

## Nebraska Cancer Specialists Research Trials

ADVANCED MALIGNANCY						
Advanced solid tumor malignancy; documentation of an <b>FGFR1-3 gene mutation</b> or translocation; progression after atleast 1 prior therapy and no therapy that is likely to provide clinical benefit	Pemigatinib	19079	(INCB 54828-207) A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib in Participants With Previously Treated Locally Advanced/Metastatic or Surgically Unresectable Solid Tumor Malignancies Harboring Activating FGFR Mutations or Translocations (FIGHT-207)	Available*	Legacy Methodist Papillion	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03822117?term=NCT03822117&amp;draw=1&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03822117?term=NCT03822117&amp;draw=1&amp;rank=1</a>
Cohort D: Other tumor types excluding NSCLC and CRC with <b>KRAS G12C</b> mutation Cohort E: NSCLC with <b>KRAS G12C</b> and <b>STK11</b> mutations)	MRTX849 600 mg	19151	A Phase I/II multiple expansion cohort trial of MRTX849 in patients with advanced solid tumors with KRAS G12C mutation	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03785249">https://clinicaltrials.gov/ct2/show/NCT03785249</a>
Patient has a MAPK pathway altered solid tumor including but not limited to KRAS,NRAS,HRAS,BRAF, MEK and ERK mutations. Patient has exhausted or has inadequate response to available anti-cancer treatments	Ulixertinib (BVD-523)	ULI-EAP-100	Expanded Access to Ulixertinib(BVD-523) in patients with advanced MAPK pathway altered malignancies	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04566393?term=ULI-EAP-100&amp;draw=1&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04566393?term=ULI-EAP-100&amp;draw=1&amp;rank=1</a>
Dose expansion tumor types include squamous cell carcinoma of the head and neck, NSCLC, breast cancer, ovarian, NSLC high PDL1, CRC Locally advanced (unresectable) or metastatic disease (no limit to prior therapies) Measurable disease per RECIST 1.1	ASP 1948+ Pembrolizumab Q3W	1948-CL-0101	A Phase Ib Study of ASP1948, Targeting an Immune Modulatory Receptor, as a Single Agent and in combination with a PD-1 inhibitor (Nivolumab or Pembrolizumab) in Subjects with Advanced Solid Tumors	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1</a>
locally advanced, metastatic solid tumor and has measurable disease per RECIST1.1. Patient has exhausted standard options; ECOG 0-2	ASP1570	1570-CL-0101	A Phase I study of ASP1570 in participants with advanced solid tumors	pending	Legacy Methodist Bergan	not yet available
Patients diagnosed with advanced/metastatic solid tumors for whom no approved therapy with clinical benefit is available. Tumor types include NSCLC, SCCHN, non-MSI high CRC, checkpoint inhibitor naïve (CPI) RCC, cervical, soft tissue sarcoma, CSP mCRPC, cutaneous melanoma	MGD019	CP-MGD019-01	A Phase 1, First-in-Human, Open-Label, Dose Escalation and Cohort Expansion Study of MGD019, a Bispecific DART® Protein Binding PD-1 and CTLA-4 in Patients with Unresectable or Metastatic Neoplasms	pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03761017?term=cp-mgd019-01&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03761017?term=cp-mgd019-01&amp;draw=2&amp;rank=1</a>
Diagnosis during expansion (Part 2) - All patients in Groups 1, 2, 5 and 6 must have oncogenic <b>RET</b> -rearrangement/fusion or mutation (excluding synonymous and nonsense mutations) solid tumor, as determined by local testing of tumor or circulating tumor nucleic acid in blood	BLU-667	18164	A Phase 1 Study of the Highly-selective RET Inhibitor, BLU-667, in Patients with Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC) and Other Advanced Solid Tumors (BLU-667-1101)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03037385?term=03037385&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03037385?term=03037385&amp;rank=1</a>
Histologically or cytologically confirmed diagnosis of locally-advanced unresectable or metastatic solid tumor, including primary brain tumors Participants with disease types other than breast cancer, biliary tract cancer, non-squamous NSCLC, and cervical cancer: Disease progression on or after the most recent systemic therapy for locally-advanced unresectable or metastatic disease	Tucatinib+Trastuzumab	20344	A Phase 2 Basket Study of Tucatinib in Combination with Trastuzumab in Subjects with Previously Treated, Locally-Advanced Unresectable or Metastatic Solid Tumors Driven by HER2 Alterations (SGNTUC-019)	Open	Legacy Methodist	<a href="https://clinicaltrials.gov/ct2/show/NCT04579380?term=NCT04579380&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04579380?term=NCT04579380&amp;draw=2&amp;rank=1</a>
Locally-advanced or metastatic solid tumor with an <b>NRG1 gene fusion</b> identified through molecular assays Availability of fresh or archived FFPE tumor sample to be submitted to a central laboratory for confirmation of NRG1 gene fusion status	Seribantumab	20245	CRESTONE: A Phase 2 Study of Seribantumab in Adult Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors (ELVCP-001-01)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04383210?term=NCT04383210&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04383210?term=NCT04383210&amp;draw=2&amp;rank=1</a>
patients with NSCLC, melanoma, PD-L1 basket of HNSCC, Gastric, GEJ, RCC, UC who have exhausted options. Refractory to PD-1 or anti PD-L1 and anti CTLA-4. Antibiotics within 4 weeks of starting study medication is excluded	INBRX-105 or INBRX-105+Pembrolizumab	INBRX-105	An Open Label, First in human (FIH), dose escalation, phase I study of INBRX-105 and INBRX-105 in combination with pembrolizumab in patients with locally advanced or metastatic solid tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03809624?term=INBRX-105&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03809624?term=INBRX-105&amp;draw=2&amp;rank=1</a>

## Nebraska Cancer Specialists Research Trials

Metastatic locally advanced solid tumors Exhausted all standard options. Thrombotic events within the last 6 months excludes patients. Willingness to do pre-treatment and on treatment biopsies * Only ENROLLING OVARIAN*	CDX527-01	CDX527-01	A Phase I study of PD-L1 xCD27 Bispecific antibody CDX527 in patients with advanced malignancies	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04440943?term=cdx527&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04440943?term=cdx527&amp;draw=2&amp;rank=1</a>
advanced solid tumor malignancy that has progressed or intolerant to all available therapies; ECOG 0 to 1	NGM707-IO-101	NGM707	A Phase 1/2 Dose Escalation/Expansion Study of NGM707 as Monotherapy and in Combination with Pembrolizumab in Advanced or Metastatic Solid Tumor Malignancies	pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04913337?term=ngm707&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04913337?term=ngm707&amp;draw=2&amp;rank=1</a>
Measurable disease per RECIST; Small Cell Lung Cancer, Gastric or GEJ, Squamous Cell of the genitalia, pancreatic, endometrial dx; neuropathy grade 2 or higher excluded.	PEN-866	PEN-866-01	A Phase I/IIA, open label, multicenter study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and anti tumor activity of PEN-866 in patients with advanced solid malignancies	pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03221400?term=pen-866&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03221400?term=pen-866&amp;draw=2&amp;rank=1</a>
NSCLC with atleast one prior line of therapy, including platinum chemo and check point inhibitor given together or separate; Patients with ALK, EGFR, ROS1,BRAF, NTRK must have received therapy directed at molecular aberration in order to enroll NSCLC or breast origin with brain mets; breast cancer patients must have had prior CDK4/6 inhibitor Glioblasoma (first recurrence) and candidate for surgical resection	GLR2007	GLP-CDK-1009	An Open Label, Phase IB/II Study to establish the safety, tolerability, and optimal dosing strategy for GLP2007 in subjects with advanced solid tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04444427?term=GLP-CDK&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04444427?term=GLP-CDK&amp;draw=2&amp;rank=1</a>
<b>BREAST</b>						
<b>Patient Population</b>	<b>Treatment Design</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>(Neo)Adjuvant</b>						
T1c-T2 (tumor size > or = 2 cm), clinical node stage (cN) 1-cN2, or T3-T4, cN0-cN2; ER+/HER2- grade 2 or 3 with Ki67 of at least 30% breast cancer of ductal histology; female or male	Neoadjuvant: Pembro or placebo + paclitaxel (4 cycles) followed by pembro or placebo+ doxorubicin or epirubicin+ Cyclophosphamide (4 cycles) Adjuvant: pembro or placebo + ET	MK3475-756	A Randomized, Double-blind, phase III study of Pembrolizumab versus Placebo in combination with neoadjuvant chemotherapy and adjuvant endocrine therapy for the treatment of high risk early stage estrogen receptor positive, HER2 negative breast cancer	Open	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03725059?term=mk3475-756&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03725059?term=mk3475-756&amp;rank=1</a>
<b>Adjuvant</b>						
HR+, HER2+ in initial diagnostic tissue, early invasive breast cancer without evidence of disease recurrence or distant metastases; received a minimum of four cycles of chemotherapy in either the neoadjuvant or adjuvant setting per standard of care therapy; Have high risk disease, defined by one of the following: •For participants treated with neoadjuvant therapy (as defined above): Pathologically detected axillary nodal disease in the surgical specimen •For participants not treated with neoadjuvant therapy: Axillary node positive disease meeting one of the following criteria: Pathological tumor involvement in > four ipsilateral axillary lymph nodes OR Pathological tumor involvement in one to three ipsilateral axillary lymph node(s) and at least 1 of the following criteria: Histological Grade 2 or Grade 3 Primary invasive tumor size >5 centimeters determined pathologically	Abemaciclib +ET vs placebo+ ET	20364	eMonarchER: A Randomized, Double Blind, Placebo-Controlled Phase 3 Study of Abemaciclib plus Standard Adjuvant Endocrine Therapy in Participants with High-Risk, Node-Positive, HR+, HER2+ Early Breast Cancer Who Have Completed Adjuvant HER2 Targeted Therapy (I3Y-MC-JPCW)	Open	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04752332?term=NCT04752332&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04752332?term=NCT04752332&amp;draw=2&amp;rank=1</a>

