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<th><strong>BRAIN</strong></th>
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| CCCWFU 91105: Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain | - Life expectancy of at least > 30 weeks.  
- Must have received a prior course of at least 30 Gy fractionated whole or partial brain irradiation for treatment of a primary brain tumor or metastatic disease to the brain.  
- Must have completed radiation > 6 months prior to enrollment and have no radiographic evidence of brain disease, or stable brain disease defined as no evidence of tumor progression in the 3 months prior to enrollment.  
- Patients who have undergone one or more treatments with single fraction stereotactic radiosurgery (SRS) in addition to whole or partial brain irradiation are eligible, as long as the SRS was completed > 6 months prior to registration if NED or stable disease.  
- Patients who have received PCI (prophylactic cranial irradiation) are eligible.  
- Karnofsky Performance Status must be > 60 or ECOG 0-2.  
- Treatment with steroids, anti-cholinergics, anti-epileptics, anti-depressants, and/or sedatives/benzodiazepines is acceptable, but the patient must be on a stable or decreasing dose at the time of study entry.  
- Patients using narcotic analgesics on a stable dose and/or prn basis are eligible.  
- Patients currently on a stable dose of Methylphenidate or Dextramphetamine are eligible.  
- For patients with brain metastases, if extracranial primary or metastatic disease is present, it must have responded to local and/or systemic treatment. Must be stable in the 3 months prior to enrollment.  
- Patient must not have any planned therapy, including surgery, brain radiation of any type, chemotherapy, or immunotherapy during the next 30 weeks for brain or extracranial primary metastatic disease.  
- Hormonal therapy for patients with breast or prostate cancer is acceptable.  
- Breast patients receiving therapy with Herceptin are allowed.  
- Patients cannot be currently taking dementia drugs, cognitive enhancers, neuroleptics, and/or anti-parkinsonian agents. For patients who have used these drugs in the past, they must not have used them in the 2 weeks prior to enrolling on the study. | Arm A:  
Donepezil tablets x 24 weeks  
(Week 1-6: one 5 mg tablet per day)  
(Weeks 7-24: two 5 mg tablets per day)  
Arm B:  
Placebo tablets x 24 weeks  
(Week 1-6: one tablet per day)  
(Weeks 7-24: two tablets per day) | MBPCC  
CCS  
Oncologics |
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<tr>
<td>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 Adjuvant</td>
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| Node positive or high risk node negative | • 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, anthracyclinedione, or a taxane for any condition. | 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  
Followed by  
Paclitaxel 175mg/m2 IV D1 q2wks x 6 cycles  
Pegfilgrastim 6mg SC D2 q2wks x 6 cycles | BRGMC  
LSUHSC  
MBPCC  
Med Onc  
Rbt Veith  
CCS |
| 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  
Followed by  
Paclitaxel 175mg/m2 IV D1 q2wks x 6 cycles  
Pegfilgrastim 6mg SC D2 q2wks x 6 cycles | 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  
Followed by  
Paclitaxel 80mg/m2 IV qwk x 12 weeks | 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  
Followed by  
Paclitaxel 80mg/m2 IV qwk x 12 weeks | |

1 rx credit

Note: GCSF provided by study.
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<tr>
<td>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</td>
<td>Patients must have stage 0, I, or II breast cancer. If stage II, tumor size must be &lt;3 cm. On histological exam, tumor must be DCIS or invasive adenocarcinoma of the breast. Surgical treatment must have been lumpectomy with clean margins (see Sec. 6.1.6). Gross disease must be unifocal with pathologic tumor size &lt;3 cm (see Sec. 6.1.7). Invasive breast cancer requires axillary staging (see Sec 6.1.8). No more than 3 histologically positive axillary nodes, and no positive non-axillary sentinel node(s) are allowed. Must be randomized within 42 days following the last surgery for this breast cancer.</td>
<td>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 &gt; 60 Gy</td>
<td>LSUHSC</td>
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<td>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</td>
<td>MBPCC</td>
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<td>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) **************************************************** ***</td>
<td>CCS</td>
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<td>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.</td>
<td>Oncologics</td>
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1 rx credit

