Research Base	Protocol #	Official Study Title	Institution/Disease	Planned Intervention	Additional Eligibility Criteria Please refer to the protocol for the full inclusion/exclusion criteria of the protocol.	Primary Objective	# Sites/Pts per Site	# CCDR Activations	Approximate Start Date	Note
s2132012CS	s2132012CS	PAGODA: Randomized Trial of a Proactive Outpatient Dose Modification Algorithm for Patients Receiving Chemotherapy to Prevent Unplanned Delays	Gastrointestinal Cancer	Hospitalization and medicalization happen frequently during chemotherapy. A participant is complete after the first of: 1) completion of day 1 of their first chemotherapy cycle as determined by the treating physician, or 2) completion of day 1 of cycle 2 of FOLFIRI-based chemotherapy. The duration of treatment after randomization is at the discretion of the treating physician. Patients will be followed for 30 days after treatment to avoid lately, infrequent serious illness. Home refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.	**PTIS: 10/01/2020** **Histologic Documentation:** Histologic confirmation of invasive cancer that is amenable to treatment with a regimen of chemotherapy that includes 5-FU, oxaliplatin, and FOLFIRI-based chemotherapy is an appropriate initial systemic therapy. • Stage: Any stage or clinical setting. • Tumor Site: Eligible primary tumor sites include the esophagus, gastroesophageal junction, stomach, small intestine, ampulla of Vater, appendix, colon/rectum, and pancreatic adenocarcinoma, including with unresectable stages. **Treatment Setting:** Cycle 1, day 1 of FOLFIRI-based chemotherapy must be completed 1 to 8 days prior to randomization. • Cycle 2, day 1 of FOLFIRI-based chemotherapy must include minimum ordered doses of oxaliplatin (85 mg/m2) and irinotecan (180 mg/m2-240 hours). Concomitant monoclonal antibodies are permitted (e.g., anti-VEGF, anti-EGFRs, anti-PD1/PDL1, and anti-HER2). • The planned duration of FOLFIRI-based chemotherapy must be at least four cycles (i.e., 8 weeks). • Cycle 1, day 1 of FOLFIRI-based chemotherapy must be completed 1 to 8 days prior to randomization. • Cycle 2, day 1 of FOLFIRI-based chemotherapy must include minimum ordered doses of oxaliplatin (85 mg/m2) and irinotecan (180 mg/m2-240 hours). Use of the 5-FU bolus is at the discretion of the treating physician. • Patients who require primary prophylactic white blood cell growth factor with cycle 1 of FOLFIRI chemotherapy due to high risk for fever and neutropenia are not eligible for randomization. Secondary prophylactic white blood cell growth factor is permitted, at the treatment, at the investigator and the recipients in their formulations are not eligible. Age: ≥18 years	To compare the proportion of chemotherapy cycles with unplanned delays in patients receiving FOLFIRI chemotherapy under standard care versus a proactive dose modification algorithm according to the PAGODA dose modification algorithm (proactive intervention).		1/1/26	420	
Wake Forest	NP 2104120	Practical Delivery of Geriatric Assessment in Community Oncology Settings (PGA)	Intensive assessment of geriatric sociological up to understand heterogeneity in aging2 through examples of diseases and function and identifying conditions that need to be addressed prior to treatment	very practice within their Community Site consented to participating in the organization listed below should complete the Interest Survey within the Recruitment Email to be considered. Sites will be selected based on ease of use to recruit NCORP affiliates, or sub-affiliates, which have a sensitive administrative structure and share providers and/or patients.	Oncology Clinician: 1) Oncology clinician (MDs, DOs, APPs (e.g. NP, PA)); 2) Involved in the planning or delivery of new systemic therapies (e.g., chemotherapy, immunotherapy and/or targeted therapy) in patients including those age 65+ Clinic Staff: Support Staff: Nurse, practice manager, or other oncology support staff who work with oncology clinicians who provide systemic therapy, help with office workflows for oncology patients with referrals (including patients age 65 or older). May include staff that have a dual role in research and clinical support. • Patients: 1) ≥ 65 years of age, 2) Must have initiated a new line of chemo/immunotherapy or targeted therapy in the last 12 months. • Caregivers: Must self-report as having cared for a patient age 65 or older who initiated chemotherapy, immunotherapy or targeted therapy in the last 12 months. To allow the differences in how the term "caregiver" is used, we will include any family member or friend who considering their cancer treatment, regardless of whether they define themselves as a caregiver.	To refine proposed implementation strategies for delivering PGA through feedback from stakeholders.		12/23/24	5 practices (up to 5 clinics) 200 patients	