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2021

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Stage I-III EBC; patients with multicentric or multifocal bc are eligible if all examined tumors meet pathogenic criteria for ER+ and HER2 negativity. History of DCIS or LCIS is excluded and any other malignancy within 5 years prior to screening.	GDC-9545 or physician's choice endocrine therapy	20408	A Phase III, randomized, open-label multicenter study evaluating the efficacy and safety of adjuvant GDC-9545 compared with physician's choice of adjuvant endocrine therapy in patients with HR+, HER2- early breast cancer	Pending	Legacy Methodist Papillion	<a href="#">not yet available</a>
<b>1st line Metastatic</b>						
Unresectable or metastatic TNBC. Treatment naïve. Must have at least 1 lesion that can be measured.	Arm 1: durvalumab + paclitaxel Arm 2: durvalumab + paclitaxel + capivasertib Arm 5: durvalumab + paclitaxel + oleclumab Arm 6: durvalumab + trastuzumab deruxtecan	20417	A Phase IB/II, 2-Stage, Open-label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab (MEDI4736) + Paclitaxel and Durvalumab (MEDI4736) in Combination With Novel Oncology Therapies With or Without Paclitaxel for First-line Metastatic Triple Negative Breast Cancer (D933LC00001)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03742102?term=NCT03742102&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03742102?term=NCT03742102&amp;draw=2&amp;rank=1</a>
<b>2nd line Metastatic</b>						
HER2+, received prior treatment with a taxane and trastuzumab and had progression after the last systemic therapy or be intolerant of last systemic therapy.	tucatinib or placebo + ado-trastuzumab emtansine	SGNTUC-016	Randomized, double-blind, phase III trial of tucatinib or placebo in combination with ado-trastuzumab emtansine (T-DM1) for subjects with unresectable locally advanced or metastatic HER2+ breast cancer	Open	Legacy Methodist Bergan	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04444427?term=SGNTUC-016&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04444427?term=SGNTUC-016&amp;rank=1</a>
Histologically or cytologically confirmed breast cancer at primary site. Participants with inoperable brain metastases (prior radiation therapy and/or stereotactic radiosurgery is allowed). A neurosurgical consult is at the discretion of the investigator. Participants with brain metastases from breast cancer who have previously received CDK4/6 inhibitors	GLR 2007 (CDK4/6 inhibitor)	GLP-CDK-1009	An Open-Label, Multi-center, phase Ib/II Study to establish safety, tolerability, and optimal dosing strategy of GLR2007 in subjects with advanced solid tumors	Open	Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04444427?term=GLP-CDK-1009&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04444427?term=GLP-CDK-1009&amp;draw=2&amp;rank=1</a>
HR+/HER2- breast cancer not previously treated with cytotoxic chemotherapy in the noncurative setting. Has progressed on two or more lines of endocrine therapy with at least one given in combination with a CDK 4/6 inhibitor.	Pembrolizumab or placebo + SOC chemotherapy	MK3475-B49	A Randomized, Double-blind, placebo controlled, phase III study of Pembrolizumab plus Chemotherapy versus placebo plus chemotherapy for the treatment of chemotherapy candidate hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+/HER2-) Metastatic breast cancer (KEYNOTE B-49)	Open	Legacy Methodist Bergan Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04895358?term=mk3475-b49&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04895358?term=mk3475-b49&amp;draw=2&amp;rank=1</a>
HR+, HER2- with prior endocrine therapy with CDK 4/6 inhibitor unless endocrine therapy is not indicated. Patients may have had prior therapy with one chemotherapy regimen in the metastatic setting however patient must be taxane naïve in the metastatic setting.	Paclitaxel (oral) + Encequidar (oral)	19150	A Phase IV multicenter, single arm study to assess the efficacy, safety, and tolerability of oral Paclitaxel and Encequidar in HR+/HER2- locally advanced or metastatic breast cancer patients who progressed on or after prior endocrine treatment with CDK 4/6 inhibitors in first or second line of therapy	Pending	Legacy Methodist Papillion	<a href="#">not yet available</a>
Cohort 1: HR+/HER2- breast cancer; or- Advanced and received at least 1 prior cytotoxic regimen Cohort 2: TNBC;- advanced disease; progressed after at least 1 prior cytotoxic regimen	Enfortumab Vedotin days 1, 8, 15	7465-CL-202	An Open-label, Multicenter, Multicohort, Phase 2 Study to Evaluate Enfortumab Vedotin in Subjects with Previously Treated Locally Advanced or Metastatic Malignant Solid Tumors (EV-202)	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT04225117?term=7465-cl-202&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04225117?term=7465-cl-202&amp;draw=2&amp;rank=1</a>

