Active Clinical Trials @ CCH

Alisha Blake 4-5242

Tolulope Ogunkelu 4-7255

Bharathi Reddivari 4-7258

Namrata Das Batra
CP: 312-404-6676, 4-7254

Juan Moreno 4-5464

Ola's pager: 390-2348 (8 AM - 3:30 PM) PM

	Protocol	Description	Basic Eligibility
Cancer Site:	**Multiple**		
1.	**DCP-001** **CRA: All CRAs** Anticipated accrual: 362 ☑ Spanish Consent	Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP).	All patients are eligible if they are being screend for a clinical trial. Study must be on the Protocol List (leave it up to CRA to look up).
2.	**DCP-002** **CRA: Namrata Das Batra** Anticipated accrual: 5 ☑ Spanish Consent	Early Onset Malignancies Initiative (EOMI): Molecular profiling of Breast, Prostate, Colorectal, Liver, Kidney, and Multiple Myeloma among Racially and Ethnically Diverse Populations.	New (untreated) patients with high suspicion for cancer, going for Biopsy/Resection. Breast Cancer <= 45 y/o. Prostate Cancer <= 55 y/o. Colorectal Cancer <= 55 y/o. HCC <= 55 y/o. RCC <= 55 y/o (Asian and Non-Hispanic White only) Multiple Myeloma <= 55 y/o Fresh tissue will be collected (NO FORMALIN).
3.	**NCI 10323 (Moonshot)** **CRA: Namrata Das Batra** Anticipated accrual: ☑ Spanish Consent	Cancer Moonshot Biobank Research Protocol.	Patient (13 y/o or older of any gender) diagnosed with Stage IV colorectal cancer, Stage III/IV non-small cell or small cell lung cancer, metastatic castration-resistant prostate cancer, Stage IV gastroesophageal cancer, Stage III/IV melanoma, newly diagnosed acute myeloid leukemia or treatment refractory multiple myeloma, is undergoing standard of care therapy. Patients with ECOG Performance Status (PS) 0 or 1 may be enrolled retrospectively if archival material is submitted that contains the cancer type forwhich the participant is enrolled and that was collected up to 5 years prior to initiation of a therapy.
4.	**P9846** **CRA: Namrata Das Batra** Anticipated accrual: 100 ☐ Spanish Consent	Patient-Derived Models Tissue Procurement Protocol For The National Cancer Institute (NCI).	-Any cancer diagnosis, histologically proven, high suspicion with imaging. -Recurrence/Progression going for re-biopsy. -Biopsy proven going for surgery for definitive resection. -Not on active treatment/chemotherapy. -No active infection. Fresh tissue will be collected (NO FORMALIN).

	Protocol	Description	Basic Eligibility
5.	**P9846 (2)** **CRA: Namrata Das Batra** Anticipated accrual: 100 ☑ Spanish Consent	Patient-Derived Models Tissue Procurement Protocol For The National Cancer Institute (NCI).	Any cancer diagnosis, histologically proven, high suspicion with imaging. Recurrence/Progression going for re-biopsy. Biopsy proven going for surgery for definitive resection. Not on active treatment/chemotherapy. No active infection. Fresh tissue will be collected (NO FORMALIN).
6.	**URCC-21038** **CRA: Bharathi/Juan** Anticipated accrual: ☑ Spanish Consent	Disparities in Results of Immune Checkpoint Inhibitor Treatment (DiRECT): A Prospective Cohort Study of Cancer Survivors Treated with anti-PD-1/anti-PD-L1 Immunotherapy in a Community Oncology Setting	Be 18 years of age or older. Self-identify as African/African American/Black (AA), or European American/ Caucasian/white (EA) - Patients may identify a Hispanic/Latino ethnicity in combination with an AA or EA racial identity. Have a current diagnosis of invasive cancer at stage I-IV (Patients may have a history of previous cancer diagnosis and cancer treatment not involving immunotherapy). Be scheduled to receive anti-PD-1/-L1 ICI-containing therapy according to FDA labels or NCCN guidelines at Category 1 or 2A as standard of care treatment alone or in combination with co-treatments (including alternative ICIs). Be able to speak and read English or Spanish. Be able to provide written or remote informed consent.

