

OPEN STUDIES UPDATE: MAY 2012

Hartford Hospital Cancer Clinical Research Office (Ext. 5-5363)

CCRO Patient Referral Line (Ext. 5-4700)

Breast Cancer Clinical Trials (NEOADJUVANT)

<u>Cooperative Group/Industry Sponsor:</u>	<u>Trial Title:</u>	<u>Inclusion Criteria:</u>
NSABP FB-7 Patricia Hinckley, RN Ext. 5-4062	A Phase II Randomized Clinical Trial Evaluating Neoadjuvant Therapy Regimens with Weekly Paclitaxel and Neratinib or Trastuzumab Followed by Doxorubicin and Cyclophosphamide with Postoperative Trastuzumab in Women with Locally Advanced HER2-Positive Breast Cancer	Fresh core biopsy sample required prior to randomization. ER/PR +/- HER2 +

Breast Cancer Clinical Trials (ADJUVANT)

<u>Cooperative Group/Industry Sponsor:</u>	<u>Trial Title:</u>	<u>Inclusion Criteria:</u>
NSABP B-39 Patricia Hinckley, RN Ext. 5-4062	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	DCIS < 49 years + ER/PR Node (-) Invasive + ER/PR Node (+) Invasive + ER/PR NO Node (-) Invasive ER/PR (+) > 50 yo
NSABP B-43 (NCCCP Endorsed) Patricia Hinckley, RN Ext. 5-4062	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	DCIS resected lumpectomy, Pre-HER2 central testing required prior to study entry, must be HER2 (+), ER/PR (+) (-)
NSABP B-47 Patricia Hinckley, RN Ext. 5-4062	A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer	Resected node +/-high risk node - HER2 low / IHC score (1+, 2+) 2+ requires FISH or CISH testing ER/PR +/-
NCIC MA.32 Patricia Hinckley, RN Ext. 5-4062	A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer	Dx of invasive breast cancer Enrolled within 12 months of dx. Must have SLN bx or axillary dissection Surgery /and or chemotherapy completed 4 weeks prior to randomization Can be receiving herceptin, avastin, endocrine therapy, RT ER, PR, Her2 status must be known PS 0-2 Ineligible if type 1 or 2 diabetes or baseline fasting glucose 126 mg/dL

Breast Cancer Clinical Trials (MISCELLANEOUS)

<p>Nipple Sparing Study Patricia Hinckley, RN Ext. 5-4062</p>	<p>Outcomes of Nipple Sparing Mastectomy</p>	<p>Patients > 18 years of age requiring mastectomy for cancer tumor clinically T1 or T2 and <3 cm, no multicentric tumors, no current smoking, no tumor involvement in nipple or axillary nodes</p>
--	--	---

Gastrointestinal Cancer Clinical Trials

Cooperative Group/Industry Sponsor:	Trial Title:	Inclusion Criteria:
<p>CALGB 80702 (NCCCP Endorsed)</p>	<p>A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients With Resected Stage III Colon Cancer</p>	<p>At least 12 cm from anal verge No NSAIDS except low dose ASA < 100 mg qd</p>
<p>NSABP P-5 (NCCCP Endorsed) Patricia Hinckley, RN Ext. 5-4062</p>	<p>Statin Polyp Prevention Trial in Patients with Resected Colon Cancer</p>	<p>Stage I + II rosuvastatin vs. placebo (x 5 years) cannot be taking statins for high cholesterol already</p>
<p>CHESS Colon Survivorship Kathy Alexander, CRA Ext. 5-3553</p>	<p>Evaluating an Interactive Cancer Communication System (ICCS) Directed Physical Activity Enhancement for Colon Cancer Survivors</p>	<p>Stage I, II, or III colon cancer Completed chemotherapy (no radiation) w/in the last 12months, <3 hours per week of physical activity, be able to participate in unsupervised exercise, >21 years of age, comfortable reading English</p>
<p>RTOG 0848</p>	<p>A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma</p>	<p>Histologic proof of primary head of pancreas invasive adenocarcinoma tx w/potentially curative resection via Whipple procedure or a pylorus preserving pancreaticoduodenectomy, invasive adenocarcinoma + component of IPMN are eligible.</p>
<p>Clovis Oncology/CO-101-001 CLOSED TO ACCRUALS</p>	<p>A Phase II Randomized, Open-Label, Multicenter Study Comparing CO-1.01 With Gemcitabine as First-Line Therapy in Patients with Metastatic Pancreatic Adenocarcinoma</p>	<p>Metastatic pancreatic ductal carcinoma, adjuvant chemo/radiotherapy allowed ≥ 6 mos prior to randomization, ECOG 0 or 1, No radical pancreatic resections < 6 mos prior to randomization</p>

