

HSHS Wisconsin Clinical Research Institute – Adult - Active Study List

| Protocol | Sponsor | NCT Number | Disease Site | Title |
|-----------------|----------------|---|--|---|
| NHLBI-MDS | ECOG-A | NCT02775383 | Blood Disorders-Other | The National Myelodysplastic Syndromes (MDS) Study |
| PTG-300-11 | DRUG CO | NCT05210790 | Blood Disorders-Other | A Phase 3 Study of the Hepcidin Mimetic Rusfertide (PTG-300) in Patients with Polycythemia Vera |
| BN011 | NRG | NCT05095376 | Brain | A Phase III Trial of Lomustine-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients with Methylated MGMT Promoter Glioblastoma |
| S1703 | SWOG-L | NCT03723928 | Breast-Advanced (Metastatic/Recurrent) | Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive Breast Cancer |
| A011801 | ALLIANCE | NCT04457596 | Breast-Early Stage | 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-DMI and Placebo Compared with T-DMI and Tucatinib |
| A191901 | ALLIANCE | NCT04379570 | Breast-Early Stage | Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions |
| BR007 | NRG | NCT04852887 | Breast-Early Stage | A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score ≤ 18 Breast Cancer |

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| EA1211 | ECOG | NCT05710328 | Breast-Early Stage | Interim FDG-PET/CT for PreDlcting REsponse of HER2+ Breast Cancer to Neoadjuvant Therapy: DIRECT Trial |
| MA.39 | CCTG | NCT03488693 | Breast-Early Stage | Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer |
| NRG-BR009 | NRG | NCT05879926 | Breast-Early Stage | A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression Plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score |
| S2010 | SWOG-L | NCT05568472 | Breast-Early Stage | A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone To Improve Persistence With Endocrine Therapy In Young Women With Stage I-III Breast Cancer (ASPEN) |
| S2206 | SWOG-L | NCT06058377 | Breast-Early Stage | Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for Adults with MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive / Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer. |
| S2212 | SWOG-L | NCT05929768 | Breast-Early Stage | Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study |
| DCP-001 | DCP | | Cancer Control-Other | Use of a Clinical Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP) |

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| EAQ202 | ECOG-A | NCT05108298 | Cancer Control-Other | Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials |
| URCC 19075 | URCC | NCT04888988 | Cancer Control-Other | Multi-Center Randomized Controlled Phase II Trial of Exercise to Treat Chemotherapy-Induced Peripheral Neuropathy (CIPN) |
| A221805 | ALLIANCE | NCT04137107 | Colon | Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study |
| CC005 | NRG | NCT05080673 | Colon | FORTE (Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps) |
| GI008 | NRG | NCT05174169 | Colon | Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (CIRCULATE-US) |
| A022104 | ALLIANCE | NCT05610163 | Colon and Rectal | The Janus Rectal Cancer Trial: A Randomized Phase II/III Trial Testing the Efficacy of Triplet Versus Doublet Chemotherapy Regarding Clinical Complete Response and Disease-Free Survival in Patients with Locally Advanced Rectal Cancer |
| WF-1806 | WAKE | NCT03998202 | Colon and Rectal | Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer: The M&M Study |
| EA2174 | ECOG-A | NCT03604991 | Esophageal | A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma |
| EA2183 | ECOG-A | NCT04248452 | GI Cancers- Miscellaneous | A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA) |

For more information call the HSHS Wisconsin Clinical Research Institute at (920) 433-8889.
04/30/2024

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| GI-1810 | ACCRU | NCT04660760 | GI Cancers- Miscellaneous | Ramucirumab Plus trifluridine/tipiracil (TAS-102) for Patients With Previously Treated Advanced Gastric or Gastroesophageal Junction Adenocarcinoma: An Investigator-Initiated, Randomized Non-inferiority Phase 2 Study |
| EA3161 | ECOG-A | NCT03811015 | Head and Neck | A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPCA |
| EA3191 | ECOG-A | NCT04671667 | Head and Neck | 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 |
| HN005 | NRG | NCT03952585 | Head and Neck | A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients with Early-Stage, P16-Positive, Non-Smoking Associated Oropharyngeal Cancer |
| R1216 | RTOG | NCT01810913 | Head and Neck | 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 |
| WF-1805CD | WAKE | NCT04208490 | Head and Neck | Implementation and Effectiveness Trial of HN-STAR |
| A031704 | ALLIANCE | NCT03793166 | Kidney (Renal) | 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) |

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| AREN1721 | COG-AYA | NCT03595124 | Kidney (Renal) | A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Axitinib or Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups |
| MDS/AML Registry | DRUG CO | NCT01688011 | Leukemia-Acute Myelogenous Leukemia (AML) | Connect® Myeloid: The Myelofibrosis (MF), Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry |
| S1925 | SWOG-L | NCT04269902 | Leukemia-Chronic Lymphocytic Leukemia (CLL) | Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study |
| A081801 | ALLIANCE | NCT04267848 | Lung- Non-Small Cell Lung Cancer | Integration of immunotherapy into adjuvant therapy for resected NSCLC: ALCHEMIST chemo-IO |
| A151216 | ALLIANCE | NCT02194738 | Lung- Non-Small Cell Lung Cancer | Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) |
| E4512 | ECOG-A | NCT02201992 | Lung- Non-Small Cell Lung Cancer | A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein |
| LungMAP | SWOG-L | NCT03851445 | Lung- Non-Small Cell Lung Cancer | A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study) |

