

	Neoadjuvant	Adjuvant	Metastatic (First Line)	Metastatic, Advanced, Relapsed/Refractory (Second or Third Line)
Colorectal	<p><b>A022104 / JANUS (Poe/Sanoff)</b></p> <p>The Janus rectal cancer trial: a randomized phase II trial testing the efficacy of triplet versus doublet chemotherapy to achieve clinical complete response in patients with locally advanced rectal cancer</p> <p><u>Brief eligibility/info:</u></p> <ul style="list-style-type: none"> <li>- Clinical stage II or III rectal adenocarcinoma defined as T4N0 or any T with node positive disease (any T, N+); also T3N0 requiring APR or coloanal anastomosis</li> <li>- Tumor site: rectum ≤ 12cm from the anal verge</li> <li>- No prior systemic chemotherapy, targeted therapy, or immunotherapy, or radiation therapy administered as treatment for colorectal cancer within the past 5 years is allowed. <ul style="list-style-type: none"> <li>- ECOG ≤ 2</li> </ul> </li> </ul> <p><b>NEW M24-533 (TBD/Sanoff)</b></p> <p>A Phase 2, Open-label, Randomized Study to Evaluate the Efficacy and Safety of Telisotuzumab Adizutecan in Combination with 5-FU, Folinic acid, and Panitumumab in Subjects with Treatment-naïve Left-sided Metastatic Colorectal Cancer</p> <p><u>Brief eligibility/info:</u></p>	<p><b>SUSPENDED - TERMINATING NRG-GI005-CIRB / COBRA (Schiessl/Sanoff)</b></p> <p>A Phase II/II Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)</p> <p><b>NRG-GI008 -CIRB / CIRCULATE (Schiessl/Sanoff)</b></p> <p>Colon Adjuvant chemotherapy based on evaluation of residual disease (circulate-US)</p> <p><u>Brief eligibility/info:</u></p> <ul style="list-style-type: none"> <li>- ECOG = 0-1</li> <li>- <b>Histological/pathologically confirmed Stage IIIA or Stage IIIB colon adenocarcinoma (T1-3, N1/N1c) with R0 resection.</b></li> <li>- <b>No radiographic evidence of overt metastatic disease within 45 days prior to study entry.</b></li> <li>- The distal extent of the tumor must be ≥12 cm from the anal verge on colonoscopy or above the peritoneal reflection as documented during surgery or on pathology specimen.</li> <li>- Tumor must be documented as MSS or have intact mismatch repair proteins through CLIA-certified lab testing. Patients whose tumors as MSI-H or dMMR are excluded.</li> <li>- <b>The interval between surgery (post-operative day 7) and study entry must be no more than 60 days.</b></li> </ul>	<p><b>61186372COR3001/OrigAMI-2 (Schiessl/Sanoff)</b></p> <p>A Randomized, Open-label Phase 3 Study of Amivantamab and mFOLFOX6 or FOLFIRI Versus Cetuximab and mFOLFOX6 or FOLFIRI as First-line Treatment in Participants With KRAS/NRAS and BRAF Wild-type Unresectable or Metastatic Left-sided Colorectal Cancer</p> <p><u>Brief eligibility/info:</u></p> <ul style="list-style-type: none"> <li>- Left-sided CRC. KRAS, NRAS and BRAF WT tumor determined by local testing.</li> <li>- Must agree to the submission of fresh tissue</li> <li>- Must have measurable disease according to RECIST 1.1</li> <li>- Not received any prior systemic therapy for unresectable or metastatic CRC <ul style="list-style-type: none"> <li>- ECOG 0-1</li> </ul> </li> </ul> <p><b>NRG-GI004-CIRB / COMMIT (Poe/Sanoff)</b></p> <p>COMMIT Study: Randomized Phase 3 trial of mFOLFOX6/bev w/w/o atezolizumab or atezolizumab monotherapy in 1<sup>st</sup> line dMMR mCRC</p> <p><u>Brief eligibility/info:</u></p> <ul style="list-style-type: none"> <li>- 1<sup>st</sup> line mCRC with MSI-H (dMMR) mCRC <ul style="list-style-type: none"> <li>- ECOG = 0-2</li> </ul> </li> <li>- Diagnosis of metastatic adenocarcinoma