

All Active and Enrolling Cancer Care Delivery Research (CCDR) Trials

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	Note
ECOG-ACRIN	EAQ221CD	Improving Medication Adherence in Metastatic Breast Cancer Using a Connected Customized Treatment Platform (CONCURxP)	Pathologically proven HR+ HER2- metastatic breast cancer	<p>Arm A: Patients use the WiseBag medication dispenser and receive access to educational materials q4 weeks for a year.</p> <p>Arm B: Patients use the WiseBag medication dispenser and receive personalized messages as part of the CONCURxP platform over 12 months</p> <p>Arm C: Participants complete an interview over 15-39 months post-first patient enrollment.</p>	<p>PVD: May 10, 2024</p> <p>Patient Eligibility:</p> <ul style="list-style-type: none"> * Must be ≥ 18 * Must be fluent in English or Spanish * Must have new or established pathologically proven HR+ HER2- metastatic breast cancer * Patient must have initiated any of the CDK4/6 inhibitors (palbociclib or Ibrance, ribociclib or Kisqali, abemaciclib or Verzenio) or other anticancer treatment within 30 days prior to consenting to Step 0 or have received a prescription order with stated intent to initiate within 30 days following Step 0 consent. Patients who have been treated previously with anticancer treatments other than CDK4/6 inhibitors are eligible. See protocol for CDK4/6 prescription/supplier requirements * Must not already be enrolled in a therapeutic clinical trial that monitors CDK4/6 inhibitor * Must have an email address and personal mobile phone in which they are able to send and receive messages * Must be able to understand and sign the ICF; patients requiring an legally authorized representative (LAR) are not eligible. * Must not have an ECOG Performance Status ≥ 3 * Must not be enrolled in other trials offering financial assistance (gift cards for surveys or parking are allowed) 	To compare CDK4/6i adherence at 12 months after randomization captured using electronic monitoring between the EUC (Arm A) and CONCURxP (Arm B) arms.	NCT06112613	10/31/2023	390 patients 20 providers from 10 sites who treated patients in Arm B	See protocol for provider/site requirements that are needed to achieve Study Goal #3 (To describe the patient and provider experience with the CONCURxP intervention using mixed methods based on adherence rate and race.)
ECOG-ACRIN	EAQ222CD	Effectiveness of Out-of-Pocket Cost Communication and Financial Navigation (CostCOM) in Cancer Patients	New diagnosis of any solid cancer of any stage	<p>Arm A: Patients receive Patient Advocate Foundation (PAF) brochure describing financial navigation services.</p> <p>Arm B: Patients receive usual financial care per practice standard of care and CostCOM financial counseling sessions over 1 hour within 30 days after enrollment and at 3, 6 and 12 months.</p>	<p>PVD 9/24/2024</p> <p>Patient Eligibility:</p> <ul style="list-style-type: none"> * Be within 120 days of a new diagnosis of any solid cancer of any stage at the time of Step 0. Stage 0 or in-situ are eligible if systemic therapy has been planned. Patients with a history of prior cancer diagnosis and/or treatment more than 24 months ago are eligible. * Must not have a new recurrence of a primary * Patients with a history of prior cancer diagnosis and/or treatment in the previous 24 months are not eligible. Patients with prior non-melanoma, in-situ are eligible. * Must have initiated oral or IV cancer systemic therapy either any time before Step 0 registration or have received a prescription order with stated intent to initiate within 30 days following Step 0 registration. * Patients must not be receiving any of the following along: palliative care, hospice care, curative surgery, or radiation therapy * Must be ≥ 18 * Must be able to understand and sign an English or Spanish ICF; patients requiring an legally authorized representative (LAR) are not eligible. * Must not have an ECOG Performance Status ≥ 3. * Must not be enrolled in EAQ221CD or S1912CD given financial navigation is offered as part of these two trials. * Must not be enrolled in treatment clinical trials where cancer systemic therapy is provided at no cost to the patient. * Must not be enrolled in other trials offering financial assistance. The following are allowed: gift cards for surveys or parking or financial counseling alone without financial navigation <p>See protocol for provider/site requirements that are needed to achieve Study Goal #3 (To describe CostCOM arm patient and provider experience with the CostCOM intervention using mixed methods.)</p>	To compare patient-reported cost-related cancer care nonadherence at 12 months after randomization between the EUC and CostCOM study arms.	NCT06295367	2/29/2024	720 patients 40 providers from 15 sites	New sites must receive approval prior to initiating any study start-up activities.