Cancer Site: Breast

1.	**Alliance A011801** **CRA: Tolulope Ogunkelu** Anticipated accrual: ☑ Spanish Consent	The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSessment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib. Study has QoL component.	Patients must have received neoadjuvant chemotherapy with one of the following regimens: THP, TMP, AC-TH(P); TCH(P); FAC-TH(P), or FEC-TH(P). Prior receipt of T-DM1 in the neoadjuvant setting is not allowed. Prior treatment must have consisted ≥ 6 cycles of chemotherapy and HER2-directed therapy, with a total duration of ≥ 12 weeks, including at least 9 weeks of preoperative taxane and trastuzumab with or without pertuzumab. Patients who received neoadjuvant systemic therapy which included experimental HER2-directed therapy are potentially eligible, as long as the investigational agent was not a HER2-targeted antibody-drug. Both of the following points must be true: -An interval of no more than 12 weeks between the completion date of the last definitive treatment and the date of registration. All systemic chemotherapy should have been completed preoperatively. Not pregnant and not nursing. Age ≥ 18 years (male or female).

	Protocol	Description	Basic Eligibility
2.	**ECOG EA1151 (TMIST)** **CRA: Alisha Blake** Anticipated accrual: 40 ☑ Spanish Consent	Tomosynthesis Mammographic Imaging Screening Trial (TMIST).	Patients must be women age 45 or older and under age 75 at the time of study entry. Women of childbearing potential must not be known to be pregnant or lactating. Patients must be scheduled for, or have intent to schedule, a screening mammogram. Patients must be able to tolerate digital breast tomosynthesis and full field digital mammographic imaging required by protocol. Patients must be willing and able to provide a written informed consent. Patients must not have new symptoms or signs of benign or malignant breast disease. Patients must not have had a screening mammogram within the last 11 months prior to date of randomization. Patients must not have previous personal history of breast cancer including ductal carcinoma in situ.
3.	**NRG-BR007** **CRA: Tolulope Ogunkelu** Anticipated accrual: ☐ Spanish Consent	A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer (DEBRA)	The patient or a legally authorized representative must provide study-specific informed consent prior to study entry and, for patients treated in the U.S., authorization permitting release of personal health information. The patient must be ≥ 50 years and < 70 years of age. The trial is open to female and male patients. The patient must have an ECOG performance status of 0 or 1. The patient must have undergone a lumpectomy and the margins of the resected specimen or re excision must be histologically free of invasive tumor and DCIS with no ink on tumor as determined by the local pathologist. If pathologic examination demonstrates tumor at the line of resection, additional excisions may be performed to obtain clear margins. (Patients with margins positive for LCIS are eligible without additional resection.) The tumor must be unilateral invasive adenocarcinoma of the breast on histologic examination. Patient must have undergone axillary staging (sentinel node biopsy and/or axillary node dissection). The following staging criteria must be met postoperatively according to AJCC 8th edition criteria: -By pathologic evaluation, primary tumor must be pT1 (≤ 2 cm). -By pathologic evaluation, ipsilateral nodes must be pN0. (Patients with pathologic staging of pN0(i+) or pN0(mol+) are NOT eligible.

Cancer Site: Colorectal

	Protocol	Description	Basic Eligibility
1.	**A022104** **CRA: Juan Moreno** Anticipated accrual: ☐ Spanish Consent	The Janus Rectal Cancer Trial: A Randomized Phase II Trial Testing the Efficacy of Triplet Versus Doublet Chemotherapy to Achieve Clinical Complete Response in Patients with Locally Advanced Rectal Cance.	-Histologic Documentation: Stage: Clinical stage II or III rectal adenocarcinoma defined as T4N0 or any T with node positive disease (any T, N+); also T3N0 requiring APR or coloanal anastomosis Tumor Site: Rectum; ≤ 12cm from the anal verge - No prior systemic chemotherapy, targeted therapy, or immunotherapy; or radiation therapy administered as treatment for colorectal cancer within the past 5 years is allowed. -Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects.
2.	**NRG-CC005** **CRA: Juan Moreno** Anticipated accrual: ☑ Spanish Consent	Study 22-044N NRG-CC005, FORTE (Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps) (NCT05080673)	Participants □ 50 and □ 70 years of age at the time of randomization. Participants with a first-time diagnosis of 1-2 non-advanced tubular adenomas (□ 10 mm without tubulovillous or villous changes or high grade or severe dysplasia) from the qualifying colonoscopy within 4 years prior to randomization. Sessile serrated polyps/adenomas, as long as they do not meet the criteria for advanced adenomas, will be considered as non-advanced adenomas. Qualifying colonoscopy must be a complete colonoscopy with visualization of the cecum and with adequate cleansing within 4 years prior to randomization. Complete excision of all observed polyps in qualifying colonoscopy (see Section 3.3.7). Participants must be able to read or understand English or Spanish.
3.	**WF-1806** **CRA: B.Reddivari** Anticipated accrual: ☑ Spanish Consent	Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer: The M&M Study (NCT03998202)	Older adults (age ≥60y) with either newly diagnosed metastatic CRC or newly recognized metastatic recurrence of CRC greater than 1 year from completion of treatment of non-metastatic CRC. -Planning to undergo immunotherapy and/or 5-FU based chemotherapy as first line of treatment. 5-FU chemotherapy can be 5-FU alone or in combination with oxaliplatin and/or irinotecan; +/- immunotherapy. -Clinical stage (AJCC, 8th ed.) as indicated in the tables below, including no distant metastases based on the following diagnostic workup:

