumpectomy. The margins of the resected specimen must be histologically free of DCIS. For patients in whom pathologic examination demonstrates DCIS present at the line of resection, re-excision(s) may be performed to obtain clear margins. (Patients who require mastectomy are not eligible.) • If axillary staging is performed, nodal staging must be pN0, pN0(i-), pN0(i+) which is defined as isolated tumor cells ≤ 0.2 mm, regardless of the method of detection, i.e., IHC or H&E, pN0(mol-), or pN0(mol+). Note: Axillary staging is not required. • The interval between the last surgery for excision of DCIS (lumpectomy or reexcision of lumpectomy margins) and randomization must be no more than 120 days. 	<p>Group 1*: Radiation Therapy</p> <p>Group 2*: Radiation Therapy + Trastuzumab x 2 doses</p> <p>Dose 1: 8 mg/kg IV</p> <p>Dose 2: 6 mg/kg IV</p> <p>given 3 weeks after Dose 1</p> <p><i>Trastuzumab will be provided free of charge by Genentech, Inc., and distributed by the NCI Pharmaceutical Management Branch (PMB).</i></p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
<p>N063D/BIG 2-06, ALTO: Adjuvant Lapatinib and/or Trastuzumab Treatment Optimization Study: A randomized, multi-centre, open-label, phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer</p>	<ul style="list-style-type: none"> • Patients with histologically-confirmed, nonmetastatic, operable primary invasive adenocarcinoma of the breast. • Tumor must be adequately excised (see Section 4.2.3.b for exception). • Axilla must be dissected; patients must be axillary node positive or node negative with a tumor \geq 1.0 cm. • Hormone receptor status must be known (ER/PgR or ER alone). • Patients must have received at least four cycles of an approved anthracycline-based (neo-) adjuvant chemotherapy regimen (see Section 4.1, Table 5 of the protocol). • There must be over expression and/or amplification of HER2 in the invasive component of the primary tumor which must be confirmed by the central laboratory prior to randomization. • Patients must not have a history of any prior (ipsiand/or contralateral) invasive breast carcinoma. • Patients must not have bilateral tumors. • Patients must not have a clinically staged T4 tumor, including inflammatory breast cancer. • Patients must not have had (neo-) or adjuvant chemotherapy using peripheral stem cell or bone marrow stem cell support. • Patients must not have had any prior mediastinal irradiation except internal mammary node irradiation for the present breast cancer. • Patients must not have positive or suspicious internal mammary nodes identified by sentinel node technique which will have not been irradiated or will not be irradiated, nor supraclavicular lymph node involvement (confirmed by FNA or biopsy). • Patients must not have had prior use of anti-HER2 therapy for any reason or other prior biologic or immunotherapy for breast cancer. • Patients must not have concurrent anti-cancer treatment, except hormonal therapy or radiotherapy for the present breast cancer. 	<p>Treatment Plan</p> <p>See Section 5.0 for Complete Treatment Details</p> <p>Design 2</p> <p><u>Trastuzumab Arm</u></p> <ul style="list-style-type: none"> • Paclitaxel 80 mg/m² IV q 7 days x 12 weeks, with Trastuzumab 2mg/kg* IV q 7 days x 12 weeks, followed by Trastuzumab 6mg/kg IV q 21 days x 40 weeks <p><u>Lapatinib Arm</u></p> <ul style="list-style-type: none"> • Paclitaxel 80 mg/m² IV q 7 days x 12 weeks, with Lapatinib 1500 mg PO QD x 52 weeks Trastuzumab followed by Lapatinib Arm · Paclitaxel 80 mg/m² IV q 7 days x 12 weeks, with Trastuzumab 2 mg/kg* IV q 7 days x 12 weeks 6-week washout, followed by Lapatinib 1500 mg PO QD x 34 weeks <p><u>Lapatinib combined with Trastuzumab Arm</u></p> <ul style="list-style-type: none"> • Paclitaxel 80 mg/m² IV q 7 days x 12 weeks, with Lapatinib 750 mg PO QD x 12 weeks, and · Trastuzumab 2mg/kg* IV q 7 days x 12 weeks, followed by Lapatinib 1000 mg PO QD x 40 weeks, with Trastuzumab 6mg/kg IV q 21 days x 40 weeks <p>* A loading dose of trastuzumab is given on Day 1 that is 2 mg/kg higher than the regular dose shown here.</p>

BREAST		
TITLE	ELIGIBILITY	TREATMENT
CALGB 70604: A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer	<ul style="list-style-type: none"> • Histo confirmed adenocarcinoma of prostate or breast or multiple myeloma • At least 1 bone mets confirmed by radiographic imaging • No prior IV bisphosphonate tx • No prior radiopharmaceuticals • ≥ 4 week since completion of radio-therapy • No current investigational therapy • No brain mets • ECOG status of 0-2 	zoledronic acid (every 12 weeks) versus zoledronic acid (every 4 weeks)
IRB# 7310: Z1071: A Phase II Study Evaluating the Role of Sentinel Lymph Node Surgery and Axillary Lymph Node Dissection Following Preoperative Chemotherapy in Women with Node Positive Breast Cancer (T1-4, N1-2, M0) at Initial Diagnosis	<ul style="list-style-type: none"> • ECOG/Zubrod Performance Status 0-1 • Histologic diagnosis of invasive breast cancer, clinical stage T1-4 N1-2 (excluding inflammatory breast cancer). • FNA biopsy or core needle biopsy of an axillary node documenting nodal disease at time of diagnosis and prior to preoperative chemotherapy. • Preoperative chemotherapy must be completed or planned for patient. • Non-pregnant and non-lactating (breast feeding). • No prior ipsilateral axillary surgery, such as excisional biopsy of lymph node(s) or treatment of hidradenitis. • No prior SLN surgery/excisional lymph node biopsy for pathological confirmation of axillary status. 	Surgery followed by chemo

CANCER CONTROL		
TITLE	ELIGIBILITY	TREATMENT
See specific disease site for current cancer control studies.		

