Active Clinical Trials @ CCH

Wendy's pager: 556-0034 (8 AM - 4-5 PM)
Karen's pager: 556-9068 (8:30 AM - 4:30 PM)
Vanessa's pager: 556-6839 (7:30 AM - 3:30 PM)
Namrata's pager: 250-2010 (7:30 AM - 3:30 PM)
Basia's pager: 556-0052 (8:30 AM - 4 PM)
Ola's pager: 390-2348 (8 AM - 3:30 PM)

Cancer Site: Multiple

	Protocol	Description	Basic Eligibility
1.	**Alliance A221805** **CRA: Basia Lukaszczyk** Anticipated accrual: ☐ Spanish Consent	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II To Phase III Study.	Stage II-III colorectal patients (Age ≥ 25 years) scheduled to receive Oxaliplatin over 12 weeks as a component of adjuvant FOLFOX or CAPOX treatment over 12 weeks. - No prior neurotoxic chemotherapy. - Not pregnant and not nursing. - ECOG Performance Status 0-2. - Patients must be able to speak and read English.
2.	**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)
3.	**DCP-002** **CRA: Basia/Namrata** 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).
4.	**ECOG E-1Q11 (EROS)** **CRA: Basia Lukaszczyk** Anticipated accrual: 10 ☑ Spanish Consent	EROS Trial: Engendering Reproductive Health Within Oncologic Survivorship.	Females ages 15-55; pre-menopausal, no prior treatment/chemo, RT, hormonal. Histology Types: All.
5.	**ECOG EAQ171CD** **CRA: Wendy A. Rogowski** Anticipated accrual: ☑ Spanish Consent	Implementing a Virtual Tobacco Treatment in Community Oncology Practices: "Smoke Free Support Study 2.0"	Age ≥18 years Patient presenting with any type of cancer with a date of diagnosis within the past 4 months. Recurrence, diagnosed within the last 4 months, of tumors in patients with past cancer diagnoses will be considered eligible. Patients with a new primary cancer, diagnosed within the last 4 months, who have been treated previously for other types of cancer will also be considered eligible. “In situ” cancers, diagnosed within the past 4 months, will also be considered eligible. Patient must be a current smoker. Current smoker is defined as any cigarette smoking (even a puff) in the past 30 days. Patient must be fluent in both, written and spoken, English or both, written and spoken, Spanish. Patient must have telephone, web and e-mail access.

	Protocol	Description	Basic Eligibility
6.	**NCI 10323 (Moonshot)** **CRA:** 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 per NCCN guidelines and has consented to provide longitudinal biospecimens. Patients with ECOG Performance Status (PS) 0 or 1 may be enrolled retrospectively (i.e. at time of progression) if archival material is submitted that contains the cancer type for which the participant is enrolled and that was collected up to 5 years prior to initiation of a therapy listed in Table 1, assuming that no intervening molecular targeted or immunotherapies were administered (Archival Material Collection; Section 7.2.1). Patients with a PS of 2 may be enrolled only at the discretion of the treating physician and radiologist.
7.	**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).

Cancer Site: Brain

1.	**NRG-CC003** **CRA: Basia Lukaszczyk** Anticipated accrual: 3 ☐ Spanish Consent	A Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer.	1. Proven dx of small cell ca either: limited or extensive 2. Stealth MRI or CT of brain must have been done prior to initiating lung treatment 3. Radiographic partial or complete response response to chemotherapy

Cancer Site: Breast

1.	**AFT-25 COMET** **CRA: Wendy A. Rogowski** Anticipated accrual: 5 ☐ Spanish Consent	Comparison of Operative to Monitoring and Endocrine Therapy (COMET) Trial for Low Risk DCIS: A phase III Prospective Randomized Trial.	
2.	**Alliance A011202** **CRA: Wendy A. Rogowski** Anticipated accrual: 5 ☑ Spanish Consent	A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy.	
3.	**Alliance A011202 QOL** **CRA: Wendy A. Rogowski** Anticipated accrual: ☐ Spanish Consent	Lymphedema Companion study for Alliance A011202 (A011202-E-01).	

	Protocol	Description	Basic Eligibility
4.	**Alliance A011801** **CRA:** 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.	
5.	**Alliance A231701CD** **CRA: Wendy A. Rogowski** Anticipated accrual: ☐ Spanish Consent	Increasing Socioeconomically Disadvantaged Patients' Engagement in Breast Cancer Surgery Decision Making Through a Shared Decision Making Intervention.	
6.	**ECOG EA1151 (TMIST)** **CRA: Wendy A. Rogowski** Anticipated accrual: 40 ☑ Spanish Consent	Tomosynthesis Mammographic Imaging Screening Trial (TMIST).	
7.	**ECOG EAZ171** **CRA: Wendy A. Rogowski** Anticipated accrual: ☑ Spanish Consent	Prospective Validation Trial of Taxane Therapy (Docetaxel or Weekly Paclitaxel) and Risk of Chemotherapy-Induced Peripheral Neuropathy in African American Women.	Women with a known stage I-III invasive breast cancer diagnosis; registration must occur within 84 days from date of diagnosis. Age 18 years and older. ECOG PS 0-1. Must self-identify their race as Black, African American or of African descent. Must not have pre-existing peripheral neuropathy. Must not have received prior Taxane or prior/concurrent platinum therapy. Not have received neoadjuvant anti-HER2 therapy. Must have plans to receive neoadjuvant/adjuvant: • Every 3 week docetaxel X 4-6 cycles or • Weekly paclitaxel X 4 cycles
8.	**NRG-BR004** **CRA:** Anticipated accrual: ☐ Spanish Consent	A randomized double-blind, phase III trial of paclitaxel/trastuzumab/pertuzumab with atezolizumab or placebo in First-Line HER2-Positive metastatic breast cancer. *EKR gave to OO for initial review and acuity scoring on 4/4/19. 6/18/2021: NRG-BR004 registration and accrual will be temporarily on hold for approximately 4-6 weeks at all sites, effective the release of an impending NCI Action Letter for Atezolizumab. The hold is NOT due to safety issues, but instead, is due to a need for reprogramming of the database in order to accommodate design changes in Amendment #3, which is administratively tied to Amendment #4 (an amendment requested in response to the NCI Action Letter.)	
9.	**SWOG S1501** **CRA: Ola Olorunfemi** Anticipated accrual: ☑ Spanish Consent	Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III.	