Cancer Site: **Gyne**

1.	**NRG-CC008** **CRA: Juan Moreno** Anticipated accrual: ☑ Spanish Consent	A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROCk]	Women 35-50 years of age, inclusive. Patients who have declined or elected to defer RRSO after proper counselling to clearly explain the standard of care for BRCA1 mutation carriers. At least one intact ovary and fallopian tube is in situ at the time of counseling and consent. Positive CLIA-approved test results for pathogenic or likely pathogenic germline BRCA1 mutation in the patient herself. Documentation of the result is required. Premenopausal; defined as <12 months of amenorrhea. Transvaginal ultrasound (TVUS) and CA-125 within 180 days of registration. The patient or a legally authorized representative must provide study-specific informed consent prior to study entry.

	Protocol	Description	Basic Eligibility
2.	**NRG-GY012** **CRA:** Anticipated accrual: ☐ Spanish Consent	A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer.	Recurrent or persistent endometrial carcinoma. Histologic types: Endometrioid adenocarcinoma, serous adenocarcinoma, undifferentiated carcinoma, mixed epithelial carcinoma, adenocarcinoma not otherwise specified.

Cancer Site: Head-Neck

1.	**EA3161** **CRA:** **Namrata Das Batra** Anticipated accrual: ☑ Spanish Consent	A Phase II/III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPSCC	Age ≥ 18 years. ECOG performance status of 0 or 1. Patients must have oropharynx cancer (AJCC 8) that is p16-positive by immunohistochemistry OR p16 equivocal by IHC and HPV positive by in situ hybridization with the following criteria: ≥10 pack-years, stage T1-2N2-N3 or T3-4N0-3 OR<10 pack-years, stage T4N0-N3 or T1-3N2-3. Patients must not have known hypersensitivity to nivolumab or compounds of similar chemical or biologic composition. Patients with a history of allergic reactions attributed to platinum-based chemotherapy agents are excluded. Patients must not have had prior systemic therapy, radiation treatment or surgery for p16 positive OPSCC. Patients must not have received previous irradiation for head and neck tumor, skull base, or brain tumors.
2.	**EA-3163** **CRA:** **Namrata Das Batra** Anticipated accrual: ☑ Spanish Consent	Phase II Randomized Trial of Neoadjuvant Chemotherapy Followed by Surgery and Post-Operative Radiation versus Surgery and Post-Operative Radiation for Organ Preservation of T3 and T4a (and Selected T4b) Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC)	Patients must be ≥ 18 years of age. Patients must have an ECOG performance status of 0 or 1. Patients must have a general physical condition compatible with the proposed chemotherapy and surgery. Patients must have stage T3 or T4a, histologically-confirmed NPNSCC requiring orbital or skull base resection. Patients with T4b who have the following characteristics leading to a T4b definition but who in the opinion of the treating surgeon can have resectable disease can be included provided they fulfill all other eligibility criteria and provided they have one of the following presentations: 1. Invasion of orbital apex without involvement of the cavernous sinus 2. Dura invasion depending on extent of involvement and if total resection is deemed feasible. 3. Brain/middle cranial fossa invasion depending on extent of involvement if total resection is deemed feasible. 4. Nasopharynx invasion if very limited invasion if very limited.