GASTROINTESTINAL		
TITLE	ELIGIBILITY	TREATMENT
IRB# 6736: SWOG C80405: A Phase III Trial Of Irinotecan/5-Fu/Leucovorin Or Oxaliplatin/5-Fu/Leucovorin With Bevacizumab, Or Cetuximab (C225), Or With The Combination Of Bevacizumab And Cetuximab For Patients With Untreated Metastatic Adenocarcinoma Of The Colon Or Rectum	<ul style="list-style-type: none"> • . Patients with histologically or cytologically documented locally advanced or metastatic adenocarcinoma of the colon or rectum that has not been resected. • . Patients may have a history of colorectal cancer treated by surgical resection and now have evidence of metastatic cancer. • . Patients must have a wildtype K-ras gene as determined by the SWOG Solid Tumor Repository. • . Patients may not have received any prior systemic treatment for advanced or metastatic disease, but may have received prior adjuvant chemo that concluded > 12 months prior to registration or prior neoadjuvant chemo-radiation with capecitabine or 5-FU. • . No prior exposure to agents that target VEGF or EGF receptors; no prior exposure to bevacizumab or Cetuximab. • . Patients may not have had prior RT to greater than 25% of bone marrow. • . No major surgery < 4 weeks prior. • . Patients to receive FOLFIRI may not have evidence of Gilbert's Syndrome or be known to be homozygous for the UGT1A1*28 allele, and those to receive FOLFOX may not have sensory peripheral neuropathy of > grade 2 at baseline. 	<p>Arm A:</p> <ul style="list-style-type: none"> ☐ Bevacizumab 5mg/kg IV q 2 weeks ☐ FOLFOX/FOLFIRI* q 2 weeks ☐ 1 cycle = 8 weeks <p>Arm B</p> <ul style="list-style-type: none"> ☐ Cetuximab 400mg/m2 IV on Day 1, then Cetuximab 250mg/m2 IV Weekly thereafter ☐ FOLFOX/FOLFIRI* q 2 weeks ☐ 1 cycle = 8 weeks <p>*The decision to use FOLFOX or FOLFIRI is at the patient/treating physician's discretion (while complying with eligibility criteria 4.5 and 4.6).</p> <p><u>Cetixumab is provided free of charge</u></p>

GASTROINTESTINAL		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 6541; 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</p>	<ul style="list-style-type: none"> • Histologically confirmed adenocarcinoma of the colon that is Stage II (T3,4 N0 M0). • Distal extent of tumor must be > 12 cm from the anal verge as determined via endoscopy or surgery. • Patients must have ≥ 8 lymph nodes evaluated and reported. • Patients must have paraffin-embedded tumor specimen (and normal mucosa) available for central evaluation and risk assessment. • Patients must not have isolated, distant, or non-contiguous intra-abdominal metastases, even if restricted. • Patients must not have presented with complete obstruction or perforation of the bowel. • Patients must not have synchronous tumors, apendiceal tumors, or history of IBD. • Patients may not have had any systemic or radiation therapy for this malignancy. • Patients must be > 18 yrs old; ECOG PS 0-2. • There must be postoperative evidence of adequate hepatic and renal function. • Patients should not have any concurrent systemic disease that would preclude participation in the study. 	<p>High Risk Patients:</p> <p>Arm A:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Oxaliplatin 85mg/m2 IV on Day 1 <input type="checkbox"/> Leucovorin 400mg/m2 IV on Day 1 <input type="checkbox"/> 5-FU 400mg/m2 IVP on Day 1 <input type="checkbox"/> 5-FU 2.4gm/m2 CIVI on Days 1 and 2 <input type="checkbox"/> Administer 12 2-week cycles <p>Arm B</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bevacizumab 5mg/kg IV on Day 1 <input type="checkbox"/> Oxaliplatin 85mg/m2 IV on Day 1 <input type="checkbox"/> Leucovorin 400mg/m2 IV on Day 1 <input type="checkbox"/> 5-FU 400mg/m2 IVP on Day 1 <input type="checkbox"/> 5-FU 2.4gm/m2 CIVI on Days 1 and 2 <input type="checkbox"/> Administer 12 2-week cycles, then continue Bevacizumab alone for an additional 12 2-week cycles. <p>Low Risk Patients:</p> <p>Arm C</p> <ul style="list-style-type: none"> <input type="checkbox"/> Observation <p><u>Bevacizumab and oxaliplatin is provided free of charge for all patients</u></p>

GASTROINTESTINAL		
TITLE	ELIGIBILITY	TREATMENT
IRB# 6705: N0147 A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer	<ul style="list-style-type: none"> • • Patients must have histologically documented adenocarcinoma of the colon that has been completely resected (see sec 3.111). • • There must be at least one pathologically confirmed positive lymph node identified. • • There must be no evidence of residual involved lymph node disease (see sec 3.113). • • Patients may have > one synchronous primary colon cancer (see sec 3.115). • • Patients must be willing to provide blood and tissue samples for eligibility and research purposes; they can later withdraw consent for research on their specimens. • • Tumor tissue must be provided after preregistration for central KRAS testing; this must be submitted ≤ 42 days post-op in order to allow time for testing prior to registration/randomization. • • ECOG performance status must be 0, 1, or 2. • • Patients may not have distant metastatic disease. • • Patients may not have received prior chemotherapy or radiation therapy for this malignancy or any prior therapy with agents directed against EGFR. 	<p>For patient that are determined to have KRAS wild-type status, randomize to Arm A or D (must take place ≤ 56 days post-op):</p> <p>Arm A (FOLFOX):</p> <ul style="list-style-type: none"> • Oxaliplatin 85mg/m2 IV Day 1 • Leucovorin 400mg/m2 IV Day 1 • 5-FU 400mg/m2 IVP Day 1 • 5-FU 2400mg/m2 IV CIV1 over 46-48 hours Day 1 • Give 12 14-day cycles <p>Arm D (FOLFOX + Cetuximab):</p> <p>Cycle 1:</p> <ul style="list-style-type: none"> • Cetuximab 400mg/m2 IV Day 1 • FOLFOX as above • Cetuximab 250mg/m2 IV Day 8 • 14-day cycle <p>Cycles 2-12:</p> <ul style="list-style-type: none"> • Cetuximab 250mg/m2 IV Days 1 and 8 • FOLFOX as above • 14-day cycles <p>For patients that are determined to have KRAS mutant status, register to Arm G:</p> <p>Arm G: Locally Directed Therapy</p> <ul style="list-style-type: none"> • Adjuvant regimen determined by the treating oncologist • Basic event monitoring <p><i>oxaliplatin and cetuximab are provided free of charge.</i></p>

GASTROINTESTINAL		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB#6985C: S0600: Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab with or without Bevacizumab as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with either FOLFOX, OPTIMOX or XELOX</p> <p><i>temp closure</i></p>	<ul style="list-style-type: none"> • must have histologically or cytologically confirmed metastatic colorectal cancer. Confirmation may be from primary tumor or metastasis. • must have progressed on first-line chemotherapy with bevacizumab plus either FOLFOX, OPTIMOX, or XELOX within 90 days after last bevacizumab dose and within 28 days prior to registration. • must have measurable and/or nonmeasurable disease. • At least 14 days must have passed since the last dose of first-line chemotherapy and bevacizumab. • must not have received prior treatment with irinotecan (adjuvant or metastatic). • must not have received prior treatment with Cetuximab or other agents targeting VEGF or EGFR (except for bevacizumab). • Prior RT and surgery are allowed as long as 28 days have passed and all related adverse events are resolved. • must not have a history or known presence of brain metastases. 	<p>Treatment Plan See Section 7 for Complete Treatment Details</p> <p>Arm 1:</p> <ul style="list-style-type: none"> ☐ Cetuximab 400 mg/m² IV Day 1 Week 1 only ☐ Cetuximab 250 mg/m² IV Day 1 Week 2+ ☐ Chemotherapy* <p>Arm 2:</p> <ul style="list-style-type: none"> ☐ Cetuximab 400 mg/m² IV Day 1 Week 1 only ☐ Cetuximab 250 mg/m² IV Day 1 Week 2+ ☐ Bevacizumab ☐ If irinotecan: 7.5 mg/kg Day 1 q 3 weeks ☐ If FOLFIRI: 5 mg/kg Day 1 q 2 weeks ☐ Chemotherapy* <p>Arm 3:</p> <ul style="list-style-type: none"> ☐ Cetuximab 400 mg/m² IV Day 1 Week 1 only ☐ Cetuximab 250 mg/m² IV Day 1 Week 2+ ☐ Bevacizumab ☐ If irinotecan: 15 mg/kg Day 1 q 3 weeks ☐ If FOLFIRI: 10 mg/kg Day 1 q 2 weeks ☐ Chemotherapy* <p>*Chemotherapy regimen at investigator's discretion, either:</p> <ul style="list-style-type: none"> ☐ Irinotecan 350 mg/m² IV Day 1 q 3 weeks <p>Or</p> <ul style="list-style-type: none"> ☐ FOLFIRI ☐ Irinotecan 180 mg/m² IV Day 1 q 2 weeks ☐ Leucovorin 400 mg/m² IV Day 1 q 2 weeks ☐ 5-FU 400 mg/m² IV Day 1 q 2 weeks ☐ 5-FU 2,400 mg/m² CIVI Day 1 x 48 hrs q 2 weeks <p><i>bevacizumab and cetuximab are free-of-charge for all patients</i></p>

