PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
BILIARY TRACT				
S1815	Phase III randomized trial of Gemcitabine, Cisplatin and Nab-Paclitaxel vs Gemcitabine and Cisplatin in newly diagnosed, advanced biliary tract cancers	≥ 18 Confirmed intrahepatic or extrahepatic cholangiocarcinoma or gallbladder CA Unresectable disease No – prior systemic therapy for current metastatic CA, grade 2 or higher neuropathy	Gemcitabine + Cisplatin + Nab-Paclitaxel vs Gemcitabine + Cisplatin	Cooperative

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
BREAST				
A011401 Breast Cancer WEight Loss (BWEL study)	Randomized phase III trial evaluation the role of weight loss in adjuvant treatment of overweight and obese women with early *breast* cancer	Dx < 12 months Stage II or III HER2 – ER/PR + or – ≥ 18 (women) BMI ≥ 27 Chemo/Rad/Surg complete > 21 days No – DMII with insulin/sulfonylurea	Health education x 2 years vs Health education + weight loss intervention	Cooperative
A011502 Aspirin for Breast Cancer (ABC trial)	Randomized phase III double blinded placebo-controlled trial of aspirin as adjuvant therapy for HER2 negative *breast* cancer	HER2 – Node + ER/PR + or - ≥ 18 and < 70 No – hx GI bleed, stroke anticoagulation therapy, afib, MI, hx met breast CA	Aspirin 300mg qd x 5 years vs Placebo	Cooperative
A5481082 Pfizer/POLARIS	Palbociclib in hormone receptor positive advanced *breast* cancer: a prospective multicenter non-interventional study	HER2 – HR+ (ER and/or PR +) Adeno with metastatic or advanced disease Palbociclib indicated	Observational with QOL questionnaires q1m x 3m then q3m until EOT with Palbociclib *optional blood	Pharmaceutical
NRG-BR003	Randomized phase II trial of adjuvant therapy comparing doxorubicin plus cyclophosphamide followed by weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive *Breast* Cancer	HER2 – ER/PR – ≥ 18 Mastectomy or lumpectomy Tumor unilateral No – T4 including inflammatory breast CA, Metastatic disease	AC IV q2w x 4 cycles → Paclitaxel IV qweek x 12 doses vs AC IV q2w x 4 cycles → Paclitaxel IV qweek x 12 doses + Carboplatin AUC5 IV q3w x 4 cycles	Cooperative

RTOG 1119	Phase II randomized study of whole brain radiotherapy/stereotactic radiosurgery in combination with concurrent Lapatinib in patients with *brain metastasis* from HER2-positive breast cancer	HER2+ Brain Mets ≥ 18 Able to swallow PO med	WBRT vs WBRT + PO Lapatinib qd x 6 weeks	Cooperative
S1416	Phase II randomized placebo-controlled trial of Cisplatin with or without ABT-888 (Veliparib) in metastatic triple-negative breast cancer and/or BRCA mutation-associated *breast* cancer	HER2 – Triple Neg – OR BRCA mutation ≥ 18 Metastatic and/or recurrent breast CA Able to swallow PO med	Cisplatin vs Cisplatin + Veliparib	Cooperative
S1418 Adjuvant	Randomized phase III trial to evaluated the efficacy and safety of MK-3475 as adjuvant therapy for triple receptor-negative *breast* cancer with ≥ 1 cm residual invasive cancer or positive lymph nodes after neoadjuvant chemotherapy	ER/PR/HER2 – (weekly ER or PR+ are eligible if no endocrine therapy) ≥ 18 Lymph node dissection after neoadjuvant chemotherapy Complete adjuvant chemotherapy prior to starting Pembrolizumab No – Metastatic disease	Observation vs MK-3475 (Pembrolizumab) IV q3w x 52 weeks	Cooperative