Wake Forest	NP 2102120	Surgical Transformation(s) Practices in Oncology Patients within the NCORP Network (STOP VTE)	Surgeons who perform abdomen/pelvis cancer surgery (i.e., colorectal/anal (GI), gastrointestinal (GI), gynecologic (GYN) or urologic (GU)) practice providers (APPs) who assist with post-operative care for these patients within the NCORP network	Aim 1: A survey will be distributed to identify surgeons performing abdomen/pelvis cancer surgery or surgical APPs who assist with post-operative care for patients within NCORP sites. Surgeons/surgical APPs: n = 300 (mean 8 (min: n = 2) sites). Aim 2: Surgeons and surgical APPs that participate in Aim 1 will be identified using purposive sampling to ensure a robust inclusion of key characteristics of surgeons and surgical APPs. Surgeons/surgical APPs from Part 1 for interviews: n = 20 (2 per site). Aim 3: Surgeons and surgical APPs from Part 1 will be invited to be on a focus group to explore the feasibility of remission of standard venous thromboembolism (VTE) prophylaxis using a report from the electronic health record (EHR) and to retrospectively assess adherence to VTE prophylaxis using a chart audit. A patient is defined for this study as one at more NCORP affiliate/sub-affiliate sites, which have a shared income of an electronic health record. Surgeons/surgical APPs: n=300 (mean 8 (min: n=2) sites)	**PTIS 10/17/2020** Both men and women of all races and ethnic groups who understand English are eligible for this trial. We will work with our Wake Forest NCORP Research Base Community Engagement Leader (CEL) and the PRIDE Clinic Leader to receive feedback on our recruitment strategy and develop study related materials. (e.g., study flyer, etc.) that are appropriate for attracting and enrolling surgeons or surgical APP participants from diverse populations and NCORP sites.	The purpose of the research study is to evaluate the consistent use of standard venous thromboembolism (VTE) prophylaxis (APPs) for patients after major cancer surgery in community oncology practices across the United States, and, in institution.	NCT05214820	12/23/24	300 Practices 700 Sites Patients	
s2122003CS	s2122003CS	GTA Assess Study: An Implementation Study to Test Novel Delivery Models for Clinical Genetic Services in Community ATA Cancer Patients	ATA cancer patients. Eligible cancer sites include patients at any stage of diagnosis (e.g., newly diagnosed, in treatment, in survivorship) and a variety of cancer types (including/excluding breast cancer) at age ≥ 20 years old	A link to the Eligibility Verification Form (Qualtrics) and the Consent Form will be provided to potential participants by site research staff. Paper versions are also available. **Arm 1: Standard Remote Genetic Services** **Arm 2: Genetic Journey Chatbot** Access to the Genetic Journey Chatbot, digital power education, and ongoing access to the chatbot.) Both arms will receive/have access to a Genetic Counselor for patient genetic education, NCCN genetic testing, telehealth visits, review results of genetic testing.	**PTIS 9/12/2020** All patients enrolled in this trial will receive genetic counseling and testing through the Pan Prime Telegenetics Program. Patients should be informed that they must forgo genetic testing if they are unwilling to sign consent and participate in interviews. Risk Assessment (RA) screening shorthes or Pan Telegenetics will confirm eligibility for genetic testing and notify the potential participant (via the FVA Screening Chatbot) and clinic of the eligibility for genetic testing. **Patient Eligibility** * Age ≥ 20 years and ≤ 39 years. * any stage of diagnosis (e.g., newly diagnosed, in treatment, in survivorship) * Must be able to speak and read English or Spanish **Non-Patient** Oncology providers, nurses and clinic staff, genetic counselors and insurers (i.e., Medicaid, non-profit financial services and/or for insurance companies) that participate in the genetic services among ATA in the community for this study that are willing to sign consent and participate in interviews	Ex vivo/Clinical	9/26/24	400 Patients 50 Non-patients	