GASTROINTESTINAL		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB#6868: E3205: Phase II Trial of Cetuximab Plus Cisplatin, 5-Fluorouracil and Radiation in Immunocompetent Patients with Anal Carcinoma</p>	<ul style="list-style-type: none"> • histologically proven stage I-IIIb invasive anal canal or perianal (anal margin) squamous cell carcinoma • must be > 18 years • ECOG performance status of 0-2 • No concurrent malignancies • no history of prior radiation or chemotherapy for this malignancy • must not have had prior potentially curative surgery (abdominal, peritoneal resection) for carcinoma of the anus • must not have an active infection, uncontrolled diabetes, congestive heart failure > NYHA Class II, CVA/TIA, uncontrolled hypertension, unstable angina or myocardial infarction within the last 6 months • no hx of rheumatic disorders, irritable bowel disease, or inflammatory bowel disease • no HIV • see protocol for labs 	<p>Cetuximab Plus Cisplatin, 5-Fluorouracil and Radiation</p> <p><u><i>Cetuximab is provided free of charge</i></u></p>
<p>IRB#6935C:S0518, "Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha Versus Depot Octreotide Plus Bevacizumab (NSC #704865) in Advanced, Poor Prognosis Carcinoid Patients</p>	<ul style="list-style-type: none"> • Patients with unresectable metastatic or locally advanced, low- or intermediate-grade neuroendocrine carcinoma. • Patients must have high-risk disease as defined by at least one of the following: a) progressive disease, b) refractory carcinoid syndrome while receiving octreotide, c) atypical histology and more than 6 lesions, d) metastatic colorectal carcinoid, and/or e) metastatic gastric carcinoid. • Patients must have measurable disease. • Patients may have had up to one prior regimen of cytotoxic chemotherapy; at least 28 days must have elapsed since its completion. • Patients may have had prior hepatic artery embolization; at least 28 days must have elapsed since its completion and there must be residual disease. Chemoembolization will count as one prior chemotherapy regimen. • Patients must not have received prior interferon, bevacizumab, or any other therapy targeting VEGF or VEGF receptors. • Patients may have received prior therapy targeting c-kit, abl, PDGFR, mTOR, and somatostatin receptors (not counted towards past chemotherapy). • Patients may have received prior radiation, but there must be measurable disease and at least 28 days must have elapsed since its completion. If there was prior peptide receptor radiotherapy, the target lesion(s) must have shown disease progression. • At least 21 days must have elapsed since any prior octreotide therapy. 	<p>Arm 1*</p> <ul style="list-style-type: none"> • Octreotide LAR depot 20mg IM Day 1 • Bevacizumab 15mg/kg IV Day 1 • 21-day cycles • Continue until progression or other conditions for discontinuation are met (Section 7.6) <p>Arm 2*</p> <ul style="list-style-type: none"> • Octreotide LAR depot 20 mg IM Day 1 • Interferon alpha-2b 5 million units SC TIW (Days 1, 3, 5, 8, 10, 12, 15, 17, 19) • 21-day cycles • Continue until progression or other conditions for discontinuation are met (Section 7.6) <p>*Octreotide-naïve patients will be given a test dose of short-acting octreotide 100 mcg SC per section 7.2.a prior to receiving full protocol treatment.</p> <p><i>Bevacizumab will be provided free of charge</i></p>

GENITOURINARY		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 6915; RTOG 0526: A Prospective Phase II Trial Of Transperineal Ultrasound-Guided Brachytherapy For Locally Recurrent Prostate Adenocarcinoma Following External Beam Radiotherapy</p>	<ul style="list-style-type: none"> • Biopsy-documented locally recurrent prostatic adenocarcinoma > 30 months after the completion of EBRT, biopsied ≤ 180 days prior to registration and with diagnosis confirmed by central pathology review (see Section 10.0). • Disease-related characteristics at initial diagnosis (i.e., prior to EBRT) that fit one of the following categories (Appendix III): <ul style="list-style-type: none"> □ Stages T1-T2c, Gleason scores 2-6, and PSA ≤ 20 ng/mL, or □ Stages T1-T2c, Gleason score 7, and PSA ≤ 10 ng/mL • Baseline serum PSA value < 10 ng/mL performed with an FDA-approved assay (e.g., Abbott, Hybritech) within 8 weeks prior to registration. PSA should not be performed within 10 days of a prior prostate biopsy, and if the patient has been started on hormonal therapy, the PSA should be performed within 8 weeks prior to the commencement of hormonal therapy. • Treatment must begin within 8 weeks of registration. 	<p>Prostate brachytherapy*</p> <p>*96 patients will receive either 125-iodine (I-125)140 Gy minimum target dose or 103-palladium (Pd-103)120 Gy minimum target dose.</p>
<p>IRB #6951C: R0534: A Phase III Trial Of Short-term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed-Only Radiotherapy (SPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy</p>	<ul style="list-style-type: none"> • Patients must have adenocarcinoma of the prostate treated primarily with radical prostatectomy, pathologically proven to be LN negative by pelvic lymphadenopathy (pN0) or LN status pathologically unknown (undissected pelvic LNs [pNx]) • Post-prostatectomy PSA of ≥ 0.1 and < 2.0 ng/mL • Disease must be pathologic T3N0/Nx or pathologic T2N0/Nx with or without a positive prostatectomy margin. • There must be no distant metastases. • Patients must not have a palpable prostatic fossa abnormality or mass suggestive of recurrence, unless it has been shown by biopsy under US guidance not to contain cancer. • Patients must not have N1 disease or pelvic LN enlargement ≥ 1.5 cm in greatest dimension by CT or MRI of the pelvis (unless proven negative by biopsy). • Patients must not have received androgen deprivation therapy that was started prior to prostatectomy for > 6 months duration. • Patients must not have received androgen deprivation therapy that was started after prostatectomy and prior to registration. • Patients must not have had prior pelvic radiotherapy. 	<p>Arm 1: PBRT alone RT to prostate bed to 64.8-70.2 Gy</p> <p>Arm 2: PRBT plus NC-STAD LHRH agonist injections to cover 4-6 months E.g., leuprolide, goserelin, triptorelin Antiandrogen for 4-6 months Flutamide or bicalutamide RT to prostate bed to 64.8-70.2 Gy beginning 2 months after start of drug therapy</p> <p>Arm 3: PLNRT plus PBRT plus NC-STAD LHRH agonist injections to cover 4-6 months E.g., leuprolide, goserelin, triptorelin Antiandrogen for 4-6 months Flutamide or bicalutamide RT to pelvic lymph nodes to 45 Gy beginning 2 months after start of drug therapy RT to prostate bed to 64.8-70.2 Gy beginning 2 months after start of drug therapy</p> <p>PBRT = prostate bed radiation therapy PLNRT = pelvic lymph node radiation therapy NC-STAD = neoadjuvent and concurrent short term androgen deprivation.</p>

