Lynn Cancer Institute Oncology Trials

Clinical Trials – May 2018

Eugene M. and Christine E. Lynn Office of Research Administration **561.955.4800**

Center for Hematology-Oncology **561.955.6400** *Radiation Oncology* **561.955.4111**

		BREAST	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Advanced breast Cancer, metastatic breast cancer	Pfizer A5481082 NCT03280303	POLARIS: Palbociclib in Hormone Receptor Positive Advanced Breast Cancer: A Prospective Multicenter Non-Interventional Study	• Age ≥ 18 years or older. • Diagnosis of adenocarcinoma of the breast with evidence of metastatic disease or advanced disease not amenable to treatment with curative intent. • Documented HR+ (ER+ and/or PR+) tumor based on local standards • Documented HER2- tumor based on local standards • Physician had determined that treatment with palbociclib is indicated
		GASTROINTESTINAL	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Liver Humanitarian Device TX	MDS Nordion **Contact** **Dr. George Khoriaty**	Treatment of Unresectable Hepatocellular Carcinoma with TheraSphere® (Yttrium-90 Glass Microspheres): An HDE Treatment Protocol	• Hepatocellular carcinoma of the liver • ECOG PS score of ≤ 2 with a life expectancy of > 3 months • > 4 weeks since prior RT or surgery • > 1 month post other chemotherapy. • Excludes contraindications to angiography and selective visceral catheterization • Excludes extra-hepatic disease representing an imminent life-threatening outcome or active infection
Pancreas	AstraZenca D081FC00001 **POLO** NTC02184195	A Phase III, Randomized, Double Blind, Placebo Controlled, Multicentre Study of Maintenance Olaparib Monotherapy in Patients with gBRCA Mutated Metastatic Pancreatic Cancer whose Disease Has Not Progressed on First Line Platinum Based Chemotherapy	• Histologic/pathologic confirmation pancreatic adenocarcinoma • Receiving initial chemotherapy for metastatic disease and without evidence of disease progression on treatment • 1st Line with platinum-based regimen received a minimum of 16 weeks of continuous platinum treatment with no evidence of progression • Documented mutation in gBRACA1 or gBRACA2 that is predicted to be deleterious or suspected deleterious • ECOG performance status 0-1

Met. Colorectal	BTG International Inc. TS-102 **EPOCH** NCT01483027	A Phase III Clinical Trial Evaluating TheraSphere® in Patients with Metastatic Colorectal Carcinoma of the Liver who have Failed First Line Chemotherapy	• ECOG PS 0-1 through screening to first treatment on study • Unresectable metastatic disease to the liver with disease progression in the liver with oxaliplatin or irinotecan based 1st line chemotherapy • No prior external beam radiation treatment to liver or any prior intra-arterial liver directed therapy • No clinically evident ascites • Tumor replacement <50% of total liver volume
Pancreas	ARMO Biosciences AM0010-301 NCT02923921	A Randomized Phase 3 Study of AM0010 in Combination with FOLFOX Compared with FOLFOX Alone as Second-line Therapy in Patients with Metastatic Pancreatic Cancer that has Progressed During or Following a First-Line Gemcitabine Containing Regimen	• Presence of metastatic pancreatic adenocarcinoma • Tumor progression on 1st line therapy • Only one prior gemcitabine containing therapy and no other prior therapies for metastatic disease • ECOG performance status 0-1 • Complete prior chemotherapy and any investigational therapy at least 2 weeks prior to randomization • No prior radiation therapy or surgery for treatment of pancreatic cancer
		HEMATOLOGY	
		ANEMIA	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
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		MULTIPLE MYELOMA	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
MM, relapsed / refractory	Millennium Pharmaceuticals C16029 NCT03170882	A Phase 2/3, Randomized, Open-Label Study Comparing Oral Ixazomib/Dexamethasone and Oral Pomalidomide/Dexamethasone in Relapsed and/or Refractory Multiple Myeloma	• Male/female,18 years or older • Relapse or PD after having received 2 or more prior lines of systemic therapy. • Refractory to lenalidomide, defined as having received at least 2 consecutive cycles • Received at least 2 consecutive cycles of a bortezomib- or carfilzomib-containing regimen • ECOG score 0 – 2 • Measurable disease defined by serum M-protein or urine M-protein and documented MM isotype by immunofixation

		LYMPHOMA	
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		CHRONIC LYMPHOCYTIC LEUKEMIA	
CLL, PD while on UTX-TGR-304	TG Therapeutics UTX-TGR-204 NCT02612311	A multi-center, open-label, study to evaluate the safety and efficacy of Ublituximab (TG-1101) in combination with TGR-1202 for patients previously enrolled in protocol UTX-TGR-304	• ECOG PS ≤ 2 • After confirmed progression receiving treatment and randomized onto Arms B, C, or D while on UTX-TGR-304
NHL	TG Therapeutics UTX-TGR-205 NCT 02793583	UTX-TGR-205: A Phase 2b Randomized Study To Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 with or without Bendamustine and TGR-1202 alone in Patients with previously Treated Non-Hodgkin's Lymphoma.	• Histologically confirmed diagnosis of B-cell NHL • FL/SLL patients: relapsed or refractory after ≥ 2 prior lines of systemic therapy. • MZL patients: prior treatment with one or more lines of therapy. • Measurable disease, defined as at least 1 measurable disease lesion >1.5 cm in at least one diameter by CT/CT-PET or MRI. • ECOG performance status ≤ 2. • Ability to swallow and retain oral medication.