Genitourinary Cancer Clinical Trials

Cooperative Group/Industry Sponsor:	Trial Title:	Inclusion Criteria:
<p>CALGB 90203</p>	<p>A 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</p>	<p>Prostate adenocarcinoma T1-T3, M0 No evidence of metastatic disease. No prior treatment for prostatic adenocarcinoma including radiation, chemotherapy, and</p>

	Prostate Cancer	surgery (excluding TURP).
Dana Farber 05-043	Docetaxel Plus 6-month Androgen Suppression and Radiation Therapy Versus 6-month Androgen Suppression and Radiation Therapy for Patients With High Risk Localized or Locally Advanced Prostate Cancer: A Randomized Controlled Trial	No metastatic disease. Clinical category T2c, T3b, or T4; OR T1b to T2b AND either PSA>10ng/ml, Gleason score \geq (4+3=7); OR any minor tertiary grade of 5; OR Gleason score \geq (3+4=7) with at least 50% cores +; OR >2.0 ng/ml rise in PSA in year prior to tx (or average of 2.0 in prior 3 years); OR + radiographic finding of SVI by MRI or biopsy.
CALGB 90601	A randomized double-blinded Phase III study comparing gemcitabine, cisplatin, and bevacizumab to gemcitabine, cisplatin, and placebo in patients with Advanced transitional cell carcinoma	Histologically documented metastatic or unresectable transitional cell carcinoma of the urinary tract, no prior combo chemotherapy for metastatic disease, Radiosensitizing single agent chemo is allowed, no prior tx w/bevacizumab or other angiogenesis inhibitors, interval from end of therapy w/neoadjuvant or adjuvant therapy to dx of met. disease is at least 1 year
CALGB 90802	Randomized Phase III Trial Comparing Everolimus Plus Placebo Versus Everolimus Plus Bevacizumab for Advanced Renal Cell Carcinoma Progressing After Treatment with Tyrosine Kinase Inhibitors	Stage IV, path proven, metastatic renal carcinoma w/clear cell component, must have failure of at least 1 prior VEGFR TKI therapy defined as progressive disease or treatment intolerance, no prior systemic therapy with either VEGF binding or mTOR inhibitor, prior cytokine therapy is allowed.

Gynecologic Cancer Clinical Trials (CERVICAL)

<u>Cooperative Group:</u>	<u>Trial Title:</u>	<u>Inclusion Criteria:</u>
GOG 227G Karen Cuddy, RN Ext. 5-5361	A Phase II evaluation Of Brivanib (BMS582664, IND #108417) In The treatment of persistent or recurrent carcinoma of the cervix	Measurable disease; must have 1 prior systemic chemo; can have additional cytotoxic regimen
GOG 233 Karen Cuddy, RN Ext. 5-5361	Utility of Preoperative FDG-PET/CT Scanning to Detect Retroperitoneal Lymph Node Metastasis in Patients with Locoregionally Advanced Carcinoma of the Cervix and High Risk Endometrial Cancer	Cervical Cancer: stages IB2, IIA > 4 cm, IIB-IVA, no prior tx, no mets outside pelvis or abd nodes, candidate for chemo RT, no prior pelvic RT Endometrial Cancer: grade 3 endometriod; clear cell, pap serous or carcinosarcoma (any grade); grade 1 or 2 endometriod w/ stromal inv; no mets outside pelvis or abd nodes, no prior pelvic RT