GENITOURINARY		
TITLE	ELIGIBILITY	TREATMENT
IRB# 6900; E2804: The BeST Trial: A Randomized Phase II Study of VEGF, RAF kinase, and mTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib and Temsirolimus in Advanced Renal Cell Carcinoma	<ul style="list-style-type: none"> • required to have the clear cell variant with less than 25% of any other hist (including, but not limited to, papillary or chromophobe or oncocytic). There must be hist confirmation by treating center of either primary or metastatic lesion. • required to have measurable metastatic disease that is not curable by standard RT or surgery. All sites must be assessed within 4 weeks prior to study entry. • Previous nephrectomy is required with some exception allowed no more than one prior regimen containing a vaccine or cytokine based immunotherapy for advanced disease. • No prior anti-angiogenic therapy including, but not limited to, SU11248, ZD6474 or VEGF Trap. No prior therapy with bevacizumab, mTOR inhibitors (including, but not limited to, temsirolimus), or sorafenib will be allowed. Thalidomide or IFNα are allowed either for adjuvant therapy or stage IV disease. • No immunotherapy within 4 weeks of randomization. • No history or clinical evidence of CNS disease • Age > 18 years of age. • ECOG performance status of 0 or 1 • Life expectancy of greater than 12 weeks. 	<p>Arm A: Bevacizumab 10 mg/kg IV every 2 weeks (days 1 and 15) Arm B: Temsirolimus 25 mg IV weekly (days 1, 8, 15 and 22) Bevacizumab 10 mg/kg IV every 2 weeks (days 1 and 15) Arm C: Bevacizumab 5 mg/kg IV every 2 weeks (days 1 and 15) Sorafenib 200 mg PO twice daily on days 1-5, 8-12, 15-19 and 22-26 Arm D: Sorafenib 200 mg PO twice daily (days 1-28) Temsirolimus 25 mg IV weekly (days 1, 8, 15 and 22)</p> <p><u>Bevacizumab, temsirolimus and sorafenib are provided free of charge</u></p>
IRB#6867: E2805: ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma	<ul style="list-style-type: none"> • Patients with histological or cytological confirmed RCC of the following types (see Section 3.2.3): <ul style="list-style-type: none"> • pT1b G3-4 N0 M0; • pT2 G(any) N0 M0; • pT3 G(any) N0 M0; • pT4 G(any) N0 M0; • T(any) G(any) N+(fully resected) M0. • Patients can be pre-registered prior to surgery (see Section 3.1.1 for pre-surgical criteria) or after surgery; randomization occurs following surgery. • Patients must have undergone full surgical resection (radical or partial nephrectomy) by either open or laparoscopic technique, with clear margins. Positive regional LNs require regional lymphadenectomy. • Patients must not have CT (or MRI) evidence of residual or metastatic disease. • Patients must have paraffin-embedded tumor specimen available for submission. • Patients must not have collecting duct or medullary carcinoma. • Patients must not have had any prior anticancer treatment for RCC in either the adjuvant or neoadjuvant setting. • Patients must be 3-10 weeks post surgery at randomization in order to begin protocol treatment 4-12 weeks from surgery. 	<p>Arm A (Sunitinib):</p> <ul style="list-style-type: none"> • Sunitinib 37.5 mg PO QD x 28 days followed by 14 days rest; then mandatory escalation to 50 mg PO QD X 28 days followed by 14 days rest (*) • Placebo for Sorafenib 400mg PO QD x 42 days for 9 cycles; then mandatory escalation to 400 mg PO BID X 42 days (*) • Give 9 6-week (42-day) cycles <p>Arm B (Sorafenib):</p> <ul style="list-style-type: none"> • Sorafenib 400 mg PO QD x 42 days; then mandatory escalation to 400mg PO BID X 42 days • Placebo for Sunitinib 37.5mg PO QD x 28 days followed by 14 days rest; then mandatory escalation to 50 mg PO QD X 28 days followed by 14 days rest • Give 9 6-week (42-day) cycles <p>Arm C (Placebo):</p> <ul style="list-style-type: none"> • Placebo for Sorafenib 400mg PO QD x 42 days; then mandatory escalation to 400 mg PO BID X 42 days • Placebo for Sunitinib 37.5 mg PO QD x 28 days followed by 14 days rest; then mandatory escalation to 50mg PO QD X 28 days followed by 14 days rest • Give 9 6-week (42-day) cycles <p>NCI, will provide Sorafenib, Sunitinib and Placebo capsules free of charge. Uncovered MUGAs reimbursed by Pfizer.</p>

GENITOURINARY		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB#6972: CCCWFU 97405: Randomized Study of Soy Protein and Effexor™ on Vasomotor Symptoms of Men with Prostate Cancer</p>	<ul style="list-style-type: none"> • Histologic documentation of prostate cancer, any stage • Life expectancy of > nine months • Prior or current androgen deprivation for treatment or control of prostate cancer to include: <ul style="list-style-type: none"> • <input type="checkbox"/> Bilateral Orchiectomy • <input type="checkbox"/> LHRH agonist (with or without antiandrogen therapy) ie: leuprolide (Lupron), goserelin (Zoladex), bicalutamide (Casodex), flutamide (Eulexin), or similar agents • <input type="checkbox"/> Chemotherapy • <input type="checkbox"/> Radiation (Patients may undergo concurrent radiation therapy to the prostate , prostate + seminal vesicles, and/or pelvis). • report of mod to severe hot flash frequency of an average of four or more per day, as defined by sweating, flushing, sensation of warmth, night sweats (Average of 28 per week) • Age >21 • No allergies to soy or dairy products • No current use of SSRIs, SNRI's, MAOIs • No uncontrolled hypertension (160/90) or greater than Class I American Heart Association functional capacity • No history of mania, hypomania, bipolar disorder, or anorexia nervosa • No history of seizures • Adequate hepatic function (total bilirubin <2; AST (SGOT) <2 x institutional ULN) • Must have a telephone • Signed protocol-specific Informed Consent • Participant must be willing to discontinue and/or avoid consuming soy foods or soy based supplements during study participation 	<p>Arm A: One soy protein powder supplement containing 20 grams protein and 160 mg isoflavones (active powder) and an inactive pill (placebo)</p> <p>Arm B: One casein powder supplement containing 20 grams of protein-inactive powder (placebo) and Venlafaxine (Effexor™) 75 mg (active pills)</p> <p>Arm C: One soy protein powder supplement containing 20 grams protein (active powder) and 160 mg isoflavones and Venlafaxine (Effexor™) 75 mg (active pill)</p> <p>Arm D: One casein powder supplement containing 20 grams of protein-inactive powder (placebo) and an inactive pill (placebo).</p>