		General Oncology	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Newly diagnosed cancer	LCI Senior Exercise Project/ SPP-2014-38-LCI No NCT #	Senior Adult Cancer Treatment Optimization of Performance Project (Pilot study)	• 70 years or older at time of cancer diagnosis • Understand and adhere to study related assessments/procedures • No prior cancer treatment • Scheduled to start cytotoxic chemotherapy and/or radiation therapy • No restriction on tumor stage

High risk Genetics Registry	City of Hope National Medical Center 96144 No NCT # *GENETICS STUDY*	Molecular Genetic Studies of Cancer Patients and Their Relatives	• Personal history or family history of cancer suggestive of presence of an inherited predisposition • In a group known or suspected to have increased risk of carrying genetic alteration or of sustaining exposure that would place them at risk of cancer • Willing historian to provide information or access • Young age cancer diagnosis • Multiple primary neoplasms in affected member • Presence of rare tumor types in family • Congential malformations • Any other family clustering of cancer • Any other cancer-predisposing genetic disease/conditions
General Oncology: adult solid tumor	Mitra Biotech Inc. MIT-201701 NCT03253575	C**AN**script™ **C**linical Outcom**E**s in a **R**eal-World **S**etting (ANCERS)-2: A Prospective, Multicenter, Observational Study Examining the Clinical Utility of CANscript™ in Routine Clinical Practice	• 18 years and older • ECOG performance status of ≤2 • Patient's tumor must be amenable to a tumor biopsy sampling, so that CANscript can be performed • Patient must have disease that is measurable by standard imaging techniques, per the RECIST 1.1 • Histologically- or cytologically-confirmed, locally advanced or metastatic: o HNSCC o TNBC o Stage 3b or 4 NSCLS after failure of appropriate 1st line therapy o Epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, after failure of 1st line platinum-based chemotherapy o Stage IV metastatic CRC
		LUNG	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Resected Stage IB-IIIA NSCLC	Roche GO29527 NCT02486718	A Phase III, open label, randomized study to investigate the efficacy and safety of MPDL3280A (Anti-PD-L1 Antibody) compared with best supportive care following adjuvant cisplatin based chemotherapy in PD-L1 selected patients with completely resected stage IB-IIIA non-small-cell lung cancer	• ECOG PS: 0 or 1 • Histological or cytological diagnosis of Stage IB (tumors ≥ 4 cm)−IIIA (T2−3 N0,T1−3 N1, T1-3 N2) • Tumor PD-L1 expression of TC3 or IC3 performed by central lab • No prior treatment with systemic chemotherapy • No segmentectomy or wedge resection

IIIA, II or IB Resected Non-Squamous NSCLC	NCI A151216 ALCHEMIST NCT02194738	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) **This is the pre-registration study which randomizes to either A081105 or E4512**	• ECOG PS: 0 or 1 • No neoadjuvant (chemo or radio-therapy) for this lung cancer • No prior treatment with agents targeting EGFR mutation or ALK rearrangement • No pure squamous carcinoma • Pre-surgical: Suspected clinical stage of IIIA, II or large IB (defined as size ≥4cm) • Post-surgical: Pathologic stage IIIA, II or IB (defined as size ≥4 cm) • Patients may be receiving adjuvant chemotherapy at the time of registration. • Adequate FFPE tissue for central EGRF and ALK genotyping for all patients, include those already locally tested • Complete resection.
IIIA, II or IB Resected Non-Squamous NSCLC	NCI A081105 ALCHEMIST NCT029193282	Randomized double blind placebo controlled study of erlotinib or placebo in patients with completely resected epidermal growth factor receptor (EGFR) mutant non-small cell lung center (NSCLC)	• ECOG PS: 0 or 1 • Registered to A151216 with result of EGFR exon 19 deletion or L858R mutation • Completely resected stage IB (≥ 4cm), II, or IIIA non-squamous NSCLC with negative margins • Patients with known resistant mutations in the EGFR TK domain (T790M) are **not** eligible. • Patients that are **both** *EGFR* mutant and ALK rearrangements will be registered to A081105
IIIA, II or IB Resected Non-Squamous NSCLC	NCI E4512 **ALCHEMIST** NCT02201992	A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein	• ECOG PS: 0 or 1 • Pre-registered to A151216 • Completely resected stage IB (≥ 4cm), II, or IIIA non-squamous NSCLC with negative margins • Positive for translocation or inversion events involving the ALK gene locus • No prior treatment with crizotinib or another ALK inhibitor • No known interstitial fibrosis or interstitial lung disease.

Locally advanced or metastatic NSCLC	Incyte INCB 39110-207 NCT2917993	An Open-Label Phase 1/2 Study of INCB039110 in Combination with Osimertinib in Subjects with Locally Advanced or Metastatic Non-Small Cell Lung Cancer LCI is participating in Phase 2	•Histologically or cytologically confirmed unresectable locally advanced (Stage IIIB) or metastatic (Stage IV) NSCLC •Documented evidence of somatic activating mutation in EGFR (eg, G719X, exon 19 deletion, L858R, L861Q) in a tumor tissue sample •Must not have received more than 1 prior line of therapy •Radiographically measurable or evaluable disease per RECIST •ECOG performance status 0 or 1 •Life expectancy of at least 12 weeks from screening • Completion of previous therapy regimen before the initiation of study therapy
SCLC	Pharma Mar PM1183-C-003-14 **Atlantis** NCT02566993	Phase III randomized clinical trial of Lurbinectedin (PM01183)/ Doxorubicin (DOX) versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as treatment in patients with Small Cell Lung Cancer (SCLC) who failed one prior platinum-containing line	• ECOG PS ≤ 2 • Histologically or cytologically confirmed limited or extensive SCLC • 4 weeks since completion whole brain RT and two weeks since PCI completion • No more than one prior chemotherapy containing regimen and not treated with PM01183, topotecan or anthracyclines
NSCLC Unknown EGFR status	Biodesix BDX-00146 No NCT #	An Observational Study Assessing the Clinical Effectiveness of VeriStrat® and Validating Immunotherapy Tests in Subjects with Non-Small Cell Lung Cancer	• EGFR mutation status wildtype or unknown • If prior treatment then documented disease progression prior to VeriStrat
Advanced ALK positive NSCLC	Pfizer B7461006 NCT03052608	A Phase 3, Randomized, Open-Label Study of Lorlatinib (PF-06463922) Monotherapy Versus Crizotinib Monotherapy in the First-Line Treatment of Patiets with Advanced ALK-Positive Non-Small Cell Lung Cancer	• Histologically or cytologically confirmed diagnosis of locally advanced or metastatic ALK positive NSCLC • At least 1 extracranial measurable lesion per RECIST • Archival FFPE tissue block must be available. If not, then mandatory de novo biopsy required. • No prior systemic NSCLC treatment. Adjuvant/neoadjuvant treatment allowed if completed >12 months prior to randomization • ECOG performance status 0-2
Stage IV SCLC	AstraZeneca D419QC00001 NCT03043872	A Phase III, Randomized, Multicenter, Open-Label, Comparative Study to Determine the Efficacy of Durvalumab or Durvalumab and Tremelimumab in Combination With Platinum-Based Chemotherapy for the First-Line Treatment in Patients with Extensive Disease (Stage IV) Small-Cell Lung Cancer (SCLC)	• Histologically or cytologically documented extensive disease IV SCLC [T any, N any, M1 a/b]), or T3-4 due to multiple lung nodules. • Patients must be considered suitable to receive a platinum based chemotherapy regimen as 1st line treatment. • No prior exposure to immune-mediated therapy • No history of leptomeningeal carcinomatosis.