<p>GOG 237 Karen Cuddy, RN Ext. 5-5361</p>	<p>A Comparative Analysis of CA-IX,p16,Proliferative Markers and Human Papilloma Virus (HPV) in the Diagnosis of Significant Cervical Lesions in Patients with a Cytologic Diagnosis of Atypical Glandular Cells (AGC)</p>	<p>Must wait 1 week after dx. LBC specimen No hyst, No HIV No chemo/no XRT If pregnant no bleeding risk No hx endo hyperplasia No hx endo, vag, or cerv ca</p>
---	--	---

Gynecologic Cancer Clinical Trials (ADJUVANT)

<u>Cooperative Group:</u>	<u>Trial Title:</u>	<u>Inclusion Criteria:</u>
<p>GOG 212 Karen Cuddy, RN Ext. 5-5361</p>	<p>A Randomized Phase III Trial of Maintenance Chemotherapy Comparing 12 Monthly Cycles of Single Agent Paclitaxel or Xyotax vs. No Treatment Until Documented Relapse in Women with Advanced Ovarian or Primary Peritoneal Cancer Who Achieve A Complete Clinical Response to Primary Platinum/Taxane Chemotherapy</p>	<p>Optimal or suboptimal debulked 5-8 platinum cycles with normal CT and CA-125</p>
<p>GOG 235 Karen Cuddy, RN Ext. 5-5361</p>	<p>A prospective, longitudinal study of YKL-40 in patients with Figo stage III or IV invasive epithelial ovarian, primary peritoneal, or fallopian tube cancer undergoing primary chemotherapy.</p>	<p>Cell types: serous, mucinous, endometriod, clear cell, transitional, mixed epithelial, undifferentiated, adenocarcinoma, NOS, malignant Brennan tumor are eligible</p>
<p>Moffitt NCI 8489</p>	<p>A phase II evaluation of SJG-136 in women with cisplatin-refractory or resistant epithelial ovarian, primary peritoneal, or fallopian tube carcinoma</p>	<p>Must have had one prior platinum-based chemo regimen, no more than 3 prior treatment regimens.</p>

Gynecologic Cancer Clinical Trials (ADVANCED/RECURRENT/METASTATIC)

<u>Cooperative Group:</u>	<u>Trial Title:</u>	<u>Inclusion Criteria:</u>
<p>GOG 186G Karen Cuddy, RN Ext. 5-5361</p>	<p>A Phase II Randomized, Double-Blinded Evaluation of Oral Everolimus (RAD001) Plus Bevacizumab vs. Oral Placebo Plus Bevacizumab in the Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer</p>	<p>One prior platinum; can have 2 additional cytotoxic regimens, no more than 1 non-platinum, non-taxane regimens; can have biologic (non-cytotoxic) as part of primary tx but NOT for recurrent/persistent disease; measurable or detectable disease</p>
<p>GOG 186J Karen Cuddy, RN Ext. 5-5361</p>	<p>A Randomized Phase IIB Evaluation of weekly Paclitaxel plus Pazopanib versus weekly Paclitaxel plus Placebo in the treatment of persistent or recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma</p>	<p>One prior platinum containing Carboplatin, Cisplatin or another Organoplatinum compound; can have 2 additional cytotoxic regimens; no mor than 1 non-platinum, non-taxane regimens; can have biologic (non-cytotoxic) as part of</p>