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| NRG-LU008 | NRG | NCT05624996 | Lung- Non-Small Cell Lung Cancer | Phase III Prospective Randomized Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed by Concurrent Mediastinal Chemoradiation for Locally-Advanced Non-Small Cell Lung Cancer |
| S1900E | SWOG-L | NCT04625647 | Lung- Non-Small Cell Lung Cancer | A Phase II Study of AMG 510 in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LUNG-MAP SUB-STUDY) |
| S1914 | SWOG-L | NCT04214262 | Lung- Non-Small Cell Lung Cancer | A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC |
| S2302 | SWOG-L | NCT05633602 | Lung- Non-Small Cell Lung Cancer | PRAGMATICA – LUNG: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) plus Pembrolizumab (MK-3475; NSC 776864) versus Standard of Care for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer” |
| AHOD2131 | COG-AYA | NCT05675410 | Lymphoma-Hodgkin's | A Randomized Phase 3 Interim Response Adapted Trial Comparing Standard Therapy with Immunology Therapy for Children and Adults with Newly Diagnosed Stage I and II Classic Hodgkin Lymphoma |
| EAQ211 | ECOG-A | NCT06002828 | Lymphoma-Hodgkin's | Social Genomic Mechanisms of Health Disparities among Adolescent and Young Adult (AYA) Survivors of Hodgkin and Non-Hodgkin Lymphoma |

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| EA4151 | ECOG-A | NCT03267433 | Lymphoma-Non Hodgkin's | A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma In Minimal Residual Disease-Negative First Complete Remission) |
| UW16086 | WON | NCT03311126 | Lymphoma-Non Hodgkin's | Bendamustine + obinutuzumab induction chemoimmunotherapy with risk-adapted obinutuzumab maintenance therapy in previously untreated mantle cell lymphoma |
| A091903 | ALLIANCE | NCT05111574 | Melanoma | A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma |
| 2021-05 | DRUG CO | | Multiple Disease Sites | Specimen Collection Study to Evaluate Biomarkers in Subjects with Cancer |
| A211901 | ALLIANCE | NCT05008848 | Multiple Disease Sites | Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions |
| A212102 | ALLIANCE | NCT05334069 | Multiple Disease Sites | Blinded Reference Set For Multicancer Early Detection Blood Tests |
| A222004 | ALLIANCE | NCT04939090 | Multiple Disease Sites | A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia |
| AGCT1531 | COG-AYA | NCT03067181 | Multiple Disease Sites | A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors |
| EAY191 | ECOG | 05564377 | Multiple Disease Sites | Molecular Analysis for Combination Therapy Choice (ComboMATCH) |

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| S1912CD | SWOG-L | NCT04960787 | Multiple Disease Sites | A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT) |
| S2013 | SWOG-L | NCT04871542 | Multiple Disease Sites | Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study |
| URCC 21038 | URCC | NCT05364086 | Multiple Disease Sites | 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 |
| URCC-18007 | URCC | NCT03996265 | Multiple Disease Sites | Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue |
| URCC-19185 | URCC | NCT04829539 | Multiple Disease Sites | Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL) |
| URCC-22063 | URCC | NCT06073431 | Multiple Disease Sites | Longitudinal Observational Trial to Uncover Subtypes of Cancer Cachexia |
| EAA173 | ECOG | NCT03937635 | Multiple Myeloma | Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) |
| EAA181 | ECOG-A | NCT04566328 | Multiple Myeloma | Effective Quadruplet Utilization After Treatment Evaluation (EQUATE): A Randomized Phase 3 Trial for Newly Diagnosed Multiple Myeloma Not Intended for Early Autologous Transplantation |

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| S1803 | SWOG-L | NCT04071457 | Multiple Myeloma | Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study) |
| CC008 | NRG | NCT04251052 | Ovarian | 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] |
| EA8184 | ECOG-A | NCT04597359 | Prostate | 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 |
| GU009 | NRG | NCT04513717 | Prostate | Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (PREDICT-RT*) |
| GU010 | NRG | NCT05050084 | Prostate | Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification And Intensification Clinical Trial Evaluation (GUIDANCE) |
| URCC-22053 | URCC | | Prostate | High-dose Vitamin D Supplementation for ADT-Induced Bone Loss in Older Prostate Cancer Patients |

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| ARST2031 | COG-AYA | NCT04994132 | Sarcoma | A Randomized Phase 3 Trial of Vinorelbine, Dactinomycin, and Cyclophosphamide (VINO-AC) Plus Maintenance Chemotherapy with Vinorelbine and Oral Cyclophosphamide (VINO-CPO) vs Vincristine, Dactinomycin and Cyclophosphamide (VAC) Plus VINO-CPO Maintenance in Patients with High Risk Rhabdomyosarcoma (HR-RMS) |
| AGCT1532 | COG-AYA | NCT02582697 | Solid Tumor- Other | A Randomized Phase 3 Trial of Accelerated Versus Standard BEP Chemotherapy for Patients with Intermediate and Poor-Risk Germ Cell Tumors |
| EA6174 | ECOG-A | NCT03712605 | Solid Tumor- Other | A Phase III Randomized Trial Comparing Adjuvant MK-3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma |
| S1823 | SWOG-L | NCT04435756 | Solid Tumor- Other | A Prospective Observational Cohort Study to Assess miRNA 371 For Outcome Prediction in Patients With Newly Diagnosed Germ Cell Tumors |
| GY026 | NRG | NCT05256225 | Uterine-Endometrial | A Phase II/III Study Of Paclitaxel/Carboplatin Alone Or Combined With Either Trastuzumab And Hyaluronidase-Oysk (Herceptin Hylecta) Or Pertuzumab, Trastuzumab, And Hyaluronidase-Zzxf (Phesgo) In Her2 Positive, Stage I-IV Endometrial Serous Carcinoma Or Carcinosarcoma |