Treatment Trials Activated June-July 2025

Research Base	Protocol #	Official Study Title	Indication/Disease	Planned Intervention	Abbreviated Eligibility Criteria Please refer to CTSU for the most recent version of the protocol.	Primary Objective	ClinicalTrials.gov NCT #	CTSU Activation Date	Approx. Target Accrual
Alliance	A012303	ShortStop-HER2: Shortened Duration of Adjuvant Therapy in Patients with Early-Stage HER2+ Breast Cancer Who Achieve pCR After Neoadjuvant Chemotherapy with HER2 Blockade	Breast Cancer	**Arm 1:** Adjuvant trastuzumab +/- pertuzumab every 3 weeks for a total of 51 weeks (12 months) of treatment **Arm 2:** Adjuvant trastuzumab +/- pertuzumab every 3 weeks for a total of 27 weeks (6 months) of treatment	**PVD: 6/16/2025** * Must have clinical stage T1c-T3 (or Tx) and nodal stage N0-N1 (except T3N1 tumors, which are not eligible). (Male patients are allowed) * Must have no residual invasive disease in the breast or lymph nodes after the completion of neoadjuvant therapy. Residual DCIS is allowed. * Must be HER2+ by ASCO/CAP guidelines * Must be ≥ 18 years * Must have ECOG 0-2 * Must have received neoadjuvant chemotherapy in combination with trastuzumab with or without pertuzumab for a minimum of 12 weeks. All chemotherapy must have been completed preoperatively. * Must have had adequate excision: surgical removal of all clinically evident disease in the breast and lymph nodes (see the protocol for specific resection expectations). * Patients who completed breast-conserving surgery must have received or plan to receive adjuvant radiation. Adjuvant radiation can be given on study, and in this case is encouraged to be given concurrently with adjuvant HER2-directed therapy, per investigator discretion. * Must not have a history of any prior (ipsi- or contralateral) invasive breast cancer. Prior DCIS is allowed. * There are no specific required laboratory values for eligibility. Patients with HIV,HBC, or HCV are allowed, if deemed appropriate by their MD. * Patients with inadequate cardiac function (< 50% on echocardiogram (echo) or multiple-gated acquisition (MUGA) are not eligible for this trial.	To evaluate whether 6 months of combined neo/adjuvant HER2 blockade results in a non-inferior recurrence-free survival (RFS) compared to 12 months of combined neo/adjuvant HER2 blockade, in patients with early stage HER2+ breast cancer who achieve pCR after neoadjuvant chemotherapy with HER2 blockade.	NCT06876714	7/25/2025	1524
Alliance	A032303	A032303: GAIN-BCG: Gemcitabine Alternating with INtravesical BCG Randomized Against BCG Alone for Patients with Recurrent High Grade Non-Muscle Invasive Bladder Cancer	Urothelial Carcinoma	* **Arm A: BCG Alone – Induction followed by Maintenance[1]:** Induction: Full Strength Intravesical BCG once weekly for 6 weeks (6 total) Maintenance: BCG once weekly for 3 weeks * **Arm B: Gemcitabine + BCG (GemBCG) – Induction followed by Maintenance[1]:** Induction: Intravesical Gemcitabine (2000 mg) twice weekly on weeks 1 & 10 + once weekly on weeks 4 & 7 (6 total). Full Strength Intravesical BCG on weeks 2, 3, 5, 6, 8, 9 (6 total) Maintenance: Gemcitabine (2000 mg) once weekly the first week followed by BCG once weekly for 3 weeks 1: Maintenance therapy given at months 3, 6, 12	**PVD: 6/3/2025** * Has histologic confirmation of high grade Ta, high grade T1, or Tis/CIS urothelial carcinoma. BCG-Exposed NMIBC, defined as recurrent high grade NMIBC within 24 months of last BCG exposure, but does not meet the definition of BCG Unresponsive NMIBC * Age ≥18 years. * No prior history or current evidence of muscle-invasive or metastatic urothelial carcinoma. * No history of intolerance to BCG or other intravesical treatments. * No contraindications to BCG. * Any component of neuroendocrine carcinoma, pure squamous cell carcinoma, or pure adenocarcinoma without a urothelial component are not allowed * More than one prior induction course of BCG and/or prior maintenance BCG is allowed so long as the patient does not currently met the definition of BCG unresponsive disease * Prior treatment with any intravesical chemotherapy (both perioperative and induction course) for NMIBC is allowed BCG = bacillus calmette-guerin; NMIBC = non-muscle invasive bladder cancer	To compare high-grade recurrence-free-survival between treated with GemBCG compared to those treated with BCG alone.	NCT07000084	6/5/2025	380