0.5 cc credit
### BREAST

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| 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 | • Patients with histologically confirmed adenocarcinoma of the breast at significant risk of distant recurrence based on at least one of the following criteria:  
  - involvement of at least 1 axillary LN on routine histologic exam (if + on IHC only, must also meet one of the other criteria)  
  - ER negative tumor ≥ 1 cm  
  - ER+ tumor ≥ 5 cm regardless or recurrence score  
  - ER+ tumor ≥ 1 cm but < 5 cm with recurrence score of ≥ 11 (may be enrolled in TAILORx trial)  
  - Must have completed definitive breast surgery. Margins must be histologically free of invasive breast cancer and DCIS (LCIS is allowed).  
  - Interval between last surgery for breast cancer and Day 1 of treatment must be > 28 days and ≤ 84 days.  
  - 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).  
  - Patients must not have HER2+ breast cancer.  
  - Patients must not have clinical evidence of inflammatory disease or fixed axillary LNs at diagnosis.  
  - Patients must not have received prior cytotoxic chemotherapy or hormonal therapy for this breast cancer. Prior treatment with an anthracycline, anthracedione, or taxane for any condition is not allowed.  
  - Prior use of tamoxifen (for prevention) and raloxifine must be discontinued at study entry. | | MBPCC |
<p>| | | Step 1 (Cycles 1-8) | | Veith |
| | Arm A: | | MOL |
| | □ AC (classic or DD) x 4 cycles along with | | MCLNO |
| | □ Placebo q 14 or 21 days* x 4 cycles | | LKRMC |
| | Followed by | | CCS |
| | □ Paclitaxel q week x 12 doses along with | | |
| | □ Placebo q 21 days x 4 cycles | | |
| | Arm B: | | |
| | □ AC (classic or DD) x 4 cycles along with | | |
| | □ Bevacizumab q 14 or 21 days* x 4 cycles | | |
| | Followed by | | |
| | □ Paclitaxel q week x 12 doses along with | | |
| | □ Bevacizumab q 21 days x 4 cycles | | |
| | Arm C: | | |
| | □ AC (classic or DD) x 4 cycles along with | | |
| | □ Bevacizumab q 14 or 21 days* x 4 cycles | | |
| | Followed by | | |
| | □ Paclitaxel q week x 12 doses along with | | |
| | □ Bevacizumab q 21 days x 4 cycles | | |
| | 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) Step 2 (cycles 9-18) [Prior Arm C patients only] | | |
| | Arm D: | | |
| | □ Bevacizumab q 21 days x 10 cycles | | |
| | *Depends upon AC scheduling | | |
| | Bevacizumab (NSC 704865) and matching placebo will be provided free of charge by Genentech | | |</p>
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| 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 | • 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. | Group 1*: Radiation Therapy  
Group 2*: Radiation Therapy + Trastuzumab x 2 doses  
Dose 1: 8 mg/kg IV  
Dose 2: 6 mg/kg IV  
given 3 weeks after Dose 1 | MCLNO Veith MOL MBPCC CCS Thibodaux |

1 rx credit

Trastuzumab will be provided free of charge by Genentech, Inc., and distributed by the NCI Pharmaceutical Management Branch (PMB).
### Eligibility
- 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 ≥ 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 (ipsi and/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.

### Treatment
- **Trastuzumab Arm**
  - Paclitaxel 80 mg/m² IV q 7 days x 12 weeks, with Trastuzumab 2 mg/kg* IV q 7 days x 12 weeks, followed by Trastuzumab 6 mg/kg IV q 21 days x 40 weeks.

- **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, followed by Lapatinib 1500 mg PO qD x 34 weeks.

- **Lapatinib combined with Trastuzumab Arm**
  - 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.