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
COLORECTAL				
A021502 Adjuvant	Randomized trial of standard chemotherapy alone or combined with Atezolizumab as adjuvant therapy for patients with stage III *colon* cancer and deficient DNA mismatch repair	≥ 18 Stage III adenocarcinoma DNA mismatch Tumor resected No - prior therapy, rectal involvement, metastatic disease at time of registration	mFOLFOX6 IV x 12 cycles (6m) + atezolizumab x 25 cycles (12m) vs mFOLFOX6 x 12 cycles (6m) 1 cycle = 14 days *survival status 5-8y	Cooperative
NRG-GI002	Phase II clinical trial platform of sensitization utilizing total neoadjuvant therapy in *rectal* cancer	≥ 18 Rectal adenocarcinoma, stage II or III + distal location or bulky or high risk of mets or not a candidate for sphincter-sparing surgical resection Able to swallow PO med No – metastatic disease, neuropathy grade 2, active bowel disease, colon cancer, pelvic radiation	mFOLFOX6 q2w x 8 cycles followed by RT + capecitabine PO bid on RT days vs mFOLFOX6 q2w x 8 cycles followed by RT + capecitabine PO BID on RT days + veliparib PO BID vs mFOLFOX 6 q2w x 8 cycles followed by RT + capecitabine PO BID on RT days + MK-3475 IV (pembrolizumab) q3w x 6 cycles starting D1 of RT	Cooperative

NRG-GI004/SWOG S1610 Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT)	A randomized phase III study of mFOLFOX6/Bevacizumab combination chemotherapy with or without Atezolizumab or Atezolizumab monotherapy in the 1st line treatment of patients with deficient DNA mismatch repair (dMMR) metastatic *colorectal* cancer	≥ 18 Tumor determined to be mismatch-repair deficient No – previous chemo or systemic therapy for mets colorectal cancer	mFOLFOX6 until disease progression. Discontinue oxaliplatin after C10. Vs Atezolizumab monotherapy until disease progression or up to and including max of 48 cycles vs mFOLFOX6 until disease progression.	Cooperative **Request approval from NCI CIRB upon patient eligibility. SIV with PI and RN along with delegation log**
PP06490 Preventive treatment of OxaLiplatin induced peripherAl neuRopathy in Metastatic colorectal cancer (POLAR-M)	Phase 3, double blind, multicenter, placebo-controlled study of PledOx, used on top of modified FOLFOX6 (5-FU/FA and Oxaliplatin) to prevent chemotherapy induced peripheral neuropathy (CIPN) in patients with first-line metastatic *colorectal cancer*	≥ 18 Metastatic (IV) CRC Hx DMII, HbA1c ≤ 7% No – prior systemic chemotherapy, ANY grade neuropathy from any cause, hx genetic or familial neuropathy	PledOX (2 µmol/kg) + mFOLFOX6 chemotherapy vs PledOx (5 µmol-kg) + mFOLFOX6 chemotherapy vs Placebo + mFOLFOX6 chemotherapy	Pharmaceutical
S0820 Preventing Adenomas of the Colon and with Eflornithine and Sulindac (PACES)	A double blind placebo-controlled trial of Eflornithine and Sulindac to prevent recurrence of high risk adenomas and secondary primary colorectal cancers in patients with state 0-III *colon or rectal* cancer, phase III	≥ 18 Treatment per SOC with resection alone or in combo with chemoXRT 180-456 post resection with no evidence of disease Able to swallow PO med No – NSAIDs, no anticoagulants, GI ulcer	Eflornithine placebo + Sulindac placebo x 3 years vs Eflornithine and Sulindac placebo vs Eflornithine placebo + sulindac vs Elfornithine and Sulindac	Cooperative

PROTOCOL	TITLE	KEY ELIGIBILITY	TREATMENT	SPONSOR
GASTRIC				
14T-MC-JVDD	Safety and effectiveness of Ramucirumab in patients with advanced gastric cancer in the European Union and North America: a prospective observational registry	≥ 18 Advanced gastric cancer or GEJ adenocarcinoma whose disease has progressed after prior chemotherapy Initiate Ramucirumab tx as single afent or in combo with chemo No – patients who received more than 1 line of chemo	Observe patient x 12 months or until death, loss to f/u or withdrawal of consent	Pharmaceutical