Stage IV Non-Small Cell Lung Cancer	Merck MK-3475-715 NCT03322566	A Randomized Phase 3 Study of the Combination of Pembrolizumab (MK-3475) Plus Epacadostat (INCB024360) Alone or with Platinum-based Chemotherapy Versus Pembrolizumab Plus Platinum-based Chemotherapy Plus Placebo as First-Line Treatment in Patients with Metastatic Non-Small Cell Lung Cancer	• Histologically or cytologically confirmed diagnosis of stage IV NSCLC • Absence of tumor activating EGFR mutations AND absence of ALK and ROS1 gene rearrangements OR presence of a KRAS mutation • Measurable disease by RECIST 1.1 • Life expectancy of at least 3 months • ECOG status 0 or 1 within days prior to the first dose of study treatment but before randomization • Adequate organ function • Archival tumor sample or newly obtained biopsy sample

GENITOURINARY

Primary Site	Sponsor/Study ID NCT #	Protocol Description	Eligibility
Met. Hormone Sensitive Prostate Cancer	Bayer HealthCare Pharmaceuticals Inc. ARASENS 17777 NCT02799602	A randomized, double-blind, placebo-controlled Phase III study of ODM-201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer	• ECOG PS: 0 to 1 • Histologically or cytologically confirmed adenocarcinoma of prostate • Metastatic disease documented either by a positive bone scan, or for soft tissue or visceralmetastases, either by contrast-enhanced CT abdominal/pelvic/chest MRI • None of the following within 6 months before randomization: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, congestive heart failure • No prior treatment with second-generation AR inhibitors such as enzalutamide, ARN-509, ODM-201, other investigational AR inhibitors, or CYP17 enzyme inhibitor as antineoplastic treatment
Metastatic CRPC	Clovis Oncology, Inc. CO-338-052 **TRITON2** NCT02952534	A Multicenter, Open-label Phase 2 Study of Rucaparib in patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency	• ECOG PS: 0 to 1 • Histologically or cytologically confirmed adenocarcinoma or poorly differentiated carcinoma of prostate • Castrate level of serum testosterone of ≤ 50 ng/dL (1.73 nM). For patients currently being treated with LHRH agonists therapy must be continued throughout the study • Have a deleterious mutation in BRCA1/2 or ATM, or molecular evidence of other homologous recombination deficiency • No prior treatment with any PARP inhibitor, mitoxantrone, cyclophosphamide or any platinum-based chemotherapy

Metastatic CRPC	F. Hoffman-La Roche Ltd CO39385 NCT03016312	A Phase III, multicenter, randomized study of Atezolizumab (Anti-PD-L1 antibody) in combination with Enzalutamide vs. Enzalutamide alone in patients with metastatic castration-resistant prostate cancer after failure of an androgen synthesis inhibitor and failure of, ineligibility for, or refusal of a taxane regimen	• ECOG PS: 0 to 1 • Progressive disease prior to screening by PSA or imagine per PCWG3 criteria • One prior regimen of a taxane-containing regimen or refusal or ineligibility of a taxane-containing regimen along • One prior regimen of an androgen synthesis inhibitor • Tumor specimen from a site not irradiated for PD-L1 status testing via central pathology
Metastatic CRPC	Clovis Oncology, Inc. CO-338-063 **TRITON3** NCT02975934	Multicenter, Randomized, Open-label Phase 3 Study of Rucaparib versus Physician's Choice of Therapy for Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency	• ECOG PS: 0 or 1 • Surgically or medically castrated, with serum testosterone levels of ≤ 50 ng/dL (1.73 nM) • Have a deleterious mutation in a BRCA1/2 or ATM gene • Eligible for treatment with physician's choice of comparator treatment • PD after treatment with one prior next-generation AR-targeted therapy for castration-resistant disease
Metastatic CRPC	F. Hoffman-La Roche Ltd CO39303 NCT03072238	A phase III, randomized, double-blind, placebo-controlled, multicenter trial testing Ipatasertib plus Abiraterone plus prednisone/prednisolone, relative to placebo plus Abiraterone plus prednisone/prednisolone in patients with asymptomatic or mildly symptomatic, metastatic castrate resistant prostate cancer with PTEN diagnostic positive tumors	• Histologically confirmed prostate adenocarcinoma without neuroendocrine differentiation or small-cell features • Consent to provide FFPE tissue block • Valid PTEN IHC result (central testing) • Metastatic disease documented by bone lesion on bone scan or soft tissue disease by CT or MRI • Asymtomatic or mildly symptomatic form of prostate cancer • Progress disease defined using at least one; a) two rising PSA levels ≥ 1 ng/mL measured ≥ 1 week apart b) radiographic evidence of disease progression in soft tissue
Renal	Eisai Inc. E7080-G-000-307 NCT02811861	E7080-G-000-307: A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Everolimus or Pembrolizumab Versus Sunitinib Alone in First-Line Treatment of Subjects with Advanced Renal Cell Carcinoma (CLEAR).	• Histological or cytological confirmation of RCC with a clear-cell component • At least 1 measurable target lesion per RECIST 1.1 • KPS of ≥ 70 • Adequately controlled BP with or without antihypertensive meds, defined as BP ≤ 150/90 m mHg at screening and no change in antihypertensive meds within 1 week prior to C1D1 • Adequate organ function per blood work