* A loading dose of trastuzumab is given on Day 1 that is 2 mg/kg higher than the regular dose shown here.
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| CALGB 70604: A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer | • 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) | BRG MBPCC Veith CCS LSUHSC MOL MCLNO |
| 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 | • 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 | BRG MBPCC Veith CCS LSUHSC MOL MCLNO |
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| S0715 RANDOMIZED PLACEBO-CONTROLLED TRIAL OF ACETYL-L-CARNITINE (ALC) FOR THE PREVENTION OF TAXANE INDUCED NEUROPATHY PHASE III | • Patients must be women with histologically confirmed primary invasive adenocarcinoma of the breast (Stage I, II, III) with no evidence of metastatic disease (M0).  
• Patients must have undergone modified radical mastectomy or breast sparing surgery. Patients must have recovered from all side effects of the surgery.  
• Patients must be planning to receive one of the standard taxane-based systemic adjuvant chemotherapy regimens for their breast cancer as outlined below. (Participants may be receiving this treatment as part of a clinical trial.) Combined chemo/hormone therapy is allowed. No prior taxane therapy is allowed for any reason.  
• Prior neoadjuvant chemotherapy is allowed (but it must not have included a taxane).  
• Prior adjuvant chemotherapy (e.g., AC) is allowed. Study enrollment must occur post-operatively and prior to any taxane administration.  
• Allowed chemotherapy regimens:  
  - Paclitaxel at 80 mg/m² weekly x 12 weeks (12 weeks total)  
  - Paclitaxel at 175 mg/m² every other week (QOW) x 4 cycles (8 wks. total)  
  - Paclitaxel at 175 mg/m² every other week (QOW) x 6 cycles (12 weeks total)  
  - Docetaxel at 75 mg/m² q 3 weeks x 4 cycles (12 weeks total) as part of the TC regimen (docetaxel and cyclophosphamide)  
  - Docetaxel at 75 mg/m² q 3 weeks x 6 cycles (18 weeks total) as part of the TAC regimen (docetaxel, doxorubicin, cyclophosphamide) or a TC regimen (docetaxel and cyclophosphamide OR docetaxel and carboplatin)  
• Patients must not have received prior biologic therapy for the treatment of their breast cancer, but concurrent biologic therapy is allowed.  
• Patients may not be taking Vitamin E, glutamine, gabapentin, nortriptyline, amitriptyline or duloxetine HCl. If patient is taking any of these medications, she must agree to stop at the time of registration. Multivitamins containing Vitamin E are allowed, however, Vitamin E ≥ 1,000 IU must be discontinued at the time of registration.  
• Patients must be willing to submit blood sample for DNA extraction, genotyping analysis, and nerve growth factor studies, and must be given the option to consent for specimen submission for banking and future translational medicine studies as outlined in Section 15.0. Baseline samples must be obtained prior to beginning treatment.  
• Patients must have adequate renal function as documented by a serum creatinine that is ≤ 2.5 x the institutional upper limit of normal obtained within 28 days prior to registration.  
• No history of diabetes and/or any history of neuropathy.  
• No history of a seizure disorder or be on anti-seizure medications.  
• Patients must have a Zubrod performance status of 0 - 2 | • Blinded Drug 2 capsules Oral Daily for 24 weeks (ALC* or Placebo**) three times per day (TID) for a total of six capsules per day  
• Each ALC capsule = 590 mg acetyl-L-carnitine HCl (which provides 500 mg ALC) and 10 mg cellulose  
• Each placebo capsule = 600 mg cellulose | LSUHSC Veith |
## CANCER CONTROL

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<td>See specific disease site for current cancer control studies.</td>
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## GASTROINTESTINAL

### 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

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| 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 | · 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 VGEF 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. | Arm A:  
· Bevacizumab 5mg/kg IV q 2 weeks  
· FOLFOX/FOLFIRI* q 2 weeks  
· 1 cycle = 8 weeks  

Arm B  
· Cetuximab 400mg/m2 IV on Day 1, then Cetuximab 250mg/m2 IV Weekly thereafter  
· FOLFOX/FOLFIRI* q 2 weeks  
· 1 cycle = 8 weeks  

*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).  