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
HEAD AND NECK				
AG013-ODOM-201 Oragenics	A phase 2, multi-center, randomized, double-blind, placebo-controlled study to assess the safety, and efficacy of topically applied AG013 for the attenuation of oral mucositis in subjects with cancers of the head and neck receiving concomitant chemoradiation therapy	Squamous cell carcinoma of the oral cavity, oropharynx or hypopharynx or HPV-positive unknown primary presumed to be of oropharyngeal origin Primary or post-operative CRT Cisplatin during RT ≥ 21 No – prior radiation to H/N, no use of alcohol during trial	AG013 oral, topical mouth rinse vs placebo TID in conjunction with Chemoradiation therapy	Mercy Pharmaceutical
RTOG-1008	A randomized phase II/phase III study of adjuvant concurrent radiation and chemotherapy versus radiation alone in resected high-risk malignant salivary gland tumors	Malignant major/minor salivary gland tumor of the H/N of histologic subtypes (see protocol) ≥ 18 No – residual macroscopic disease	Cisplatin 40mg/m2 x 7 doses with concurrent radiation vs radiation alone	Cooperative **Request Approval from MMC IRB**

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	
LUNG				
ALCHEMIST* A151216 SCREENING TRIAL FOR **A081105, E4512, EA5142**	Adjuvant *lung* cancer enrichment marker identification and sequencing trial	Resectable non-small cell lung cancer Suspected clinical stage of IIIA, IIA, IIB, large IB (≥4cm) ≥ 18 No – neoadjuvant therapy for this lung ca, treatment with targeting EGRF mutation, ALK rearrangement, PD1/PD-L1/CTLA-4. Recurrence of lung ca after prior resection	Site must have A151216 and the two treatment trials A081105 and E4512 IRB approved before registering patients to A151216.	Cooperative
***A081105** Alliance	Randomized study of erlotinib vs observation in patients with completely resected epidermal growth factor receptor (EGFR) mutant *non-small cell lung* cancer (NSCLC)	≥ 18 Registered for A151216 Completely resected IIIA, IIA, IIB, large IB (≥4cm) non-squamous NSCLC with negative margins Randomized from surgery, 90 days if no adjuvant chemo, 240 if adjuvant chemo and 300 days if adjuvant chemo and radiation therapy was administered	Erlotinb 150mg PO QD x 2 years or until disease progression (Arm C) or Observation , Placebo (Arm D) 1 cycle = 21 days	Cooperative

***E4512**	Randomized phase III trial for surgically resected early stage *non-small cell lung* cancer: crizotinib vs observation for patients with tumors harboring the anaplastic lymphoma kinase (ALK) fusion protein	≥ 18 Registered for A151216 Complete surgical resection of stage IB, II or non-squamous IIIA and have negative margins Positive for translocation inversion events involving the ALK gene locus No – uncontrolled Afib	Crizotinib 250mg PO BID until recurrence up to 2 years vs Observation	Cooperative
***EA5142** Adjuvant Nivolumab In Resected Lung Cancers (ANVIL)	Randomized phase III study of Nivolumab after surgical resection and adjuvant chemotherapy in *non-small cell lung* cancers	≥ 18 Registered for A151216 Complete surgical resection of stage IB, II or non-squamous IIIA and have negative margins Non-squamous tumors must not be + for EGRD or L858R mutation and ALK rearrangement No – Prednsione >10mg/day	Nivolumab 480mg IV q4w x 1 year vs Observation per SOC x 1 year 1 cycle = 14 days	Cooperative **Site pending**
BDX-00146 Biodesix	An observational study assessing the clinical effectiveness of the Veristrat® test and validating immunotherapy tests in subjects with *non-small cell lung* cancer	≥ 18 Dx NSCLC EGRF mutation negative or UNK	None – assess the physician's clinical practice patterns while using the Veristrat test in subjects with NSCLC	Pharmaceutical
EA5162	Phase II study of AZD9291 (Osimertinib) in advanced *NSCLC* patients with Exon 20 Insertion Mutations in EGFR	≥ 18 NSCLC Stage IIIB or IV EGRD exon 20 insertion mutation must be detected in tumor tissue Previously at least 1 line of thearpy	AZD9291 (Osimertinib) 160mg PO QD	Cooperative **Request approval from NCI CIRB**
OSU BLCIO	Beating *Lung* Cancer in Ohio	≥ 18 Stage IV NSCLC No – treatment for advance lung cancer for over 1 month before enrollment	Monthly phone calls about QOL	Cooperative
PRO068 Oncocyte	Study to evaluate a panel of blood biomarkers for use in patients undergoing evaluation for *lung* cancer, ONC-LN-04	≥ 21 Hx smoking tobacco (current or past) Lung nodule 0.5-3cm No – current or recurrent lung CA, hx of any non-lung primary malignancy	None – one time collection up to 30mL of blood for gene expression and development of the ONC-LN-04 test	Mercy Pharmaceutical