Alliance	A222301	High-Dose Prophylactic Gabapentin (HOPE) to Prevent Opioid Use for Oral Mucositis Pain During Head and Neck Chemoradiotherapy: A Phase III Clinical Trial	Squamous cell carcinoma of the head and neck region	Arm I (Placebo): Starting by radiation treatment 8, patients receive placebo PO QD on day 1, BID on day 2, then TID starting day 3 onward. Patients also receive standard of care radiation, chemotherapy and pain medications. Experimental: Arm II (Gabapentin): Starting by radiation treatment 8, patients receive gabapentin PO QD on day 1, BID on day 2, then TID starting day 3 onward. Treatment with placebo or Gabapentin continue in the absence of disease progression or unacceptable toxicity, until the symptoms of oral mucositis and other treatment effects begin to resolve and other pain medications has been stopped.	**PVD: 3/17/2025** * Stage: I-IV, documentation of Squamous cell carcinoma of the head and neck region. * No prior treatment for head and neck cancer * Planned treatment with cisplatin-based chemoradiation therapy (weekly or q3 week) * Able to swallow capsules whole * Not on dialysis or with transplanted organs. * No prior surgery or radiation for head and neck cancer and/or are being treated for recurrent head and neck cancer. * No planned surgery or chemotherapy or immunotherapy following 7 weeks of standard chemoradiation treatment. * No known brain metastases * No nonprescribed use of any opioids (including heroin) within 6 months prior to registration. * No prescribed medications for chronic and/or long-term pain and/or neuropathy * No current treatment with mefloquine * Age ≥ 18 years * ECOG Performance Status ≤ 2 * Creatinine ≤ 1.5 x ULN * No existing diagnosis of sleep apnea * No acute narrow-angle glaucoma * Must be able to speak and read English or Spanish	To determine whether prophylactic high dose gabapentin, titrated to a dose of 3600 mg (1200 mg TID), is superior to placebo in increasing the proportion of patients not needing opiates while undergoing chemoradiation therapy.	NCT06992427	6/5/2025	228

ECOG-ACRIN	EA4231	A Phase 2 Study of Venetoclax, Ibrutinib, Prednisone, Obinutuzumab, and Revlimid (ViPOR) in Relapsed or Refractory CD10-Negative Diffuse-Large B-Cell Lymphoma (DLBCL) and High-Grade B-Cell Lymphoma with MYC and BCL2 Rearrangements (HGBCL-DH-BCL2)	Histologically or cytologically confirmed aggressive B-cell lymphoma (defined in the protocol)	This study will have two cohorts (CD10-negative DLBCL and HGBCL-DHBCL2). Patients in both cohorts will receive the same "ViPOR" treatment, for a maximum of 6 cycles: ViPOR: • Venetoclax 800 mg by mouth daily (PO QD) on Days 2-14 • Ibrutinib 560 mg by mouth daily (PO QD) on Days 1-14 • Prednisone 100 mg by mouth daily (PO QD) on Days 1-7 • Obinutuzumab 1000 mg IV Days 1 and 2 • Lenalidomide 15 mg by mouth daily (PO QD) on Days 1-14	**PVD: 5/20/2025** * Must be ≥ 18 years of age * Must have histologically or cytologically confirmed aggressive B-cell lymphoma (defined in the protocol) * Must have measurable disease * Must have an ECOG 0-2 * Must have relapsed and/or refractory disease after at least 1 prior anthracycline and anti-CD20 antibody-containing regimen. * Patient must not have confirmed or suspected primary mediastinal large B-cell lymphoma (PMBL) * Must not have confirmed or suspected primary DLBCL of the CNS (PCNSL) * Patients with a history of secondary CNS lymphoma (SCNSL) are eligible if follow-up brain imaging after central nervous system (CNS) directed therapy