Renal Adjuvant monotherapy	Merck MK3475-564 NCT03142334	A Phase III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial of Pembrolizumab (MK-3475) as Monotherapy in the Adjuvant Treatment of Renal Cell Carcinoma Post Nephrectomy (KEYNOTE-564)	• 18 years and older • Histologically confirmed diagnosis of RCC with clear cell component with or without sarcomatoid features • Intermediate-high risk, high risk, or M1 NED RCC as defined per protocol • No prior systemic therapy for advanced RCC • Undergone a partial nephroprotective or radical complete nephrectomy with negative surgical margins • Undergone a nephrectomy and/or metastasectomy ≥28 days before signing consent and ≤12 weeks before randomization • Tumor free as assessed by investigator and validated by CT or MRI and bone scan ≤28 before randomization • Provided adequate tissue per protocol • ECOG PS 0 or 1 • Adequate organ function

		Head and Neck	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
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		Neurology and Neuro-Oncology	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Newly diagnosed GBM (Glioblastoma)	National Cancer Institute/Alliance A071102 NCT02152982	A Phase II/III Randomized trial of VELIPARIB or Placebo in combination with Adjuvant Temozolomide in newly diagnosed Glioblastoma with MGMT Promoter Hypermethylation	• ECOG < or = 2 • Glioblastoma or Gliosarcoma grade IV with MGMT hypermethylation (central review) • Patients with complete resection, partial resection or biopsy are eligible • Measurable or non-measurable disease is allow as long as it has not been progression after chemo-radiation (Temozolomide & radiation therapy)
Newly diagnosed GBM (Glioblastoma)	Nativis NAT-109 NCT03276286	A Feasibility Study of the Nativis Voyager System in Patients with Newly Diagnosed Glioblastoma Multiforme (GBM)	• KPS >or=60 • Pathological evidence of GBM • Maximal debulking surgery • Investigational study device is given concomitant with standard of care radiation therapy & Temozolamide

		Neurology and Neuro-Oncology	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Recurrent GBM	Medicenna Therapeutics Inc. MDNA55-05 NCT02858895	An Open-Label Non-Randomized, Multi-Center Phase-2 Study of Convection-Enhanced Delivery (CED) of MDNA55 in Adults with Recurrent or Progressive Glioblastoma	• KPS >or=70. Life expectancy at least 12 weeks • Histological confirmed primary GBM-de novo-that has recurred or progressed (first or second recurrence, including this recurrence) after treatment including surgery & radiotherapy with or without chemotherapy. • More than 12 weeks since completion of XRT at time of study entry • Access to archival tissue from 1st diagnosis of GBM • Recurrent tumor must be solid, suprastentorial, contrast enhancing GB no smaller than 1 x1 cm & no larger than 4 cm max. in a single diameter based on MRI taken within 14 days prior to catheter placement.
Recurrent GBM	Nativis, Inc. NAT-101 NCT02296580	A Feasibility Study of the Nativis Voyager System in Patients With Recurrent Glioblastoma Multiforme (GBM)	• KPS ≥ 60 • Histologically confirmed dx of GBM • Failed or intolerant to: radiotherapy and temozolomide therapy • Progressive disease with at least 1 measurable lesion on MRI or CT • No surgery within last 4 weeks • No active implantable or electromagnetic device or metal implant that are incompatible with MRI
Recurrent Anaplastic Astrocytoma	Orbus therapeutics **STELLAR** OT-15-001 NCT02796261	A Phase 3, Randomized, Open-Label Study to Evaluate the Efficacy and Safety of Eflornithine with Lomustine Compared to Lomustine Alone in Patients with Anaplastic Astrocytoma That Progress/Recur After Irradiation and Adjuvant Temozolomide Chemotherapy.	• KPS > 70 • Surgical or biopsy-proven diagnosis of WHO grade 3 AA • Stained, unstained slides or tumor tissue block(s) are available from their most recent tumor surgery for central histological confirmation • Completion of EBRT ≥ 6 months prior to randomization • Life expectancy ≥ 6 months
Anaplastic Glioma or Low Grade Glioma	National Cancer Institute/Alliance N0577 NCT00887146	Phase III Intergroup Study of Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma	• ECOG PS: 0, 1 or 2 • Newly diagnosed and ≤ 3 months from surgical diagnosis • Histological confirmation of anaplastic glioma or low grade glioma by central pathology review submission • Surgery (partial or gross total resection or biopsy) performed ≥ 2 weeks prior to registration with recovering from effects of surgery. • Tumor must show 1p/19q codeletion

