Active Protocol Studies - Summa Health System

KEY
ACH: Akron City Hospital
SBH: Summa Barberton Hospital
RMH: Robinson Memorial Hospital
SWRH: Summa Western Reserve

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Site	Protocol #	ACH	SBH	SWRH	RMH	Medina	Sus-pended	Title	Eligibility Requirements
All Cancers									
All Cancers	Merck V212	☑	☐	☐	☐	☐	☐	A Phase III Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of V212 in Adult Patients with Solid Tumor or Hematologic Malignancy	Solid tumor or hematologic malignancy;no hematopoietic cell transplant (HCT); ≥ age 18 & tx does not include rituximab OR ≥age 50 not in remission & not receiving rituximab 3 months prior to enrollment through 28 days after dose 4. Life expect. 12 mos
BRAIN									
Anaplastic glioma	RTOG 0834	☑	☑	☐	☐	☐	☐	Phase III Trial on Concurrent and Adjuvant Temozolomide Chemotherapy in Non-1P/19Q Deleted Anaplastic Glioma: The Catnon Intergroup Trial	No prior chemo and no prior radiotherapy to the brain; PS 0-2; prior surgery for a low grade tumor is allowed, provided histological; Start of radiotherapy within 8 days from randomization; start of radiotherapy within 7 weeks (49 days) from surgery
Brain Mets from Breast Cancer	RTOG 1119	☑	☑	☐	☐	☐	☐	Phase II Randomized Study of Whole Brain Radiotherapy in Combination With Concurrent Lapatinib in Patients With Brain Metastasis From HER2-Positive Breast Cancer: A Collaborative Study of RTOG and KROG	Invasive breast cancer; HER2+; ≥ 1 measurable, new or progressive after SRS or surgical resection (1-3 mets);Karnofsky ≥60;No Prior WBRT;No Prior lapatinib tx;No Leptomeningeal dz
Glioblastoma or Gliosarcoma - Recurrent	RTOG 1122 Suspended	☑	☑	☐	☐	☐	☑	Phase II Double-Blinded Placebo-Controlled Study of Bevacizumab With or Without AMG 386 in Patients With Recurrent Glioblastoma or Gliosarcoma	Glioblastoma, gliosarcoma, glioblastoma w/ oligodendroglial features, giant cell glioblastoma; Karnofsky≥70; Chemo >28 days; RT>90 days;No surgical procedure < 28 days; No prior tx with anti-VEGF; < 2 relapses
Glioblstoma	RTOG 0913	☑	☑	☐	☐	☐	☐	Phase I/II Trial of Concurrent RAD001 (Everolimus) with Temozolomide/Radiation Followed by Adjuvant RAD001/Temozolomide in Newly Diagnosed Glioblastoma	GBM (WHO Grade IV);Gliosarcoma OK; No recurrent/malignant glioma;No mets; Karnofsky 70-100; No prior temozolomide, mTOR inhibitor, Gliadel wafers or other intratumoral or intracavitary tx; No prior RT,radiosensitizers or chemo to the head, neck or brain
Glioblstoma (recurrent)	RTOG 0929 Bev-naïve: temp closed Bev-failure: perm closed	☑	☑	☐	☐	☐	☑	A Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblstoma (Now recruiting for Phase II)	Intracranial glioblastoma or gliosarcoma for the phase II component;evidence of tumor progression ≤ past 14 days; Completed a course of RT; Pts in phase II must also have completed ≥ 2 courses of temozolomide; Karnofsky ≥70; no hx of seizures

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Low Grade Gliomas	ECOG E3F05	☑	☑	☑	☑	☑	☐	Phase III Study of Radiation Therapy with or without Temozolomide for Symptomatic or Progressive Low-Grade Gliomas	Grade 2 astrocytoma, oligodendroglioma or oligoastrocytoma; ≥1 of the following: uncontrolled headaches, seizures, focal neurological symptoms or Cognitive symptoms or deficits OR new or progressive enhancement; > 2wks brain surgery; no prior tx; PS ≥60
Resected Brain Mets	N107C (RTOG credit) ACH Only	☑	☐	☐	☐	☐	☐	A Phase III Trial of Post-Surgical Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease	≤ 4 brain mets; at least 1 lesion resected; non-CNS primary site; unresected lesions ≤ 3.0 cm, PS 0-2; no prior cranial RT; no planned chemo; no germ cell, small cell or lymphoma
WBRT & Stereotactic for 1-3 mets	N0574 (RTOG credit)	☑	☑	☐	☐	☐	☐	Stereotactic Radiation Therapy With or Without Whole-Brain Radiation Therapy in Treating Patients With 1-3 Brain Metastases	1-3 brain mets, maximum tumor dimension </= 3 cm. per lesion, PS 0-2; no prior RT; no chemo during trt; ineligible primaries: germ cell, small cell, lymphoma
BREAST									
DCIS	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	HER2+,No pN1,must submit tumor block for central review prior to randomization. DO NOT ORDER HER-2 STUDIES (Done centrally)
Early Stage	RTOG 1005	☑	☑	☐	☐	☐	☐	A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation Plus Concurrent Boost versus Standard Whole Breast Irradiation Plus Sequential Boost for Early-Stage Breast Cancer	Stage I or II + 1 more requirement (see protocol) OR Stage 0 with grade 3 DCIS OR Stage 0, I, II resected by lumpectomy after neoadj systemic tx; No mets; No prior breast ca; No T4, N2 or N3, or M1; no prior RT; PS 0-2
HER2 Neg Node + or High Risk Node -	B-49	☑	☑	☑	☑	☑	☐	A Phase III Clinical Trial Comparing the Combination of Docetaxel plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer	HER2-,unilateral invasive adenoca,pT1-3;pN0, pN1(pN1mi, pN1a, pN1b, pN1c),pN2a, pN3a, or pN3b; If pN0,must be:ER- & PgR- OR >2.0 cm OR T1c and ER+ and either grade 3 OR Oncotype DX ≥25;rand ≤ 84 days;no T4 or inflammatory;no mets;PS 0-1;central rev tissue
HER2 neg; Node +; ER+ and/or PR+;	S1007 (NSABP credit)	☑	☑	☑	☐	☑	☐	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	1-3 node+; ER+ and/or PR+; HER2 neg; Recurrence Score (RS) by Oncotype DX® ≤ 25; Prior DCIS OK only if treated with mastectomy alone; No metastatic dz; PS 0-2; No prior chemo or endocrine tx