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
LYMPHOMA				
DB102-02 (ENGINE Study)	Randomized phase III study to evaluate the efficacy and safety of enzastaurin pluse R-CHOP vs R-CHOP in treatment-naïve subjects with high-risk diffuse l*arge b-cell lymphoma* who possess the novel genomic biomarker DGMI™	CD20-positive DLBCL Able to swallow PO med No – hx long QT syndrome, or meds that can prolong QT/QTc interval, grade 2 neuropathy	RCHOP + Enzasturin 1125mg x 1d then 500mg qd x 6 cycles vs RCHOP + Placebo x 6 cycles	Pharmaceutical
S1608	Randomized phase II trial in early relapsing or refractory *follicular lymphoma*	Grade I, II, IIIa follicular lymphoma at initial dx and at relapse ≥ 18 See prior/concurrent therapy criteria	TGR-1202 800mg PO + Obinutuzumab 1000mg IV qcycle x 12 vs Lenalidomide 20mg PO + Obinutuzumab 1000mg IV qcycle x 12 vs CHOP PO qcycle x 6 + Obinutuzumab 1000mg IV qcycle x 12 *1 cycle = 28 days	Cooperative **Request approval from NCI CIRB**

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
MELANOMA				
EA6141	**SUSPENSION 06/23/17** Randomized phase II/III study of Nivolumab plus Ipilimumab plus Sargramostim vs Nivolumag plus Ipilimumab in patients with unresectable stage III or stage IV melanoma	**SUSPENSION 06/23/17** ≥ 18 BRAF mutational status of tumor, wild type or mutated Unresectable stage III or IV No – pior Ipil and/or anti PD-1/PD-L1 agent in metastatic setting, ongoing systemic corticosteroids use including oral. No hx diverticulitis (diverticulosis ok), autoimmune disease	**SUSPENSION 06/23/17** Cycle 1-4; Nivolumab IV, + Ipilimumab IV + Sargramostim SC Cycle 5- x 2 years or progression; Nivolumab IV + Sargramostin SC vs Cycle 1-4 Nivolumab IV +, Ipilimumab IV. Cycle 5 – x 2 years or progression; Nivolumab IV	
S1801	Phase II randomized study of adjuvant vs neoadjuvant MK-3475 (pembrolizumab) for clinically detectable stage III-IV high-risk melanoma	≥ 18 Resectable melanoma. Stage III (N1b, N1c, N2b, N2c, N3b, N3c) or Stage IV No – previous neoadjuvant tx, prior non-immunotherapy adjuvant therapy.	Adjuvant → Surgery → Resection → Adjuvant Pembrolizumab → Adjuvant MK-3475 200mg IV q3w x 18 doses vs Neoadjuvant → MK3475 q3w x 3 doses → surgery → surgical resection → adjuvant Pembrolizumab → Adjuvant MK3475 200mg IV q3w x 15 doses	Cooperative

