Hybrid DCT Portfolio

Bringing Trials to Patients in Your Community (Most, if not ALL, Assessments/Procedures Done Locally)

Indication	Status	Trial Information	Contact
Breast	**Open**	**LCCC 2437: PROGRESS** **Oncology using Genomic Reflexive Evaluations for Study Selection and Survival** **Hybrid Decentralized Single-arm Interventional Study** • Precision oncology navigator helps handoff NGS testing to ultimately recommend relevant clinical treatment trials to primary providers • PROs at baseline and six months from baseline **Brief Eligibility Inclusion:** • Stage four bladder, breast, MSCLC, and CRC patients Plan to undergo genomic tumor test	PI: Carrie Lee, MD, MPH carrie_lee@med.unc.edu SC: LCCC_DCT@med.unc.edu
	Open	**LCCC 1829: HARMONY** **Harnessing Analysis of RNA Expression and Molecular Subtype to Optimize Novel Therapy MBCA** **Blood Draw Study at Baseline and Every 6 Months** • PAM50/RNA sequencing for 1st line met pts • Both patient & local physician consented—provider preference testing **Brief Eligibility Inclusion:** • 1st line met patients (no later)	PI: Lisa Carey, MD Lisa_Carey@med.unc.edu SC: LCCC_DCT@med.unc.edu)

	Open	**LCCC 2437: PROGRESS** **Oncology using Genomic Reflexive Evaluations for Study Selection and Survival** **Hybrid Decentralized Single-arm Interventional Study** • Precision oncology navigator helps handoff NGS testing to ultimately recommend relevant clinical treatment trials to primary providers • PROs at baseline and six months from baseline **Brief Eligibility Inclusion:** • Stage four bladder, breast, MSCLC, and CRC patients • Plan to undergo genomic tumor test	PI: Carrie Lee, MD, MPH carrie_lee@med.unc.edu SC: LCCC_DCT@med.unc.edu
	Open	**LCCC 2332** **Dyadic Analysis of Unmet Social Needs Among Breast and Gynecologic Patients and Their Informal Caregivers** **Non-interventional study with questionnaires at baseline, 3, 6, and 9 months** • Quantitatively measures the unmet social needs among female patients with cancer and their caregivers • Participants will be surveyed four times over the course of 9 months. In addition, the geographical context for the results will also be explored **Brief Eligibility Inclusion:** • Age ≥ 18 years at the time of consent • Household annual income below $60,000 • Self-describes as a woman • Within 12 weeks of a new first diagnosis breast or gynecologic cancer	PI: Tess Thompson, PhD, MPH Tess.Thompson@unc.edu SC: LCCC_DCT@med.unc.edu

		• A caregiver willing and able to participate	
	Open	**LCCC 2412** **Molecular Residual Disease Assessment in Populations with Early-stage Breast Cancer** **Non-interventional study investigating the utility of using ctDNA to tailor therapy in breast cancer patients with nodal disease** • Blood collections at pre-adjuvant therapy, 3, 6, 9, and 12 months **Brief Eligibility Inclusion:** • Age ≥ 18 years at the time of consent • Subject must have had surgical intervention and must have sufficient archival specimen from either the primary tumor or a lymph node for ctDNA assay development • Subject must have not had any systemic treatment or radiation for their current breast cancer prior to surgery • Subject must have histological or cytological evidence/confirmation of breast cancer with 1-3 positive lymph nodes	PI: Yara Abdou, MD Yara_Abdou@med.unc.edu SC: LCCC_DCT@med.unc.edu
	Open	**LCCC 2341** **Patient Outcomes and Experiences in Metastatic Breast Cancer (POEM)** **Non-interventional study of social determinants of health, biomarkers of allostatic load, and disparities in breast cancer outcomes** • Blood collection at baseline • Patient reported outcomes at baseline, 3, 6, and 12 months **Brief Eligibility Inclusion:**	PI: Katie Reeder-Hayes, MD kreeder@med.unc.edu SC: LCCC_DCT@med.unc.edu

		• Age ≥ 18 years at the time of consent • Pathologic diagnosis of metastatic breast cancer • Able to answer survey questions in English • Indicate intent to receive ongoing cancer care at the enrolling institution	
	Open	**LCCC 2424** **Promoting Resilience in Stress Management for Metastatic Breast Cancer (PRISM-MBC)** **Non-treatment interventional study evaluating changes in reported resilience among PRISM participants** • Biospecimen collection at baseline and 3 months • Patient reported outcomes at 3, 6, and 12 months • Remote intervention counseling sessions lasting 30-60 minutes beginning after completion of baseline patient survey and continuing every 1-2 weeks through Day 90 **Brief Eligibility Inclusion:** • Age ≥ 18 years at the time of consent • Pathologic diagnosis of metastatic breast cancer • Able to answer surveys and participate in counseling sessions in English • Indicate intent to receive ongoing cancer care at the enrolling institution	PI: Katie Reeder-Hayes, MD kreeder@med.unc.edu SC: LCCC_DCT@med.unc.edu
	Coming Soon!	**LCCC 2426** **P-RAD (+) TN: A Phase II Randomized Study of Preoperative Chemotherapy, Pembrolizumab and Low or High Dose Radiation in an Expansion Cohort of Node (+), Triple Negative Breast Cancer** **Brief Eligibility:**	