HER2-Positive	SCUSF 0806 (not endorsed yet)	☑	☑	☑	☐	☑	☐	Phase II placebo-controlled trial of lisinopril and Coreg CR® to reduce cardiotoxicity in patients with breast cancer receiving (neo)adjuvant chemotherapy with trastuzumab (Herceptin®)	HER2-positive breast ca; males ok; Scheduled to receive adjuvant or neoadjuvant trastuzumab therapy; Hormone receptor and menopausal status not specified; No prior trastuzumab or anthracyclines; No known cardiac history; no met dz; no ARB's

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Local Recurrence	RTOG 1014	☑	☑	☐	☐	☐	☐	A Phase II Study of Repeat Breast Preserving Surgery and 3D-Conformal Partial Breast Re-Irradiation (PBrI) for Local Recurrence of Breast Carcinoma	Locally recurrent breast cancer < 120 days; Tumor ≤ 3 cm; Initial lumpectomy followed by whole breast RT > 1year; whole-body PET-CT scan OR CT scan of the chest, abdomen, pelvis, & bone scan < 120 days; PS 0-1; No concurrent tx including trastuzumab
Metastatic	ECOG 2108	☑	☑	☑	☑	☑	☐	A Randomized Phase III Trial of the Value of Early Local Therapy (Surgery + RT after Chemo vs continued chemo only as needed for control of distant disease) for the Intact Primary Tumor in Patients with Metastatic Breast Cancer	Stage IV intact primary(not recurrent);prior DCIS OK if no recurrence;both M & F;no synch/contraltrl ca;≥1 distant met;CNS mets OK if LE >6 mos;had 16 wks chemo;no dz prog w/in 2 wks enrolling;candidates for complete resection w/ free margins following RT
Node + or High Risk Node - HER2-Low	B-47	☑	☑	☐	☐	☑	☐	A Randomized Phase III Trial Comparing Chemotherapy Alone to Chemotherapy + Trastuzumab in Women with Node+ or High-Risk Node- HER2-Low Invasive Breast Cancer	Adenoca; primary pT1-3, ipsilateral nodes pN0, pN1 (pN1mi, pN1a, pN1b, pN1c), pN2a, pN2b, pN3a, or pN3b; No T4 tumors or inflammatory dz; no mets; no synchronous or previous contralateral invasive dz; HER2-low; PS 0-1; no prior tx;
RT	RTOG 0413 (NSABP B-39)	☑	☐	☐	☐	☐	☐	A Randomized, Phase III Study of Conventional Whole Breast Radiation (WBI) vs. Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer	Stage 0-II breast cancer, lumpectomy, tumor size ≤ 3.0 cm, ≤ 3 positive LNs (Ineligible: women ≥ age 50 with DCIS, or node negative & hormone receptor +)
GI									
Colon	CALGB 80702 (NSABP Credit)	☑	☑	☑	☐	☑	☐	A phase III trial of 6 versus 12 treatments of adjuvant FOLFOX plus celecoxib or placebo for patients with resected stage III colon cancer	Stage III completely resected; ≥ 1+ lymph node; no rectal ca; PS 0-2;No hx of upper GI ulceration, bleeding, or perforation ≤ 3 years; No concurrent NSAIDs > 2x wk or aspirin at > 325 mg ≥ 3 times per week;
Colon Prevention	P-5	☑	☑	☑	☑	☑	☐	Statin (Crestor) Polyp Prevention Trial in Patients with Resected Colon Cancer	Stage 0, I, II or III adenocarcinoma of the colon w/ curative intent <1 year;complete resection;pre-op or post-op colonoscopy <180 days; >30 days since prior statins & prior investigational agents; no chronic use of NSAIDS (low dose aspirin OK);PS 0-1
Colorectal	ECOG 7208 Temporarily suspended	☑	☑	☐	☐	☑	☑	A Randomized Phase II Study of Irinotecan and Cetuximab With or Without the Anti-Angiogenic Antibody, Ramucirumab (IMC-1121B), in Advanced, K-ras Wild-Type Colorectal Cancer Following Progression on Bevacizumab-Containing Chemotherapy	Adenoca of the colon or rectum:adv dz,K-ras wild type;meas dz;had prior first-line therapy w/oxaliplatin-based fluoropyrimidine-containing chemo + bevacizumab; progression <42 days; no brain or CNS mets;PS 0-1;bevacizumab 28-90 days;surgery >28 days
Esophageal	RTOG 1010	☑	☑	☐	☐	☐	☐	A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment Of HER2-Overexpressing Esophageal Adenocarcinoma	Stage T1, N1-2 or T2-3, N0-2; No T1,N0 or T4 disease; No metastatic dz; able to have curative resection within 56 days after completion of chemoRT; No evidence of tracheoesophageal fistula or invasion into trachea or major bronchi; PS 0-2; No prior tx

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Esophagus	S1201 (ECOG Credit)	☑	☑	☐	☐	☐	☐	A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Pts Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced/Metastatic Esophageal, Gastric, or Gastroesophageal Junction Cancer	Unresectable adv or met adenoca of esophagus, stomach or GEJ; no prior tx for met dz;HER-2 neg; prior neo or adj tx ≥ 180 days;PS 0-1;no motor or sensory neuropathy;no plans for other concurrent tx; central review (Arm 1:FOLFOX; Arm 2:Taxotere+Irinotecan)
GEJ	S1201 (ECOG Credit)	☑	☑	☐	☐	☐	☐	A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Pts Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced/Metastatic Esophageal, Gastric, or Gastroesophageal Junction Cancer	Unresectable adv or met adenoca of esophagus, stomach or GEJ; no prior tx for met dz;HER-2 neg; prior neo or adj tx ≥ 180 days;PS 0-1;no motor or sensory neuropathy;no plans for other concurrent tx; central review (Arm 1:FOLFOX; Arm 2:Taxotere+Irinotecan)
Liver (Locally advanced or metastatic)	CALGB 80802 (ECOG Credit)	☑	☑	☑	☑	☑	☐	Phase III Randomized Study of Sorafenib plus Doxorubicin Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC)	Locally adv or met HCC;meas dz; no CNS/brain mets;PS 0-2; No prior allografts; no prior VEGF; prior tx OK if >6 mo; no prior chemo for met dz; > 4 wks prior locoregional tx, interferon, surgery, or RT;