GENITOURINARY		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 7011C: S0421, "Phase III Study of Docetaxel and Atrasentan versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer"</p>	<ul style="list-style-type: none"> • Patients with histologic diagnosis of adenocarcinoma of the prostate which is measurable or non-measurable. • Stage Tany, Nany, M1b with evidence of bone metastases on bone scan (no past or current brain mets). • The cancer must be deemed unresponsive or refractory to hormone therapy per criteria in Section 5.2. • Patients must have been surgically or medically castrated. • Patients may have had prior RT and prior surgery as long as at least 21 days have passed since the completion of treatment. • Patients may have had one prior systemic therapy (vaccine or biologic) as long as at least 28 days have passed since completion. • Patients may not have received prior cytotoxic chemotherapy for metastatic disease, but may have received adjuvant therapy with non-taxane containing regimen if more than 2 years have passed since completion. • Any prior ketoconazole must have been discontinued at least 14 days prior to registration; any other non-steroidal antiandrogens must have been discontinued at least 28 days prior to registration; patients must have demonstrated progression. • Patient may take bisphosphonates during the study as long as they were started prior to enrollment. • Patients must not have \geq grade 2 symptomatic sensory neuropathy. • Patients must not have taken CYP3A4 inhibiting/inducing drugs within 14 days (6 months for amiodarone) prior to starting Docetaxel (see Section 5.18 for list). • Patients must have Zubrod PS 0-3 (3 only if 2° to bone metastases). • Patients taking finasteride, dutasteride, or other 5 alpha reductase inhibitors for indications other than BPH must discontinue them prior to registration. 	<p>Chemotherapy and Atrasentan/Placebo</p> <ul style="list-style-type: none"> • Dexamethasone -Per institutional guidelines • Atrasentan or matched placebo - 10mg/dose PO daily for 12 cycles (36 weeks) • Docetaxel - 75 mg/m² IV q 21 days for a max of 12 cycles • Prednisone - 10mg PO daily for 12 cycles <p>A maximum of 12 cycles of docetaxel/prednisone will be administered. Patients who discontinue the docetaxel/prednisone prior to completing 12 cycles, but have not progressed, will continue taking the atrasentan/placebo for the complete 12 cycles (see Section 7.4).</p> <p>Continued Atrasentan/Placebo Patients who have not progressed after 12 cycles of protocol treatment are eligible for Step 2 Registration and may continue atrasentan/placebo for a maximum of 52 weeks or until disease progression (see Section 7.7)</p> <p><i>Atrasentan is provided free of charge</i></p>
<p>IRB# 7111C: CALGB 90203: Randomized Phase III Study Of Neo-Adjuvant Docetaxel And Androgen Deprivation Prior To Radical Prostatectomy Versus Immediate Radical Prostatectomy In Patients With High-Risk, Clinically Localized Prostate Cancer</p>	<ul style="list-style-type: none"> • Histologic documentation of prostate adenocarcinoma (no small cell, neuroendocrine, or transition cell allowed). • Must have known Gleason sum by biopsy or TURP at registration. • Clinical stage T1-T3a and no radiographic evidence of metastatic disease. • Deemed high risk by either a) Kattan nomogram predicted probability of being free from biochemical progression at 5 years after surgery of < 60% or b) prostate biopsy Gleason sum \geq 8. • No prior treatment for prostate cancer, including surgery (except TURP), LN dissection, radiation, or chemotherapy. • May have received up to 3 months of androgen deprivation therapy. • Must be appropriate candidate for radical prostatectomy with life expectancy of > 10 years as determined by a urologist. • Age > 18 years; ECOG PS 0-2 	<p>Arm A:</p> <ul style="list-style-type: none"> • Docetaxel 75 mg/m² IV Day 1q 21 days x 6 cycles <p><i>Concurrently with</i></p> <ul style="list-style-type: none"> • LHRH agonist x 18-24 weeks <p><i>Followed within 60 days by</i></p> <ul style="list-style-type: none"> • Staging pelvic lymphadenectomy • Radical Prostatectomy* <p>Arm B:</p> <ul style="list-style-type: none"> • Staging pelvic lymphadenectomy • Radical Prostatectomy* <p><i>Docetaxel supplied free of charge</i></p>