**Cetuximab is provided free of charge** | LSU  
MBPCC  
BRGMC  
Med Onc  
EKL  
MCLNO  
CCS |
## GASTROINTESTINAL

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| 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 | • Histologically confirmed adenocarcinoma of the colon that is Stage II (T3, 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, appendiceal 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. | High Risk Patients:  
Arm A:  
• Oxaliplatin 85mg/m² IV on Day 1  
• Leucovorin 400mg/m² IV on Day 1  
• 5-FU 400mg/m² IVP on Day 1  
• 5-FU 2.4g/m² CIVI on Days 1 and 2  
• Administer 12 2-week cycles  
Arm B:  
• Bevacizumab 5mg/kg IV on Day 1  
• Oxaliplatin 85mg/m² II on Day 1  
• Leucovorin 400mg/m² IV on Day 1  
• 5-FU 400mg/m² IVP on Day 1  
• 5-FU 2.4g/m² CIVI on Days 1 and 2  
• Administer 12 2-week cycles, then continue Bevacizumab alone for an additional 12 2-week cycles. | LSUHSC  
BRGMC  
MBPCC  
Med. Onc, LLC  
Veith, LLC  
EKL  
MCLNO  
CCS |

| IRB# 6985C: S0600 Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) or Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with Either FOLFOX, OPTIMOX or XELOX | • Metastatic colorectal cancer histologically or cytologically confirmed either from primary tumor or metastasis  
• Must have wild type KRAS  
• Must have measurable and/or non-measurable disease  
• Must have progressed on first-line chemo with bevacizumab plus either FOLFOX, OPTIMOX, or XELOX within 90 days after last bevacizumab dose and within 28 days prior to registration. Patients who discontinued oxaliplatin, continued with 5FU/LV or capecitabine and bevacizumab and then had subsequent progression while on fluoropyrimidine and bevacizumab are eligible. Patients who discontinued bevacizumab due to adverse events in first line setting are not eligible.  
• At least 14 days since last dose of first line chemotherapy and bevacizumab  
• Prior radiotherapy allowed if > 28 days since last treatment and all adverse events related to radiation resolved.  
• Prior surgery allowed if > 28 days since any major surgery and recovered from all effects  
• Zubrod performance status 0-2 | Low Risk Patients:  
Arm C: Observation  
Bevacizumab and oxaliplatin is provided free of charge for all patients | BRGMC  
EKL  
MBPCC  
Veith  
MOL  
CCS |

1 rx credit  
Arm C: 0.5 rx credit  

**Treatment Plan**  
See Section 7 for Complete Treatment Details  

Arm 1:  
Arm A: FOLFIRI or irinotecan + cetuximab  
Arm 2:  
Arm B: FOLFIRI or irinotecan + bevacizumab  