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Wake Forest	WF-1805CD	WF-1805CD: Implementation and Effectiveness Trial of HN-STAR	Head and neck cancer (HNC) survivors and their practice	Head and Neck Survivorship Tool: Assessment and Recommendations (HN-STAR) vs Usual Care	PVD 03/10/2025 Practice * Willing to incorporate the web-based HN-STAR into their clinical practice. * Treated ≥12 newly diagnosed cases of head and neck cancer patients within the last 12 months * Can identify at least one designated clinician who is willing to be trained on and use HNSTAR or conduct usual care for enrolled survivors Clinician * Age ≥18 years. * MD, DO, NP, or PA. * Able to speak and read English * Routinely provides care for cancer patients or survivors. * Willing to complete study-specific trainings and incorporate HN-STAR or provide usual care in a routine follow-up care visit. Patient * Participant enrollment closed at this time.	Evaluate the impact of HN-STAR, compared to controls, on change in patient-centered outcomes from baseline to one-year follow-up. Our primary endpoint is head and neck cancer-specific quality of life, as measured by the Trial Outcome Index from the Functional Assessment of Cancer Therapy – Head and Neck (FACT H&N), and other endpoints include symptom burden, patient activation, and perceived quality of cancer care	NCT04208490	8/10/2020	298-400 Head and neck cancer survivors presenting to 20-36 NCORP practices	Participant enrollment closed as of 2/13/2025, but practice (non-patient) enrollment reopened 4/28/2025.
Wake Forest	WF-2301CD	Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers	Lung Cancer Caregiver	Caregivers will be randomized to one of the three groups: 1) Caregiver Oncology Needs Evaluation Tool (CONNECT) 2) Usual Care 3) Generic Resource List	PVD 03/24/2025 Practice * Care for ≥ 50 newly diagnosed (new or recurrent) stage II-IV lung cancer patients annually * Able to identify 1-2 Local Practice Referral Coordinators for this trial * Able to identify a research and/or clinical champion for the study, distinct from the Local Practice Referral Coordinator(s) Caregiver * Provides the majority of unpaid care during cancer treatment (self-reported) * ≥ 18 years of age * Must have access to the internet or be willing to use CONNECT in the clinic. * Must have access to a telephone to complete sessions with the Central Caregiver Navigator. Patient * Current diagnosis of new or recurrent stage II-IV lung cancer * Enrolled after the start of anticancer systemic therapy (+/- radiation therapy) and must have at least 9 weeks of planned systemic anticancer treatment remaining. * Receiving unpaid care from eligible caregiver (self-reported) * Ambulatory and up (i.e., not bedridden) more than 50% of waking hours * ≥ 18 years of age	To assess the multi-site feasibility of the CONNECT Intervention as measured by retention of caregivers at 12 weeks via a randomized pilot trial enrolling 120 lung cancer caregiver-patient dyads (CONNECT, n=40; Usual Care, n=40; Generic Resource List, n=40).	NCT06383988	7/2/2024	120 patients and their caregiver 8-12 sites	Closed to accepting new sites. Contact Jess Sheedy (jsheedy@wakehealth.edu) to get on the waitlist.

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Wake Forest	WF-2303CD	Understanding and Enhancing Health-related Social Needs (HRSN) Screening Among Community Oncology Practices	N/A	N/A. Data will be collected using the Enhancing Health-related Social Needs (HRSN) processes	<p>Enrolling by invitation only</p> <p>PVD 11/11/2024</p> <p>Part 1 Practice Requirements:</p> <ul style="list-style-type: none"> * Must be a NCORP practice (defined as one or more NCORP affiliates/sub-affiliates, that have a common administrative structure and share providers and/or patients) * Must have identified two or more Practice Staff that are available and willing to participate on the Practice Interest Form * Must have identified at least 1-3 outpatient oncology clinics willing to participate on the Practice Interest Form. <p>Part 1 Clinic Requirements:</p> <ul style="list-style-type: none"> * 1-3 clinics within the practice, within the same physical location <p>Part 1 Practice Staff Requirements:</p> <ul style="list-style-type: none"> * Must observe in person and document 1-3 selected clinics within the practice * Must be willing to participate in necessary virtual and in-person trainings/interviews and applicable in-person workshops <p>Part 1 Clinic Key Informant Requirements (MD, social worker, navigator, clinic manager, etc.):</p> <ul style="list-style-type: none"> * Must be willing to participate in an in-person or remote interview * Must be willing to participate in a possible in-person workshop * Must be willing to be recorded when participating in interviews and workshops 	The primary objective of this study is to assess current processes around Health-related Social Needs (HRSN) screening among NCORP clinics and categorize clinics based on their implementation of HRSN screening. The primary endpoint will be a detailed understanding of current processes, with attention to variability by key clinic characteristics.	NCT06412029	7/23/2024	<p>Part 1:</p> <ul style="list-style-type: none"> * Approx. 15-20 NCORP practices * 30-40 practice staff * 45 clinics * 15-60 Clinic Key Informants <p>Part 2:</p> <ul style="list-style-type: none"> * 15 clinics from Part 1 <p>Part 3:</p> <ul style="list-style-type: none"> * 4 clinics from Part 1 * 5-10 workshop participants (patients, providers, practice managers, etc. 	Closed to accepting new sites. Contact Jess Sheedy (jsheedy@wakehealth.edu) to get on the waitlist.