of colon or rectum without previous chemotherapy or any other systemic therapy for metastatic colorectal cancer except for one cycle of FOLFOX or CAPOX, either with or w/o Bevacizumab prior to enrollment</li> <li>- No need for immediate surgical intervention for the primary tumor or palliative diversion/bypass</li> <li>- Documentation by PET/CT scan, CT scan, or MRI that the patient has measurable disease per RECIST v1.1</li> <li>- No uncontrolled hypertension defined as systolic &gt; 160mmHg or diastolic &gt; 100 mmHg w/ or w/o antihypertensive medications.</li> <li>- No symptomatic peripheral sensory neuropathy ≥ grade 2 (CTCAE v5.0)</li> </ul>	<p><b>NEW M24-064 (Poe/Sanoff)</b></p> <p>AndroMETa-CRC-064: An Open Label, Randomized, Controlled, Global Phase 3 Study Comparing ABBV-400 Monotherapy to LONSURF (Trifluridine and Tipiracil) plus Bevacizumab in Subjects with c-Met Over-Expressed Refractory Metastatic Colorectal Cancer</p> <p><u>Brief eligibility/info:</u></p>

	Neoadjuvant	Adjuvant	Metastatic (First Line)	Metastatic, Advanced, Relapsed/Refractory (Second or Third Line)
Pancreatic	<p><b><u>LCCC1843 / Neoadj panc tissue (Poe/Somasundaram)</u></b> Impact of Neoadjuvant FOLFIRINOX on Tumor and Stromal Subtypes in Subjects with Non-Metastatic Pancreatic Cancer <i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Correlative study of patients receiving neoadjuvant FFX; can receive chemotherapy locally</li> <li>- Archival tissue must be core bx or fresh bx is required</li> </ul> <p><b><u>AAAU4206 / Neoadj panc (Schiessl/Somasundaram)</u></b> A Phase 2, Open-Label, Multicenter, Randomized Study Evaluating neoadjuvant therapy targeting the Adenosine immunosuppressive pathway in combination with Immune checkpoint blockade and Radiation Therapy in Patients with advanced PANCreatic Ductal Adenocarcinoma who are candidates for surgical resection. <i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Completed 8 cycles of neoadjuvant modified FOLFIRINOX. Omission of oxaliplatin due to AEs may be allowed in cycles 5-8 w/ consultation of PI.</li> <li>- Patients with surgically resectable PDAC</li> <li>- Eligible to undergo SBRT</li> <li>- No prior surgical, systemic, or radiotherapy for PDAC except for mFOLFIRINOX <ul style="list-style-type: none"> <li>- ECOG 0-1</li> </ul> </li> <li>- No Qtc&gt;=480 msec using QTcF</li> <li>- No uncontrolled pleural effusion</li> </ul>	<p><b><u>PACER (Kowalczyk/Yanagihara) [Run out of RadOnc pod]</u></b> (Pancreatic AdenoCarcinoma with Electron intraoperative Radiation therapy): A Phase II study of electron beam intraoperative radiation therapy following chemoradiation in patients with pancreatic cancer with vascular involvement <i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Patients must receive at least 3 months of neoadjuvant chemotherapy and SBRT or CRT prior to surgery</li> </ul>	<p><b><u>NCI-10464 / Durva + Olaparib LAPC (Griffin/Somasundaram)</u></b> A Phase 1 Study of Olaparib in Combination with Durvalumab (MEDI4736) and Concurrent Radiation Therapy Following First-Line Chemotherapy in Locally Advanced Unresectable Pancreatic Cancer <i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Unresectable locally advanced pancreatic cancer as determined by a multidisciplinary tumor board applying NCCN v2.2021 criteria or as surgically determined during failed resection attempt.