**bevacizumab and cetuximab are free-of-charge for all patients**
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| **E3205: Phase II Trial of Cetuximab Plus Cisplatin, 5-Fluorouracil and Radiation in Immunocompetent Patients with Anal Carcinoma** | • 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 | Cetuximab Plus Cisplatin, 5-Fluorouracil and Radiation  
*Cetuximab is provided free of charge* | BRGMC  
MBPCC  
Med Onc  
Veith  
MCLNO  
EKL  
CCS |
| **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"** | • 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. | Arm 1*  
• 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) | BRGMC  
MBPCC  
Veith  
Med Onc  
MCLNO  
CCS |
| | | Arm 2*  
• 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) |  
*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.  
Bevacizumab will be provided free of charge |  |
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| CALGB 80702: A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer | Documented adenocarcinoma of the colon and at least one pathologically confirmed positive lymph node.  
- Patients must not have rectal cancer (i.e., the tumor must be at least 12 cm from the anal verge).  
- Patients must have had complete resection of the tumors; if tumor is adherent to adjacent structures, patients must have documentation of en bloc R0 resection.  
- Patients must not have any evidence of residual involved lymph node disease or metastatic disease at the time of registration.  
- Patients may have synchronous colon cancers, but must not have synchronous colon and rectal primary tumors.  
- Patients must not use NSAIDs at any dose or aspirin at > 325 mg more than two times per week on average (low dose aspirin, ≤ 100 mg/day is permitted).  
- Patients must not have previous or concurrent malignancy, except treated basal cell or squamous cell skin cancer, treated in situ cervical cancer, treated lobular or ductal carcinoma in situ in one breast, or any other cancer for which the patient has been disease free for ≥ 5 years.  
- Patients must not have neurosensory or neuromotor toxicity ≥ grade 2 at time of registration.  
- Patients must not have known allergy to platinum compounds, or prior allergic reaction or hypersensitivity to sulfonamides, celecoxib or NSAIDs.  
- Patients must not have a history of upper GI ulceration, bleeding or perforation within the past 3 years.  
- Patients must not have symptomatic pulmonary fibrosis or interstitial pneumonitis ≥ grade 2.  
- Patients must not have cardiac risk factors, including uncontrolled high blood pressure (systolic BP >150), unstable angina, history of documented myocardial infarction or cerebrovascular accident; or NYHA class II or IV heart failure.  
- ECOG performance status 0, 1, or 2. | Treatment must begin between 21 and 56 days after definitive surgical resection of primary tumor and within 14 days of randomization.  
One cycle = 14 days of treatment  
Medications:  
**FOLFOX:** Oxaliplatin 85 mg/m² IV over 2 hours followed by Leucovorin 400 mg/m² IV over 2 hours (may be administered concurrently via separate infusion lines) followed by 5-FU 400 mg/m² IV bolus, then 2400 mg/m² continuous IV infusion over 46-48 hours.  
**Celecoxib:** 400 mg daily PO  
**Arm A:** 12 cycles of FOLFOX + Placebo daily  
**Arm B:** 12 cycles of FOLFOX + Celecoxib daily  
**Arm C:** 6 cycles of FOLFOX + Placebo daily  
**Arm D:** 6 cycles of FOLFOX + Celecoxib daily  
Celecoxib/placebo will continue for 3 years or until unacceptable toxicity. | EKL MBP CCS Veith |
| NSABP PROTOCOL P-5 Statin Polyp Prevention Trial in Patients with Resected Colon Cancer | **Selected eligibility criteria:**  
- Resected adenocarcinoma of the colon staged as AJCC Stage I or II  
- Surgical resection of the colon adenocarcinoma with curative intent within 1 year prior to randomization (laparoscopically-assisted colectomy is permitted)  
- Patients must > 18 years old  
- Adjuvant therapy, if given, must be completed before randomization  
- Patients taking cardioprotective low-dose aspirin must be able and willing to continue at the same dose  
- Colonoscopy (preop or postop) to the cecum or small bowel anastomosis with removal of all observed polyps within 180 days prior to randomization | **P-5 study therapy**  
- Each patient will take 1 tablet of the P-5 study drug once daily for 5 years. Patients will take either:  
  - rosvastatin 10 mg (one tablet) orally without regard to meals, once a day for 5 years, or  
  - placebo (one tablet) orally without regard to meals, once a day for 5 years.  
This is a double-blind trial. Neither the patient nor the investigator/health care providers will know the treatment assignment until the completion of the trial. | MBP EKL CCS Veith |
- Within 90 days prior to randomization:
  - Serum creatinine must be < 1.5 x ULN
  - AST or ALT < 3.0 x ULN and total bilirubin must be < 1.5 x ULN (If AST & ALT obtained, both must be < 3.0 x ULN)

**Selected ineligibility criteria:**
- Tumor with the distal border located <12 cm from the anal verge
- Total colectomy or total proctocolectomy
- Classic Familial Adenomatous Polyposis, Attenuated Familial Adenomatous Polyposis, or Hereditary Nonpolyposis Colorectal Cancer (Lynch Syndrome)
- Statin use within 30 days prior to randomization
- Hyperlipidemia with clinical indication for statin therapy
- Chronic use of therapeutic aspirin (doses > 325 mg) or use of NSAIDs for more than an average of 3 days per month
- Malabsorption syndrome, ulcerative colitis, inflammatory bowel disease, resection of the stomach or small bowel, or other disease significantly affecting GI function
- Hypersensitivity or intolerance to statins
- Unwillingness to discontinue chronic use of NSAIDs other than cardioprotective low-dose aspirin.
### GENITOURINARY