Pancreas	RTOG 0848	☑	☑	☑	☐	☐	☐	A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma (Gemzar +/- Erlotinib; Step 2: +/- RT)	Resected pancreatic cancer, stage T1-3, N0-1, M0; No prior chemo; No prior total pancreatectomy, distal pancreatectomy, or central pancreatectomy; No prior RT to the region that would result in overlap of RT fields; No recurrent pancreatic cancer; PS 0-1
Pancreas	S1115 (ECOG Credit)	☑	☑	☐	☐	☐	☐	Randomized Phase II Clinical Trial of AZD6244 Hydrogen Sulfate (NSC-748727) and MK-2206 (NSC-749607) vs. mFOLFOX in Patients with Metastatic Pancreatic Cancer after Prior Chemotherapy	Distant, mets;No end/neuroend tumors, or ampullary; syst tx ≥14days; sx ≥14days; RT≥7days; meas or non meas dx; PS 0-1; must have 1 prior gemcitabine ≥28 days; no uncontrolled diabetes
Rectal, locally advanced	N1048 (RTOG credit) (can enroll but need surgeon cred)	☑	☑	☐	☐	☐	☐	A Phase II/III trial of Neoadjuvant FOLFOX with Selective Use of Combined Modality Chemoradiation vs Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision	Rectal adenoca; T2N1, T3N0, T3N1; candidate for sphincter-sparing surgical resection; tumor 5-12 cm from anal verge; PS 0-2;Radiologically measurable or clinically evaluable dz per Section 11; no APR at baseline; no bowel obstruction, no prior pelvic RT
Stomach	S1201 (ECOG Credit)	☑	☑	☐	☐	☐	☐	A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Pts Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced/Metastatic Esophageal, Gastric, or Gastroesophageal Junction Cancer	Unresectable adv or met adenoca of esophagus, stomach or GEJ; no prior tx for met dz;HER-2 neg; prior neo or adj tx ≥ 180 days;PS 0-1;no motor or sensory neuropathy;no plans for other concurrent tx; central review (Arm 1:FOLFOX; Arm 2:Taxotere+Irinotecan)
GU									
Bladder	RTOG 0926	☑	☑	☑	☐	☐	☐	A Phase II Protocol for Patients With Stage T1 Bladder Cancer to Evaluate Selective Bladder Preserving Treatment by Radiation Therapy Concurrent With Cisplatin Chemotherapy Following a Thorough Transurethral Surgical Re-Staging	T1G2 or T1G3 transitional cell ca that has recurred < 18 months after initial treatment for ≤ T1 tumors; T1, NX or N0, M0 without hydronephrosis; No pN+ or > T1 disease; no mets; PS 0-1; no prior chemo or RT

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Renal	S0931 (ECOG Credit)	☑	☑	☑	☐	☑	☐	EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study (Everolimus vs Placebo X 54 weeks)	Renal cell ca; full resection (radical or partial nephrectomy); neg margins; bilateral renal tumors OK; no residual or metastatic dz; no prior tx; Zubrod PS 0-1
Renal Advanced Sarcomatoid	ECOG 1808	☑	☑	☑	☑	☑	☐	A Randomized Phase II Trial of Sunitinib/Gemcitabine or Sunitinib in Advanced Renal Cell Carcinoma with Sarcomatoid Features	Renal cell carcinoma with sarcomatoid features; meas dz not resectable; treated brain mets OK if off steroids .≥2 weeks; No prior systemic therapy for metastatic dz; > 2 wks RT; PS 0-2
Renal Metastatic	ECOG 4805 Re-opened to Arm A only	☑	☑	☐	☐	☑	☐	A Randomized Phase II Study to Determine the Effect of 2 Different Doses of AVE0005 (VEGF Trap) in Patients with Metastatic Renal Cell Carcinoma	Unresectable or met. renal cell ca;clear cell;meas.dz;failed a TKI;prior immunotx cytokine w/ interleukin2 & interferon alpha only;no prior chemo, cellular, vaccine or hormonal tx;prior RT OK if meas dz outside RT port ;PS 0-2; no CNS mets; RT ≥ 3 wks
GYN									
Carcinosarcoma (uterus or ovary)	GOG 0261	☑	☐	☐	☐	☐	☐	A Randomized Phase III Trial of Paclitaxel + 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 or Ovary	Uterine, fall tube, peritoneal or ovarian carcinosarcoma w/≥ 1 of these:newly diagnosed dz,Stage I-IV,recurrent or chemo-naïve;PS 0-2;No prior chemo;RT > 4 wks;hormonal tx > 1 wk;No planned RT after or during study tx;may be unstaged;meas or non-meas dz
Cervical & Endometrial	RTOG 1203	☑	☑	☐	☐	☐	☐	A Randomized Phase III Study of Standard vs. IMRT Pelvis Radiation for Post-Operative Treatment of Endometrial and Cervical Cancer (Time-C)	Dx ≤ 90days; Hysterectomy ≤ 49days prior to reg; no dist mets; zubrod 0-2; no prior RT to pelvis; no prior plat chem. Tx; no para-aortic nodal dz; margins >3mm
Cervix	GOG 0263	☑	☐	☐	☐	☐	☐	Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation In Intermediate Risk, Stage I/IIA Cervical Cancer Treated With Initial Radical Hysterectomy and Pelvic Lymphadenectomy	Squamous cell,adenosquamous,adenocarcinoma; Stage I-IIA;radical hysterectomy & pelvic lymphadenectomy;no tumor in the parametria, pelvic lymph nodes, or other extra-uterine site; PS 0-2; surgery 3-8 weeks;no prior RT or chemo; Brachy boost not allowed
Cervix	GOG 0274 RTOG 1174	☑	☐	☐	☐	☐	☐	A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: The OUTBACK Trial	FIGO 2008 Stage IB1 node+, IB2, II, IIIB or IVA; no prior chemo or pelvic RT; no Stage IIIA; no mets; no prior or planned hysterectomy;no interstitial brachy tx permitted; no IMRT and Rapid Arc permitted; PS 0-2
Cervix	GOG 0278	☑	☐	☐	☐	☐	☐	Evaluation of Physical Function and Quality of Life (QOL) Before and After Non-Radical Surgical Therapy (Extra Fascial Hysterectomy or Cone Biopsy With Pelvic Lymphadenectomy) For Stage IA1 (LVSI+) and IA2-IB1 (</=2cm) Cervical Cancer	Squamous cell, adenoca or adenosquamous cell of cervix; Stage IA1 (LVSI+), IA2, IB1(≤2cm) any grade; Must have had a cone biopsy or LEEP w/ neg margins; invasion <10mm; no mets; neg pelvic nodes; PS 0-2;