IS1501-ACRIN	IS1501CS	Improving Medication Adherence Outcomes in Breast Cancer Using a Connected Continuous Care Platform (COMCARE)	Pathologically proven Stage I-IIIC breast cancer	**Arm A:** Patients use the WiseBag medication dispenser and receive a educational materials (pl weekly for 6 mo) **Arm B:** Patients use the WiseBag medication dispenser and receive educational materials (pl weekly for the 6 MO) PLUS patients receive 12 months **Arm C:** Participants complete an interview over 15-30 months post-first dispen enrollment.	**PTIS: 7/14/2020** Patient Eligibility: * Must be ≥ 18 * Must be able to English or Spanish * Must have new or modified pathologically proven IIB / IIIB/C metastatic breast cancer * Must have been initiated any of the CDK4/6 inhibitors (palbociclib or Ibrance, Ribociclib or Kisqali, abemaciclib or Verzenio) vs other anticancer treatment within 30 days prior to assessing to Step 0 or have received a prescription order with sealed patent 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 if they have not been treated with a CDK4/6 inhibitor. * Must not already be enrolled in a therapeutic clinical trial that monitors CDK4/6 inhibitors * Must have an email address and personal mobile phone to which they are able to receive Text 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 (pl/ needs for	Ex vivo/Clinical	04/01/25	250 patients 20 providers from 10 sites	Use personal for patients, provider requirements that are needed to achieve study goals. Also, describe the patient and provider interaction with the COMCARE conversation using natural methods (email or alternative text and voice)
IS1501-ACRIN	IS1502CS	Effectiveness of Oncoll. Care Plan Using Collaboration and Financial Navigation (CoolCOM) in Cancer Patients	New diagnosis of any cancer and/or recurrence of any cancer	**Arm A:** Patients receive Patient Navigation and Financial Navigation services (including financial navigation services) **Arm B:** Patients receive usual financial care per practice standard of care and CoolCOM financial counseling sessions over 1 hour within 30 days after enrollment and at 3, 6 and 12 months.	**PTIS 7/28/2020** Patient Eligibility: * Be within 120 days of a new diagnosis of any solid cancer of any stage at the time of registration. 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 eligible if they are NED and not receiving treatment for the previous cancer. * Must have initiated and is ON cancer systemic therapy either any time before Step 0 registration or have received a prescription order with sealed intent to initiate within 30 days following Step 0 registration. * Patients may 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; use of an Legally authorized representative (LAR) is not eligible. * Must not have an ECOG Performance Status ≥ 3 * Must not be enrolled in AnQ2021CS or S1912CS given financial navigation is provided as part of the study intervention. * 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 2).	Ex vivo/Clinical	09/24	250 patients Sites: 10	New sites must have the ability to initiate any study start-up activities.
S1900	S1900CS	A Pragmatic Randomized Controlled Trial To Evaluate The Effectiveness of an Intervention called Cancer Together After Cancer (CTAC) to Improve Guideline Concordant Colorectal Cancer Surveillance	Newly diagnosed pathologically proven, Stage II or Stage III colorectal cancer	**Group 1:** Intervention (usual Cancer Care + Cancer Care Together (CTAC) website • Educational materials about CRC surveillance • Prompts for supporter involvement • Brief communication training • Summary of supporter engagement **Group 2:** Control Arm • Cancer Together After Cancer (CTAC) web website • Patients will be given access to information about cancer survivorship, navigate to health care, and healthy living.	**Patient Eligibility:** * Must have newly diagnosed surgically resected, Stage II or Stage III colorectal cancer * Must have an adult in their life who supports them in their colorectal cancer journey * Must be ≥ 18 years old, English or Spanish understanding * Must have Zubrod Performance Status ≤ 2 * Must be able to read English or Spanish * Must not have been previously enrolled in a clinical trial of oncologic/cancer treatment that includes imaging and/or laboratory monitoring for the duration of this trial. (Co-enrollment on other non-treatment trials are allowed). **Non-Patient (Supporter) Eligibility:** * Must be ≥ 18 years of age at the time of registration/randomization * Must be able to read English or Spanish * Must be a family member, friend, or a person who may be willing to join them in accessing the educational website. This may be a spouse/partner, adult child, other adult family member, or a friend.	To evaluate whether the patients randomized to the Cancer Together After Cancer (CTAC) intervention website compared to the CTAC control website have higher rates of guideline concordant colorectal cancer (CRC) surveillance at 12 months after registration.	Ex vivo/Clinical	09/19	Patients: 400 Non-Patients: 400	