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HR+, HER2- advanced or metastatic breast cancer. Must have received at least 2 but no more than 4 prior lines of therapy (not including single agent hormonal therapy). One line must include CDK 4/6 inhibitor. Patient must have received 0 to 2 prior cytotoxic chemotherapy in the locally advanced or metastatic setting. Measurable disease per RECIST 1.1. ECOG 0 or 1	Arm A: CX-2009 monotherapy in HR+ HER2-	CTMX-2009-002	A Phase II, Open-Label study to evaluate the safety and anti tumor activity of CX-2009 in advanced HR+ HER2- breast cancer and of CX-2009 as monotherapy and in combination with CX-072 in advanced triple negative breast cancer	Open	Legacy Bergan Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04596150?term=CTMX-2009-002&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04596150?term=CTMX-2009-002&amp;draw=2&amp;rank=1</a>
TNBC patient must have received 1-3 prior lines of therapy (arm B and C). Measurable disease per RECIST 1.1. Patients in arm C must be PD-L1 positive. ECOG 0 or 1	Arm B: CX-2009 monotherapy TNBC Arm C: CX-2009 and CX-072 in TNBC	CTMX-2009-002	A Phase II, Open-Label study to evaluate the safety and anti tumor activity of CX-2009 in advanced HR+ HER2- breast cancer and of CX-2009 as monotherapy and in combination with CX-072 in advanced triple negative breast cancer	Open	Legacy Bergan Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04596150?term=CTMX-2009-002&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04596150?term=CTMX-2009-002&amp;draw=2&amp;rank=1</a>
<b>3rd line Metastatic</b>						
<b>HER2+</b>						
HER2+ progression of unresectable locally advanced or metastatic breast cancer after last systemic therapy or intolerant of last therapy. Received 2 or more prior lines of anti-HER2 based regimens in the metastatic setting. Measurable disease per RECIST 1.1	Tucatinib+Trastuzumab Deruxtecan	SGNTUC-025	A Single-Arm, Open Label, Phase II study of Tucatinib in combination with Trastuzumab Deruxtecan in subjects with previously unresectable locally advanced or metastatic HER2+ breast cancer	Open	Legacy Bergan Methodist	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04539938?term=sgntuc-025&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04539938?term=sgntuc-025&amp;draw=2&amp;rank=1</a>
HER2+ locally advanced/unresectable or metastatic disease. Have received a minimum of 4-8 cycles of previous treatment of trastuzumab, pertuzumab, and a taxane as first line treatment for HER2+ advanced breast cancer w/o evidence of disease progression	Tucatinib or placebo+trastuzumab+pertuzumab	SGNTUC-028	A randomized, double-blind, phase 3 study of tucatinib or placebo in combination with trastuzumab and pertuzumab as maintenance therapy for metastatic HER2+ breast cancer (HER2CLIMB-05)	pending	Legacy Bergan Methodist Papillion Grand Island	<a href="#">pending</a>
HER2+, measurable disease, less than or equal to 5 prior chemotherapy regimens for metastatic breast cancer; no limit on prior endocrine therapies.	Ibrutinib+ Trastuzumab	14059	A Phase I/II trial of Ibrutinib plus trastuzumab in HER2- amplified Metastatic Breast Cancer	Available*	Legacy Methodist Papillion	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03379428?term=03379428&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03379428?term=03379428&amp;draw=2&amp;rank=1</a>
Dose expansion tumor types include breast cancer Locally advanced (unresectable) or metastatic disease (no limit to prior therapies) Measurable disease per RECIST 1.1	ASP 1948+ Pembrolizumab Q3W	1948-CL-0101	A Phase Ib Study of ASP1948, Targeting an Immune Modulatory Receptor, as a Single Agent and in combination with a PD-I inhibitor (Nivolumab or Pembrolizumab) in Subjects with Advanced Solid Tumors	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1</a>
MBC previously treated with T-DM-1 and or T-DX-d and or tucatinib containing regimens. Subjects must have been treated with one or more of these regimens to be eligible. Subjects must have been treated with trastuzumab plus taxane. Measurable disease per RECIST 1.1	ARX-788	ACE-Breast-03	A Global, Phase 2 Study of ARX788 in HER2-positive Metastatic Breast Cancer Patients Whose Disease is Resistant or Refractory to T-DM1, and/or T-DXd, and/or Tucatinib-containing Regimens	Open	Legacy Bergan Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04829604?term=ace-breast-03&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04829604?term=ace-breast-03&amp;draw=2&amp;rank=1</a>
<b>NEUROLOGICAL</b>						
<b>Patient Population</b>	<b>Treatment Design</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>Recurrent Glioblastoma (GBM)</b>						

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<p>Histologically confirmed diagnosis of a recurrent primary IV malignant glioblastoma. Participants with prior low-grade glioma or anaplastic glioma are eligible if histologic assessment demonstrates transformation to GBM. First recurrence of GBM.</p> <p>At least 12 weeks from prior radiotherapy unless there is either histopathologic confirmation of recurrent tumor or new enhancement on MRI outside of the treatment field.</p>	GLR (CDK4/6 inhibitor)	GLP-CDK-1009	An Open-Label, Multi-center, phase Ib/II Study to establish safety, tolerability, and optimal dosing strategy of GLR2007 in subjects with advanced solid tumors	Open	Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04444427?term=GLP-CDK-1009&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04444427?term=GLP-CDK-1009&amp;draw=2&amp;rank=1</a>
<b>Recurrent</b>						
<b>GASTROINTESTINAL</b>						
<b>Adjuvant</b>						
<p>Surgically resected adenocarcinoma of the colon or rectum; Pathologic stage II or III disease; Has residual FFPE specimen available for submission to Natera; Prior history and treatment for any cancer within the past year or has another active cancer, with the exception of non-melanoma skin cancer is exclusionary</p>	Signatara Test	20-041-NCP (BESPOKE)	BESPOKE Study of ctDNA Guided Therapy in Colorectal Cancer	Open	Legacy Methodist Bergan Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04264702?term=BESPOKE+Study+of+ctDNA+Guided+Therapy+in+Colorectal+Cancer&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04264702?term=BESPOKE+Study+of+ctDNA+Guided+Therapy+in+Colorectal+Cancer&amp;draw=2&amp;rank=1</a>
<b>Ist line metastatic</b>						
<p>Presence of metastasized or locally advanced, inoperable (curative intent) histologically proven, well differentiated Grade 2 or Grade 3 (GEP-NET) tumor diagnosed within 6 months prior to screening. Expression of somatostatin receptors on all documented target lesions documented by CT/MRI scans within 3 months prior to randomization</p>	Lutathera	CAA601A22301	A Phase III multi-center, randomized, open-label study to evaluate the efficacy and safety of Lutathera in patients with Grade II and Grade III advanced GEP-NET	Open	Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03972488?term=CAA601A22301&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03972488?term=CAA601A22301&amp;draw=2&amp;rank=1</a>
<p>IV CRC; BRAFV600 E mutant local and must be sent to central lab for confirmation.</p>	Encorafenib+ Cetuximab with or without chemotherapy vs SOC	C4221015	An Open Label, multicenter, randomized, phase III study of first line Encorafenib+Cetuximab with or without chemotherapy versus standard of care with a safety lead in of Encorafenib and Cetuximab plus chemotherapy in participants with metastatic BRAF V600E mutant colorectal cancer	pending	Legacy Methodist Bergan Grand Island	<a href="https://clinicaltrials.gov/ct2/show/NCT04607421?term=C4221015&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04607421?term=C4221015&amp;draw=2&amp;rank=1</a>
<p>Histologically or cytologically confirmed diagnosis of advanced unresectable or metastatic adenocarcinoma of the stomach or gastroesophageal junction with HER2-negative disease. No prior chemotherapy within 6 months of study enrollment.</p>	TTX-030 + mFOLFOX6 or TTX-030+ ABBV-181+ mFOLFOX6	TTX-030-002	A Phase I/IB Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04306900?term=ttx-030-002&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04306900?term=ttx-030-002&amp;draw=2&amp;rank=1</a>
<p>recurrent/metastatic cholangiocarcinoma (non-resectable). Participants with gallbladder or ampulla of Vater carcinoma are not eligible. Documented <b>FGFR-2 gene fusion/translocation</b>. ECOG 0 or 1. No prior systemic anticancer therapy for recurrent or metastatic cholangiocarcinoma</p>	BGI398 or Gemcitabine+Cisplatin	18264	A Phase 3 Multicenter, Open-Label, Randomized, Controlled Study of Oral Infigratinib versus Gemcitabine with Cisplatin in Subjects with Advanced/Metastatic or Inoperable Cholangiocarcinoma with FGFR2 Gene Fusions/Translocations: The PROOF Trial (QBGJ398-301)	Available*	Legacy Methodist Papillion	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03773302?term=03773302&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03773302?term=03773302&amp;rank=1</a>