GENITOURINARY		
TITLE	ELIGIBILITY	TREATMENT
IRB# 7215C: E3805: CHAARTED: ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease Prostate Cancer	<ul style="list-style-type: none"> • Histologically or cytologically confirmed prostate cancer with metastatic disease. • · May have started hormonal therapy, but not more than 120 days prior to randomization. • Will be stratified by presence of low volume disease (metastatic disease that is not extensive) or high volume disease (any visceral metastases (extranodal) and/or at least four bone lesions, one of which must be outside the spinal column or pelvis). • · PSA must not have risen > 50% from its lowest point between the beginning of androgen deprivation and the date of randomization. • · Must have discontinued hormonal therapy in the adjuvant and/or neoadjuvant setting 12 months prior to beginning protocol therapy AND must not have exceeded 24 months of therapy AND must have been NED for at least 12 months after completing adjuvant or neoadjuvant hormonal therapy. • · No prior chemotherapy in the adjuvant or neoadjuvant setting. • · No prior hormone therapy in the metastatic setting. • · Prior palliative radiation allowed as long as it commenced 30 days within starting androgen therapy 	<p>Arm A:</p> <ul style="list-style-type: none"> • · Androgen Deprivation Therapy* • Docetaxel pre-meds <ul style="list-style-type: none"> - Dexamethasone 8 mg PO ~12, 3, and 1 hour prior to docetaxel doses - Diphenhydramine is optional • Docetaxel 75 mg/m² IV on Day 1 for up to 6 21-day cycles. • Calcium Carbonate 500 mg/day PO • Vitamin D ≥ 400 IU PO <p>Arm B:</p> <ul style="list-style-type: none"> • Androgen Deprivation Therapy* • Calcium Carbonate 500mg/day PO • Vitamin D ≥ 400 IU PO <p>*Options for androgen deprivation therapy include LHRH agonist or antagonist therapy or surgical castration. This therapy may have been started up to 120 days prior to beginning protocol therapy. Antiandrogens may be used in addition to androgen deprivation therapy, but not alone.</p>
IRB# 7214C: CALGB-90202: A Randomized, Double-Blind, Placebo-Controlled Phase III Study of Early versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone	<ul style="list-style-type: none"> • Histologic documentation of prostate adenocarcinoma (see sec 5.1) • At least one bone metastasis by radiographic imaging (see sec 5.2) • Patients must receive androgen deprivation therapy for treatment of prostate CA (see sec 5.3) • Hormone therapy (HT) at any point prior to 6 mos before enrollment is prohibited (see sec 5.4) • Prior neoadjuvant and/or adjuvant HT is allowed provided that the duration of HT was < 6 mos and HT was discontinued > 6 mos prior to study entry • No prior treatment with a bisphosphonate or with radiopharmaceuticals • ≥ 4 wks since completion of prior RT • ECOG (CTC) performance status 0-2 	<p>Double-Blinded</p> <ul style="list-style-type: none"> • Zoledronic acid: 4 mg IV Q 4 wks <p>or</p> <ul style="list-style-type: none"> • Placebo: IV Q 4 wks <p>Patients who experience PD* during the double blind portion:</p> <ul style="list-style-type: none"> • Open label Zoledronic acid 4 mg IV Q 3 wks <p>Patient who experience an SRE** at any time during the study:</p> <ul style="list-style-type: none"> • <input type="checkbox"/> End protocol treatment <p>*PD: Progressive disease **SRE: Skeletal-related event</p>
CALGB 70604: A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer	<ul style="list-style-type: none"> • Histo confirmed adenocarcinoma of lung or breast or multiple myeloma • At least 1 bone mets confirmed by radiographic imaging • No prior IV bisphosphonate tx • No prior radiopharmaceuticals • ≥ 4 week since completion of radio-therapy • No current investigational therapy • No brain mets • ECOG status of 0-2 	<p>zoledronic acid (every 12 weeks) versus zoledronic acid (every 4 weeks)</p>

GYN		
TITLE	ELIGIBILITY	TREATMENT
<p>CCCWFU 97106: A Randomized Study to Determine whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors</p> <p>OPEN ONLY TO MINORITIES</p>	<ul style="list-style-type: none"> ○ 1. Any female cancer survivor who identifies herself as concerned with her sexual quality of life and answering yes to all three of the screening questions. <ul style="list-style-type: none"> • Are you dissatisfied with your sexual quality of life? • Do you have problems with sexual arousal or fulfillment? • Are you interested in improving your sex life? ○ 2. At least 6 months following completion of all cancer therapy. Hormonal therapy and treatment with Herceptin are allowed. ○ 3. No evidence of active cancer based on physical exam and/or radiographic images obtained within 3 months of study. 	<p>Arm 1: ArginMax 3 caplets twice daily x12 wks</p> <p>Arm 2: Placebo 3 caplets twice daily x 12 wks</p>

HEAD AND NECK		
TITLE	ELIGIBILITY	TREATMENT
IRB#7079C: E1305: A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer	<ul style="list-style-type: none"> • histologically or cytologically confirmed SCCHN, from any primary site that is either (a) recurrent, judged incurable by surgery or radiation or (b) metastatic.. • No prior chemotherapy or biologic/molecular targeted therapy for recurrent or metastatic SCCHN. • No prior bevacizumab • Previous palliative radiotherapy to the head and neck is allowed if a minimum of 8 weeks has elapsed between the end of prior radiotherapy and entry into the protocol. No prior reirradiation in the head and neck region is allowed. A minimum of 3 weeks must elapse between prior radiation to other areas and study entry. • ECOG performance status of 0-1 • Patients must have fully recovered from the effects of any prior surgery, chemotherapy, or radiation therapy, and should be > 4 weeks post surgery. • Patients must have measurable disease based on RECIST (see Sec. 6.0). Baseline measurements and evaluations of all sites of disease must be obtained < 4 weeks prior to randomization. Disease in previously irradiated sites is considered measurable if there has been unequivocal disease progression or biopsy-proven residual carcinoma following radiation therapy. • Persistent disease after radiotherapy must be biopsy proven at least 8 weeks after completion of radiation therapy. (Radiographic findings are acceptable providing that clearcut measurements can be made). 	<p>Arm A: Cisplatin plus Docetaxel OR Cisplatin plus 5-FU.</p> <p>Vs.</p> <p>Arm B: Docetaxel plus Cisplatin plus Bevacizumab OR Cisplatin plus Bevacizumab plus 5-FU.</p>

LEUKEMIA		
TITLE	ELIGIBILITY	TREATMENT
IRB# 1746: S9007; Cytogenetic Studies in Leukemia Patients. ANCILLARY	<ul style="list-style-type: none"> All patients registered to any SWOG Leukemia study. Submit specimens at the times designated 	Cytogenetic studies in SWOG Leukemia patients
IRB# 4791: S9910; Leukemia Centralized Reference Laboratories and Tissue Repositories - Consent to Perform Cellular and Molecular Studies in Leukemia Patients ANCILLARY	Patients must be registered on a SWOG leukemia tx study approved on or after 4/15/1999	Leukemia Centralized Reference Laboratories and Tissue Repositories, Ancillary

LUNG		
TITLE	ELIGIBILITY	TREATMENT
IRB# 5486: S9925, Lung Cancer Specimen Repository Protocol, Ancillary	<ul style="list-style-type: none"> Patients must be enrolled on one of the following SWOG coordinated lung cancer treatment protocols: SWOG-8805, SWOG-9019, SWOG-9416, SWOG-9509, S9900, S0003, S0023, S0126, S0124, S0220, S0222, S0327, S0310, S0339, S0342, S0341, S0435, S0509, S0429, S0533, S0526 or S0536. Patients subsequently found to be ineligible for the therapeutic protocol to which they are registered will be declared ineligible for this protocol.. 	Lung Cancer Specimen Repository Protocol, Ancillary