		• TNBC, N1-3 • Has or planned for clips or fiducial placement within bx-proven axillary lymph node and breast primary tumor prior to RT simulation • Available and sufficient archival tissue from diagnostic core; if not available, biopsy is required • Neoadjuvant chemo is planned per SOC • No prior therapy with anti-pD-1, anti-PD-L1 or anti-PD-L2 agent or those directed to another stimulatory or co-inhibitory T-cell receptor	
Bladder	**Open**	**LCCC 2437: PROGRESS** **Oncology using Genomic Reflexive Evaluations for Study Selection and Survival** **Hybrid Decentralized Single-arm Interventional Study** • Precision oncology navigator helps handoff NGS testing to ultimately recommend relevant clinical treatment trials to primary providers • PROs at baseline and six months from baseline **Brief Eligibility Inclusion:** • Stage four bladder, breast, MSCLC, and CRC patients • Plan to undergo genomic tumor test	PI: Carrie Lee, MD, MPH carrie_lee@med.unc.edu SC: LCCC_DCT@med.unc.edu
Colorectal	**Open**	**LCCC 2437: PROGRESS** **Oncology using Genomic Reflexive Evaluations for Study Selection and Survival** **Hybrid Decentralized Single-arm Interventional Study** • Precision oncology navigator helps handoff NGS testing to ultimately recommend relevant clinical treatment trials to primary providers	PI: Carrie Lee, MD, MPH carrie_lee@med.unc.edu SC: LCCC_DCT@med.unc.edu

		• PROs at baseline and six months from baseline **Brief Eligibility Inclusion:** • Stage four bladder, breast, MSCLC, and CRC patients • Plan to undergo genomic tumor test	
Gyn/Onc	**Open**	**LCCC 2332** **Dyadic Analysis of Unmet Social Needs Among Breast and Gynecologic Patients and Their Informal Caregivers** **Non-interventional study to measure unmet social needs among female cancer patients and their caregivers** • Surveys at baseline, 3, 6, and 9 months **Brief Eligibility Inclusion:** • Age ≥ 18 years at the time of consent • Household annual income below $60,000 • Self-describes as a woman • Within 12 weeks of a new first diagnosis breast or gynecologic cancer • Caregiver willing and able to participate in the study	PI: Tess Thompson, PhD, MPH Tess.Thompson@unc.edu SC: LCCC_DCT@med.unc.edu
Lung	**Open**	**LCCC 2437: PROGRESS** **Oncology using Genomic Reflexive Evaluations for Study Selection and Survival** **Hybrid Decentralized Single-arm Interventional Study** • Precision oncology navigator helps handoff NGS testing to ultimately recommend relevant clinical treatment trials to primary providers • PROs at baseline and six months from baseline **Brief Eligibility Inclusion:**	PI: Carrie Lee, MD, MPH carrie_lee@med.unc.edu SC: LCCC_DCT@med.unc.edu

		• Stage four bladder, breast, MSCLC, and CRC patients • Plan to undergo genomic tumor test	
Multiple Myeloma	**Coming Soon**	**LCCC 2323** **Dara-RVd Induction for Newly Diagnosed MM with Autologous Stem Cell Transplantation** **Hybrid Decentralized Single-arm Interventional study** • Examine effect of daratumumab-based quadruplet induction therapy given at an attenuated schedule in patients with newly diagnosed multiple myeloma who are eligible for ASCT **Brief Eligibility Inclusion:** • Newly diagnosed multiple myeloma, with no prior therapy lasting more than 28 days • Must have measurable multiple myeloma • Ability to access video-enabled technology for telemedicine visits • May not have an active infection requiring systemic therapy within 14 days prior to study start	PI: Sam Rubenstein, MD Samuel_Rebenstein@med.unc.edu SC: LCCC_DCT@med.unc.edu

Sarcoma	**Open**	**LCCC 2250** **GRID Therapy for Extremity Soft Tissue Sarcoma** **Hybrid Decentralized Pilot Radiation Therapy Study** • Single arm pilot study assessing safety of spatially fractionated grid radiation therapy (GRID) in patients with resectable soft tissue sarcoma, followed by SOC conventional radiotherapy (XRT) and tumor resection **Brief Eligibility Inclusion:** • Age ≥ 18 years at the time of consent • Histological or cytological evidence/confirmation of soft tissue sarcoma as determined by core-needle biopsy or excision biopsy • The subject must be willing to provide a mandatory research biopsy 72-96 hours after receiving GRID therapy and prior to SOC XRT and tumor resection • Previous tumor resection at primary tumor site not permitted • Sarcoma is thought to be arising in a lymph node without a primary site ≥ 5 cm is not permitted	PI: Ted Yanagihara, MD, PhD tky@email.unc.edu SC: LCCC_DCT@med.unc.edu