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## Nebraska Cancer Specialists Research Trials

histologically/cytologically verified, inoperable locally recurrent/metastatic SCAC; no prior systemic therapy except chemotherapy with radiotherapy, or prior neoadjuvant/adjuvant therapy if completed $\geq$ 6 months; measurable disease per RECIST v1.1: adequate tissue sample and whole blood sample with central testing result	carboplatin+paclitaxel+placebo vs carboplatin+paclitaxel+retifanlimab	20189	A Phase 3 Global, Multicenter, Double-Blind Randomized Study of Carboplatin-Paclitaxel With INCMGA00012 or Placebo in Participants With Inoperable Locally Recurrent or Metastatic Squamous Cell Carcinoma of the Anal Canal Not Previously Treated With Systemic Chemotherapy (PODIUM-303/InterAACT 2) (INCMGA 0012-303)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04472429?term=NCT04472429&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04472429?term=NCT04472429&amp;draw=2&amp;rank=1</a>
Arm 4: locally advanced, unresectable, or metastatic pancreatic adenocarcinoma. Naive to treatment for metastatic disease and eligible to receive Gemcitabine and Abraxane	Arm 4 TTX-030 + Gem/Abraxane	TTX-030-001	A Phase I/IB Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03884556?term=ttx-030-001&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03884556?term=ttx-030-001&amp;draw=2&amp;rank=1</a>
<b>2nd line and beyond</b>						
Advanced or metastatic colon or rectum adenocarcinoma. Refractory, resistant, or intolerant to at least 2 prior lines of therapy that must include Fluoropyrimidine, Irinotecan, Platinum agents, anti VEGF, anti EGFR (if indicated); measurable disease per RECIST 1.1	US1402	U31402-A-U202	A Multicenter, Open Label, Phase II study to evaluate the safety and efficacy of U3-1402 in subjects with advanced or metastatic colorectal cancer	Hold	Legacy Papillion Bergan Methodist	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04479436?term=u31402&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04479436?term=u31402&amp;draw=2&amp;rank=1</a>
Confirmed metastatic pancreatic cancer and have received at least 2 prior lines for mPDAC, but no more than 4 prior lines of cytotoxic or myelosuppressive therapy for mPDAC. Must have received at least 1 prior gemcitabine based therapy and 1 prior fluoropyrimidine based therapy.	Relacorilant+ Nab-Paclitaxel	CORT125134-553	A Phase II Study of Relacorilant in Combination with Nab-Paclitaxel in Patients with Metastatic Pancreatic Ductal Adenocarcinoma	Hold	Legacy Bergan Methodist	<a href="https://clinicaltrials.gov/ct2/show/NCT04329949?term=relacorilant+abraxane&amp;recrs=a&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04329949?term=relacorilant+abraxane&amp;recrs=a&amp;draw=2&amp;rank=1</a>
Dx adenocarcinoma of the colon or rectum. RAS must have been previously determined based on local assessment. Has received a maximum of two prior chemotherapy regimens for the treatment of advanced colorectal cancer. ECOG 0 to 1	Avastin+Lonsurf	CL3-95005-007	An open-label, randomised, phase III study comparing trifluridine/tipiracil in combination with bevacizumab to trifluridine/tipiracil monotherapy in patients with refractory metastatic colorectal cancer (SUNLIGHT study)	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT04737187?term=cl3-95005-007&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04737187?term=cl3-95005-007&amp;draw=2&amp;rank=1</a>
Cohort 6: Gastric or GEJ or esophageal cancer- advanced cancer and progression after platinum based therapy. If HER2+ must be treated with HER2 directed therapy	Enfortumab Vedotin days 1, 8, 15	7465-CL-202	An Open-label, Multicenter, Multicohort, Phase 2 Study to Evaluate Enfortumab Vedotin in Subjects with Previously Treated Locally Advanced or Metastatic Malignant Solid Tumors (EV-202)	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT04225117?term=7465-cl-202&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04225117?term=7465-cl-202&amp;draw=2&amp;rank=1</a>
adenocarcinoma of the colon or rectum that is unresectable or metastatic and have failed therapy containing fluoropyrimidines, oxaliplatin, irinotecan, and anti-VEGR and anti-PD -1 if tumor MSI-H. Has RAS WT in primary tumor tissue	Tucatinib+Trastuzumab or Tucantib monotherapy	20216	MOUNTAINEER: A Phase 2, Open Label Study of Tucatinib Combined with Trastuzumab in Patients with HER2+ Metastatic Colorectal Cancer (ACCRU-GI-1617, SGNTUC-017)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03043313?term=NCT03043313&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03043313?term=NCT03043313&amp;draw=2&amp;rank=1</a>
Dose expansion tumor types include CRC Locally advanced (unresectable) or metastatic disease (no limit to prior therapies) Measurable disease per RECIST 1.1	ASP 1948+ Pembrolizumab Q3W	1948-CL-0101	A Phase Ib Study of ASP1948, Targeting an Immune Modulatory Receptor, as a Single Agent and in combination with a PD-1 inhibitor (Nivolumab or Pembrolizumab) in Subjects with Advanced Solid Tumors	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1</a>

## Nebraska Cancer Specialists Research Trials

G/GEA, with locally advanced, non resectable disease, which has progressed despite all standard therapies	INBRX-106	INBRX-106	An Open-Label, multicenter, First in Human, Dose Escalation, Phase 1 Study of INBRX-106 in Subjects with locally advanced or metastatic solid tumors	Pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1</a>
<b>GENITOURINARY</b>						
<b>UROTHELIAL</b>						
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>(Neo)Adjuvant</b>						
Participants with MIBC, clinical stage T2-T4a, N0 (<10 mm on CT or MRI), M0, diagnosed at TURBT and confirmed by radiographic imaging. Variant histology is acceptable if there is a predominant urothelial component. Participant must be deemed eligible for Radical Cystectomy (RC) by his/her oncologist and/or urologist, and must agree to undergo Radical Cystectomy (RC) after completion of neoadjuvant therapy. Eastern Cooperative Oncology Group (ECOG) Performance Status 0 or 1	Neoadjuvant Arm A: GC Q3W x 4 Cycles Neoadjuvant Arm B or C: GC Q3W x4 cycles, Nivolumab 360mg Q3W x 4 Cycles, BMS-986205/Placebo 100mg QD Adjuvant Post-Surgical Treatment Arm A; No further study therapy Arm B or C: Nivolumab 480 mg Q4W + BMS 986205/placebo 100mg x 9 Cycles	18095	A Phase 3, Randomized, Open-Label Study of Neoadjuvant Chemotherapy alone versus Neoadjuvant Chemotherapy plus Nivolumab or Nivolumab and BMS-986205, Followed by Continued Post-Surgery Therapy with Nivolumab or Nivolumab and BMS-986205 in Participants with Muscle-Invasive Bladder Cancer (CA017078)	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03661320?term=NCT03661320&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03661320?term=NCT03661320&amp;rank=1</a>
Histologically confirmed muscle invasive bladder cancer at clinical stage cT2-T4a. Medically fit (i.e. eligible for surgery) and scheduled for radical cystectomy. ECOG performance status of 0, 1, or 2. Participants with ECOG performance status of 2 must meet the following additional criteria: hemoglobin >10 g/dL, GFR >50 mL/min, may not have NYHA Class III heart failure. Cohort H and J: Ineligible for cisplatin-based chemotherapy and no prior systemic treatment, chemoradiation, or radiation therapy for MIBC. May have received prior intravesical Bacillus Calmette-Guerin (BCG) or intravesical chemotherapy for non-muscle invasive bladder cancer. <b>Cohort J: Eligible for pembrolizumab- Cohort J not open yet)</b>	Cohort H: Enfortumab Vedotin Cohort J: Enfortumab Vedotin+ Pembrolizumab	20172	A Study of Enfortumab Vedotin (ASG-22CE) as monotherapy or in combination with other anticancer therapies for the treatment of urothelial cancer (SGN22E-002)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03288545?term=NCT03288545&amp;raw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03288545?term=NCT03288545&amp;raw=2&amp;rank=1</a>
<b>Adjuvant</b>						
Histologically or cytologically confirmed, invasive urothelial carcinoma with susceptible FGFR2 alterations within 120 days following nephrourectomy, dista urethrectomy, or cystectomy. If the patient received neoadjuvant chemotherapy: pathologic stage at surgical resection must be $\geq$ yp T2 and/or yN+	Infgratinib or placebo	19094	QBGJ398-302: Phase 3, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infgratinib for the Adjuvant Treatment of Subjects with Invasive Urothelial Carcinoma with Susceptible FGFR3 Genetic Alterations (PROOF302)	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04197986?term=proof302&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04197986?term=proof302&amp;draw=2&amp;rank=1</a>
<b>1st line metastatic</b>						
Cohort K: Ineligible for cisplatin-based chemotherapy due to at least 1 of the following: Glomerular filtration rate (GFR) <60 mL/min and $\geq$ 30 mL/min, ECOG performance status of 2, NCI CTCAE Version 4.03 Grade $\geq$ 2 hearing loss, New York Heart Association (NYHA) Class III heart failure. No prior systemic treatment for locally advanced or metastatic disease. No adjuvant/neoadjuvant platinum-based therapy within 12 months prior to randomization	Enfortumab Vedotin days 1, 8 or Enfortumab Vedotin + Pembrolizumab	20172	A Study of Enfortumab Vedotin (ASG-22CE) as monotherapy or in combination with other anticancer therapies for the treatment of urothelial cancer (SGN22E-002)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03288545?term=NCT03288545&amp;raw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03288545?term=NCT03288545&amp;raw=2&amp;rank=1</a>
<b>2nd line Metastatic</b>						