LUNG		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB#6873C: RTOG (0617), NCCTG (N0628), CALGB (30609): A Randomized Phase III Comparison Of Standard- Dose (60 Gy) Versus High-Dose (74 Gy) Conformal Radiotherapy With Concurrent And Consolidation Carboplatin/Paclitaxel +/- Cetuximab (Ind #103444) In Patients With Stage IIIa/IIIb Non-Small Cell Lung Cancer</p>	<ul style="list-style-type: none"> • Patients with histologically or cytologically proven diagnosis of Stage IIIA or Stage IIIB NSCLC within 12 weeks of registration. • Patients must be considered unresectable or inoperable. • There must be no distant metastases. • Patients must have measurable or evaluable disease. • Patients must be at least 3 weeks from any prior thoracotomy. • Patients must not have N3 supraclavicular disease. • Patients must not have greater than minimal, exudative, or cytologically positive pleural effusions (effusions must be proven non-malignant per Section 3.1.4). • Patients must not have Pancoast tumors. • Patients must not have involved contralateral hilar nodes (i.e., greater than 1.5 cm on short axis or positive on PET scan). • Patients must not have ≥ 10% weight loss within the past month. • Patients must not have had prior systemic chemotherapy for the study cancer (prior chemo is allowed if for a different cancer). • Patients must not have had prior radiation to the region of the study cancer that would result in overlap of radiation therapy fields. 	<p>Arms A and C:</p> <ul style="list-style-type: none"> • Arm C only: Cetuximab loading dose Week 1, then Chemotherapy (given concurrently with XRT) • Arm C only: Cetuximab q week x 6 weeks • Arms A and C: Paclitaxel +Carboplatin q week x 6 weeks <p><u>Radiation Therapy (IMRT or 3DCRT)</u></p> <ul style="list-style-type: none"> • 2 Gy per fraction 5 days a week for 6 weeks • Total dose = 60 Gy in 30 fractions <p>Arms B and D:</p> <ul style="list-style-type: none"> • Arm D only: Cetuximab loading dose Week 1, then Chemotherapy (given concurrently with XRT) • Arm D only: Cetuximab q week x 7 weeks • Arms B and D: Paclitaxel +Carboplatin q week x 7 weeks <p><u>Radiation Therapy (IMRT or 3DCRT)</u></p> <ul style="list-style-type: none"> • 2 Gy per fraction 5 days a week for 7.5 weeks • Total dose = 74 Gy in 37 fractions <p>Following completion of combined therapy: Consolidation chemotherapy:</p> <ul style="list-style-type: none"> • <u>Arm A:</u> Paclitaxel and Carboplatin Days 64 and 85 • <u>Arm B:</u> Paclitaxel and Carboplatin Days 71 and 92 • <u>Arm C:</u> Paclitaxel and Carboplatin Days 71 and 92 Cetuximab Days 50, 57, 64, 71, 78, 85, 92, 99, 106 • <u>Arm D:</u> Paclitaxel and Carboplatin Days 78 and 99 Cetuximab Days 57, 64, 71, 78, 85, 92, 99, 106, 113

LUNG		
TITLE	ELIGIBILITY	TREATMENT
IRB#6937C: E1505: A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (> 4 cm) -IIIA Non-Small Cell Lung Cancer (NSCLC)	<ul style="list-style-type: none"> • Patients must have undergone complete resection of their NSCLC (stage IB [≥ 4 cm] - IIIA [T2-3N0, T1-3N1, T1-3N2]) prior to enrollment. • Patients must have had lobectomy, sleeve lobectomy, bi-lobectomy, or pneumonectomy. • Mediastinal LN sampling must have been done at time of pre-operative mediastinoscopy or intraoperatively. • Patients must be ≥ 6 weeks and ≤ 12 weeks post-thoracotomy. • Patients must not have received prior systemic chemotherapy at any time, or hormonal cancer therapy or radiation therapy as prior cancer treatment within 5 years of randomization. • Patients must not have any history of CVA or TIA; no symptomatic or uncontrolled CHF or cardiac arrhythmia. • Patients with known history of MI or other evidence of thrombotic disease (angina) must have no evidence of active disease within at least 12 months prior to randomization. 	<p>Arm A:</p> <ul style="list-style-type: none"> • Chemotherapy* • 4 21-day cycles <p>Arm B:</p> <ul style="list-style-type: none"> • Chemotherapy* • Bevacizumab 15mg/kg IV Day 1 either before or after chemotherapy • 4 21-day cycles • Bevacizumab will then continue for up to a total of one year (q 21 days) <p>*Chemotherapy Options—Must be chosen prior to randomization</p> <ul style="list-style-type: none"> • Vinorelbine 30 mg/m² IV Days 1 and 8 • Cisplatin 75 mg/m² IV Day 1 • Docetaxel 75 mg/m² IV Day 1 • Cisplatin 75 mg/m² IV Day 1 • Gemcitabine 1200 mg/m² IV Days 1 and 8 • Cisplatin 75 mg/m² IV Day 1 • Pemetrexed 500 mg/m² IV Day 1 • Cisplatin 75 mg/m² IV Day 1 <p><i>Bevacizumab is provided free of charge.</i></p>
CALGB 30607; Randomized, Phase III, Double-Blind Placebo-Controlled Trial of Sunitinib (NSC #736511, IND #74019) as Maintenance Therapy in Non-Progressing Patients following an Initial Four Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB/IV Non-Small Cell Lung Cancer	<ul style="list-style-type: none"> • histo or cyto stage IIIB/IV NSCLC • no brain mets, spinal compression, carcinomatous meningitis • no cavitory lesions • must have rec'd 4 cycles of platinum based doublet therapy w/ or w/o bevacizumab • no evidence of disease progression • no prior adjuvant chemo for stage 1-III resected or combined modality therapy for stage III NSCLC • no other primary therapy for NSCLC • no CYP3A4 inhibitors or inducers (sect 4.16) • must be able to swallow pills • some cardiac restrictions (section 4.7-9) • no bleeding disorders 	<p>sunitinib or placebo</p> <p><i>sunitinib is free of charge</i></p>

LUNG		
TITLE	ELIGIBILITY	TREATMENT
<p>N0723: MARVEL: Marker Validation of Erlotinib in Lung Cancer: A Phase III Biomarker Validation Study of Second-Line Therapy in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) Randomized to Pemetrexed Versus Erlotinib</p>	<ul style="list-style-type: none"> • Documented recurrence or disease progression of NSCLC. • NSCLC must be confirmed by pathologic examination, either on initial diagnosis or disease recurrence/progression. Mixed histology allowed if all components consistent with NSCLC. • Measurable disease as defined in Section 11.0 with at least one lesion whose longest diameter can be accurately measured as ≥ 2.0 cm with conventional techniques or as ≥ 1.0 cm with spiral CT. If spiral CT is used, it must be used for both pre- and post- treatment tumor assessments. • ECOG performance status (PS) 0, 1, or 2 (Appendix II). • Life expectancy ≥ 12 weeks. • Tissue available and willing to submit tissue for EGFR evaluation (see Section 17.0). Performed on original diagnostic/ recurrent tissue (preferably paraffin-embedded tissue blocks. If institution unable to release tissue blocks, willing to submit 25 unstained charged slides (15 slides cut at 5 microns and 10 cut at 10 microns). • Must be previously treated for advanced disease with only 1 chemotherapy regimen which must contain cytotoxic agent(s). Adjuvant/neoadjuvant treatment with cytotoxic agent(s) administered < 12 months (from date chemotherapy was started) prior to preregistration will be considered as one prior treatment. NOTE: • Adjuvant/neoadjuvant treatment administered ≥ 12 months, use of targeted agents such as monoclonal antibodies prior to pre-registration will NOT be counted as one prior treatment. Patient could have had adjuvant/neoadjuvant chemotherapy ≥ 12 months and 1 systemic chemotherapy regimen for metastatic or recurrent disease. • Able to take folic acid, vitamin B12 supplementation, and dexamethasone. • Able to permanently discontinue aspirin dose of ≥ 1.3 grams/day ≥ 10 days before and after pemetrexed treatment. • Stable brain metastasis that have been treated with either whole brain radiation therapy or gamma knife surgery and are off steroid treatment for > 14 days prior to pre-registration, if applicable. 	<p>Arm A Erlotinib daily</p> <p>Arm B Pemetrexed day 1 of each cycle</p>