		primary treatment
GOG 187 Karen Cuddy, RN Ext. 5-5361	Phase II Study of Paclitaxel for Ovarian Stromal Tumors as Second-Line Therapy	Measurable disease, 2nd line must have had 1 chemo, no XRT, not cured w/ surg
GOG 213 Karen Cuddy, RN Ext. 5-5361	A Randomized Controlled Clinical Trial of Carboplatin & Paclitaxel Alone or in Combination with Bevacizumab Followed by Bevacizumab & Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Primary Peritoneal Cancer & Fallopian Tube Cancer	CR to > 3 cycles platinum tx tx free interval > 6 months UPCR < 1, No XRT, PN < gr 2
GOG 233 Karen Cuddy, RN Ext. 5-5361	Utility of Preoperative FDG-PET/CT Scanning to Detect Retroperitoneal Lymph Node Metastasis in Patients with Locoregionally Advanced Carcinoma of the Cervix and High Risk Endometrial Cancer	Cervical Cancer: stages IB2, IIA > 4 cm, IIB-IVA, no prior tx, no mets outside pelvis or abd nodes, candidate for chemo RT, no prior pelvic RT Endometrial Cancer: grade 3 endometriod; clear cell, pap serious or carcinosarcoma (any grade); grade 1 or 2 endometriod w/ stromal inv; no mets outside pelvis or abd nodes, no prior pelvic RT
GOG 259 Karen Cuddy, RN Ext. 5-5361	Nurse-delivered WRITE Symptoms© vs. Self-directed WRITE Symptoms© vs. Care as Usual for Optimal Symptom Management for Women with Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Recurrent or persistent, 3 + symptoms, Patient must read & write English, access to internet

Gynecologic Cancer Clinical Trials (UTERINE)

Cooperative Group:	Trial Title:	Inclusion Criteria:
GOG 130F Karen Cuddy, RN Ext. 5-5361	A Phase II evaluation of Ixabepilone in the treatment of recurrent or persistent carcinosarcoma of the uterus.	path=MMMT, measurable disease, 1 prior chemo; if no prior taxane therapy, must have 2nd regimen which includes taxane
GOG 229J Karen Cuddy, RN Ext. 5-5361	A Phase II Evaluation of Cediranib in The treatment of recurrent or persistent endometrial carcinoma	Must have 1 prior chemo regimen for endometrial carcinoma; may have 1 additional cytotoxic regimen for recurrent/persistent disease; No prior non cytotoxic chemo for recurrent or resistant disease;

		must have measurable disease
GOG 233 Karen Cuddy, RN Ext. 5-5361	Utility of Preoperative FDG-PET/CT Scanning to Detect Retroperitoneal Lymph Node Metastasis in Patients with Locoregionally Advanced Carcinoma of the Cervix and High Risk Endometrial Cancer	Cervical Cancer: stages IB2, IIA > 4 cm, IIB-IVA, no prior tx, no mets outside pelvis or abd nodes, candidate for chemo RT, no prior pelvic RT Endometrial Cancer: grade 3 endometriod; clear cell, pap serious or carcinosarcoma (any grade); grade 1 or 2 endometriod w/ stromal inv; no mets outside pelvis or abd nodes, no prior pelvic RT
GOG 238 Karen Cuddy, RN Ext. 5-5361	A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus.	Positive TAH/BSO, dx & bx to confirm recurrence, no extra pelvic disease, est. survival > 3 months
GOG 249 Karen Cuddy, RN Ext. 5-5361	A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Carcinoma	Positive hyst, - pelvic and PALN Stage I-IIA with risk factors Stage IIB + or - risk factors Stage I-II B serous or clear cell + or - other risk factors
GOG 250 Karen Cuddy, RN Ext. 5-5361	A Randomized Phase III Evaluation of Docetaxel and Gemcitabine Plus G-CSF with Bevacizumab versus Docetaxel and Gemcitabine Plus G-CSF with Placebo in the Treatment of Recurrent or Advanced Leiomyosarcoma of the Uterus. NCI-Supplied Agent Bevacizumab	Advanced or recurrent, chemo naïve, histologic confirmation of the original tumor required, must be measurable, UPCR < 1, no hx other ca, cardiac parameters
GOG 258 Karen Cuddy, RN Ext. 5-5361	A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma	Not recurrent, stage III -IVA, residual tumor must be < 2cm, no prior RT, survival > 3 months
GOG 261 Karen Cuddy, RN Ext. 5-5361	A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus	May have had RT, PS 0-2, no prior cancer, no planned radiotherapy
Moffitt NCI 8489	A phase II evaluation of SJG-136 in women with cisplatin-refractory or resistant epithelial ovarian, primary peritoneal, or fallopian tube carcinoma	Must have had one prior platinum-based chemo regimen, no more than 3 prior treatment regimens.