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<td><strong>R0526: A Prospective Phase II Trial Of Transperineal Ultrasound-Guided Brachytherapy For Locally Recurrent Prostate Adenocarcinoma Following External Beam Radiotherapy</strong></td>
<td><strong>Biopsy-documented locally recurrent prostatic adenocarcinoma &gt; 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).</strong>&lt;br&gt;<strong>Disease-related characteristics at initial diagnosis (i.e., prior to EBRT) that fit one of the following categories (Appendix III):</strong>&lt;br&gt;- Stages T1-T2c, Gleason scores 2-6, and PSA ≤ 20 ng/mL, or&lt;br&gt;- Stages T1-T2c, Gleason score 7, and PSA ≤ 10 ng/mL&lt;br&gt;- Baseline serum PSA value &lt; 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.&lt;br&gt;- Treatment must begin within 8 weeks of registration.</td>
<td>Prostate brachytherapy*&lt;br&gt;*96 patients will receive either 125-iodine (I-125) 140 Gy minimum target dose or 103-palladium (Pd-103) 120 Gy minimum target dose.</td>
<td>BRGMC MBPCC</td>
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1 rx credit

| **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** | **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 (undi dissected pelvic LNs [pNx])**<br>**Post-prostatectomy PSA of ≥ 0.1 and < 2.0 ng/mL**<br>**Disease must be pathologic T3N0/Nx or pathologic T2N0/Nx with or without a positive prostatectomy margin.**<br>**There must be no distant metastases.**<br>**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.**<br>**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).**<br>**Patients must not have received androgen deprivation therapy that was started prior to prostatectomy for > 6 months duration.**<br>**Patients must not have received androgen deprivation therapy that was started after prostatectomy and prior to registration.**<br>**Patients must not have had prior pelvic radiotherapy.** | Arm 1:<br>PBRT alone RT to prostate bed to 64.8-70.2 Gy | Arm 2:<br>PRBT plus NC-STAD LHRH agonist injections to cover 4-6 months<br>E.g., leuprolide, goserelin, triptorelin Antiandrogen for 4-6 months<br>Flutamide or bicalutamide<br>RT to prostate bed to 64.8-70.2 Gy beginning 2 months after start of drug therapy | Arm 3:<br>PLNRT plus PBRT plus NC-STAD LHRH agonist injections to cover 4-6 months<br>E.g., leuprolide, goserelin, triptorelin Antiandrogen for 4-6 months<br>Flutamide or bicalutamide<br>RT to pelvic lymph nodes to 45 Gy beginning 2 months after start of drug therapy<br>RT to prostate bed to 64.8-70.2 Gy beginning 2 months after start of drug therapy | BRGMC MBPCC CCS |

1.5 rx credits

PBRT = prostate bed radiation therapy<br>PLNRT = pelvic lymph node radiation therapy<br>NC-STAD = neoadjuvant and concurrent short term androgen deprivation.
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| **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** | 1 rx credit | 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)  

*Bevacizumab, temsirolimus and sorafenib are provided free of charge* | BRGMC  
MBPCC  
LSUHSC  
Veith  
MOL  
EKL  
MCLNO  
CCS |
| **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** | 1.5 rx credits | Arm A: Docetaxel 75 mg/m² IV Day 1q 21 days x 6 cycles *Concurrently with*  
LHRH agonist x 18-24 weeks  
Followed within 60 days by  
Staging pelvic lymphadenectomy  
Radical Prostatectomy*  