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
MYELODYSPLASTIC (MDS)				
ECOG NHLBI-MDS	National Myelodysplastic Syndromes (MDS) Study	≥ 18 Suspected MDS or MDS/MPN overlap disorders OR dx w/ denovo or therapy-related MDS	Observational study with specimen acquisition	Cooperative **Physician training required when pt presents**

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
PROSTATE				
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	≥ 18 Moderate to high risk for recurrence determined by; 1. Gleason score 7-10 + T1c-T2b + PSA < 50, 2. Gleason score 6 + T2c-T4 + PSA < 50 OR Gleason score 6 ≥ 50% positive biopsies + PSA < 50 3. Gleason score 6 + T1c-T2b + PSA > 20 No – radical surgery or cryosurgery, pelvic irradiation, brachytherapy, orchiectomy, hormonal therapy	Radiation therapy (prostate and seminal vesicles) + IMRT x 19 tx or brachytherapy implant AND hormone therapy vs Radiation therapy (whole pelvis and seminal vesicles) + IMRT x 19 tx or brachytherapy implant AND hormone therapy	Cooperative
S1802	Phase III randomized trial of standard systemic therapy (SST) versus standard systemic therapy plus definitive treatment (surgery or radiation) of the primary tumor in metastatic prostate cancer	≥ 18 Adenocarcinoma (small cell or squamous cell not eligible) Intact prostate, no prior local therapy No – brain mets	Standard Systemic Therapy (SST) prior to randomization. Randomized to SST only (NCCN guidelines) or ST and definitive treatment (physician's choide or radical prostatectomy or radiation therapy to the primary tumor)	Cooperative **Request approval from NCI CIRB**

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
RENAL				
S1500	Randomized, phase II efficacy assessment of Multiple MET Kinase Inhibitors (Cabozantinib, Crizotinib, Savolitinib and Sunitinib in metastatic papillary renal carcinoma (PAPMET)	Renal cell carcinoma which is metastatic or locally advance disease not amendable to surgical resection Able to swallow PO meds	Arm1: Sunitinib 50mg Arm 2: Cabozantinib 60mg Arm 3: Crizotinib –**CLOSED 12/5/18** Arm 4 Savolitinib –**CLOSED 12/5/18**	Cooperative

PROTOCOL	TITLE			SPONSOR
RARE OR UNKNOWN	**ACTIVE**			Cooperative
S1609	11- Sarcomatoid carcinoma of lung			
	14 – Trophoblastic tumor	Choriocarcinoma		
	15 – Transitional cell carcinoma other than renal pelvis ureteral or bladder			
	16 – Cell tumor of the testes and extragonadal germ tumors	Seminoma and testicular sex cord cancer	Non seminomatous tumor	Teratoma
	17 – Epithelial tumors of penis	Squamous adenocarcinoma cell carcinoma		
	18 – Squamous cell carcinoma variants of the genitourinary (GU) system			
	19 – Spindle cell carcinoma of kidney, pelvis, ureter			
	21 – Odontogenic malignant tumors			
	27 – Dermoid tumors			
	29 – Malignant giant cell tumors			
	36 – Metaplastic carcinoma (breast)			
	TEMPORARY CLOSURE			
	4 – undifferentiated carcinoma of gastrointestinal (GI) tract			
	8 – Pancreatic tumor including acinar cell carcinoma, mucinous or serous cystadenocarcinoma			
	12 – Bronchoalveolar carcinoma lung			
	24 – Pheochromocytoma, malignant			
	25 – Paraganglioma			
	26 – Carcinomas of pituitary gland, thyroid gland parathyroid gland and adrenal cortex			
	30 – Chordoma			
	33 – Not otherwise categorized (NOC) rare tumors, after discussion with study			
	35 – Vulvar cancer			