Gynecologic Cancer Clinical Trials (MISCELLANEOUS)

<p>GOG 235 Karen Cuddy, RN Ext. 5-5361</p>	<p>A Prospective, Longitudinal Study oYKL-40 in Patients with FIGO stage III or IV Invasive Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer Undergoing Primary Chemotherapy.</p>	<p>Tumor marker comparison, no prior chemo, no neoadjuvant chemo, no chronic inflammatory problems</p>
<p>GOG 259 Karen Cuddy, RN Ext. 5-5361</p>	<p>Nurse-delivered WRITE Symptoms© vs. Self-directed WRITE Symptoms© vs. Care as Usual for Optimal Symptom Management for Women with Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer</p>	<p>Recurrent or persistent, 3 + symptoms read & write English, access to internet</p>
<p>Moffitt NCI 8489</p>	<p>A phase II evaluation of SJG-136 in women with cisplatin-refractory or resistant epithelial ovarian, primary peritoneal, or fallopian tube carcinoma.</p>	<p>Must have one had one prior platinum-based chemo regimen, no more than 3 prior treatment regimens.</p>

Lung Cancer Clinical Trials

<u>Cooperative Group:</u>	<u>Trial Title:</u>	<u>Inclusion Criteria:</u>
<p>ECOG E1505</p>	<p>A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (> 4cm)-IIIA Non-Small Lung Cancer</p>	<p>Stage 1B-IIIA Randomize between 6- 12 weeks after surgery Stratified based upon chemo (patients with squamous cell cannot receive pemetrexed), stage, histology & gender</p>
<p>ECOG E5508</p>	<p>Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed or Both Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Stage Non-Squamous Non-Small Cell Lung Cancer</p>	<p>Stage IIIB-T4Nx/and IV M1a, M1b, recurrent , nonsquamous NSCL Maintenance Adjuvant chemo allowed ≥ 12 months before registration Can have radiotherapy ≥ 3 weeks prior, but not during treatment.</p>

Leukemia Clinical Trials

<u>Cooperative Group:</u>	<u>Trial Title:</u>	<u>Inclusion Criteria:</u>
<p>CALGB 10404</p>	<p>A randomized, Phase II study of three Fludarabine/antibody combinations for patients with symptomatic, previously untreated Chronic Lymphocytic Leukemia</p>	<p>Must have moderate or high risk categories of the modified, three stage system</p>

Lymphoma Clinical Trials

Cooperative Group/Industry Sponsor:	Trial Title:	Inclusion Criteria:
Novartis PILLAR-2	A randomized, double-blind, placebo-controlled, multi-center Phase III Study of RAD001 adjuvant therapy in poor risk patients with Diffuse Large B-Cell Lymphoma (DLBCL) of RAD001 vs. matching placebo after patients have achieved complete response with first-line Rituximab chemotherapy	IPI Score 3-5, stage III or IV (or stage II bulky disease, defined as any tumor mass more than 10cm in longest diameter), CR after 5-8 cycles of R-CHOP OR EPOCH-R, last dose of R-chemotherapy 6-14 weeks prior to study entry

Lymphoma Clinical Trials

CALGB 50303	A Phase III study of R-CHOP vs. dose-adjusted EPOCH-R w/molecular profiling in untreated de novo Diffuse Large B-Cell Lymphomas (DLBCL) .	CD20(+) DLBCL with stage II, III, or IV
--------------------	--	--