## Nebraska Cancer Specialists Research Trials

Metastatic transitional cell carcinoma of the urothelium; progressive disease defined as any progression that requires a change in treatment	Arm 1A- Erdafitinib; Arm 1B- Vinflunine or Docetaxel; Arm 2A- Erdafitinib; Arm 2B Pembrolizumab	17133	A Phase III Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations	Available*	Legacy Methodist Papillion	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03390504?term=NCT03390504&amp;draw=1&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03390504?term=NCT03390504&amp;draw=1&amp;rank=1</a>
Cohort 2- Platinum ineligible previously treated with CPI Cohort 3 and 4- Previously treated with anti-PD (L)1 and another selected IO either platinum treated or platinum ineligible Cohort 6: platinum ineligible anti PD (L)-1 naïve Cohort 7 and 8: Previously treated with anti PD(L)-1 and ADC either platinum treated or ineligible	Sitavatnib+ Nivolumab	18033	A Phase II study of Sitavatnib in Combination with PD-(L)1 Checkpoint Inhibitor Regimens in Patients with Advanced or Metastatic Urothelial Carcinoma	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03606174?term=516-003&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03606174?term=516-003&amp;draw=2&amp;rank=1</a>
<b>PROSTATE</b>						
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>Metastatic (mHSPC)</b>						
Must have documented metastatic disease; biochemical recurrence of disease; prior radical prostatectomy or radiation therapy with curative intent. Prior ADT therapy within the last 6 months or other therapies targeting androgen pathway are excluded.	non treatment (diagnostic Cu64 PSMA I&T injection)	CURCu64PSM0001	A Multicenter, Open-Label, Randomized Phase I/II Study of Copper Cu64PSMA I &T injection in patients with histologically proven metastatic prostate cancer	pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04720157?term=psmaddition&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04720157?term=psmaddition&amp;draw=2&amp;rank=1</a>
Asymptomatic or mildly symptomatic, histologically-confirmed de novo metastatic hormone-sensitive prostate adenocarcinoma without small-cell tumors; A valid PTEN IHC result indicating PTEN deficiency (centralized testing)	Capivasertib+Abiraterone or placebo+ Abiraterone	20138	A Phase III Double-Blind, Randomised, Placebo-Controlled Study Assessing the Efficacy and Safety of Capivasertib + Abiraterone Versus Placebo + Abiraterone as Treatment for Patients with De Novo Metastatic Hormone-Sensitive Prostate Cancer(mHSPC)Characterised by PTEN deficiency (CAPITello-281) D361BC00001	Available*	TBD	<a href="https://clinicaltrials.gov/ct2/show/NCT04493853?term=NCT04493853&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04493853?term=NCT04493853&amp;draw=2&amp;rank=1</a>
<b>Metastatic (mHSPC)</b>						
Must have documented metastatic disease; evidence of PSMA positive disease as seen on Ga-PSMA PET; 45 days prior LHRH agonist/antagonists are allowed. 45 days prior ARDT is allowed prior	177Lu-PSMA-617 + ARDT vs ARDT	CAA617C12301	PSMAddition: An International Prospective Open-label, Randomized, Phase III Study comparing 177Lu-PSMA-617 in combination with Standard of Care, versus Standard of Care alone, in adult male patients with Metastatic Hormone Sensitive Prostate Cancer (mHSPC)	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04720157?term=psmaddition&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04720157?term=psmaddition&amp;draw=2&amp;rank=1</a>
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>2nd line Metastatic CRPC</b>						
metastatic disease; must have bone disease and or soft tissue disease by CT/MRI.	Pembrolizumab+ Enzalutamide or Placebo+ Enzalutamide	MK3475-641	A Phase III, Randomized, Double-blind trial of Pembrolizumab (MK3475) plus Enzalutamide versus placebo plus Enzalutamide in Participants with Metastatic Castration-Resistance Prostate Cancer (KEYNOTE-641)	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03834493?term=mk3475-641&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03834493?term=mk3475-641&amp;rank=1</a>
Must have DRD or CDK12 by sponsor blood or tissue assay. Measurable disease per RECIST 1.1. and received atleast 1 but no more than 2 lines of novel AR targeted therapy.	Niraparib+ Cetrelimab	19146	A Phase Ib/II Study of Niraparib combination therapies for the treatment of Metastatic Castration Resistant Prostate Cancer	Available*	Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03431350?term=NCT03431350&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03431350?term=NCT03431350&amp;draw=2&amp;rank=1</a>
mCRPC; must have received 1 prior second-generation anti-androgen therapy approved for CRPC and haven't received docetaxel in the mCRPC setting. Must be eligible to receive docetaxel	TTX-030 + ABBV-181+ Docetaxel	TTX-030-002	A Phase I/IB Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04306900?term=ttx-030-002&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04306900?term=ttx-030-002&amp;draw=2&amp;rank=1</a>
Adeno of the prostate w/o small cell features. Treatment with at least 1 line of taxane based chemotherapy in the castration sensitive prostate cancer or in CRPC. At least 1 line of novel AR hormonal therapy in the CSPC or CRPC setting for a minimum of 12 weeks	ODM-208	CYPIDES	Safety and Pharmacokinetics of ODM-208 in patients with metastatic castration resistant prostate cancer	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03436485?term=CYPIDES&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03436485?term=CYPIDES&amp;draw=2&amp;rank=1</a>