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Cervix	RTOG 0724	☑	☑	☐	☐	☐	☐	Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy	Stage IA2, IB, or IIA disease; Must have had radical hysterectomy; No neuroendocrine histology; PS 0-1;No prior chemo for the current cervical cancer; No prior RT to pelvis that would result in overlap of RT fields
Cervix Recurrent	GOG 0227-G Temp. Closed	☑	☐	☐	☐	☐	☑	A Phase II Evaluation of Brivanib (BMS582664, IND #108417) in the Treatment of Persistent or Recurrent Carcinoma of the Cervix (BMS Study CA182-048)	Persistent or recurrent cervical cancer; meas dz; not eligible for a higher priority GOG protocol; 1 or 2 prior systemic chemo regimen; no brain mets; PS 0-2; prior RT OK
Cervix, Uterine, Vulvar	GOG 0244	☑	☐	☐	☐	☐	☐	The Lymphedema and Gynecologic Cancer (LEG) Study: Incidence, Risk Factors and Impact in Newly Diagnosed Patients	Pts undergoing hyst/BSO & pelvic lymphadenectomy (Stage I-II uterine) OR radical hyst or trachelectomy & pelvic (Stage IA-IIA cervical) OR Stage I-IV vulvar cancer having vulvectomy or radical local excision w/ lymphadenectomy; PS 0-2
Endometrial	GOG 0258	☑	☐	☐	☐	☐	☐	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	Stage III or IVA endometrial ca per FIGO 2009; PS 0-2; no recurrent endometrial ca;no carcinosarcoma; no prior pelvic or abdominal RT;no prior chemo for endometrial ca; no residual > 2cm (FIGO 2009 Stage I or II clear cell or serous with + pelvic washings
Endometrial - Recurrent	GOG 0229-K Temp. Closed	☑	☐	☐	☐	☐	☑	A Phase II Evaluation of BIBF 1120 (IND# 113086) in the Treatment of Recurrent or Persistent Endometrial Carcinoma	Recurrent or persistent endometrial ca, refractory to tx;meas dz; must have 1 target lesion; not eligible for higher priority protocol; must have had 1 prior chemo tx; no prior non-cytotoxic tx; no brain mets
Gestational Trophoblastic Neoplasia (GTN) - Low Risk	GOG 0275	☑	☐	☐	☐	☐	☐	A Phase III Randomized Trial of Pulse Actinomcyin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia	FIGO Stage I, II, or III for low-risk gestational trophoblastic neoplasia (GTN): post molar GTN or choriocarcinoma; second curettage OK;WHO risk score 0-6;No non-gestational choriocarcinoma or prior chemo;No prior pelvic RT;No PSTT or ETT; PS 0-2
Leiomyosarcoma	GOG 0131-H Temp. Closed	☑	☐	☐	☐	☐	☑	A Phase II Evaluation of Ixabepilone (IND #59699, NSC #710428) in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus	Persistent or recurrent dz refractory to tx; meas. dz.;Not eligible for a higher priority GOG protocol; Must have had 1 prior regimen that included a taxane; no brain mets; PS 0-2; >1wk hormonal tx; >3 wks prior tx; >4 wks RT
Leiomyosarcoma	GOG 0250	☑	☐	☐	☐	☐	☐	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	Advanced or recurrent uterine leiomyosarcoma; meas. dz; > 1 target lesion; no CNS; PS 0-2; >1 wk hormonal tx; no prior cytotoxic chemo, VEGF, multi-kinase inhibitors; no prior docetaxel or gemcitabine; > 28 days major surgery; > 7 days minor surgery
Leiomyosarcoma	GOG 0277	☑	☐	☐	☐	☐	☐	A Phase III Randomized Trial of Gemcitabine (NSC# 613327) plus Docetaxel (NSC# 628503) Followed by Doxorubicin (NSC# 123127) versus Observation for Uterus-limited, High Grade Uterine Leiomyosarcoma	High risk uterine LMS, FIGO stage I; had complete hysterectomy; no mets; PS 0-1; no prior chemo with docetaxel, gemcitabine or doxorubicin ever; no prior whole pelvic RT; no recurrent LMS; no HIV

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Ovarian	DUKE 1810	☑	☐	☐	☐	☐	☐	Epidemiology of Ovarian Cancer in African American Women	African-American women with newly diagnosed invasive epithelial ovarian, fallopian tube or peritoneum cancer
Ovarian	GOG 0268	☑	☐	☐	☐	☐	☐	A Phase II Evaluation of Temsirolimus (CCI-779) in Combination With Carboplatin and Paclitaxel Followed by Temsirolimus (CCI-779) Consolidation as First-Line Therapy in the Treatment of Stage III-IV Clear Cell Carcinoma of the Ovary	Newly diagnosed stage III or IV clear cell ovarian ca;PS 0-2;Neuro function ≤ grade 1;No severely impaired lung function;No prior tx with a mTOR inhibitor, paclitaxel, or carbo;No prior RT or chemo to any portion of the abdomen or pelvis;surgery 2-12 wks
Ovarian or Fallopian Tube	GOG 0241	☑	☐	☐	☐	☐	☐	A Phase III Trial of Open Label Carboplatin and Paclitaxel +/- Bevacizumab Compared With Oxaliplatin and Capecitabine +/- Bevacizumab as First Line Chemotherapy in Patients With Mucinous Epithelial Ovarian Cancer or Fallopian Tube Cancer (MEOC)	Mucinous ca of ovary or fall. Tube;FIGO stage II-IV new or recurrent chemonaive OR recurrent stage I;No primary peritoneal ca;No brain mets;PS 0-2;Life expect>3 mo;No prior chemo, RT or mouse antibody;surgery >4 weeks & none planned during tx; no warfarin
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 0186-I	☑	☐	☐	☐	☐	☐	A Randomized Phase II Evaluation of Single-Agent Bevacizumab and Combination Bevacizumab with Fosbretabulin Tromethamine (CA4P) in the Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma	Platinum-sensitive or resistant recurrent dz.. No Platinum refractory.Meas. Or detectable dz; 1 prior platinum initial trt; up to 2 trt for recurrent/persistent dz; not eligible for a higher priority GOG protocol; PS 0-2 for 1 prior tx; PS 0-1 for 2+ tx;