		Neurology and Neuro-Oncology	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Meningioma Grade II	National Cancer Institute NRG-BN003 NCT 03180268	Phase III Trial of Observation versus Irradiation for a Gross Totally Resected grade II Meningioma	• Newly diagnosed unifocal intracranial meningioma • Gross totally resection with modified Simpson grade 1-3 • Histologically confirmation of WHO grade II meningioma • Previous radiotherapy to the scalp, cranium, brain or skull base & radiation-induced meningiomas are excluded
Adult Glioma and Meningioma	National Cancer Institute /Moffitt Cancer 15004 No NCT #	Southeastern Study of Cancer and the Environment	• Primary diagnosis of glioma or meningioma any grade • GBM dx within 1 year, Anaplastic astrocytoma grade III dx within 5 years, grate 2 or less gliomas no restrictions. • At least 18 years of age • Residents of the US
Brain Metastasis	NCI A221208 NCT02490878	Randomized Phase II Study: Corticosteroids and Bevacizumab vs. Corticosteroids and Placebo (BeSt) for Radionecrosis after Radiosurgery for Brain Metastases	• KPS > or = 60. Symptomatic brain radionecrosis after radiosurgery for brain metastasis from primary solid tumor including but not limited to lung, breast, colorectal cancer, excluding melanoma, choriocarcinoma, renal cell CA or gliomas. • Radionecrosis at 3-24 months following radiosurgery • New or increase headache associated with mass effect, sensory or motor abnormality, cognitive changes, speech difficulty, balance or coordination difficulty, cranial nerve deficits. Symptoms persistent or worsening despite administration of at least dexamethasone 4 mg/day for 1 week. • No Bevacizumab (Avastin) < or = 3 months of study registration. No systemic therapy within 2 weeks prior to registration • Central imaging review to confirm radionecrosis for eligibility

		Neurology and Neuro-Oncology	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Brain Tumor	NCI A221101 NCT01781468	A Phase III Randomized, Double-Blind Placebo Controlled Study of Armodafinil (Nuvigil®) To Reduce Cancer Related Fatigue in Patients With High Grade Glioma	• ECOG of 0, 1, 2,or 3 • Diagnosed with GBM, gliosarcoma, anaplastic astrocytoma, anaplastic oligodendroglioma or anaplastic oligoastrocytoma who are clinically stable & have completed radiation therapy (excluding stereotactic radiosurgery) > 21 days & < or = 24 months prior to enrollment. • Stable dose of corticosteroid > or = 14 days prior registration • Concurrent chemotherapy &/or Optune device is allowed
Brain Tumor	State of Florida NCT00811148	Florida Center for Brain Tumor Research	• All patients with brain tumors (or other problems requiring cranial surgery) are eligible

Christine E. Lynn Women's Health and Wellness Institute

Clinical Trials – January 2018

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		BREAST	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Breast	Ellman Foundation CESM NCT # N/A	Dynamic Contrast Enhanced MRI and Contrast Enhanced Spectral Mammography in the Diagnosis of Breast Cancer the Women of High Risk: A Comparison Study	• Women age 25 or older. • Greater than 20% lifetime risk of breast cancer based on risk factors. • No contraindications to gadolinium or MRI • No allergy to iodine • No pregnancy • Breast MRI done at Women's Health and Wellness Institute

Lynn Heart and Vascular Institute

Clinical Trials – January 2018

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Primary Site	Sponsor/Study ID NCT #	Protocol Description	Eligibility
Thoracoabdomnal aneurysm	W. Anthony Lee, MD NCT01524211	Physician-Sponsored IDE: "Evaluation of Branch Endografts in the Treatment of Aortic Aneurysms"	• Adult, 18 years and older Patient must have one of the following: • Degenerative, atherosclerotic thoracoabdominal, suprarenal and juxtarenal aortic aneurysms (fusiform or saccular): ≥55 mm in diameter in a male or ≥ 50 mm in diameter in a female, or • Thoracoabdominal aortic aneurysm with a history of growth ≥ 0.5 cm per year, or • Penetrating ulcers: ≥ 20 mm in depth, or • Chronic type B aortic dissections: ≥ 50 mm total aortic diameter, or • Symptomatic pathology (aneurysm, ulcer or chronic dissection) of any size. • Additional criteria for LP material: Iliofemoral access vessels < 8 mm or with significant atherosclerotic occlusive disease that would require an iliac conduit as determined by the PI.
Infrarenal Abdominal Aortic Aneurysms	Bolton Medical, Inc NCT02009644	IP-0008-12 A Phase II Clinical Study of the Safety and Performance of the Treovance Stent-Graft with Navitel Delivery System for Patients with Infrarenal Abdominal Aortic Aneurysms	• Between the ages of 18 and 85 • Diagnosed with an infrarenal abdominal aortic aneurysm (AAA), with or without iliac artery involvement • Infrarenal AAA that is ≥ 4.5 cm in diameter for mails, or ≥ 4.0 cm in diameter for females, or has increased in diameter by 0.5 cm in the last 6 months • Infrarenal landing neck length of 10 mm or greater and angle of less than 60 degrees relative to long axis of aneurysm, or • Infrarenal landing neck length of 15 mm or greater and angle of between 60 and 75 degrees relative to long axis of aneurysm and suprarenal neck angle of less than 45 degrees relative to the infrarenal neck axis and an outside diameter of 16 mm-30 mm • Infrarenal landing neck must meet the vessel size requirements specified in the instructions for use • Lowest renal artery at least 9 cm from the aortic bifurcation • Iliac landing neck with inside diameter of 8 mm – 13 mm and a length of at least 10 mm, or inside diameter of >13 mm – 20 mm and a length of at least 15 mm • Distal iliac landing neck must meet the vessel size requirements specified in instructions for use