	Protocol	Description	Basic Eligibility
3.	**EA3191** **CRA: Namrata Das Batra** Anticipated accrual: ☐ Spanish Consent	A Phase II Randomized Trial of Adjuvant Therapy with Pembrolizumab After Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma with High Risk Features	Patient must be between 18 and 79 years of age. Patient must have locoregionally recurrent or second primary HNSCC (oral cavity, oropharynx, larynx, hypopharynx) in a previously radiated field. Patient must have undergone surgery with gross total resection and must be randomized within 8 weeks of surgery. Patients must have high risk disease defined as: Positive Margins and/or Extra Nodal Extension (ENE) • Positive margins are defined as malignancy at or within 1 mm of the margin. High grade dysplasia (i.e. carcinoma in situ) at the margin is also considered positive • ENE may be either gross or microscopic 3.1.5 Patient must have a PD-L1 Combined Positive Score (CPS) ≥1 in a CLIA certified laboratory. Testing can be done locally as long as it is done in a CLIA certified laboratory. This testing must be on the tumor specimen from the resection of the patient's recurrent or second primary HNSCC. Patient must have had prior radiation to the area of recurrent or second primary tumor. This is defined as >50% of the presurgical tumor volume having previously received a dose of > 45 Gy as determined by the treating radiation oncologist.
4.	**EA3202** **CRA: Namrata Das Batra** Anticipated accrual: ☑ Spanish Consent	A Phase II/III Trial of Chemotherapy + Cetuximab vs Chemotherapy + Bevacizumab vs Atezolizumab + Bevacizumab Following Progression on Immune Checkpoint Inhibition in Recurrent/Metastatic Head and Neck Cancers	Patient must have histologically confirmed squamous cell carcinoma of the head and neck (HNSCC) (excluding SCC of salivary glands, and skin). Patient must have measurable disease as defined by RECIST v1.1 criteria in Section 6. Measurements must be obtained within 4 weeks prior to randomization. Patient must be ≥ 18 years of age. Patient must have an ECOG performance status 0-1 Patient must have received prior therapy with an immune checkpoint inhibitor (ICI) in the first-line setting for recurrent/metastatic disease with at least stable disease for at least 12 weeks by RECIST. Patient must not have a history of PD-1 inhibitor-induced hyper progression, defined as 100 increase in tumor burden within 8 weeks (or 50% within 4 weeks) of initiating ICI and associated with clinical deterioration. Patient must not have uncontrolled hypertension, a history of hypertensive crisis or hypertensive encephalopathy, or a history of grade 4 thromboembolism. Patient must not have a history of coagulopathy or hemorrhagic disorders. Patient must not have a history of thrombosis (e.g., pulmonary embolism or deep venous thrombosis) currently requiring therapeutic anticoagulation (prophylactic use of anticoagulation is allowed).

	Protocol	Description	Basic Eligibility
5.	**ECOG EA3132** **CRA: Namrata Das Batra** Anticipated accrual: 2 ☑ Spanish Consent	Phase II Randomized Trial of Adjuvant Radiotherapy with or Without Cisplatin for p53 Mutated, Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN).	Patient has undergone total resection of the primary tumor with curative intent in order to meet the 8 week deadline to register the patient to Step 1 after surgery; (full assay minimum turnaround time is 17-24 days). Patient Population: Pathologically proven diagnosis of SCCA (including variants such as verrucous carcinoma, spindle cell carcinoma, carcinoma NOS) of the head/neck (oral cavity, oropharynx, hypopharynx or larynx). Pathological Stage III or IVA (AJCC 8): T3-T4a, N0-N3, M0 or T1-T2, N1-N3, M0. For Oropharynx tumors, patient must have negative HPV status of the tumor as determined by p16 protein expression using IHC. CT Chest done needed within 8 weeks prior to registration to rule out metastatic disease. Conditions for Patient Ineligibility: - (+)margins (not superceded by an additional margin of tumor-negative tissue). - nodal extra-capsular extension, and/or gross residual disease after surgery are not eligible.
6.	**NRG-HN001** **CRA: Namrata Das Batra** Anticipated accrual: 2 ☑ Spanish Consent	Randomized Phase II And Phase III Studies Of Individualized Treatment For Nasopharyngeal Carcinoma Based On Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA).	Patient Population: Biopsy proven (from primary lesion and/or lymph nodes) diagnosis of Stage II-IVB non-metastatic cancer of the nasopharynx; detectable pre-treatment plasma EBV DNA. Minimum Diagnostic Workup Needed: MRI of the nasopharynx and neck within 28 days prior to registration. To rule out distant metastasis within 28 days prior registration: CT scan with contrast of the Chest, Abdomen/Pelvis or a total body PET/CT scan. A bone scan only when there is suspicion of bone metastases (a PET/CT scan can substitute for the bone scan. Conditions for Patient Ineligibility: 1) Patient with hearing loss assessed to be primarily sensorineural in nature. 2) >/= grade 2 peripheral sensory neuropathy. 3) Patients with undetectable pre-treatment plasma EBV DNA.