## Nebraska Cancer Specialists Research Trials

Expansion cohorts 21 CRPC prior enzalutamide or abiraterone no prior taxotere for mCRPC (single agent Cabozantinib) Expansion cohort 23 (mCRPC prior enzalutamide or abiraterone ; no prior docetaxel)	Cabozantinib monotherapy (cohort 21) Cabozantinib+ Atezolizumab (cohort; 23)	XL184-021	A Phase Ib Dose-Escalation Study of Cabozantinib (XL184) Administered Alone or in Combination with Atezolizumab in subjects with Locally advanced or Metastatic Solid Tumors	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT03170960?term=XL184-021&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03170960?term=XL184-021&amp;rank=1</a>
GA-PSMA-11 positive PET/CT scan and have had one prior approved ARDT and had documented progression. Prior cytotoxic chemotherapy for CRPC or castrate sensitive prostate cancer is exclusionary.	177Lu-PSMA-617 vs ARDT	CAA617B12302	PSMAfore: A Phase III, Open Label, Multi-Center, Randomized Study Comparing 177Lu-PSMA-617 vs. a Change of androgen receptor-directed therapy in the treatment of Taxane Naive Men with progressive metastatic castrate resistant prostate cancer	Open	Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04689828?term=CAA617B12302&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04689828?term=CAA617B12302&amp;draw=2&amp;rank=1</a>
GA-PSMA-11 positive PET/CT scan and must have been treated with a prior taxane but no more than two prior taxane regimens. Patients must have received at least 1 prior NAAD	177Lu-PSMA-617	CAA617A12001M	Managed Access Program (MAP) Cohort Treatment Plan CAA617A12001M to provide access to 177Lu-PSMA-617 for patients with metastatic castration-resistant prostate cancer	pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04825652?term=CAA617A12001M&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04825652?term=CAA617A12001M&amp;draw=2&amp;rank=1</a>
<b>3rd line Metastatic CRPC</b>						
MCRPC that has received ≥ 2 lines of approved systemic therapy for mCRPC including a second generation hormonal agent.	REGN5678+ Cemiplimab	R5678-ONC-1879	A Phase I/II study of REGN5678 (anti-PSAMAXCD28) with Cemiplimab in patients with metastatic castration resistant prostate cancer	pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03972657?term=R5678-ONC%3D1879&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03972657?term=R5678-ONC%3D1879&amp;rank=1</a>
mCRPC with two or more bone lesions; ECOG 0 to 1, prior chemotherapy in the mCRPC setting is exclusionary	Docetaxel vs Docetaxel+ Rad-223	c16-174	DORA Trial: Phase III Trial of Docetaxel vs Docetaxel and Radium-223 for Metastatic Castration-Resistant Prostate Cancer (mCRPC)	pending	Legacy	<a href="#">not yet available</a>
<b>RENAL CELL</b>						
<b>Advanced/ Metastatic 2nd-4th line</b>						
Failed up to 3 prior lines of therapy including anti-PD-L1 and TKI agents. Subjects with relapsed to anti PD-L1 containing regimen must have confirmed disease progression no earlier than 4 weeks after initial disease	TTX-030 or TTX-030 + Pembrolizumab	TTX-030-001	A Phase I/Ib Study of the Safety of TTX-030 as a single agent and in Combination with Pembrolizumab or Chemotherapy in Patients with Lymphoma or Solid Tumor Malignancies	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03884556?term=TTX-030-001&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03884556?term=TTX-030-001&amp;draw=2&amp;rank=1</a>
Locally advanced, metastatic RCC with clear cell component; measurable disease per RECIST 1.1; progression on or after receiving first line systemic treatment with prior PD-1+ TKI combination	MK6482	MK6482-013	A Phase II Study of MK-6482 in participants with advanced Renal Cell Carcinoma	Open	Legacy Bergan Methodist	<a href="https://clinicaltrials.gov/ct2/show/NCT04489771?term=mk6482-013&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04489771?term=mk6482-013&amp;draw=2&amp;rank=1</a>
RCC locally advanced, non resectable disease, which has progressed despite all standard therapies	INBRX-106	INBRX-106	An Open-Label, multicenter, First in Human, Dose Escalation, Phase I Study of INBRX-106 in Subjects with locally advanced or metastatic solid tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1</a>
advanced clear cell renal cell dx	NKT2152	NKT2152	A Phase I/II, open label dose escalation and expansion trial of NKT2152, an orally administered HIF-2a inhibitor, to investigate safety, pharmacokinetics, pharmacodynamics, and clinical activity in patients with advanced clear cell renal cell carcinoma	Open	Legacy	<a href="#">not yet available</a>
advanced rcc with clear cell component must have had radiographic disease progression following at least 6 weeks of treatment with immuno therapy. One or two prior therapies are allowed however 1 has to be immunotherapy	Tivozanib+Nivo vs Tivozanib	AV-951-20-304	TiNivo-2: A Phase 3, Randomized, Controlled, Multicenter, Open-label Study to Compare Tivozanib in Combination with Nivolumab to Tivozanib Monotherapy in Subjects with Renal Cell Carcinoma Who Have Progressed Following One or Two Lines of Therapy Where One Line has an Immune Checkpoint Inhibitor	pending	Legacy Methodist Bergan Grand Island	<a href="https://clinicaltrials.gov/ct2/show/NCT04987203?term=AV-951-20-304&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04987203?term=AV-951-20-304&amp;draw=2&amp;rank=1</a>
<b>OVARIAN</b>						
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>Locally Advanced/Metastatic</b>						
Dose expansion tumor types include ovarian, Locally advanced (unresectable) or metastatic disease (no limit to prior therapies) exhausted standard options Measurable disease per RECIST 1.1	ASP 1948+ Pembrolizumab Q3W	1948-CL-0101	A Phase Ib Study of ASP1948, Targeting an Immune Modulatory Receptor, as a Single Agent and in combination with a PD-I inhibitor (Nivolumab or Pembrolizumab) in Subjects with Advanced Solid Tumors	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1</a>
<b>HEAD AND NECK</b>						

\* STAR Trial  
2021

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## Nebraska Cancer Specialists Research Trials

Patient Population	Treatment	Trial	Title	Status	Location(s)	Trial Information
<b>1st Line</b>						
Newly dx HNSCC must be M1/ Stage IV. Oropharynx, oral cavity, hypopharnx, or larynx. PD within 6 months of completion of curatively intended systemic treatment for locoregionally advanced HNSCC is exclusionary.	Pembrolizumab with or without Lenvatinib	MK7902-010 (LEAP 010)	A Phase 3, randomized, placebo-controlled, double-blind clinical study of pembrolizumab (MK-3475) with or without lenvatinib (E7080/MK-7902) to evaluate the safety and efficacy of pembrolizumab and lenvatinib as 1L intervention in a PD-L1 selected population of participants with recurrent or metastatic head and neck squamous cellcarcinoma (R/M HNSCC) (LEAP-010).	Open	Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT04199104?term=mk7902-010&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04199104?term=mk7902-010&amp;draw=2&amp;rank=1</a>
Histopathologically confirmed unresectable, locally advanced, recurrent or metastatic ESCC (excluding mixed adenosquamous carcinoma and other histological subtypes) Subject must be unsuitable for definitive treatment, such as definitive chemoradiotherapy and/or surgery. For subjects who have received (neo)adjuvant or definitive chemotherapy/radiochemotherapy, time from the completion of last treatment to disease recurrence must be > 6 months Could provide archival or fresh tissues for PD-L1 expression analysis with obtainable results#	Sintilimab or placebo+ Cisplatin+Paclitaxel+ Fluorouracil	20171	A Multicenter, Double-Blind, Randomized Phase III Clinical Trial Evaluating the Efficacy and Safety of Sintilimab vs. Placebo, in Combination with Chemotherapy, for First-Line Treatment of Unresectable, Locally Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma (ORIENT-15)CIBI308A301	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03748134?term=NCT03748134&amp;raw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03748134?term=NCT03748134&amp;raw=2&amp;rank=1</a>
<b>2nd-3rd line Metastatic</b>						
Cohort 5: Head and neck cancer; advanced disease and progressed after CPI	Enfortumab Vedotin days 1, 8, 15	7465-CL-202	An Open-label, Multicenter, Multicohort, Phase 2 Study to Evaluate Enfortumab Vedotin in Subjects with Previously Treated Locally Advanced or Metastatic Malignant Solid Tumors (EV-202)	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT04225117?term=7465-cl-202&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04225117?term=7465-cl-202&amp;draw=2&amp;rank=1</a>
Part 3: Patients that have had progression while receiving a anti-PD-1 or and anti-PD-L1. Patients must have received at least two doses of an approved CPI. Any CPI that is experimental are not permitted to enroll. Patients must have either a NSCLC dx or SCCHN	CDX 1140+ Pembrolizumab	CDX1140-01	A Phase I, Study of CDX-1140 a fully human agonist anti-CD40 monoclonal antibody as monotherapy or in combination in patients with advanced solid tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03329950?term=CDX1140&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03329950?term=CDX1140&amp;rank=1</a>
Cohort 6: Recurrent or Metastatic HNSCC of the oral cavity, oropharynx, hypopharynx, and larynx. Up to 3 prior lines of prior systemic therapies for recurrent or metastatic disease. Subjects must have progressed on or after a CPI.	TTX-030+ budigalimab (cohorts 4-6 and 8)	TTX-030-002	A Phase I/IB Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04306900?term=ttx-030-002&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04306900?term=ttx-030-002&amp;draw=2&amp;rank=1</a>
Dose expansion tumor types include squamous cell carcinoma of the head and neck Locally advanced (unresectable) or metastatic disease (no limit to prior therapies) Measurable disease per RECIST 1.1	ASP 1948+ Pembrolizumab Q3W	1948-CL-0101	A Phase Ib Study of ASP1948, Targeting an Immune Modulatory Receptor, as a Single Agent and in combination with a PD-I inhibitor (Nivolumab or Pembrolizumab) in Subjects with Advanced Solid Tumors	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1</a>
HCSCC with locally advanced, non resectable disease, which has progressed despite all standard therapies	INBRX-106	INBRX-106	An Open-Label, multicenter, First in Human, Dose Escalation, Phase I Study of INBRX-106 in Subjects with locally advanced or metastatic solid tumors	pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1</a>
<b>HEMATOLOGY</b>						
Patient Population	Treatment	Trial	Title	Status	Location(s)	Trial Information