			• Total treatment length of at least 13 cm • Distal aortic diameter above the iliac bifurcation equal to or greater than 70% of the sum of the selected leg graft diameters. • Willing and able to comply with 1-month, 6-month, and 12-month follow-up visits, and annual visits out to 5 years • Adequate renal function to tolerate contrast enhanced CT • Adequate vascular access or introduction of Navitel Delivery System or anatomy is suitable for creation of iliac conduit
Juxtarenal aortic aneurysms	Cook Incorporated NCT02396199	Evaluation of the safety and effectiveness of the Zenith p-Branch in combination with Atrium iCAST covered stents for the treatment if paraenal or juxtarenal aortic aneurysms.	• Pararenal or juxtarenal AAA ≥ 5.0 cm in diameter or 2X normal aortic diameter,or • Pararenal or juxtarenal AAA with history of growth ≥ 0.5 cm/year, or • Saccular aneurysm with aortic diameter < 1.5X normal aortic diameter deemed at risk for rupture by physician
Aneurysm iliac arteries	Cook Incorporated NCT01208415	PRESERVE- Zenith® Iliac Branch Clinical Study Clinical Study to Evaluate the Safety and Effectiveness of the Zenith® Branch Endovascular Graft-Iliac Bifurcation	• Aortoiliac or iliac aneurysm • Unsuitable distal sealing site for a Zenith® iliac leg graft within the common iliac artery on the intended side of Branch Graft implantation
Coronary Bypass	Alexander Kulik, MD NCT02053909	Ticagrelor Antiplatelet Therapy to Reduce Graft Events and Thrombosis (TARGET Trial): Does Ticagrelor Improve Graft Patency after Coronary Bypass?	• Female and/or male aged 18 – 90 years • Undergoing first time CABG with at least 1 saphenous vein graft, irrespective of concurrent valve surgery
	Medtronic NCT # N/A	STOP Persistent AF	• Symptomatic persistent AF defined as having continuous episode lasting longer than 7 days but less than 6 months by consecutive ECG • Failure or intolerance to at least one Class I or III antiarrhythmic drug • Age 18 to 80
	St. Jude Medical, Inc. NCT # N/A	MultiPoint Pacing™ Post Market Study (MPP PMS)	• Scheduled to receive new CRT implant or upgrade from an existing ICD/Pacemaker implant with no prior LV lead placement

Lynn Cancer Institute Oncology Trials

Clinical Trials – July 2017

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Center for Hematology-Oncology **561.955.6400** *Radiation Oncology* **561.955.4111**

		BREAST	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Breast HER2 + MBC third line	PUMA- NER-1301 **NALA** NCT01808573	A Study of Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in Patients with Her2+ Metastatic Breast Cancer Who Have Received Two or More Prior Her2-Directed Regimens in the Metastatic Setting (NALA)	• Histologically confirmed MBC; stage IV • HER2+ (IHC3+ or FISH+), by central lab • Prior tx w/≥ two (2) HER2-directed regimens for MBC • >1 measurable metastatic lesion by RECIST v1.1 • LVEF >50% by MUGA or ECHO; • ECOG status of 0 or 1 • No prior treatment w/ capecitabine, neratinib, lapatinib, • No prior HER2 directed TKI • No cumulative exposer to anthracyclines • No active CNS metastases • No active uncontrolled cardiac disease
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HER2 – Metastatic or Locally Advanced Unresetable BRCA Associated Breast Cancer	AbbVie M12-914 NCT02163694	A Phase 3 Randomized, Placebo-Controlled Trial of Carboplatin and Paclitaxel With or Without the PARP Inhibitor Veliparib (ABT-888) in HER2-Negative Metastatic or Locally Advanced Unresectable BRCA-Associated Breast Cancer	• Histologicallyor cytologically confirmed breast cancer advanced or metastatic • Suspected deleterious or deleterious BRCA1 or BRCA2 germline mutation • HER2 negative • Measurable or non-measurable disease • ECOG 0-2 • 1st, 2nd or 3rd line
Genetic Registry	City of Hope National Medical Center 96144 *GENETICS STUDY*	Molecular Genetic Studies of Cancer Patients and Their Relatives	• Personal History of family history of cancer suggestive of presence of an inherited predisposition • In a group known or suspected to have increased risk of carrying genetic alteration or of sustaining exposure that would place them at risk of cancer • Willing historian to provide information or access
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		GASTROINTESTINAL	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**

Liver Humanitarian Device TX	MDS Nordion **Contact** **Dr. George Khoriaty**	Treatment of Unresectable Hepatocellular Carcinoma with TheraSphere® (Yttrium-90 Glass Microspheres): An HDE Treatment Protocol	• Hepatocellular carcinoma of the liver • ECOG PS score of ≤ 2 with a life expectancy of > 3 months • > 4 weeks since prior RT or surgery • > 1 month post other chemotherapy. • Excludes contraindications to angiography and selective visceral catheterization • Excludes extra-hepatic disease representing an imminent life-threatening outcome or active infection
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Pancreas	AstraZenca D081FC00001 **POLO** NTC02184195	A Phase III, Randomized, Double Blind, Placebo Controlled, Multicentre Study of Maintenance Olaparib Monotherapy in Patients with gBRCA Mutated Metastatic Pancreatic Cancer whose Disease Has Not Progressed on First Line Platinum Based Chemotherapy	• Histologic/pathologic confirmation pancreatic adenocarcinoma • Receiving initial chemotherapy for metastatic disease and without evidence of disease progression on treatment • 1st Line with platinum-based regimen received a minimum of 16 weeks of continuous platinum treatment with no evidence of progression • Documented mutation in gBRACA1 or gBRACA2 that is predicted to be deleterious or suspected deleterious • ECOG performance status 0-1 •
Met. Colorectal	BTG International Inc. TS-102 **EPOCH** NCT01483027	A Phase III Clinical Trial Evaluating TheraSphere® in Patients with Metastatic Colorectal Carcinoma of the Liver who have Failed First Line Chemotherapy	• ECOG PS 0-1 through screening to first treatment on study • Unresectable metastatic disease to the liver with disease progression in the liver with oxaliplatin or irinotecan based 1st line chemotherapy • No prior external beam radiation treatment to liver or any prior intra-arterial liver directed therapy • No clinically evident ascites • Tumor replacement <50% of total liver volume
		HEMATOLOGY	
		ANEMIA	