shows no evidence of progression. * Must not have taken or require warfarin or other strong CYP3A inhibitors or inducers within 7 days prior to registration * Must not have had: any chemotherapy, targeted therapy, anti-cancer antibodies, antibody-drug conjugates, or bi-specific antibodies received within 2 weeks prior to registration; more than 3 prior lines of cytotoxic chemotherapy; Radio- or toxin-immunoconjugates within 10 weeks prior to registration; previous treatment with venetoclax, ibrutinib, or lenalidomide; prior ASCT, CAR-T, or allogeneic stem cell (or other organ) transplant within 3 months prior to registration; any evidence of active GVHD or requirement for immunosuppressants within 28 days prior to registration * See the protocol for organ, marrow, HIV, HBV, HCV, and cardiac requirements requirements	To evaluate the complete response (CR) rate of ViPOR in relapsed/refractory (R/R): • CD10-negative DLBCL, and • CD10-positive or negative HGBCL with MYC and BCL2 (with or without BCL6) translocations (HGBCL-DH-BCL2)	NCT06649812	6/24/2025	120
ECOG-ACRIN	EA5231	A Randomized Phase III Trial of Checkpoint Blockade in Lung CancEr Patients in the Adjuvant Setting Based on Pathologic Response Following Neoadjuvant Therapy (CLEAR)	Stage II- IIIB NSCLC	**Arm A: Durvalumab for 12 cycles** * Durvalumab: 1500mg IV on Day 1 of each cycle. 1 cycle= 28 days **Arm B: AZD6738 (ceralasertib) + Durvalumab for 12 cycles** * AZD6738 (ceralasertib): 240 mg (2 x 120 mg tablets) orally twice daily on Days 1-7 of each cycle. * Durvalumab: 1500 mg IV on Day 8 of each cycle 1 cycle= 28 days	**PVD: 4/16/2025** Step 0 (Registration): * Must have Stage II to select Stage IIIB (N2 but excluding N3) non-small cell lung cancer (NSCLC) * Must planning to undergo, be currently undergoing, or recently completed any standard of care neoadjuvant chemoimmunotherapy with plans to undergo surgical resection; Recently completed any standard of care neoadjuvant chemoimmunotherapy AND completed surgical resection and are awaiting pCR status; or recently completed any standard of care neoadjuvant chemoimmunotherapy AND completed surgical resection with confirmed non-path CR status. * Must have completed at least 3 cycles of neoadjuvant chemo-immunotherapy before surgery in order to be eligible for Step 1 randomization Step 1 (Randomization): EA5231 CLEAR randomization for patients without a pCR post-surgery. Patient's with pCR after surgery will be offered to enroll in the SWOG study S2414 INSIGHT instead Refer to the protocol for specific Step 1 screening requirements	The primary objective will be to assess for improvement in disease free survival (DFS) in patients who do not achieve pCR (pathologic complete response) following neoadjuvant therapy and patients who receive adjuvant combination immunotherapy with durvalumab and AZD6738 (ceralasertib) compared to those who receive monotherapy with durvalumab.	NCT06732401	6/13/2025	Step 0: 630 Step 1: 630
NRG	NRG-CC015	Harnessing E-Mindfulness Approaches for Living After Breast Cancer --- HEAL-ABC	First-time diagnosis of non-metastatic breast cancer which is Stage 0, I, II, or III	**Mindfulness (MAPs) Live Online (Arm 1):** Participants assigned to MAPs Live Online (MAPs LO) will be asked to attend 2-hour group sessions once a week for 6 weeks conducted live online over Zoom. Both English and Spanish language participants will be randomized to Arm 1. **Mindfulness (MAPs) Digital App (Arm 2):** Participants assigned to this condition will be asked to access the MAPs App on their home computer, smartphone, or study supplied tablet over the 6-week intervention period. This will be provided by the UCLA research team. Only English language speakers will be assigned to Arm 2, as the app is available only in English at this time.	