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 0212	☑	☐	☐	☐	☐	☐	A Randomized Phase III Trial of Paclitaxel or Polyglutamate Paclitaxel (CT-2103) or Observation in Treating Patients With Stage III or Stage IV Ovarian Epithelial or Peritoneal Cancer or Fallopian Tube Cancer	Primary peritoneal or Stage III or IV epithelial ovarian or fallopian tube ca with either optimal ≤ 1 cm residual dz or suboptimal residual dz after initial surgery; had 5-8 cycles tx ≤ 12 wks; no sx of persistent ca, normal CT scan & CA-125; PS 0-2
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 0260 Suspended effective 4.5.12	☑	☐	☐	☐	☐	☑	A Phase II Evaluation of Elesclomol Sodium and Weekly Paclitaxel in the Treatment of Recurrent or Persistent Platimum-Resistant Ovarian, Fallopian Tube or Primary Peritoneal Cancer	Meas dz; must have had 1 prior platinum-based chemo tx; must be platinum-resistent or refractory; not elig. for higher GOG protocol; PS 0-2; >1 wk prior hormonal tx; >3 wks prior biological or immunotherapy; see RT tx rule
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 0267 QOL STUDY	☑	☐	☐	☐	☐	☐	Quality of Life and Care Needs in Patients with Persistent or Recurrent Platinum-Resistant Ovarian, Fallopian tube, and Peritoneal Cancer	Recurrent or persistant ovarian, peritoneal or fallopian tube platinum-resistant cancer(< 6 months from date of last platinum tx to recurrence); life expectancy > 6 months; any PS but must be able to verbally consent and participate in the first asessment
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 3001	☑	☐	☐	☐	☐	☐	A Phase 3 Randomized,Double-Blind,Placebo-Controlled,Multi-Center Study of AMG 386 With Paclitaxel & Carboplatin as First-line Treatment of Subjects With FIGO Stage III-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers (Amgen #2010129)	FIGO III-IV ov, prim peri or fall.tube receiving 1st line tx w/ Taxol/carbo x 6 cycles.IIIA or IIIB must have had PDS ≤12 wks prior to reg.IIIC or IV PDS ≤12 wks prior OR Plan to have IDS following 3 cycles Taxol/carbo + AMG 386. PS 0-1;No prior tx or CNS
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 0186-J	☑	☐	☐	☐	☐	☐	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	Platinum-sensitive or resistant recurrent dz. No Platinum refractory.Meas. or detectable dz; 1 prior platinum initial tx; up to 2 trt for recurrent/persistent dz; not eligible for a higher priority GOG protocol; PS 0-2 for 1 prior tx; PS 0-1 for 2+ tx;

Site	Protocol #	ACH	SBH	SWRH	RMH	Medina	Sus-pended	Title	Eligibility Requirements
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 3003	☑	☐	☐	☐	☐	☐	A Randomized,Double-Blind,Placebo-Controlled Phase II Study Of VTX-2337 In Combination With Pegylated Liposomal Doxorubicin (PLD) In Patients With Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer (VentiRx)	Recurrent or persistent dz; must have had 1 prior platinum-based tx; must be platinum resistant; platinum-refractory are NOT eligible; Meas dz; 1; PS 0-1; no prior anthracyclines; no CNS;may have 1 prv tx for recurrent or persis dz; no invest drug <30days
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 0273 ≥ age 70	☑	☐	☐	☐	☐	☐	GOG 0273 Chemotherapy Toxicity in Elderly Women with Ovarian, Primary Peritoneal or Fallopian Tube Cancer	≥ age 70;Adenoca of ovary, peritoneum or fallopian tube;FIGO I, II, III & IV;no prior tx except for surgery;register ≤ 8 weeks confirmation of dx or 12 wks of primary/staging surgery;PS 0-3;phys choice primary surgery vs chemo + 2 chemo regimen choices
Ovarian, Fallopian tube, or Peritoneal Cavity Cancer	GOG 0213	☑	☐	☐	☐	☐	☐	Phase III Randomized Controlled Clinical Trial of Carboplatin & Paclitaxel Alone or In Combination with Bevacizumab Followed By Bevacizumab & Secondary Cytoreductive Surgery In Platinum-Sensitive, Recurrent Ovarian, Peritonerimary & Fallopian Tube Cancer	Recurrent, meas. disease; dz-free=6 mo; MUST BE CANDIDATES FOR CYTOREDUCTIVE SURGERY AND CONSENT TO HAVE THEIR SURGICAL TREATMENT DETERMINED BY RANDOMIZATION; PS 0-2; only 1 prior chemo tx; no prior RT; no CNS;No concurrent immunotherapy or radiotherapy
Uterine carcinosarcoma	GOG 0130-F	☑	☐	☐	☐	☐	☐	A Phase II Evaluation of Ixabepilone (IND #59699, NSC #710428) in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus	Recurrent or progressive uterine carcinosarcoma; meas dz; > 3 wks prior tx; >1 wk prior hormonal tx; PS 0-2; not eligible for higher priority GOG protocol; prior tx with Taxane required
Uterine Recurrence	GOG 0238	☑	☐	☐	☐	☐	☐	A Randomized Trial of Pelvic Irradiation With or Without Concurrent Weekly Cisplatin in Patients With Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus	Biopsy proven recurrent endometrial ca confined to the pelvis and/or vagina;No evidence of extra pelvic dz;PS 0-2;Prior primary surgical debulking OK; no exenterative surgery;>6 mo prior hormone or chemo tx; no prior RT;no neoadj.chemo for recurrent dz
Vulva	GOG 0279	☑	☐	☐	☐	☐	☐	A Phase II Trial Evaluating Cisplatin (NSC #119875) and Gemcitabine (NSC #613327) Concurrent with Intensity-Modulated Radiation Therapy (IMRT) in the Treatment of Locally Advanced Squamous Cell Carcinoma of the Vulva	Locally-adv untreated squamous cell ca of the vulva.T2 or T3(N0-3, M0) not amenable to surgical resection by standard radical vulvectomy. PS 0-2. No prior pelvic RT or chemo.No vulvar melanomas or sarcomas; not eligible for higher priority GOG protocol
HEAD & NECK									
Advanced (includes thyroid)	RTOG 0920	☑	☑	☐	☐	☐	☐	A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer	Squamous cell T1, N1-2 or T2-4a, N0-2, M0; no + margins;no prior chemo,anti-EGF or RT;PS 0-1;≥ 1 risk factor: perineural or lymph. invasion,1 node >3cm or ≥2+ nodes <6cm,close margin(s),T3 or T4a primary,T2 oral ca >5mm depth;T1-2, N0, M0 resected thyroid