Primary Site	Sponsor/Study ID NCT #	Protocol Description	Eligibility
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		MULTIPLE MYELOMA	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
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		LYMPHOMA	
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		CHRONIC LYMPHOCYTIC LEUKEMIA	
Newly Dx or Relapsed or Refractory CLL	TG Therapeutics UTX-TGR-304 NCT02656303	A Phase 3, Randomized Study to Assess the Efficacy and Safety of Ublituximab in Combination with TGR-1202 Compared to Obinutuzumab in Combination with Chlorambucil in Patients with Chronic Lymphocytic Lymphoma	• ECOG PS ≤ 2 • B-cell CLL that warrants treatment consistent with accepted IWCLL criteria for initiation of therapy • Massive, progressive, or symptomatic splenomegaly or lymphadenopathy • No prior therapy with obinutuzumab and/or chlorambucil
CLL, PD while on UTX-TGR-304	TG Therapeutics UTX-TGR-204 NCT02612311	A multi-center, open-label, study to evaluate the safety and efficacy of Ublituximab (TG-1101) in combination with TGR-1202 for patients previously enrolled in protocol UTX-TGR-304	• ECOG PS ≤ 2 • After confirmed progression receiving treatment and randomized onto Arms B, C, or D while on UTX-TGR-304

		General Oncology	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**

General Oncology	LCI Senior Exercise Project/ SPP-2014-38-LCI No NCT #	Senior Adult Cancer Treatment Optimization of Performance Project (Pilot study)	• 70 years or older at time of cancer diagnosis • Understand and adhere to study related assessments/procedures • No prior cancer treatment • Scheduled to start cytotoxic chemotherapy and/or radiation therapy • No restriction on tumor stage
		LUNG	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
Stage IV Non-Squamous NSCLC	Roche GO29431 NCT02409342	A Phase III, open-label, randomized study of MPDL3280A (Anti−PDL1 Antibody) compared with Cisplatin or Carboplatin + Pemetrexed for PD-L1−selected chemotherapy naïve patients with stage IV non-squamous-non-small cell lung cancer	• ECOG PS: 0 or 1 • Histologically or cytologically confirmed stage IV **non-squamous** NSCLC • No prior chemo treatment for Stage IV unless patient had previously detected EGFR or ALK. Previous targeted therapy for those is allowed. • Treated stable brain mets is allowed • Tumor PD-L1 expression (TC3 or IC3) determined by an IHC assay performed by central laboratory on previous archival tumor tissue or tissue obtained from biopsy at screening
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IIIA, II or IB Resected Non-Squamous NSCLC	NCI A151216 ALCHEMIST NCT02194738	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) **This is the pre-registration study which randomizes to either A081105 or E4512**	• ECOG PS: 0 or 1 • No neoadjuvant (chemo or radio-therapy) for this lung cancer • No prior treatment with agents targeting EGFR mutation or ALK rearrangement • No pure squamous carcinoma • Pre-surgical: Suspected clinical stage of IIIA, II or large IB (defined as size ≥4cm) • Post-surgical: Pathologic stage IIIA, II or IB (defined as size ≥4 cm) • Patients may be receiving adjuvant chemotherapy at the time of registration. • Adequate FFPE tissue for central EGRF and ALK genotyping for all patients, include those already locally tested • Complete resection.
IIIA, II or IB Resected Non-Squamous NSCLC	NCI A081105 ALCHEMIST NCT029193282	Randomized double blind placebo controlled study of erlotinib or placebo in patients with completely resected epidermal growth factor receptor (EGFR) mutant non-small cell lung center (NSCLC)	• ECOG PS: 0 or 1 • Registered to A151216 with result of EGFR exon 19 deletion or L858R mutation • Completely resected stage IB (≥ 4cm), II, or IIIA non-squamous NSCLC with negative margins • Patients with known resistant mutations in the EGFR TK domain (T790M) are **not** eligible. • Patients that are **both** *EGFR* mutant and ALK rearrangements will be registered to A081105
IIIA, II or IB Resected Non-Squamous NSCLC	NCI E4512 **ALCHEMIST** NCT02201992	A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein	• ECOG PS: 0 or 1 • Pre-registered to A151216 • Completely resected stage IB (≥ 4cm), II, or IIIA non-squamous NSCLC with negative margins • Positive for translocation or inversion events involving the ALK gene locus • No prior treatment with crizotinib or another ALK inhibitor • No known interstitial fibrosis or interstitial lung disease. •

IIIA, II or IB Resected Non-Squamous NSCLC	Mirati 265-109 NCT02544633	Phase 2, Parallel-Arm Study of MGCD265 in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with Activating Genetic Alterations in Mesenchymal-Epithelial Transition Factor	• ECOG PS 0-2 • Tumor tissue and/or ctDNA • No prior positive test for EGFR mutation or ALK gene rearrangement • No prior treatment with small molecule or antibody inhibitor of MET or HGF
Resected Stage IB-IIIA NSCLC	Roche GO29527 NCTO2486718	A Phase III, open label, randomized study to investigate the efficacy and safety of MPDL3280A (Anti-PD-L1 Antibody) compared with best supportive care following adjuvant cisplatin based chemotherapy in PD-L1 selected patients with completely resected stage IB-IIIA non-small-cell lung cancer.	• ECOG PS 0 or 1 • Histological or cytological diagnosis of Stage IB (tumors greater than or equal 4cm)- IIIA (T2-3, NO, T1-3, N1, T1-3, N2) • Tumor PD-L1 expression of TC3 or IC3 performed by central lab • No prior treatment with systemic chemotherapy • No segmentectomy or wedge resection
Met. Squamous NSCLC 1st Line	Merck & Co. MK3475-407 NCT02775435	A Randomized, Double-Blind, Phase III Study of Carboplatin-Paclitaxel/Nab-Paclitaxel Chemotherapy with or without Pembrolizumab (MK-3475) in First Line Metastatic Squamous Non-small Cell Lung Cancer Subjects (KEYNOTE-407)	• ECOG PS: 0-1 • Stage IV Squamous NSCLC • Creatinine or calculated CrCl (≤1.5 X upper limit of normal (ULN) **OR** ≥60 mL/min for subjects with creatinine levels > 1.5 X institutional ULN • No radiation therapy to lung > 30 Gy w/in 6 mths of 1st dose of trial treatment • Completed palliative radiotherapy < 7 days of 1st dose of trial treatment
SCLC	Pharma Mar PM1183-C-003-14 **Atlantis** NCT02566993	Phase III randomized clinical trial of Lurbinectedin (PM01183)/ Doxorubicin (DOX) versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as treatment in patients with Small Cell Lung Cancer (SCLC) who failed one prior platinum-containing line	• ECOG PS ≤ 2 • Histologically or cytologically confirmed limited or extensive SCLC • 4 weeks since completion whole brain RT and two weeks since PCI completion • No more than one prior chemotherapy containing regimen and not treated with PM01183, topotecan or anthracyclines