## Nebraska Cancer Specialists Research Trials

untreated DLBCL; one measurable lesion of transverse diameter of $\geq 1.5$ cm and greatest perpendicular diameter of $\geq 1.0$ cm. ECOG 0 to 2; prior non-hematologic malignancy is exclusionary except for malignancy treated with curative intent and not more than 2 years before screening and adequately treated carcinoma in situ without evidence of disease.	Tafasitamab+ Lenalidomide+ R-CHOP vs R-CHOP	20133	A Phase III, multicenter, open-label, randomized trial comparing the efficacy and safety of Tafasitamab plus Lenalidomide in addition to R-CHOP versus R-CHOP for high risk patients with previously untreated Diffuse Large B-Cell Lymphoma	Open	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04824092?term=NCT04824092&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04824092?term=NCT04824092&amp;draw=2&amp;rank=1</a>
PMF, PPV-MK, or PET-MF; platelet $<50,000/uL$ based on two measurements taken on different days and both measurements must be $<50,000/uL$ ; Palpable splenomegaly $\geq 5$ cm below the lower costal margin.If the patient has received prior JAK2 inhibitor treatment, this treatment must meet at least one of the following criteria: a.Prior treatment with any JAK2 inhibitor, irrespective of dose, with a duration of 90 days or less. The 90-day period starts on the date of first administration of JAK2 inhibitor therapy and continues for 90 calendar days, regardless of whether therapy is administered continuously or intermittently during that interval. b.Prior treatment with ruxolitinib, at no more than 10 mg total daily dose on any day, with a duration of 180 days or less. The 180-day period starts on the date of first ruxolitinib administration and continues for 180 calendar days, regardless of whether therapy is administered continuously or intermittently. The patient may not have received $>10$ mg of ruxolitinib on any day during that interval.	Pacritinib 200 mg vs Physician's Choice (limited to single drugs from the following list: corticosteroids, hydroxyurea, thalidomide, lenalidomide, or low dose ruxolitinib)	19171	A Randomized, Controlled Phase 3 Study of Pacritinib Versus Physician's Choice in Patients with Primary Myelofibrosis, Post Polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis with Severe Thrombocytopenia (Platelets Counts $<50,000/\mu L$ ) (PAC203)	Available*	Legacy Methodist Papillion	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03165734?term=NCT03165734&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03165734?term=NCT03165734&amp;draw=2&amp;rank=1</a>
<b>2nd Line</b>						
<b>2nd Line</b>						
Relapsed AML or high risk MDS relapsed or refractory following at least 6 cycles of hypomethylating agents or evidence of early progression	CA-4948 BID (PO)	CA-4948-102	A Phase 1, Open Label Dose Escalation Trial Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of Orally Administered CA-4948 in Patients with Acute Myelogenous Leukemia or Myelodysplastic Syndrome	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04278768?term=CA-4948-102&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04278768?term=CA-4948-102&amp;draw=2&amp;rank=1</a>
DLBCL relapsed/refractory; at least 1 prior line of therapy; at least 1 bi-dimensional measurable lesion; ECOG 0-2	Polatuzumab Vedotin+R-GEMOX vs R-GEMOX	MO40598	A Phase III, open label, randomized study evaluating the safety and efficacy of Polatuzumab vedotin in combination with Rituximab plus Gemcitabine plus Oxaliplatin (R-GEMOX) versus R-GEMOX alone in relapsed/refractory Diffuse Large B Cell Lymphoma	on hold	Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04182204?term=mo40598&amp;draw=1&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04182204?term=mo40598&amp;draw=1&amp;rank=1</a>
Previously treated with a minimum of 1 prior line of standard chemotherapy-containing regimen (with completion of $>2$ treatment cycles) Documented failure to achieve at least partial response (PR) or documented disease progression after response to the most recent treatment regimen. Refractory disease is defined as treatment failure (stable disease, non-response, progressive disease [PD]) or disease progression within 6 months after the most recent prior therapy ; ECOG 0-2	Zanubrutinib 160 mg BID	18263	A Phase 2, Multicenter, Single-arm Study of Zanubrutinib (BGB-3111) in Patients with Previously Treated B-Cell Lymphoma Intolerant of Prior Treatment with Ibrutinib and/or Acalabrutinib (BGB-3111-215)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04116437?term=BGB-3111-215&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04116437?term=BGB-3111-215&amp;draw=2&amp;rank=1</a>

## Nebraska Cancer Specialists Research Trials

diagnosis of CML-CP; 2 prior ATP-site TKIs (i.e. imatinib, nilotinib, bosutinib, dasatinib or ponatinib) in case of absence of T315I mutation • 1 prior ATP site TKI (i.e. imatinib, nilotinib, bosutinib, dasatinib or ponatinib) in case of presence of T315I mutation	Cohort A: 40 mg asciminib orally twice daily (BID) Cohort B: 80 mg asciminib orally once daily (QD) Cohort C: 200 mg asciminib orally twice daily (BID)	20282	An open label, multi-center Phase IIIb study of asciminib (ABL001) monotherapy in previously treated patients with chronic myeloid leukemia in chronic phase (CML-CP) with and without T315I mutation (AIM4CML)(CABL001AUS04)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04666259?term=NCT04666259&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04666259?term=NCT04666259&amp;draw=2&amp;rank=1</a>
<b>3rd Line</b>						
Multiple myeloma with measurable disease. Has failed at least 3 prior lines of anti myeloma treatments including an anti CD38. Refractory to at	TAK-981+ Mezagitamab (dose escalation) TAK981+ Daratumumab + hyaluronidase-fihj (Lead In)	TAK-981-1503	A Phase Ib/II Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of TAK-981 in combination with monoclonal antibodies in adult patients with relapsed and or refractory multiple myeloma	Open	Legacy Methodist	<a href="https://clinicaltrials.gov/ct2/show/NCT04776018?term=TAK981-1503&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04776018?term=TAK981-1503&amp;draw=2&amp;rank=1</a>
<b>LUNG</b>						
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
Histologically or cytologically documented nonsquamous NSCLC Stage IV (M1a-c, AJCC 8th Edition) disease not previously treated with systemic therapy for metastatic NSCLC a. Patients who received adjuvant or neoadjuvant therapy (with or without immunotherapy) for localized NSCLC are eligible if all adjuvant/neoadjuvant therapy (including immunotherapy) was completed at least 6 months prior to the development of metastatic disease. Known mutation KEAP1 or NRF2	Telaglenastat or placebo + Pembrolizumab+Chemotherapy	19239	CX-839-014 "KEAPSAKE": A Phase 2, Randomized, Multicenter, Double-blind, Study of the Glutaminase Inhibitor Telaglenastat with Pembrolizumab and Chemotherapy versus Placebo with Pembrolizumab and Chemotherapy in First-line Metastatic KEAP1/NRF2-mutated Nonsquamous, Non-Small Cell Lung Cancer (NSCLC)	Available*	Methodist Legacy Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04265534?term=NCT04265534&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04265534?term=NCT04265534&amp;draw=2&amp;rank=1</a>
NSCLC dx with KRAS G12c and STK11 mutations in the first line systemic treatment setting	MRTX849	MRTX849-001	A Phase I/II multiple expansion cohort trial of MRTX849 in patients with advanced solid tumors with KRAS G12C mutation	Hold	Methodist Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03785249?term=mrx849&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03785249?term=mrx849&amp;draw=2&amp;rank=1</a>
locally advanced or metastatic non-small cell lung cancer (NSCLC) not amenable to curative therapy; Participant must have a tumor that was previously determined to have exon 19 deletions (Exon 19del) or Exon 21 L858R substitution. No prior systemic therapy for locally advanced or metastatic disease.	Amivantamab+Lazertinib (Arm A) Osimertinib+placebo+Lazertinib (Arm B) Lazertinib+placebo+ Osimertinib (Arm C)	20250	A Phase 3, Randomized Study of Amivantamab and Lazertinib Combination Therapy Versus Osimertinib Versus Lazertinib as First-Line Treatment in Patients with EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer (73841937NSC3003)MARIPOSA	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04487080?term=NCT04487080&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04487080?term=NCT04487080&amp;draw=2&amp;rank=1</a>
Confirmed advanced, metastatic NSCLC and hasn't been treated with systemic anticancer therapy. Must have documented RET fusion and measurable disease per RECIST 1.1	Pralsetinib (BLU-667) vs Platinum Doublet with or without pembrolizumab	19208	A Randomized, Open-Label, Phase 3 Study of Pralsetinib versus Standard of Care for First Line Treatment of RET fusion-positive, Metastatic Non-Small Cell Lung Cancer (BLU-667-2303)	Available*	Legacy Methodist Papillion	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04222972?term=NCT04222972&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04222972?term=NCT04222972&amp;draw=2&amp;rank=1</a>
<b>1st-2nd Line Metastatic</b>						
Treatment naïve stage IV squamous or nonsquamous NSCLC. Mixed histologies are allowed. Participants who receive adjuvant/neoadjuvant therapy are eligible if the therapy was completed at least 12 months prior to development of metastatic disease. Participant is able to provide archival tissue or newly obtained core biopsy. Participants in substudy 2 must have PD-L1 > 1%. Substudy 3: Participants must have progressed on PD-(L)1 plus platinum doublet therapy given in combination; progressed on PD-(L)1 plus platinum double therapy given in sequence; for patients receiving prior platinum doublet as management of earlier disease, platinum therapy must be within 12 months of signing consent	Substudy 1: Carboplatin+ Paclitaxel+pembrolizumab+ MK7684 (IP) (4 cycles) then Pembro+ MK7684+ pemetrexed (nonsquamous only) Substudy 2: Pembrolizumab+ MK4830 Substudy 3: Pembrolizumab+MK5890 or MK4830	MK3475-U01	A Phase II, Umbrella Study with Rolling Arms of Investigational Agents with either Pembrolizumab in combination with Chemotherapy or with Pembrolizumab alone in Patients with Advanced Non- small cell Lung Cancer	Open	Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04165070?term=MK3475-U01&amp;draw=1&amp;rank=2">https://www.clinicaltrials.gov/ct2/show/NCT04165070?term=MK3475-U01&amp;draw=1&amp;rank=2</a> <a href="https://www.clinicaltrials.gov/ct2/show/NCT04165083?term=MK3475-U01&amp;draw=1&amp;rank=3">https://www.clinicaltrials.gov/ct2/show/NCT04165083?term=MK3475-U01&amp;draw=1&amp;rank=3</a> <a href="https://www.clinicaltrials.gov/ct2/show/NCT04165096?term=MK3475-U01&amp;draw=1&amp;rank=4">https://www.clinicaltrials.gov/ct2/show/NCT04165096?term=MK3475-U01&amp;draw=1&amp;rank=4</a>