</li> <li>- Patients must have had prior first-line chemotherapy for this cancer for at least 16 weeks without clinical, biochemical, or radiological progression. There should be a washout of at least 2 weeks from first-line chemotherapy and start of therapy on clinical trial. <ul style="list-style-type: none"> <li>- Hemoglobin <math>\geq</math> 9.0</li> </ul> </li> <li>- Patients with HCV must have been treated and cured.</li> <li>- Patients must have radiologically measurable or evaluable diseases</li> <li>- Must be able to tolerate CT and/or MRI with contrast.</li> <li>- Must have recovered from grade <math>\geq</math> 2 AEs due to prior anti-cancer therapy with exceptions</li> </ul> <p style="text-align: center;"><b>OPENING SOON</b> <b><u>LCCC2220/Metastatic Pancreatic (Schiessl/Somasundaram)</u></b> A phase I/II study of subjects with advanced basal-like pancreatic adenocarcinoma treated with Gemcitabine, Erlotinib and nab-paclitaxel (PANGEA) versus subjects with classical pancreatic adenoarcinoma treated with triplet standard of care therapy. <i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Histological or cytological confirmation of metastatic pancreatic adenocarcinoma</li> <li>- Subject must consent to a mandatory pre-study biopsy if archival tissue is not available or sufficient <ul style="list-style-type: none"> <li>- ECOG 0-1</li> </ul> </li> </ul>	<p><b><u>NCI-10522-CIRB / IL1Ri met PDAC (Poe/Somasundaram)</u></b> A Phase 1 Clinical Trial of CA-4948 in Combination with Gemcitabine and Nab-Paclitaxel in Metastatic or Unresectable Pancreatic Ductal Carcinoma <i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Confirmed adenocarcinoma of the pancreas that is metastatic or unresectable</li> <li>- Disease progression on or after 5-FU-based therapy for metastatic or unresectable PDAC. If received gemcitabine-based regimen as adjuvant therapy, should be &gt;12 mo from study enrollment</li> <li>- Age <math>\geq</math>18 years. ECOG <math>\leq</math>2. Adequate organ and marrow function.</li> <li>- No hx of other malignancy. No severe obstructive pulmonary disease</li> <li>- <b>PROCESS FOR ADDING SOMEONE TO STUDY – NOT IMMEDIATE CONSENTING</b></li> </ul> <p><b><u>LCCC 2223- B7-H3 directed CAR-T with inducible iC9 safety switch (Ratzlaff/ Somasundaram): [Run out of Car-T pod]</u></b> A Phase I Study of Autologous CAR-T Cells Targeting the B7-H3 Antigen and Containing the Inducible Caspase 9 Safety Switch in Subjects with Refractory Pancreatic Ductal Adenocarcinoma (PDAC) <i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Adequate performance status (ECOG of 0 or 1)</li> <li>- 1+ prior lines of therapy for metastatic pancreatic cancer</li> <li>- Willing to undergo biopsy prior to treatment, after CAR-T and at progression (if safe)</li> <li>- Measurable disease per RECIST 1.1</li> <li>- Life expectancy &gt; or = 12 weeks</li> <li>- Not on corticosteroids</li> <li>- Adequate organ function (LVEF &gt; or = 40%, ANC &gt; or = 1.0K/mm<sup>3</sup>; Platelets &gt; or = 100K/mm<sup>3</sup>; CrCl &gt; 30 mL/min; Bili &lt; or = 1.5x ULN; AST and ALT &lt; or = 3 x ULN)</li> <li>- No rapidly progressive disease</li> </ul>

	Neoadjuvant	Adjuvant	Metastatic (First Line)	Metastatic, Advanced, Relapsed/Refractory (Second or Third Line)
	<ul style="list-style-type: none"> <li>- No uncontrolled hypercalcemia</li> <li>- No HIV infection</li> <li>- No active TB</li> </ul>		<ul style="list-style-type: none"> <li>- No active infection</li> <li>- Cannot be currently using tobacco products or vaping.</li> </ul>	