	Protocol	Description	Basic Eligibility
7.	**NRG-HN009** **CRA: Namrata Das Batra** Anticipated accrual: ☐ Spanish Consent	Randomized Phase II/III Trial of Radiation with Cisplatin at 100 mg/m2 Every Three Weeks Versus Radiation with Weekly Cisplatin at 40 mg/m2 for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)	Pathologically (histologically or cytologically) proven diagnosis of SCCHN of the oropharynx, larynx, hypopharynx, or p16-positive unknown primary prior to registration; specimen from cervical lymph nodes with a well-defined primary site documented clinically or radiologically is acceptable; in patients with carcinoma of unknown primary this will be sufficient for pathologic confirmation without a clinically or radiographically defined primary site. Clinical stage (AJCC, 8th ed.) Known human immunodeficiency virus (HIV) infected patients on effective anti retroviral therapy with undetectable viral load within 6 months and CD4 T Cell count > 200 cells/mm3 are eligible for this trial. Testing is not required for entry into protocol Patients must have clinically or radiographically evident measurable disease at the primary site or at nodal stations. Simple tonsillectomy or local excision of the primary without removal of nodal disease is permitted, as is excision removing gross nodal disease but with intact primary site. Limited neck dissections retrieving ≤ 4 nodes are permitted and considered as non-therapeutic nodal excisions. Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the nvestigational regimen are eligible for this trial.
8.	**RTOG 1216** **CRA: Namrata Das Batra** Anticipated accrual: 20 ☑ Spanish Consent	Randomized Phase II/III Trial of Adjuvant Radiation Therapy with Cisplatin, Docetaxel-Cetuximab, or Cisplatin-Atezolizumab in Pathologic High-Risk Squamous Cell Cancer of the Head and Neck	Pathologically (histologically or cytologically) proven diagnosis of head and neck squamous cell carcinoma (HNSCC) involving the oral cavity (excluding lips), oropharynx (p16 negative), larynx, or hypopharynx. Patients must have undergone gross total surgical resection of high-risk oral cavity, oropharynx (p16 negative), larynx, or hypopharynx within 63 days prior to registration. Patients must have at least 1 of the following high-risk pathologic features: extracapsular nodal extension or invasive cancer at the primary tumor resection margin. Pathologic stage III or IV HNSCC, including no distant metastases, based upon the following minimum diagnostic workup: - General history and physical examination by a Radiation Oncologist and/or Medical Oncologist within 84 days prior to registration; - Examination by an ENT or Head & Neck Surgeon prior to surgery; a laryngopharyngoscopy.

Cancer Site: # Liquid Tumors

	Protocol	Description	Basic Eligibility
1.	**EA9152** **CRA: B.Reddivari** Anticipated accrual: ☐ Spanish Consent	A Phase IB/II Study of Venetoclax (ABT-199) in Combination with Liposomal Vincristine or Vincristine Sulfate in Patients with Relapsed or Refractory T-Cell or B-Cell Acute Lymphoblastic Leukemia	Patients must have a diagnosis of: A) Relapsed or refractory B-cell or T-cell ALL after multi-agent chemotherapy. B) Patients with < 5% blasts may enroll on trial in phase I portion provided that minimal residual disease (MRD) is present at > 10-3 as tested on an assay with minimum sensitivity of 10-4. OR C) Relapsed lymphoblastic lymphom Age ≥ 18 years ECOG performance status 0-2 Adequate liver function with AST/ALT less than 3X upper limit of normal and total bilirubin less than 2 mg/dL within 10 days prior to first dose of study agent. Circulating WBC count must not be above 25 x109 /L at the time of registration. Glomerular filtration rate (GFR) of at least 40 mL/min within 7 days prior to first dose of study agent. Patients of childbearing potential must not be pregnant or breast feeding due to risk of fetal harm by the chemotherapeutic agents prescribed in this protocol. All patients of childbearing potential must have a blood test or urine study with a minimum sensitivity 25 IU/L or equivalent units of HCG within 2 weeks prior to registration to rule out pregnancy.A patient of childbearing potential is defined as anyone, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy; or 3) has not been naturally postmenopausal for at least 24 consecutive months.