Oropharynx	RTOG 1016 (QOL Component Closed)	☑	☑	☐	☐	☐	☐	Phase III Trial of Radiotherapy Plus Cetuximab Versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer (HPV+)	Squamous cell carcinoma of the oropharynx (tonsil, base of tongue, soft palate or oropharyngeal walls) stage T1-2, N2a-3, or T3-4 any N; TUMOR MUST BE p16 POSITIVE. No mets; measurable dz; PS 0-1;No prior tx; Central path for review to confirm

Site	Protocol #	ACH	SBH	SWRH	RMH	Medina	Sus-pended	Title	Eligibility Requirements
Recurrent/ Metastatic	ECOG 1305	☑	☑	☐	☐	☑	☐	A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer	Recurrent or metastatic SCCHN; no prior tx for recurrence/mets;no prior bevacizumab; prev. palliative RT OK if > 8 wks; surgery > 4 wks; no brain mets; no lung mets;no bleeding disorders; no chronic daily aspirin, PS 0-1
Salivary Gland Tumors	RTOG 1008	☑	☑	☐	☐	☐	☐	A Randomized Phase II Study of Adjuvant Concurrent Radiation and Chemotherapy Versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors	Stage T3-4 or N1-3 or T1-2, N0 with a positive margin; high-grade mucoepidermoid carcinoma, high-grade adenocarcinoma, or salivary duct carcinoma; Surgical resection <8 wks; no mets; PS 0-1; No prior chemo or RT for salivary gland cancer
Thyroid	RTOG 0912 temp closed	☑	☑	☐	☐	☐	☑	Randomized Phase II Study of Concurrent Intensity Modulated Radiation Therapy (IMRT), Paclitaxel, and Pazopanib (NSC 737754)/Placebo for the Treatment of Anaplastic Thyroid Cancer	Anaplastic thyroid cancer;No brain mets;PS 0-2; No prior chemo for anaplastic thyroid cancer; No chemo or RT < 4 weeks of registration; No other investigational agents; No prior RT that would result in overlap of RT fields; No pts who require heparin
LEUKEMIA									
AML (Older Adults)	ECOG 2906 NOTE: Daunorubicin Shortage check with Pharmacy before enrolling	☑	☑	☐	☐	☑	☐	Phase III Randomized Trial of Clofarabine as Induction & Post-Remission Tx vs Standard Daunorubicin & Cytarabine Induction & Intermediate Dose Cytarabine Post-Remission Tx, Followed by Decitabine Maint vs Observation in Newly-Diag AML in Adults ≥ 60 Years	≥ 60 Years;newly diag AML;no AML-M3 or t (15;17)(q22;q21);no blastic trans of CML;no CNS; Must also enroll on ECOG 3903;PS 0-3;no prior tx with azacitidine, decitabine or low-dose cytarabaine for MDS;prior hydroxyurea OK;bone marrow aspirate req to enroll
CLL	Connect CLL Registry	☑	☑	☑	☑	☑	☐	Connect CLL: The Chronic Lymphocytic Leukemia Disease Registry	New diagnosis within 2 months of enrollment; >/= age 18; able to read & speak English; agrees to complete all questionnaires; cannot participate in a treatment clinical study in which study treatment is blinded; life expectancy > 6 months
Lab Study (to determine eligibility- mandadory with	ECOG 3903	☑	☑	☑	☑	☑	☐	Ancillary Laboratory Protocol for the Collection of Diagnostic Material on Patients Considered for ECOG Treatment Trials for Leukemia or Related Hematologic Disorders	Must be planing to enroll in an ECOG leukemia treatment clinical trial
PNH	PNH Registry	☑	☑	☑	☑	☑	☐	Paroxysmal Nocturnal Hemoglobinuria (PNH) Subject Registry	Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) or a detected PNH clone. May or may not be receiving Soliris; also including patients previously treated with Soliris who have withdrawn from treatment.
LUNG									
Mesothelioma	CALGB 30901 (ECOG Credit)	☑	☑	☐	☐	☑	☐	Randomized Phase II Study of Maintenance Pemetrexed Versus Observation For Patients With Malignant Pleural Mesothelioma Without Progression After First-Line Chemotherapy	Completed 4 cycles of 1st line chemo w/ pemetrexed AND either cisplatin or carbo with CR, PR or stable dz; prior surgery and/or RT OK

Site	Protocol #	ACH	SBH	SWRH	RMH	Medina	Sus-pended	Title	Eligibility Requirements
NSCLC	Amgen Anemia 20070782	☑	☐	☐	☐	☐	☐	A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Long-term Safety & Efficacy of Darbepoetin Alfa Administered at 500 ug Once-Every-3-Weeks in Anemic Subjects With Advanced Stage NSCLC Receiving Multi-cycle Chemotherapy	Stage IV NSCLC; must be receiving 2 cycles of 1st line chemo; PS 0-1 < 21 days randomization; Life Exp. > 6 mo; Hemoglobin ≤ 11.0 w/in 7 days rand; no prior adj or neoadj tx for NSCLC; no brain mets; no RBC transfusion or ESAs < 28 days;
NSCLC	RTOG 0813	☑	☐	☐	☐	☐	☐	Seamless Phase I/II Study of Stereotactic Lung Radiotherapy (SBRT) for Early Stage, Centrally Located, Non-Small Cell Lung Cancer (NSCLC) in Medically Inoperable Patients	NSCLC, Stage T1-2, N0, M0;Tumor resectable; patient "medically inoperable"; Measurable dz<8 weeks; PS 0-2; No prior RT that would result in overlap of RT fields;No prior chemo;No other concurrent local therapy or systemic therapy
NSCLC	RTOG 0839 Barberton needs credentialing	☑	☐	☐	☐	☐	☐	Randomized Phase II Study of Pre-operative Chemoradiotherapy +/- Panitumumab Followed by Consolidation Chemotherapy in Potentially Operable Locally Advanced (Stage IIIA, N2+) Non-Small Cell Lung Cancer	Stage IIIA (T1-T3) (N1 or N2) meas dz; no palpable LN in the supraclavicular areas or higher unless benign by bx; no mets; PS 0-1;No prior chemo, biological tx or RT