HCC	<p><b>EMERALD Y-90 (Griffin/Jia)</b> Phase II Single-Arm Study of Durvalumab and Bevacizumab Following Transarterial Radioembolization Using Yttrium-90 Glass Microspheres (TheraSphere™) in Unresectable Hepatocellular Carcinoma Amenable to Locoregional Therapy</p> <p><u>Brief eligibility/info:</u></p> <ul style="list-style-type: none"> <li>- Future liver remnant volume (FLRV) <math>\geq</math> 30% of whole liver volume.</li> <li>- No evidence of extrahepatic disease on any available imaging</li> <li>- One or more measurable lesions, unilobar disease for participants with Vp1/Vp2 portal vein invasion and eligible for Y90 glass microsphere TARE, Bilobar disease is allowed for participants that do not have portal vein invasion if only a single Y90 glass microsphere TARE procedure is required.</li> <li>- Child-Pugh score class A <ul style="list-style-type: none"> <li>- ECOG 0-1</li> </ul> </li> <li>- Disease burden must be amenable to complete treatment w/ TARE in one session w/ no more than 70% of liver radiated determined by MAA mapping angiogram</li> <li>- Must have upper EGD to evaluate varices within 6 months prior to enrollment</li> </ul>		<p><b>NEW CHS-388-202 (TBD/Jia)</b> A Randomized Phase 2 Study of Casdozokitug in Combination With Toripalimab Plus Bevacizumab in Participants With Unresectable and/or Locally Advanced or Metastatic Hepatocellular Carcinoma</p> <p><u>Brief eligibility/info:</u></p> <p><b>CLOSED TO ENROLLMENT CO44668 / IMBrave 152 (Schiess/Soma)</b> A Phase III, randomized, double-blind, placebo-controlled study evaluating atezolizumab and bevacizumab, with or without tiragolumab, in patients with untreated locally advanced or metastatic hepatocellular carcinoma.</p>	<p><b>CLOSED TO ENROLLMENT M24-147 / TGF Abbvie HCC (Poe/Somasundaram)</b> A Phase 2, Randomized Study to Evaluate the Optimized Dose, Safety, and Efficacy of Livmoniplimab in Combination with Budigalimab for Locally Advanced or Metastatic Hepatocellular Carcinoma (HCC) Patients who Have Progressed After an Immune Checkpoint Inhibitor Containing Regimen in First-Line HCC-LIVIGNO-1</p>

	Neoadjuvant	Adjuvant	Metastatic (First Line)	Metastatic, Advanced, Relapsed/Refractory (Second or Third Line)
	- No persistent grade 2 toxicities from prior therapies			
Gastric/GEJ			<p><b><u>A022102</u></b>  <b><u>(Poe/Somasundaram)</u></b>            NCI-A022102-CIRB  <i>Randomized Phase III Trial of MFOLFIRINOX +/- NIVOLUMAB VS. FOLFOX +/- NIVOLUMAB for First-Line Treatment of Metastatic HER2-Negative Gastroesophageal Adenocarcinoma</i>  <u>Brief eligibility/info:</u></p> <ul style="list-style-type: none"> <li>- Histologic documentation: HER2 negative adenocarcinoma with known PD-L1 CPS, unresectable, esophagus, GEJ or stomach</li> <li>- No prior TX for unresectable or metastatic disease</li> <li>- No baseline grade &gt;=2 peripheral neuropathy, neurosensory toxicity, or neuromotor toxicity per CTCAE v5.0</li> <li>- No untreated, symptomatic brain metastasis</li> </ul>	
Neuroendocrine				
Phase I				<p><b><u>849-001</u></b>  <b><u>(Caldwell/Weis)</u></b>  <b>[Run out of Phase I pod]</b>            A Phase 1/2 Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation  <u>Brief eligibility/info:</u></p> <ul style="list-style-type: none"> <li>- Phase 2 Cohorts C, F, and G, adenocarcinoma of the colon or rectum</li> <li>- Pancreatic and CRC with KRAS G12C mutations</li> </ul> <p><b>TAPUR (Cole/Patel)</b>  <b>[Run out of Phase I pod]</b>            Testing the Use of Food and Drug Administration (FDA) Approved Drugs That Target a Specific Abnormality in a</p>

	Neoadjuvant	Adjuvant	Metastatic (First Line)	Metastatic, Advanced, Relapsed/Refractory (Second or Third Line)
