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	**Arm A:** Patients use the WiseBag medication dispenser and receive access to educational materials q4 weeks for a year. **Arm B:** Patients use the WiseBag medication dispenser and receive personalized messages as part of the CONCURxP platform over 12 months **Arm C:** Participants complete an interview over 15-39 months post-first patient enrollment.	**PVD: May 10, 2024** Patient Eligibility: * 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 CKD4/6 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	**Arm A:** Patients receive Patient Advocate Foundation (PAF) brochure describing financial navigation services. **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.	**PVD 9/24/2024** Patient Eligibility: * 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 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.)	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.

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
NRG	NRG-CC012	Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment (SYMON)	Hematopoietic, Lymphoid, or Solid Neoplasms	Arm 1: Patients receive IVR symptom monitoring calls once a week for 12 weeks Arm 2: Patients receive the Symptom Management and Survivorship handbook and receive IVR symptom monitoring calls for 12 weeks	**PVD 10/31/2024** Practice Requirements: * Administer oral therapy to at least 40 patients annually * Complete the NRG-CC012CD Letter of Intent (posted on CTSU) * Has licensed behavioral counselor or willingness to work with a contractor * Must not currently have a telephone symptom management program that is beyond symptom and oral monitoring Practice Retention Requirements: * Must enroll at least 8 patient in the first 6 months * Must complete monthly forms as required * Must participate in monthly study calls Patient Eligibility: * Must be starting a new course of oral anti-cancer within 4 weeks after registration or have started an oral anti-cancer agent in the past 4 weeks. * Must be ≥ 18 * Must be able to speak and understand English or Spanish * Must have a telephone to complete phone surveys * Must not be receiving treatment with immune checkpoint inhibitor * Must not receiving sex hormone inhibitor alone * Must not be in the intervention arm of another symptom management trial at intake into the trial. Participation in lifestyle trials with primary outcomes other than symptoms is acceptable. * Must not be receiving regular behavioral counseling for psychological symptoms. Counseling for weight loss or smoking cessation is allowed.	Test the effectiveness of Automated Telephone System Management (ATSM) + Telephone Interpersonal Counseling (TIPC) versus active control on patient-level outcome of the summary toxicity index of 24 PRO-CTCAE symptoms that include depressive, anxiety, and other symptoms commonly experienced during oral anti-cancer treatment over weeks 1-12 (immediate effect) and 13-17 (sustained effect).	NCT06279013	5/20/2024	12 practices and 43 patients from each practice.	Closed to accepting new practices. NRG may accept LOIs for new practices in April-May 2025 if current practices do not meet the requirements per the protocol. Sites can reach out to symon@miami.edu.
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	**Enrolling by invitation only** **PVD 11/11/2024** **Part 1 Practice Requirements:** * 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. **Part 1 Clinic Requirements:** * 1-3 clinics within the practice, within the same physical location **Part 1 Practice Staff Requirements:** * 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 **Part 1 Clinic Key Informant Requirements (MD, social worker, navigator, clinic manager, etc.):** * 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	**Part 1:** * Approx. 15-20 NCORP practices * 30-40 practice staff * 45 clinics * 15-60 Clinic Key Informants **Part 2:** * 15 clinics from Part 1 **Part 3:** * 4 clinics from Part 1 * 5-10 workshop participants (patients, providers, practice managers, etc.	All NCORP practice spots have been filled. Contact Jess Sheedy at jsheedy@wakehealth.edu to get on the waitlist.