NSCLC (need 2 cycles paclitaxel on hand to enroll)	ECOG 3508	☑	☑	☐	☐	☑	☐	A Phase II Randomized Trial of Paclitaxel, Carboplatin, Bevacizumab with or without IMC-A12 in Patients with Advanced Non-Squamous, Non-Small Cell Lung Cancer	Stage IV or recurrent non-squamous NSCLC; meas dz; treated brain mets OK; no prior tx for advanced dz; > 1 year prior tx; > 3 wks RT; > 4wks surgery; no concurrent cancer tx or anticoagulation tx; no HIV+ pts; no uncontrolled diabetes; PS 0-1;
NSCLC Protocol Notice: Shortage of Paclitaxel	ECOG 1505	☑	☑	☐	☑	☑	☐	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)	Completely resected, Stage IB (> 4 cm) – IIIA (T2-3N0, T1-3N1, T1-3N2 per AJCC 6th ed;); proper lymph node level resection; 6-12 weeks post surgery; PS 0-1; no prior chemo (Cisplat w/ Vinorelbine/Alimta/Gemzar-MD choice)
SCLC	CALGB 30610 (RTOG Credit) Temp closed effective Mar. 11th	☑	☑	☑	☐	☑	☐	Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin and Etoposide	Limited stage SCLC; must have measurable dz; no contralateral hilar or supraclav lymph nodes; no prior RT; no prior mediastinal or thoracic RT; no complete surgical resection; PS 0-2
SCLC (prophylactic Cranial RT for extensive disease)	RTOG 0937	☑	☑	☐	☐	☐	☐	Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for Extensive Disease Small Cell Lung Cancer (ED-SCLC)	Extensive stage SCLC ≤ 6 months;1-3 extracranial mets;completed 4-6 courses of platinum-based chemo ≤ 8 wks AND one of the following: partial or complete response in ≥ 1 site of dz OR No progression in any site; PS 0-2; No brain or CNS mets;
LYMPHOMA									
B CELL	C05013	☑	☐	☐	☐	☐	☐	An Open-Label, Randomized, Phase 2 Study to Assess the Effectiveness of RCHOP With or Without VELCADE in Previously Untreated Patients with Non-Germinal Center B-Cell-like Diffuse Large B-Cell Lymphoma	Pts previously untreated DLBCL subclassified as non-GCB subtype; least 1 measurable tumor mass that is > than 1.5 cm in the long axis and > than 1.0 cm in the short axis; No CNS lymphoma

Site	Protocol #	ACH	SBH	SWRH	RMH	Medina	Sus-pended	Title	Eligibility Requirements
CNS	ECOG E1F05 Temporarily suspended	☑	☑	☑	☑	☑	☑	(Suspended for toxicity analysis) Phase II Study of Rituximab Given in Conjunction with Standard Chemotherapy in Primary Central Nervous System (CNS) Lymphoma	Primary CNS Non-Hodgkin's lymphoma; no prior chemo or RT for CNS; pre-treatment steroid administration OK; meas dz; HIV-1 neg; HepB neg; PS 0-3
Follicular	ECOG 2408	☑	☑	☐	☐	☑	☐	A 3-Arm Randomized Phase II Trial of Bendamustine-Rituximab (BR) Followed by Rituximab vs Bortezomib-BR (BVR) Followed by Rituximab vs BR Followed by Lenalidomide/Rituximab in High Risk Follicular Lymphoma	Stage II, III, or IV AND grade 1, 2, or 3a; must have FLIPI-1 score of 3, 4, or 5 (1 point per criterion): Age ≥ 60, Stage III-IV, Hemoglobin level <12 g/dL ,>4 nodal areas,Serum LDH level above normal;Meas dz;PS 0-2; No prior chemo, RT, or immunotherapy
Mantle Cell	ECOG 1411	☑	☑	☑	☑	☑	☐	Intergroup Randomized Phase II Four Arm Study In Patients >/= Age 60 with Previously Untreated Mantle Cell Lymphoma of Therapy with Rituximab, Bendamustine Hydrochloride, and Bortezomib Followed by Rituximab and Lenalidomide	Age 60+; untreated mantle cell; meas dz; PS 0-2; no CNS; meas. dz; HIV+ OK (must meet criteria)
MELANOMA									
Mucosal, Acral, & Solar	ECOG 2607	☑	☑	☑	☑	☑	☐	A Phase II Trial of Dasatinib in KIT-Positive Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Vulvovaginal Melanomas	Metastatic or unresectable melanoma (acral, vagina and/or vulva, or other mucosal surface); meas. dz; must be KIT+; prior trt. OK, but NO targeted tx permitted; prior trt. > 4 weeks; CNS OK if treated and stable; PS 0-1 **Mandatory central review-tissue
Resected, high-risk	ECOG 1609	☑	☑	☐	☐	☑	☐	A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy versus High-Dose Interferon á-2b for Resected High-Risk Melanoma	Stage IIIB, IIIC, or IV (M1a or M1b); No ocular or mucosal melanoma; completely resected w/ neg margins <12 wks; Dz recurrence OK but see protocol; No prior adjuvant treatment after resection; >30 days RT; > 4wks IL-2 or other chemo; PS 0-1
PREVENTION									
Colon	P-5	☑	☑	☑	☑	☑	☐	Statin Polyp Prevention Trial in Patients with Resected Colon Cancer	Stage 0, I, II or III adenocarcinoma of the colon w/ curative intent <1 year;complete resection;pre-op or post-op colonoscopy <180 days; >30 days since prior statins & prior investigational agents; no chronic use of NSAIDS (low dose aspirin OK);PS 0-1
PROSTATE									
3D/IMRT	RTOG 0534	☑	☑	☑	☐	☐	☐	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	T3N0/Nx or T2N0/Nx with + or - margin; PSA DOUBLING TIME > 6 MONTHS PRIOR TO REG.; no hormones prior to reg; Zubrod 0-1, no mets; NO TIME LIMIT FROM PROSTECTOMY; No CNCMO, No RT; prostate Gleason ≤ 9, PSA ≥0.1 - <2.0
3D/IMRT	RTOG 0815	☑	☑	☐	☐	☐	☐	A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients With Intermediate-Risk Prostate Cancer	Adenoca of the prostate diagnosed < 6 months; Gleason 7 or PSA > 10 but ≤ 20 ng/mL or stage T2b or T2c; Clinically negative lymph nodes; No evidence of bone mets; PS 0-1; no prior radical surgery, hormonal therapy, chemo or RT; No finasteride </= 30 days

Site	Protocol #	ACH	SBH	SWRH	RMH	Medina	Sus-pended	Title	Eligibility Requirements
Favorable Risk	RTOG 0938 IGRT Credentialing Pending	☑	☐	☐	☐	☐	☑	A Randomized Phase II Trial of Hypofractionated Radiotherapy for Favorable Risk Prostate Cancer	Adenoca of the prostate; T1-2a; Gleason 2-6; PSA < 10; PS 0-1; no prior or concurrent invasive dz; no mets; no LN involved; no prior pelvic surgery, chemo, RT or hormones; ≥ 30 days after finasteride use; ≥ 90 days after dutasteride use