*Docetaxel supplied free of charge* | MBPCC  
BRGMC  
LSUHSC  
Veith  
MOL  
MCLNO |
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| 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 | 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 | Double-Blinded  
- Zoledronic acid: 4 mg IV Q 4 wks  
or  
- Placebo: IV Q 4 wks | MBPCC  
BRGMC  
LSUHSC  
Veith  
MOL  
CCS  
MCLNO |
| CALGB 70604: A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer 1 cc credit | Histo confirmed adenocarcinoma of prostate or breast or MM  
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 0-1 | zoledronic acid (every 12 weeks) versus zoledronic acid (every 4 weeks) | BRG  
MBPCC  
Veith  
CCS  
LSUHSC  
MOL  
MCLNO |
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<td>CALGB 90601: A Randomized Double Blind Phase III Study comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, cisplatin and Placebo in Patients with Advanced Transitional Cell Carcinoma</td>
<td>Histologically documented metastatic or unresectable transitional cell carcinoma of the urinary tract (renal pelvis, ureter, bladder, prostate, or urethra), with progressive metastatic or locally advanced disease. Patients must not be candidates for potentially curative surgery or radiotherapy.</td>
<td>Gemcitabine 1000mg/m² IV on Day 1 and Day 8 of every cycle, Cisplatin 70mg/m² IV on Day 1 and Placebo 15mg/kg IV on Day 1 every 21 days for 6 cycles then placebo 15mg/kg IV every 21 days Versus Gemcitabine 1000mg/m² IV on Day 1 and Day 8 of every cycle, cisplatin 70mg/m² IV on Day 1, and Bevacizumab 15mg/kg IV on Day 1 Then Bevacizumab 15mg/kg IV every 21 days</td>
<td>Veith MBPCC CCS</td>
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<td>E3805: CHAARTED: ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease Prostate Cancer</td>
<td>Histologically or cytologically confirmed prostate cancer with metastatic disease.</td>
<td>Arm A: - Androgen Deprivation Therapy* - Docetaxel pre-meds - 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 Arm B: - Androgen Deprivation Therapy* - Calcium Carbonate 500mg/day PO - Vitamin D ≥ 400 IU PO</td>
<td>*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</td>
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*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.
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| **E1305: A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer** | • 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 clear cut measurements can be made). | Arm A: Cisplatin plus Docetaxel OR Cisplatin plus 5-FU.  
Vs.  
Arm B: Docetaxel plus Cisplatin plus Bevacizumab OR Cisplatin plus Bevacizumab plus 5-FU. | MBPCC  
BRGMC  
LSUHSC  
Veith  
MOL  
MCLNO  
CCS  
EKL |
| **RTOG 0920: A PHASE III STUDY OF POSTOPERATIVE RADIATION THERAPY (IMRT) +/- CETUXIMAB FOR LOCALLY-ADVANCED RESECTED HEAD AND NECK CANCER** | • *Patients must have histologically proven diagnosis of squamous cell carcinoma of the head/neck (oral cavity, oropharynx or larynx; hypopharynx primaries not allowed).*  
• *Patients must have diagnosis of clinical stage T1, N1-2 or T2-3, N0-2, M0 including no distant metastases ≤ 8 weeks of registration.*  
• *Patients must have had gross total resection of primary tumor with curative intent ≤ 7 weeks prior to registration with surgical pathology demonstrating at least one of the following “intermediate” risk factors: perineural invasion; lymphovascular invasion; single lymph node > 3 cm or ≥ 2 lymph nodes (all < 6 cm) [no extracapsular extension]; close margin(s) of resection, defined as cancer extending to within 5 mm of a surgical margin; T3 or microscopic T4a primary tumor; T2 oral cavity cancer with > 5 mm depth of invasion.*  
• *Patients must not have prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for ≥ 3 years.*  
• *Patients may not have simultaneous primaries or bilateral tumors.*  
• *Patients must not have positive margin(s) [defined as tumor present at the cut or inked edge of the tumor], nodal extracapsular extension, and/or gross residual disease after surgery.*  
• *Patients must not have had prior systemic chemotherapy or anti-EGF therapy for the study cancer.* | Arm 1: Radiation Therapy  
Radiation for a total dose of 60 Gy in 30 fractions of 2 Gy/day  
Arm 2: Radiation Therapy + Cetuximab  
Cetuximab initial dose of 400 mg/m2 IV x 1 dose  
Followed at least 5 days later by:  
Radiation for a total dose of 60 Gy in 30 fractions of 2 Gy/day  
Cetuximab 250 mg/m2 IV q week x 6 weeks concurrently with RT.  
Followed by:  
Cetuximab 250 mg/m2 IV q week x 4 weeks post--RT. | EKL  
MBP  
CCS |
- Patients must not have had prior RT to the region of the study cancer that would result in overlap of RT fields.
- Patients must not have had allergic reaction to cetuximab.
- Patients must not be eligible for an RTOG “high risk” head and neck cancer protocol (e.g., RTOG 0619).