Wake Forest	NP 1808120	NT-1802120: Implementation and Effectiveness Trial of HS-STAR	Head and neck cancer survivors and their practice	Head and Neck Survivorship Tool Assessment and Recommendations (HS-STAR) vs. Usual Care	PTIS 02/10/2020 **Provider** * Willing to incorporate the web-based HS-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 HS-STAR or another usual care for enrolled survivors **Clinician** * Age ≥18 years * Treat HNC pts, or PA * Able to speak and read English * Routinely provides care for cancer patients or survivors. * Willing to complete study specific trainings and incorporate HS-STAR or provide usual care in a similar fashion per usual care. **Patient** * Participant enrollment closed at this time	Evaluate the impact of HS-STAR, compared to controls, on changes in unmet survivorship concerns (primary outcome). Secondary: The median reduction in Head and neck cancer specific quality of life, as measured by the Total Outcome Index from the Functional Assessment of Cancer Therapy – Head and Neck (FACT HNCS), and other endpoints: patient-reported outcomes, health utilization, and perceived quality of cancer care	Ex vivo/Clinical	9/19/19	250-400 Head and neck cancer survivors Sites: Recruiting 36 sites, 20 clinic sites	Participant enrollment closed as of 2/13/2023. See protocol for provider requirements. Enrollment suspend 4/28/2023
Wake Forest	NP 2106120	Multi-level Community Implementation Strategies for the CONNECT Intervention Targeting Long Cancer Caregivers	Long Cancer Caregiver	Caregivers will be randomized to one of two study arms: 1) Caregiver Oncology Needs Evaluation Tool (CONNECT) 2) Usual Care • Cancer Resource List	**PTIS 04/28/2020** **Provider** * 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 * Has access to or the internet or be willing to use CONNECT to the clinic * Must have access to a telephone to complete sessions with the Cancer Caregiver Navigator. **Patient** * Current diagnosis of new or recurrent stage II-IV lung cancer * Familial after the care of antecancer system (therapy (+/- radiation therapy) and must have at least 9 weeks of planned systemic antecancer treatment remaining. * Ambulatory and ECOG performance status ≤ 2 (karnofsky ≥ 60) * Ambulatory and ≥ 18 - not hobbifitted more than 50% of waking hours * ≥ 18 years of age	To assess the multi-site feasibility and fidelity of CONNECT Intervention as measured by: retention of caregivers at 12 weeks Secondary Endpoints: Enrolling 120 lung cancer caregiver patients dyads (CONNECT, n=60 Usual Care, n=60; Generic Resource List, n=60)	Ex vivo/Clinical	7/21/21	120 patients Sites: 10 sites caregiver 8 CT sites	Closed to accepting new sites. Contact Amy Moody (amoody@wakehealth.edu) to get on the waitlist.
Wake Forest	NP 2105120	Understanding and Enhancing Health-related Social Needs (HRSN) Screening Processes in Community Oncology Practices	VA	VA. Data will be collected using the Screening Health-related Social Needs (HRSN) processes	**Enrolling by invitation only** **PTIS 02/05/2020** **Part 1 Site 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 in the Practice Interest Form. * Must have identified at least 1-2 competent 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 2 Practice Staff Requirements:** * Must have identified a minimum of one/two 1-3 informed clinics within the practice * Must be willing to participate in necessary virtual and in-person training/interviews and applicable in-person workshops. **Part 2 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 screening processes in NCORP clinics and compare clinics based on their implementation of HRSN screening. The primary endpoint will be a detailed understanding of current HRSN implementation as modified by key clinic characteristics.	Ex vivo/Clinical	7/21/21	Part 1: * Approx. 15 NCORP practices * 30-45 practices staff * 45 clinics * 15-45 Clinic KI Informants Part 2: * 3 practices * 9 clinics * 3 KI workshop participants (practices, providers, practice managers, etc.	Closed to accepting new sites. Contact Amy Moody (amoody@wakehealth.edu) to get on the waitlist.