Melanoma Clinical Trials

ECOG E1609	A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High Dose Interferon a-ab for Resected High-Risk Melanoma	Patients must have been completely surgically resected; surgically rendered free of disease with negative margins. Patients must have primary cutaneous melanoma belonging to IIIB, IIIC or IV. Must be randomized within 12 weeks of surgical resection. No prior chemotherapy/biotherapy/limb perfusion allowed; prior radiation okay if completed >30 days of tx.
-------------------	---	--

Clinical Trials (MISCELLANEOUS)

Cooperative Group/Industry Sponsor:	Trial Title:	Inclusion Criteria:
NCI: PRO-CTCAE (NCCCP Endorsed) Kathy Alexander, CRA Ext. 5-3553	Quality of Care: Testing the Electronic Pt. Reported Outcomes Version of the Common Terminology Criteria for Adverse Events in the Community Setting (PRO-CTCAE)	Patients with any cancer receiving chemotherapy or targeted agent therapy in first cycle, or radiation therapy > 21 days
MOFFITT Total Cancer Care Jess Bello or Lin Skiff Ext. 5-4666	Tissue and clinical data will be used to create a centralized data and tissue repository to improve capacity to predict diagnosis, prognosis and response to therapy for cancer patients.	For probable and diagnosed cancer patients
Alexion Pharmaceuticals (PNH Registry)	Paroxysmal Nocturnal Hemoglobinuria (PNH) Registry	Patients who are receiving Soliris for any indication or PNH patients that are not on Soliris treatment

<p>Janssen Karen Cuddy ext. 5-5361 **ALL SUB-INVESTIGATORS MUST COMPLETE PROTOCOL TRAINING PRIOR TO ENROLLING PARTICIPANTS**</p>	<p>A Randomized Controlled study of YONDELIS (Trabectedin) or Dacarbazine for the Treatment of Advanced Liposarcoma or Leiomyosarcoma Previously Treated with an Anthracycline and Ifosfamide</p>	<p>Histological confirmation of Liposarcoma or Leiomyosarcoma, prior treatment with a regimen containing at least an anthracycline and ifosfamide (combined or sequential)</p>
--	---	---

CHES Quality of Life/Survivorship Trials

Cooperative Group/Industry Sponsor:	Trial Title:	Inclusion Criteria:
<p>CHES Colon Survivorship Kathy Alexander, CRA Ext. 5-3553</p>	<p>Evaluating an Interactive Cancer Communication System (ICCS) Directed Physical Activity Enhancement for Colon Cancer Survivors.</p>	<p>Stage I, II, or III colon cancer Completed chemotherapy (no radiation) w/in the last 12 months, <3 hours per week of physical activity, be able to participate in unsupervised exercise, >21 years of age, comfortable reading English</p>

COMING SOON

Cooperative Group/Industry Sponsor:	Trial Title:	Inclusion Criteria:
<p>Sanofi-Aventis EFC11784</p>	<p>Randomized, Open Label Multi-Center Study Comparing Cabazitaxel at 25 mg/m² and at 20 mg/m² in Combination with Prednisone Every 3 Weeks to Docetaxel in Combination with Prednisone in Patients with Metastatic Castration Resistant Prostate Cancer Not Previously Treated With Chemotherapy</p>	<p>Histological/cytological confirmation of prostate adenocarcinoma, progressive disease while receiving hormonal therapy or after surgical castration, No prior chemo for prostate cancer except estramustine and except adjuvant/neoadjuvant treatment completed > 3 years ago, No prior isotope therapy, whole pelvic radiotherapy or radiotherapy > 30% of bone marrow</p>
<p>Celldex Pharmaceuticals</p>	<p>An International, Randomized, Double-Blind, Controlled Study of Rindopepimut/GM-CSF with Adjuvant Temozolomide in Patients with Newly Diagnosed, Surgically Resected, EGFRvIII-positive Glioblastoma</p>	<p>Histologically confirmed, newly diagnosed, de novo glioblastoma including the following recognized variants of glioblastoma: small cell glioblastoma, giant cell glioblastoma, gliosarcoma and glioblastoma with oligodendroglial component (central pathologic review will be performed and histologic confirmation will be required prior to study entry), Attempted surgical resection followed by chemoradiation, Systemic corticosteroid therapy at ≤2 mg of dexamethasone or equivalent QD for at least 3 days prior to randomization</p>
<p>SWOG S1007 Patricia Hinckley, RN Ext. 5-4062</p>	<p>A Phase III Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less</p>	<p>Node positive (1-3 nodes) +ER/PR/ - HER2 Recurrence Score ≤ 25 PS 0-2 Physician's choice of protocol approved chemo/endocrine therapy</p>