				<p>Tumor Gene in People with Advanced Stage Cancer (TAPUR)</p> <p><i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- All advanced solid tumors</li> </ul> <p><b>Link to available cohorts:</b> <a href="https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/research-data/documents/Public-facing_Cohort_Report.pdf">https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/research-data/documents/Public-facing_Cohort_Report.pdf</a></p> <p><b>OPENING SOON</b></p> <p><b><u>NX-1607-101 (Caloggero/Weiss)</u></b></p> <p><b>[Run out of Phase I pod]</b></p> <p>A Phase 1a, Dose Escalation, Safety and Tolerability Study of NX-1607, a Casitas B-lineage lymphoma proto-oncogene (CBL-B) inhibitor, in Adults with Advanced Malignancies, with Phase 1b Expansion in Select Tumor Types</p> <p><i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Gastric cancer, MSS CRC</li> </ul>
Translational	<p><b>EA2185</b> <b>(Yeh/Maddy Ledenyi)</b></p> <p>Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs</p> <p><b>LCCC 2309 (Merker/Maddy Ledenyi)</b></p> <p>Molecular biomarker development registry</p>	<p><b>LCCC 2234</b> <b>(Yeh/Maddy Ledenyi)</b></p> <p>PRomoting CLinical TrIal EngageMent for Pancreatic Cancer App Study (PROCLAIM Study)</p>	<p><b>OPENING SOON</b></p> <p><b>LCCC 2218</b> <b>(Yeh/Maddy Ledenyi)</b></p> <p>Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs</p>	<p><b>IN DEVELOPMENT</b></p> <p><b>LCCC 2409</b> <b>(Yeh/Maddy Ledenyi)</b></p> <p>SURGIMEDIA: Utilization of Multimedia for Enhanced Surgical Consent</p>
Other				<p><b>TRANSITIONED TO MELANOMA POD AUG 2024</b></p> <p><b><u>LCCC1736 / Ulix/Palbo in PDAC + Melanoma (Flores/Moschos)</u></b></p> <p>A Phase I Trial of Ulixertinib (BVD-523) in Combination with Palbociclib in Patients with Advanced Solid Tumors with Expansion Cohort in Previously Treated Metastatic Pancreatic Cancer and Metastatic RAS-mutant Melanoma</p> <p><i>Brief eligibility/info:</i></p> <ul style="list-style-type: none"> <li>- Histologically confirmed unresectable stage III or stage IV melanoma with the following additional eligibility requirements:</li> </ul>

	Neoadjuvant	Adjuvant	Metastatic (First Line)	Metastatic, Advanced, Relapsed/Refractory (Second or Third Line)
				<ul style="list-style-type: none"> <li>- <i>Molecular profiling documenting any of the following genetic aberrations: NRASG12/G13/Q61, KRASG12/G13, HRASG12/G13, any amplifications of the NRAS, KRAS, or HRAS genes</i></li> <li>- <i>Documented disease refractory to at least one PD1/PD-L1 inhibitor</i></li> <li>- <i>Previously received treatment with ipilimumab</i></li> </ul>
Contacts				<b>Research Contacts (Coordinator/Email/Phone/Pager)</b>
				<p style="text-align: center;"><b>GI Pod:</b></p> <p style="text-align: center;">Catherine Griffin (Lead) –  <a href="mailto:catherine_griffin@med.unc.edu">catherine_griffin@med.unc.edu</a>, 984-974-8771, 216-2573, 919-423-2570</p> <p style="text-align: center;">Maggie Schiessl – <a href="mailto:maggie_schiessl@med.unc.edu">maggie_schiessl@med.unc.edu</a>,  919- 445-6312, 920-573-3217</p> <p style="text-align: center;">Alaina Poe – <a href="mailto:Alaina_poe@med.unc.edu">Alaina_poe@med.unc.edu</a>, 919- 962-5117, 919-393-0104, 336-214-4026</p> <p style="text-align: center;">PACER: Claire Kowalczyk  <a href="mailto:Claire_kowalczyk@med.unc.edu">Claire_kowalczyk@med.unc.edu</a></p> <p style="text-align: center;">TSHS:  Maddy Ledenyi - <a href="mailto:Madeleine_Ledenyi@med.unc.edu">Madeleine_Ledenyi@med.unc.edu</a></p>

Updated 1/2/2025 CAG.