Metastatic or Locally Advanced Solid Tumors	EMD Serono EMR200647-001 NCT02517398	A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0011359C in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications	• Life expectancy ≥ 12 weeks • ECOG performance status of 0 to 1 • Beyond this further cohort inclusion/ exclusion is site specific.
NSCLC Unknown EGFR status	Biodesix BDX-00146 No NCT #	An Observational Study Assessing the Clinical Effectiveness of VeriStrat® and Validating Immunotherapy Tests in Subjects with Non-Small Cell Lung Cancer	• EGFR mutation status wildtype or unknown • If prior treatment then documented disease progression prior to VeriStrat

GENITOURINARY

Primary Site	Sponsor/Study ID NCT #	Protocol Description	Eligibility
Non-metastatic CRPC	Bayer HealthCare Pharmaceuticals Inc. ARAMIS 17712 NCT02200614	A Phase III multination randomized, double-blind, placebo-controlled efficacy and safety study of ODM-201 in men with high-risk non-metastatic castration-resistant prostate cancer	• Histologically or cytologically confirmed adenocarcinoma of prostate without neuroendocrine differentiation or small cell features • CRPC with 3 rising PSA levels at least 1 week apart during ADT. History of antiandrogen use, most recent PSA must be at least 4 weeks after antiandrogen withdrawal • ECOG PS: 0 to 1 • Castrate level of serum testosterone (< 1.7 nmol/l [50 ng/dl]) on GnRH agonist or antagonist therapy or after bilateral orchiectomy. Patients who have not undergone bilateral orchiectomy must continue GnRH therapy during the study
Met. Hormone Sensitive Prostate Cancer	Bayer HealthCare Pharmaceuticals Inc. ARASENS 17777 NCT02799602	A randomized, double-blind, placebo-controlled Phase III study of ODM-201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer	• ECOG PS: 0 to 1 • Histologically or cytologically confirmed adenocarcinoma of prostate • Metastatic disease documented either by a positive bone scan, or for soft tissue or visceralmetastases, either by contrast-enhanced CT abdominal/pelvic/chest MRI • None of the following within 6 months before randomization: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, congestive heart failure • No prior treatment with second-generation AR inhibitors such as enzalutamide, ARN-509, ODM-201, other investigational AR inhibitors, or CYP17 enzyme inhibitor as antineoplastic treatment

Metastatic CRPC	Clovis Oncology, Inc. CO-338-052 **TRITON2** NCT02952534	A Multicenter, Open-label Phase 2 Study of Rucaparib in patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency	• ECOG PS: 0 to 1 • Histologically or cytologically confirmed adenocarcinoma or poorly differentiated carcinoma of prostate • Castrate level of serum testosterone of ≤ 50 ng/dL (1.73 nM). For patients currently being treated with LHRH agonists therapy must be continued throughout the study • Have a deleterious mutation in BRCA1/2 or ATM, or molecular evidence of other homologous recombination deficiency • No prior treatment with any PARP inhibitor, mitoxantrone, cyclophosphamide or any platinum-based chemotherapy
Metastatic CRPC	F. Hoffman-La Roche Ltd CO39385 NCT03016312	A Phase III, multicenter, randomized study of Atezolizumab (Anti-PD-L1 antibody) in combination with Enzalutamide vs. Enzalutamide alone in patients with metastatic castration-resistant prostate cancer after failure of an androgen synthesis inhibitor and failure of, ineligibility for, or refusal of a taxane regimen	• ECOG PS: 0 to 1 • Progressive disease prior to screening by PSA or imagine per PCWG3 criteria • One prior regimen of a taxane-containing regimen or refusal or ineligibility of a taxane-containing regimen along • One prior regimen of an androgen synthesis inhibitor • Tumor specimen from a site not irradiated for PD-L1 status testing via central pathology
Metastatic CRPC	Clovis Oncology, Inc. CO-338-063 **TRITON3** NCT02975934	Multicenter, Randomized, Open-label Phase 3 Study of Rucaparib versus Physician's Choice of Therapy for Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency	• ECOG PS: 0 or 1 • Surgically or medically castrated, with serum testosterone levels of ≤ 50 ng/dL (1.73 nM) • Have a deleterious mutation in a BRCA1/2 or ATM gene • Eligible for treatment with physician's choice of comparator treatment • PD after treatment with one prior next-generation AR-targeted therapy for castration-resistant disease
Metastatic CRPC	F. Hoffman-La Roche Ltd CO39303 NCT03072238	A phase III, randomized, double-blind, placebo-controlled, multicenter trial testing Ipatasertib plus Abiraterone plus prednisone/prednisolone, relative to placebo plus Abiraterone plus prednisone/prednisolone in patients with asymptomatic or mildly symptomatic, metastatic castrate resistant prostate cancer with PTEN diagnostic positive tumors	• Histologically confirmed prostate adenocarcinoma without neuroendocrine differentiation or small-cell features • Consent to provide FFPE tissue block • Valid PTEN IHC result (central testing) • Metastatic disease documented by bone lesion on bone scan or soft tissue disease by CT or MRI • Asymtomatic or mildly symptomatic form of prostate cancer • Progress disease defined using at least one; a) two rising PSA levels ≥ 1 ng/mL measured ≥ 1 week apart b) radiographic evidence of disease progression in soft tissue

		Head and Neck	
Primary Site	**Sponsor/Study ID NCT #**	**Protocol Description**	**Eligibility**
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