High Risk	RTOG 1115	☑	☑	☐	☐	☐	☐	Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer	Prostate adenoca;neg LN;PSA≤150;no mets;PS 0-1;no prior radical prostatectomy,cryosurgery or bilateral orch;no prior chemo or hormones;no prior RT or brachy that would overlap fields;Gleason 7-9 with high risk for recurrence (see 3.1 for PSA & T-Stage)
Intermediate or Favorable High Risk	RTOG 0924	☑	☑	☐	☐	☐	☐	Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial	Dx'd within past 180 days, GS 7-10 + T1c-T2b + PSA <50; GS 6 + T2c-T4 or >50% positive biopsies + PSA <50; GS 6 + T1c-T2b + PSA >20; no mets; no previous tx ; PS 0-1
Local Recurrence	RTOG 0526	☑	☐	☐	☐	☐	☐	A Prospective Phase II Trial of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma Following External Beam Radiotherapy	Bx documented locally recurrent prostate adeno >30 months after EBRT and ≤ 180 days prior to reg; initial diagnosis T1-T2c, GS 2-6, PSA ≤20; OR T1-T2c, GS 7, PSA ≤10; N0; hormonal tx OK; no mets; PS 0-1; PSA<10
Non-Metastatic Prostate Cancer	RTOG 0622	☑	☑	☐	☐	☐	☐	A Phase II Trial of Samarium 153 Followed By Salvage Prostatic Fossa 3C-CRT or IMRT Irradiation In High-Risk, Clinically Non-Metastatic Prostate Cancer After Radical Prostatectomy	Prostate ca, stage T2-T4, N0-N1; no distant mets; postop PSA 2.0; or postop PSA rising above 0.2 with a surgical tumor Gleason score of 9 or 10; or rapidly rising PSA profile with a doubling time < 6 months; no prior chemo; no hormones < 3 months; PS 0-1
SARCOMA									
Leiomyosarcoma	GOG 0131-H Temp. Closed	☑	☐	☐	☐	☐	☑	A Phase II Evaluation of Ixabepilone (IND #59699, NSC #710428) in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus	Persistent or recurrent dz refractory to tx; meas. dz.;Not eligible for a higher priority GOG protocol; Must have had 1 prior regimen that included a taxane; no brain mets; PS 0-2; >1wk hormonal tx; >3 wks prior tx; >4 wks RT
Leiomyosarcoma	GOG 0250	☑	☐	☐	☐	☐	☐	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	Advanced or recurrent uterine leiomyosarcoma; meas. dz; > 1 target lesion; no CNS; PS 0-2; >1 wk hormonal tx; no prior cytotoxic chemo, VEGF, multi-kinase inhibitors; no prior docetaxel or gemcitabine; > 28 days major surgery; > 7 days minor surgery
Leiomyosarcoma	GOG 0277	☑	☐	☐	☐	☐	☐	A Phase III Randomized Trial of Gemcitabine (NSC# 613327) plus Docetaxel (NSC# 628503) Followed by Doxorubicin (NSC# 123127) versus Observation for Uterus-limited, High Grade Uterine Leiomyosarcoma	High risk uterine LMS, FIGO stage I; had complete hysterectomy; no mets; PS 0-1; no prior chemo with docetaxel, gemcitabine or doxorubicin ever; no prior whole pelvic RT; no recurrent LMS; no HIV

Site	Protocol #	ACH	SBH	SWRH	RMH	Medina	Sus-pended	Title	Eligibility Requirements
Liposarcoma or Leiomyosarcoma	ET743-SAR-3007	☑	☐	☐	☐	☐	☐	A Randomized Controlled Study of YONDELIS® (Trabectedin) or Dacarbazine for the Treatment of Advanced Liposarcoma or Leiomyosarcoma Previously Treated With an Anthracycline and Ifosfamide	Locally advanced or spreading liposarcoma or leiomyosarcoma that is unable to be removed by surgery; prior tx with an anthracycline & ifosfamide; Meas dz; PS 0-1; no prior tx with trabectedin or dacarbazine; > 3 weeks from prior tx; no CNS mets
SPINE									
Metastatic	RTOG 0631	☑	☐	☐	☐	☐	☐	(ACH ONLY) Phase II/III Study of Image-Guided Radiosurgery/SBRT for Localized Spine Metastasis	Localized spine metastasis from C1 to L5, a solitary spine metastasis; two sep. spine levels; or up to 3 separate site, Zubrod 0-2
SUPPORTIVE CARE									
HER2-Positive	SCUSF 0806 (not endorsed yet)	☑	☑	☑	☐	☑	☐	Phase II placebo-controlled trial of lisinopril and Coreg CR® to reduce cardiotoxicity in patients with breast cancer receiving (neo)adjuvant chemotherapy with trastuzumab (Herceptin®)	HER2-positive breast ca; males ok; Scheduled to receive adjuvant or neoadjuvant trastuzumab therapy; Hormone receptor and menopausal status not specified; No prior trastuzumab or anthracyclines; No known cardiac history; no met dz; no ARB's
NSCLC	Amgen Anemia 20070782	☑	☐	☐	☐	☐	☐	A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Long-term Safety & Efficacy of Darbepoetin Alfa Administered at 500 ug Once-Every-3-Weeks in Anemic Subjects With Advanced Stage NSCLC Receiving Multi-cycle Chemotherapy	Stage IV NSCLC; must be receiving 2 cycles of 1st line chemo; PS 0-1 < 21 days randomization; Life Exp. > 6 mo; Hemoglobin ≤ 11.0 w/in 7 days rand; no prior adj or neoadj tx for NSCLC; no brain mets; no RBC transfusion or ESAs < 28 days;
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 0267 QOL STUDY	☑	☐	☐	☐	☐	☐	Quality of Life and Care Needs in Patients with Persistent or Recurrent Platinum-Resistant Ovarian, Fallopian tube, and Peritoneal Cancer	Recurrent or persistant ovarian, peritoneal or fallopian tube platinum-resistant cancer(< 6 months from date of last platinum tx to recurrence); life expectancy > 6 months; any PS but must be able to verbally consent and participate in the first asessment
Ovarian, Fallopian Tube and Primary Peritoneal	GOG 0273 ≥ age 70	☑	☐	☐	☐	☐	☐	GOG 0273 Chemotherapy Toxicity in Elderly Women with Ovarian, Primary Peritoneal or Fallopian Tube Cancer	≥ age 70;Adenoca of ovary, peritoneum or fallopian tube;FIGO I, II, III & IV;no prior tx except for surgery;register ≤ 8 weeks confirmation of dx or 12 wks of primary/staging surgery;PS 0-3;phys choice primary surgery vs chemo + 2 chemo regimen choices