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<td>IRB# 5486: S9925, Lung Cancer Specimen Repository Protocol, Ancillary Ancillary</td>
<td>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.</td>
<td>Lung Cancer Specimen Repository Protocol, Ancillary</td>
<td>BRGMC MBPCC Veith MOL</td>
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| LUNG  | - 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. | **Arms A and C:**  
- 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  
  - Radiation Therapy (IMRT or 3DCRT)  
  - 2 Gy per fraction 5 days a week for 6 weeks  
  - Total dose = 60 Gy in 30 fractions  
**Arms B and D:**  
- 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  
  - Radiation Therapy (IMRT or 3DCRT)  
  - 2 Gy per fraction 5 days a week for 7.5 weeks  
  - Total dose = 74 Gy in 37 fractions  
**Following completion of combined therapy:**  
**Consolidation chemotherapy:**  
- Arm A: Paclitaxel and Carboplatin Days 64 and 85  
- Arm B: Paclitaxel and Carboplatin Days 71 and 92  
- Arm C: Paclitaxel and Carboplatin Days 71 and 92  
  - Cetuximab Days 50, 57, 64, 71, 78, 85, 92, 99, 106  
- Arm D: Paclitaxel and Carboplatin Days 78 and 99  
  - Cetuximab Days 57, 64, 71, 78, 85, 92, 99, 106, 113 | MBPCC  
BRG  
EKL  
CCS  
MCLNO |

1 rx credit  
0.5 cc credit
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| 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) | - 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. | **Arm A:**  
- Chemotherapy*  
- 4 21-day cycles  
**Arm B:**  
- 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)  
*Chemotherapy Options—Must be chosen prior to randomization  
- Vinorelbine 30 mg/m2 IV Days 1 and 8  
- Cisplatin 75 mg/m2 IV Day 1  
- Docetaxel 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 | BRG  
MBPCC  
Veith  
MOL  
MCLNO  
CCS |
| 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 | - histo or cyto stage IIIB/IV NSCLC  
- no brain mets, spinal compression, carcinomatous meningitis  
- no cavity 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-II 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 | **sunitinib or placebo**  
**sunitinib is free of charge** | BRG  
MBPCC  
Veith  
MOL  
EKL  
LKRMC  
MCLNO  
CCS |
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| 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)" | • 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 | Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab | BRG  
MBPCC  
Veith  
MOL  
CCS  
Pending MCLNO |

1 rx credit
### LUNG

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<td>IRB# 7239: S0802, &quot;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)&quot;</td>
<td>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.</td>
<td>Arm 1: AVE0005 plus topotecan Arm 2: Single-agent topotecan</td>
<td>BRG MBPCC Veith CCS MCLNO EKL</td>
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1 rx credit

### LYMPHOMA

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<td>IRB# 1576: S8947; Central Lymphoma Serum Repository Protocol ANCILLARY</td>
<td>For patients registered to a currently active Southwest Oncology Group-coordinated treatment protocol for previously untreated non-Hodgkin’s lymphoma.</td>
<td>Central Lymphoma Serum Repository Protocol</td>
<td>BRGMC MBPCC</td>
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0 rx credits
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### MELANOMA

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| IRB# 7287: S0826, "A Phase II Study of SCH 727965 in Stage IV Melanoma" | Biopsy-proven malignant melanoma of cutaneous or mucosal origin  
No ocular melanoma.  
Stage IV disease.  
Unknown primary eligible.  
Must be offered submission/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 | BRG  
MBPCC  
Veith  
CCS  
LSUHSC  
MOL  
EKL |

### MULTIPLE MYELOMA

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| CALGB 70604: A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer | 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) | BRG  
MBPCC  
Veith  
CCS  
LSUHSC  
MOL  
MCLNO |
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 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 more than 50% of waking hours.
4  Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5  Dead