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.	**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: 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).
3.	**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.
4.	**ECOG EAQ171CD** **CRA: Vanessa/Basia** Anticipated accrual: ☐ Spanish Consent	Implementing a Virtual Tobacco Treatment in Community Oncology Practices: "Smoke Free Support Study 2.0"	
5.	**ECOG EAZ171** **CRA: Karen Carter** 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
6.	**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).

	Protocol	Description	Basic Eligibility

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).	
4.	**Alliance A011401** **CRA: Wendy A. Rogowski** Anticipated accrual: 3 ☐ Spanish Consent	Randomized Phase III Trial Evaluating The Role Of Weight Loss In Adjuvant Treatment of Overweight And Obese Women With Early Breast Cancer.	
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.	**Diet and exercise** **CRA: Ola Olorunfemi** Anticipated accrual: ☐ Spanish Consent	Dr. McDunn's in-house trial. Prevention of Weight gain in Patients with Early Stage Breast Cancer. A Pilot Trial of Diet and Exercise Modification During Adjuvant Therapy in Patients With Early Stage Breast Cancer.	
7.	**ECOG EA1131** **CRA: Wendy A. Rogowski** Anticipated accrual: 5 ☐ Spanish Consent	A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy.	
8.	**ECOG EA1151 (TMIST)** **CRA: Wendy A. Rogowski** Anticipated accrual: 40 ☐ Spanish Consent	Tomosynthesis Mammographic Imaging Screening Trial (TMIST).	
9.	**NRG-BR003** **CRA: Wendy A. Rogowski** Anticipated accrual: 5 ☐ Spanish Consent	A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer.	

	Protocol	Description	Basic Eligibility
10.	**NSABP B-51** **CRA: Wendy A. Rogowski** Anticipated accrual: 5 ☐ Spanish Consent	NSABP B51 (RTOG 1304) A randomized Phase III clinical trial evaluating post-mastectomy chestwall and regional nodal XRT and post-lumpectomy regional nodal XRT in patients with positive axillary nodes before neoadjuvant chemotherapy who concert to pathologically negative axillary nodes after neoaduvant chemotherapy.	

Cancer Site: Gyne

1.	**NRG-GY005** **CRA: Basia Lukaszczyk** Anticipated accrual: 3 ☑ Spanish Consent	A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS).	Platinum resistant or refractory disease defined by disease progression via imaging within 6 months of last receipt of platinum-based chemotherapy. Histology Types: serous or endometrioid high grade. Patients with clear cell, mixed epithelial, undifferentiated carcinoma, or transitional cell carcinoma are eligible, but must have known deleterious germline mutation BRCA 1 or 2 (trial pays for test.)

Cancer Site: Head-Neck

1.	**ECOG EA3132** **CRA:** 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:** 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.	**NRG-HN004** **CRA:** Anticipated accrual: ☐ Spanish Consent	Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Stage III-IVB Head and Neck Cancer with a Contraindication to Cisplatin.	Pathologically confirmed, previously untreated, unresected squamous cell carcinoma of larynx, hypopharynx, oropharynx, oral cavity, or carcinoma of unknown head/neck primary Mandatory submission of H&E stained slides and FFPE tissue block (or punch biopsy of FFPE block) for oropharyngeal and unknown primaries and for p16 analysis for all other non-oropharyngeal primaries. Mandatory submission of H&E and p16 stained slides for ooropharyngeal and unknown primaries. Patients must have locoregionally advanced HNSCC: (See table below) - for p16-positive oropharyngeal/unknown primaries, AJCC 8th edition stage III and selected stage I-II based on smoking status in pack-years - for laryngeal, hypopharyngeal, and oral cavity primaries and p16-negative oropharyngeal/unknown primaries, AJCC 8th edition stage III-IVB Contraindication(s) to cisplatin (see comogram.org) Not Eligible: - Prior invasive malignancy with the past 3 years - Prior radiotherapy to the region of the study cancer - Prior immunotherapy - Distanct metastases
4.	**RTOG 1008** **CRA:** Anticipated accrual: ☐ Spanish Consent	A Randomized Phase II Study of Adjuvant Concurrent Radiation And Chemotherapy Versus Radiation Alone In Resected High-Risk Malignant Salivary Gland Tumors.	Patients with salivary gland carcinomas involving the major (parotid, submandibular, or sublingual glands) and minor salivary glands of head and neck with the following histologies: - Intermediate-grade adenocarcinoma or intermediate-grade mucoepidermoid carcinoma - High-grade adenocarcinoma or high grade mucoepidermoid carcinoma or salivary duct carcinoma - High-grade acinic cell carcinoma or high grade (>30% solid component) adenoid cystic carcinoma - No evidence of metastasis Surgical Resection with curative intent within 8 weeks prior to registration. Does patient have one of the following risk factors for recurrence?: - Pathologic Stage T3-4 or - Pathologic N1-3 disease or - T1-2, N0 with positive or close (</= 1mm) or microscopic margins of resection.

	Protocol	Description	Basic Eligibility
5.	**WF-97115** **CRA: Vanessa/Basia** Anticipated accrual: 5 ☐ Spanish Consent	A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer.	1. Pt suffers from xerostomia- grade 1 or 2 2. Must not be on any treatment for cancer

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 A081105** **CRA: Ola Olorunfemi** Anticipated accrual: 5 ☐ Spanish Consent	Related to Alliance A151216 "ALCHEMIST". 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 Cancer (NSCLC).	
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.	
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 S1800A** **CRA: Namrata Das Batra** Anticipated accrual: ☐ Spanish Consent	SWOG LungMAP Sub-study. A Phase II Randomized Study of Ramucirumab Plus MK3475 (Pembrolizumab) Versus Standard of Care for Patients Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study).	
6.	**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).	

	Protocol	Description	Basic Eligibility
7.	**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:** 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