	Protocol	Description	Basic Eligibility
2.	**EAA181** **CRA: B.Reddivari** Anticipated accrual: ☑ Spanish Consent	Effective Quadruplet Utilization After Treatment Evaluation (EQUATE): A Randomized Phase 3 Trial for Newly Diagnosed Multiple Myeloma Not Intended for Early Autologous Transplantation	Patient must be ≥ 18 years of age. Patient must have the ability to understand and the willingness to sign an informed consent document. Patients with impaired decision making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be eligible. Patient must have an ECOG performance status (PS) of 0-2 (PS 3 allowed if secondary to pain). Patient must have suspected or confirmed newly diagnosed multiple myeloma (MM) by International Myeloma Working Group (IMWG) criteria and must not have received more than one cycle of treatment. NOTE: Patient does not need to have bone marrow evaluation prior to Step 0 pre-registration. Bone marrow evaluation may be deferred to after Step 0 pre-registration to confirm presence of >10% clonal bone marrow plasma cells per IMWG criteria. Patient must be considered ineligible for autologous stem cell transplantation by the treating physician, or willing to delay stem cell transplantion until first relapse or later. Patient must agree to register to the mandatory Celgene Revlimid REMS program and be willing and able to comply with the requirements of the Revlimid REMS program. Patient must not have any known allergies, hypersensitivity, or intolerance to corticosteroids, monoclonal antibodies or human proteins, or their excipients (refer to respective package inserts or Investigator's Brochure), or known sensitivity to mammalian-derived products. Patient must be able to undergo diagnostic bone marrow aspirate

Cancer Site: Lung

	Protocol	Description	Basic Eligibility
1.	**Alliance A081801** **CRA: Namrata Das Batra** Anticipated accrual: ☑ Spanish Consent	Integration of immunotherapy into adjuvant therapy for resected NSCLC: ALCHEMIST chemo-IO (ACCIO).	Resected NSCLC enrolled on A151216. NSCLC of any histologic subtype. Resected NSCLC enrolled on A151216. NSCLC of any histologic subtype. Stage IIA, IIB, IIIA or IIIB (T3-4N2). Complete R0 resection ECOG PS 0-1 EGFR and ALK negative locally or centrally on A151216 Candidate for adjuvant platinum-doublet chemotherapy Eligible for treatment with an immune checkpoint inhibitor 30-77 days post-surgery

	Protocol	Description	Basic Eligibility
2.	**Alliance A151216** **CRA: B.Reddivari** Anticipated accrual: 10 ☑ Spanish Consent	A.K.A "ALCHEMIST". Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST).	For pre-surgical patients Suspected diagnosis of resectable non-small cell lung cancer. Cancers with a histology of "adenosquamous" are considered a type of adenocarcinoma and thus a "nonsquamous" histology. Patients with squamous cell carcinoma are eligible. Suspected clinical stage of IIA, IIB, IIIA or IIIB (T3-4N2). The 8th edition of AJCC staging will be utilized. For post-surgical patients Completely resected non-small cell lung cancer with negative margins (R0). Patients with squamous cell carcinoma are eligible only if they have not received adjuvant therapy. Pathologic stage IIA, IIB, IIIA or IIIB (T3-4N2). The 8 th edition of AJCC staging will be utilized. Age ≥18 years. No patients who have received neoadjuvant therapy. No locally advanced or metastatic cancer requiring systemic therapy within 5 years; no secondary primary lung cancer concurrent or within 2 years. No prior treatment with agents targeting EGFR mutation, ALK rearrangement or PD-1/PD-L1/CTLA-4 Non-pregnant and non-lactating. Patients with local genotyping are eligible, regardless of the local result. No recurrent lung cancer patients.
3.	**EA5163/51709** **CRA: Tolulope Ogunkelu** Anticipated accrual: ☑ Spanish Consent	A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-Driven Analysis	Patients must have histologically or cytologically confirmed stage IV non-squamous NSCLC (includes M1a, M1b, and M1c stage disease. Patients with Stage IIIB and IIIC disease are eligible if they are not candidates for combined chemotherapy and radiation. Patients must have PD-L1 expression Tumor Proportion Score (TPS) ≥ 1% in tumor cells. Patients must have measurable or non-measureable disease is sufficient to satisfy this eligibility criterion. Study registration. Patients must be ≥ 18 years of age. Patients must have an ECOG Performance Status of 0 to 1.
4.	**ECOG E-4512** **CRA: Namrata Das Batra** Anticipated accrual: 5 ☑ Spanish Consent	Related to Alliance A151216 "ALCHEMIST". 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.	Age ≥ 18 years. Patients must have undergone complete surgical resection of their stage IIA, IIB, IIIA or IIIB non-squamous or squamous b NSCLC. Baseline Chest CT with or without contrast must be performed within 6 months (180 days) prior to randomization to ensure no evidence of disease. ECOG performance status 0 or 1. Patients must be registered to the ALCHEMIST-SCREEN. Positive for translocation or inversion events involving the ALK gene locus.