CLOSED TO ACCRUAL

Cooperative Group:	Trial Title:	Inclusion Criteria:
<p>GOG 86P Karen Cuddy, RN Ext. 5-5361</p>	<p>A Three Arm Randomized Phase II Study of Paclitaxel/Carboplatin/Bevacizumab, Paclitaxel/Carboplatin/Temsirolimus, and Ixabepilone/Carboplatin/Bevacizumab as Initial Chemotherapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer</p>	<p>Histologic confirm of dx, PS 0-2, UPCR < 1, no > grade 1 cholesterol, no prior chemo, chemo no HTN, no uncontrolled DM, no PN > grade 1, No hypoxia, interstitial pneumonia, or hx CVA</p>
<p>Novartis TELESTO</p>	<p>A multi-center, randomized, double-blind, placebo-controlled clinical trial of deferasirox in patients with myelodysplastic syndromes (low/int-1risk) and transfusional iron overload (TELESTO)</p>	<p>Low or intermediate risk MDS, as determined by IPSS score, Ferritin > 1000 micrograms/L and < 3500 @ screening, history of transfusion of 15 to 75 PRBC units, Anticipated to be transfused with at least 8 units of PRBCs annually during the study, LVEF < 50% by ECHO</p>
<p>GOG 224 Karen Cuddy, RN Ext. 5-5361</p>	<p>A Randomized Controlled Phase II Evaluation of Megestrol in Different Dose and Sequence in the Treatment of Endometrial Intraepithelial Neoplasia from a Referred Cohort of a Typical Endometrial Hyperplasia or Endometrial Intraepithelial Neoplasia</p>	<p>Dx with Bx or D+C agree to hyst no prior chemo and no other history of cancer</p>
<p>Quintiles Melanoma Trial</p>	<p>An Open-Labeled, Multicenter, Dose and Schedule Exploration Study of ONTAK in Patients with Stage IIIC and Stage IV Melanoma</p>	<p>Histologically confirmed Stage IIIC or IV, naïve to prior chemo or immunotherapy for tx of melanoma, at least 1 site of radiographically measurable disease by RECIST 1.1, melanoma of ocular, mucosal or conjunctival origin NOT ELIGIBLE</p>
<p>Novartis CRAD001W2301</p>	<p>Bolero-3: A randomized Phase III, double-blind, placebo-controlled multicenter trial of daily everolimus in combination with trastuzumab and vinorelbine, in pretreated women with HER2/neu over-expressing locally advanced or metastatic breast cancer</p>	<p>Histologically or cytologically confirmed invasive breast carcinoma w/local recurrence not amenable to resection with curative intent, or radiologic evidence of metastatic disease; resistant to trastuzumab; prior Taxane therapy; NO prior tx w/MTOR inhibitors or vinca alkaloid agents</p>
<p>Quintiles, Inc.</p>	<p>Project MAXX Bladder: An Open-Label, Multicenter, Randomized Phase Ib/II Study of Eribulin Mesylate Administered in Combination with Gemcitabine Plus Cisplatin Versus Gemcitabine Plus Cisplatin Alone in First-Line Therapy for Locally Advanced or Metastatic Bladder Cancer</p>	<p>Not previously treated w/systemic chemo for metastatic bladder cancer (one regimen of adjuvant or neoadjuvant chemo allowed), ECOG 0 or 1, palliative radiotherapy NOT permitted throughout study period</p>