Cancer Site: Colorectal

	Protocol	Description	Basic Eligibility
1.	**Alliance A021703 (SOLARIS)** **CRA:** Anticipated accrual: ☐ Spanish Consent	Randomized Double-Blind Phase III Trial Of Vitamin D3 Supplementation In Patients With Previously Untreated Metastatic Colorectal Cancer (SOLARIS).	
2.	**WF-1806** **CRA: Vanessa/Basia** Anticipated accrual: ☑ Spanish Consent	Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer: The M&M Study (NCT03998202)	

Cancer Site: Gyne

1.	**NRG-GY006** **CRA: Basia Lukaszczyk** Anticipated accrual: 3 ☐ Spanish Consent	A Randomized phase II trial of radiation therapy and cisplatin alone or in combination with intravenous triapine in women with newly diagnosed bulky stage IB2, or stage II, IIIB, or IVA cancer of the uterine cervix or stage II-IVA vaginal cancer.	IB2 (> 5cm), II, IIIB, or IVA with negative para-aortic nodes via PET/CT. Histology Types: squamous, adenocarcinoma, or adenosquamous.
2.	**NRG-GY009** **CRA: Basia Lukaszczyk** Anticipated accrual: ☑ Spanish Consent	A Randomized, Phase II/III Study of Pegylated Lipsomal Doxorubicin and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer.	Histology Types: high grade serous; clear cell; endometrioid; grade 3; and others adenocarcinoma, NOS, mixed epithelial carcinoma, & undifferentiated carcinoma.

Cancer Site: Head-Neck

1.	**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.

	Protocol	Description	Basic Eligibility
2.	**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
3.	**RTOG 1216** **CRA: Namrata Das Batra** Anticipated accrual: 20 ☑ Spanish Consent	Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin Versus Docetaxel Versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer Of The Head and Neck.	

Cancer Site: Liquid Tumors

1.	**ASH RC COVID-19 Registry** **CRA:** Anticipated accrual: ☐ Spanish Consent	The ASH Research Collaborative (ASH RC) COVID-19 Registry for Hematology, a global public reference tool that is part of the ASH RC Data Hub platform, captures data on individuals who test positive for COVID-19 and have a hematologic condition (past or present) and/or have experienced a post-COVID-19 hematologic complication. Consent Waiver: Yes HIPAA Waiver: Yes	Hematologic malignancy or complication (past or present) + Positive COVID-19 test.

Cancer Site: Lung

1.	**Alliance A081801** **CRA: Namrata Das Batra** Anticipated accrual: ☐ Spanish Consent	Integration of immunotherapy into adjuvant therapy for resected NSCLC: ALCHEMIST chemo-IO (ACCIO).	
2.	**Alliance A151216** **CRA: Vanessa Barrera** Anticipated accrual: 10 ☑ Spanish Consent	A.K.A "ALCHEMIST". Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST).	
3.	**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.	

	Protocol	Description	Basic Eligibility
4.	**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).	
5.	**SWOG S1900A** **CRA: Namrata Das Batra** Anticipated accrual: ☐ Spanish Consent	SWOG LungMAP Sub-study. A Phase II Study of Rucaparib in Patients with Genomic LOH High and/or Deleterious BRCA1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (LUNG-MAP Sub-Study).	
6.	**UIC EDPR** **CRA:** Anticipated accrual: ☐ Spanish Consent	Epigenetic biomarkers for Early Detection and Prognosis in Non-Small Cell Lung Cancer and Small Cell Lung Cancer.	

Cancer Site: # Prostate

1.	**NRG-CC007CD** **CRA: Basia Lukaszczyk** Anticipated accrual: ☐ Spanish Consent	Increasing The Dose Of Survivorship Care Planning In Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy.	1. Diagnosis of prostate adenocarcinoma and planned to be treated with RT plus ADT (intact prostate & post-prostatectomy) RT patients are eligible. 2. ADT must be planned for at least 4 months & must include LHRH agonist or LHRH antagonist
2.	**NRG-GU002** **CRA: Basia Lukaszczyk** Anticipated accrual: 5 ☑ Spanish Consent	Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy With or Without Adjuvant Docetaxel.	1. Post-prostatectomy with baseline Gleason > or equal to 7 2. Dx of adenocarcinoma of the prostate as confirmed at time of prostatectomy 3. Prior androgen deprivation therapy is allowed if discontinued at least 90 days prior study enrollment 4. Any pT-stage, but only pN0 or pNx is allowed
3.	**WF-1802** **CRA: Vanessa/Basia** Anticipated accrual: ☐ Spanish Consent	Influence of Primary Treatment for Prostate Cancer on Work Experience (PCW).	1. Dx with adenocarcinoma for the prostate, stages I, II, or III anticipated initiating of primary treatment for the prostate 2. Pt must be employed within 14 days prior to enrollment to study