	Protocol	Description	Basic Eligibility
5.	**SWOG LungMAP** **CRA: Namrata Das Batra** Anticipated accrual: 30 ☑ Spanish Consent	A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study). SUBSTUDIES - Pending IRB Approval - S1800D - S1900E - S1900F	Patients must have pathologically or cytologically proven non-small cell lung cancer. Patients must have Stage IV disease or recurrent/progressive disease without a curative treatment option available. Patients must either have progression on prior systemic treatment. Patients must either have adequate tissue available to submit on-study or have a prior known commercial FoundationOne CDx tissue-based (not liquid) tumor test for biomarker profiling.

Cancer Site: Pancreas Carcinoma

1.	**A021806** **CRA: Tolulope Ogunkelu** Anticipated accrual: ☑ Spanish Consent	A Phase III Trial of Perioperative Versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer	Disease Status Confirmation of resectable disease by real-time central imaging review by the Alliance Imaging Core Lab at IROC Ohio. Determined to be appropriate candidate for curative-intent pancreatectomy by surgeon intending to perform the resection. No prior radiation therapy, chemotherapy, targeted therapy, investigational therapy, or surgery for pancreatic cancer. Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic, and teratogenic effects. Age ≥ 18 years ECOG Performance Status 0-1 Total Neuropathy Score < 2 Required Initial Laboratory Values -Absolute Neutrophil Count (ANC) ≥ 1,500/µL -Platelet Count ≥ 100,000/µL -Total Bilirubin ≤ 1.5 x upper limit of normal (ULN)* -Creatinine ≤ 1.5 x ULN

Cancer Site: Prostate

1.	**EA8184** **CRA: B.Reddivari** Anticipated accrual: ☑ Spanish Consent	A Phase II Randomized Double Blinded Study of Green Tea Catechins (GTC) vs. Placebo in Men on Active Surveillance for Prostate Cancer: Modulation of Biological and Clinical Intermediate Biomarkers.	Patient must be ≥ 21 years of age, speak English or Spanish and have biopsy-proven adenocarcinoma of the prostate with cancer present in at least one biopsy core in the most recent biopsy using mpMRI-Prostate or TP Biopsy or TRUS Biopsy. Patient must be on active surveillance [local – Gleason 3+3 or Gleason 3+4) very low, low and favorable intermediate risk. Patient's baseline biopsy must have occurred at least 6 months but not more than 18 months prior to preregistration to Step 0.
2.	**WF-1802** **CRA: B.Reddivari** Anticipated accrual: ☐ Spanish Consent	Influence of Primary Treatment for Prostate Cancer on Work Experience (PCW).	Dx with adenocarcinoma for the prostate, stages I, II, or III anticipated initiating of primary treatment for the prostate. Pt must be employed within 14 days prior to enrollment to study.

Cancer Site: Renal

	Protocol	Description	Basic Eligibility
1.	**A031704 (PDGREE)** **CRA: Tolulope Ogunkelu** Anticipated accrual: ☑ Spanish Consent	PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab Vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated REnal Cell CancEr [PDIGREE]	Documentation of Disease: Histologic Documentation: Histologically documented renal cell carcinoma with clear cell component, including patients who have sarcomatoid features. Must be intermediate or poor risk patient per IMDC criteria CNS disease permitted, if stable and not otherwise causing symptoms or needing active treatment Karnofsky performance status 70% No prior treatment with PD-1, PD-L1, or CTLA-4 targeting agents, or any other drug or antibody specifically targeting T cell co-stimulation or checkpoint pathways. Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects. Age ≥ 18 years