LUNG		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 7297C: S0819, "A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)"</p>	<ul style="list-style-type: none"> • Patients must have histologically or cytologically proven newly diagnosed Stage IV, advanced primary non-small cell lung cancer (adenocarcinoma, large cell carcinoma, squamous or unspecified) or recurrent disease after previous surgery and/or irradiation. • Patients with controlled (for a minimum of 2 months) brain metastases after treatment, • Patients may have measurable or non-measurable disease (see Section 10.1) documented by CT or MRI. • Translational Medicine Studies: Patients must agree to submission of specimens for EGFR FISH testing and other translational medicine studies as outlined in Section 15.0. Patients must be offered participation in banking for future research. • Patients must not have received for any purpose prior chemotherapy, cetuximab, gefitinib, erlotinib or other investigational agents that target the EGFR pathway. Patients must not have received for any purpose prior VEGF-related agents. Patients must not have received for any purpose prior chimerized or murine monoclonal antibody therapy or have documented presence of human anti-mouse antibodies (HAMA). • Prior radiation is permitted; however, patients must have recovered from all associated toxicities at time of registration. • At least 28 days must have elapsed since surgery • Zubrod Performance Status of 0 - 1 (<p>Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab</p>

LUNG		
TITLE	ELIGIBILITY	TREATMENT
<p>IRB# 7239: S0802, "A Randomized Phase II Trial of Weekly Topotecan with and without AVE0005 (Aflibercept; NSC-724770) in Patients with Platinum Treated Extensive Stage Small Cell Lung Cancer (E-SCLC)"</p>	<ul style="list-style-type: none"> • Histologically or cytologically confirmed diagnosis of extensive stage small cell lung cancer (E-SCLC) with progression or recurrence after receiving exactly one standard first-line platinum-containing regimen. Measurable or non-measurable disease. • Brain mets eligible only if has been treated and stable for at least 3 months. No leptomeningeal involvement or brain stem mets. • At least 21 days since prior RT. • At least 28 days since surgery. • No prior bevacizumab or other anti-angiogenic tx. • Zubrod PS 0-1. • No active infection or bleeding. • No uncontrolled hypertension. • No history of recent arterial embolic events or congestive heart failure. • No significant history of bleeding diathesis including hemoptysis or underlying coagulopathy. • No prior history of encephalitis or encephalopathy. No diverticulitis, GI bleeding, or peptic ulcer within prior 3 months. • Must be willing to provide smoking history. • No known AIDS or HIV-1. 	<p>Arm 1: AVE0005 plus topotecan</p> <p>Arm 2: Single-agent topotecan</p>

LYMPHOMA		
TITLE	ELIGIBILITY	TREATMENT
NHL WORKING FORMULATION	Intermediate Grade <ul style="list-style-type: none"> • D Follicular Large Cell • E Diffuse Small Cleaved Cell • F Diffuse, Mixed, small and large cell • G Diffuse, Large Cell High Grade <ul style="list-style-type: none"> • H Large cell, Immunoblastic • J Small, non-cleaved cell 	See protocols below
NHL REAL Classification	B-cell <ul style="list-style-type: none"> • Follicular • Diffuse, Large B-Cell • Mantle Cell • B-CLL/SLL • Malt • Burkitts/Burkitts-like • Lymphoplasmocytoid • Other B-cell T-Cell <ul style="list-style-type: none"> • Peripheral T-cell • Anaplastic Large Cell • Angioimmunoblastic • T-LBL • Other T-cell 	See protocols below
IRB# 1576: S8947; Central Lymphoma Serum Repository Protocol ANCILLARY	<ul style="list-style-type: none"> • For patients registered to a currently active Southwest Oncology Group-coordinated treatment protocol for previously untreated non-Hodgkin's Lymphoma. 	Central Lymphoma Serum Repository Protocol

Melanoma		
TITLE	ELIGIBILITY	TREATMENT
IRB# 7287: S0826, "A Phase II Study of SCH 727965 in Stage IV Melanoma"	<ul style="list-style-type: none"> • Biopsy-proven malignant melanoma of cutaneous or mucosal origin. • No ocular melanoma. • Stage IV disease. • Unknown primary eligible. • Must be offered participation in submission and banking of tissue for future use. • Measurable or non-measurable disease. • No hx of brain mets. • Zubrod PS 0-1. • May have received up to one prior systemic regimen for Stage IV melanoma excluding prior tx with a cdk inhibitor. May have received any number of prior adjuvant therapy regimens. May have received prior RT. May have received prior surgery. Side effects from any prior treatment must have resolved to <= Grade 1. • Must not be pregnant or nursing. • Must not be receiving or planning to receive any non-protocol treatment. • No other prior malignancy except adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, adequately treated Stage I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease-free for 5 years. 	SCH 727965

Myeloma		
TITLE	ELIGIBILITY	TREATMENT
CALGB 70604: A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer	<ul style="list-style-type: none"> • Histo confirmed adenocarcinoma of lung or breast or multiple myeloma • At least 1 bone mets confirmed by radiographic imaging • No prior IV bisphosphonate tx • No prior radiopharmaceuticals • ≥ 4 week since completion of radio-therapy • No current investigational therapy • No brain mets • ECOG status of 0-2 	zoledronic acid (every 12 weeks) versus zoledronic acid (every 4 weeks)

Sarcoma		
TITLE	ELIGIBILITY	TREATMENT

None

Miscellaneous		
TITLE	ELIGIBILITY	TREATMENT
CCCWFU 97106: A Randomized Study to Determine Whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors MINORITIES ONLY	Survivor of any cancer Female	Arginmax vs placebo

PERFORMANCE STATUS SCALES

ZUBROD PERFORMANCE SCALE

- 0** Fully active, able to carry on all pre-disease activities without restriction.
- 1** Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature. For example, light housework, office work.
- 2** Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3** Capable of only limited self-care, confined to bed or chair 50% or more of waking hours.
- 4** Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.

KARNOFSKY PERFORMANCE SCALE

- 100** Normal; no complaints; no evidence of disease
- 90** Able to carry on normal activity; minor signs or symptoms of disease
- 80** Normal activity with effort; some sign or symptoms of disease
- 70** Cares for self; unable to carry on normal activity or do active work
- 60** Requires occasional assistance, but is able to care for most personal needs
- 50** Requires considerable assistance and frequent medical care
- 40** Disabled; requires special care and assistance
- 30** Severely disabled; hospitalization is indicated, although death not imminent
- 20** Very sick; hospitalization necessary; active support treatment is necessary
- 10** Moribund; fatal processes progressing rapidly
- 0** Dead

ECOG PERFORMANCE SCALE

- 0** Fully active, able to carry on all pre-disease performance without restriction
- 1** Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2** Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3** Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4** Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5** Dead