**PVD 5/1/2025** * Must have a first-time diagnosis of non-metastatic breast cancer which is Stage 0, I, II, or III * Must have a score of ≥ 5 and ≤ 14 on the Patient Health Questionnaire-8 item (PHQ-8). * Must have been ≥ 18 or <51 years of age at the time of breast cancer diagnosis. * Must have completed all primary breast cancer treatments at least 6 months prior to and no more than 5 years prior to registration * Must be able to understand, speak, read, and write in English or Spanish. * Must be able to use a smartphone, tablet, or other digital device * Must not have a current or past history of another cancer. Participants with a history of only nonmelanoma skin cancer or in situ cervical cancer without chemotherapy treatment would be eligible. * Must not be enrolled in other cancer control or behavioral intervention trials that require frequent assessments or training activities	Primary objective 1 is to determine the efficacy of Mindful Awareness Practices (MAPs) live online (LO) relative to the meditation only (MO) control group on depressive symptoms, as indicated by the difference in CES-D change score from baseline to postintervention between the intervention and control groups. Primary objective 2 is to determine the efficacy of the Mindful Awareness Practices (MAPs) App relative to the meditation only (MO) control group on depressive symptoms, as indicated by the difference in CES-D change score from baseline to postintervention between the intervention and control groups.	NCT06748222	6/12/2025	402

NRG	NRG-GI011	A Phase III Randomized Trial of Dose Escalated Radiation in Locally Advanced Pancreas Cancer (LAPC) Patients (LAP100)	Pancreatic Ductal Adenocarcinoma.	**Arm 1:** Patients randomized to Arm 1 will receive standard of care delivered as one of the following three treatment options per physician's decision: 1: Continuation of chemotherapy: patients are encouraged to complete 6 months total (pre- and post-randomization) of 1 of the following chemotherapy regimens: FOLFIRINOX or NALIRIFOX or gemcitabine/nab-paclitaxel. 2: Standard chemoradiation 3: Observation (no further therapy) **Arm 2:** Patients randomized to Arm 2 will receive dose-escalated radiation in either 5 (default prescription is 10 Gy x 5 fractions) or 25 fractions and remaining chemotherapy as applicable. Patients are encouraged to complete 6 months total chemotherapy (pre- and post-randomization) of 1 of the following chemotherapy regimens: FOLFIRINOX or NALIRIFOX or gemcitabine/nab-paclitaxel.	**PVD: 5/14/2025** At time of enrollment, the patient must have received 4-6 months of active chemotherapy with FOLFIRINOX (8-12 cycles) or NALIRIFOX (8-12 cycles) or gemcitabine/NabPaclitaxel (4-6 cycles) (1 regimen, no sequential chemotherapy). * Must have pathologically (histologically or cytologically) proven diagnosis of pancreatic ductal adenocarcinoma. * Must be age ≥ 18 years * Must have ECOG 0-2 * Must have baseline CA19-9 with a normal bilirubin level (defined as ≤ 1.2 mg/dl). AST and ALT ≤ 3x ULN. (see protocol for post-entry chemo requirements) * No cardiac condition that was the primary reason for hospitalization in the last 6 months. * New York Heart Association Functional Classification II or better (NYHA Functional Classification III/IV are not eligible) (Note: Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification.) * HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. * Required Tumor Staging and Characteristics: • No active duodenal or gastric ulcers. • No direct tumor invasion of the bowel or stomach. • Restaging scans showing at least stable disease (no progression). Options for scans include: CT chest/abdomen/pelvis, CT chest/MRI abdomen/pelvis, or CT chest/CT pelvis/MRI abdomen performed prior to enrollment, with restaging CT showing at least stable disease	The primary endpoint is 3-year overall survival (OS), with failure defined as death due to any cause up to 3 years. Hypothesis: The 3-year OS will be higher for patients treated with dose-escalated radiation compared to patients who are treated with standard of care.	NCT06958328	6/11/2025	356