\* STAR Trial  
2021

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## Nebraska Cancer Specialists Research Trials

Participant must have histologically or cytologically confirmed, locally advanced or metastatic, nonsquamous non-small cell lung cancer (NSCLC) with documented primary epidermal growth factor receptor (EGFR) Exon 20ins activating mutation Participant must have measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.	Amivantamab + Chemotherapy vs chemotherapy alone	20249	A Randomized, Open-label Phase 3 Study of Combination Amivantamab and Carboplatin-Pemetrexed Therapy, Compared with Carboplatin-Pemetrexed, in Patients with EGFR Exon 20ins Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer (61186372NSC3001)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04538664?term=NCT04538664&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04538664?term=NCT04538664&amp;draw=2&amp;rank=1</a>
NSCLC of squamous or non-squamous histology with stage IV disease. ECOG 0 or 1; Measurable disease per RECIST 1.1. Untreated CNS metastases are excluded	Nivolumab + Relatimab dose + Platinum Chemotherapy Nivolumab+ placebo + Platinum Chemotherapy	CA224-104	A Study of Relatlimab plus Nivolumab in Combination with Chemotherapy vs. Nivolumab in combination with Chemotherapy as first line treatment for participants with Stage IV or recurrent Non Small Cell Lung Cancer	Open	Legacy Bergan Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04623775?term=ca224-104&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04623775?term=ca224-104&amp;draw=2&amp;rank=1</a>
expression and no prior treatment)	Cabozantinib+ Atezolizumab	XL184-021	Administered Alone or in Combination with Atezolizumab in	Open	Methodist	<a href="https://clinicaltrials.gov/ct2/show/NCT03170960?term=XL184-">https://clinicaltrials.gov/ct2/show/NCT03170960?term=XL184-</a>
<b>2nd-3rd line Metastatic</b>						
Cohort 3: Squamous NSCLC; or progressed after platinum based treatment and CPI Cohort 4: Non-squamous NSCLC; progressed after platinum based treatment and CPI	Enfortumab Vedotin days 1, 8, 15	7465-CL-202	An Open-label, Multicenter, Multicohort, Phase 2 Study to Evaluate Enfortumab Vedotin in Subjects with Previously Treated Locally Advanced or Metastatic Malignant Solid Tumors (EV-202)	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT04225117?term=7465-cl-202&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04225117?term=7465-cl-202&amp;draw=2&amp;rank=1</a>
Patients that have had progression while receiving a anti-PD-1 or anti-PD-L1. Patients must have received at least two doses of an approved CPI. Any CPI that is experimental are not permitted to enroll. Patients must have either a NSCLC dx or SCCHN	CDX 1140+ Pembrolizumab	CDX1140-01	A Phase I, Study of CDX-1140 a fully human agonist anti-CD40 monoclonal antibody as monotherapy or in combination in patients with advanced solid tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT03329950?term=CDX1140&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03329950?term=CDX1140&amp;rank=1</a>
ALK+ NSCLC and progression after crizotinib; history of pulmonary interstitial disease, drug related pneumonitis, or radiation pneumonitis is excluded	Brigatinib or Alectinib	18129	Brigatinib-3001- A Phase 3 Randomized Open-label Study of Brigatinib (ALUNBRIG <sup>TM</sup> ) Versus Alectinib (ALECENSA <sup>®</sup> ) in Advanced Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer Patients Who Have Progressed on Crizotinib (XALKORI <sup>®</sup> )	Available*	Legacy Methodist Papillion	<a href="https://www.clinicaltrials.gov/ct2/show/NCT03596866?term=NCT03596866&amp;draw=1&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT03596866?term=NCT03596866&amp;draw=1&amp;rank=1</a>
Histologically or cytologically confirmed diagnosis of NSCLC with KRAS G12C mutation. Candidacy to receive treatment with docetaxel	MRTX849 vs Docetaxel	20269	A Randomized Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously Treated Non-Small Cell Lung Cancer with KRAS G12C Mutation (849-012)	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT04685135?term=NCT04685135&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04685135?term=NCT04685135&amp;draw=2&amp;rank=1</a>
2.Participants must have received at least 1 line of standard therapy for metastatic disease, including platinum-based chemotherapy and an immune checkpoint inhibitor given together or as separate lines of therapy, unless participants are ineligible for or cannot tolerate	GLR (CDK4/6 inhibitor)	GLP-CDK-1009	An Open-Label, Multi-center, phase Ib/II Study to establish safety, tolerability, and optimal dosing strategy of GLR2007 in subjects with advanced solid tumors	Pending	Legacy	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04444427?term=GLP-CDK-1009&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04444427?term=GLP-CDK-1009&amp;draw=2&amp;rank=1</a>

## Nebraska Cancer Specialists Research Trials

Prior platinum therapy required. Must have received at least two prior lines of therapy. Measurable disease per RECIST 1.1	RRX+ Platinum Doublet vs Platinum Doublet	RRx-001-33	A Phase III, Controlled, Open Label, Randomized Study of RRx-001 administered Sequentially with a Platinum Doublet or a Platinum Doublet in Third-Line or Beyond Small Cell Lung Cancer	Hold	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT03699956?term=rrx001-33&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03699956?term=rrx001-33&amp;draw=2&amp;rank=1</a>
NSCLC with locally advanced, non resectable disease, which has progressed despite all standard therapies	INBRX-106	INBRX-106	An Open-Label, multicenter, First in Human, Dose Escalation, Phase I Study of INBRX-106 in Subjects with locally advanced or metastatic solid tumors	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1</a>
Dose expansion tumor types include NSCLC (all comers), NSCL high PDL1 Locally advanced (unresectable) or metastatic disease (no limit to prior therapies) Measurable disease per RECIST 1.1	ASP 1948+ Pembrolizumab Q3W	1948-CL-0101	A Phase Ib Study of ASP1948, Targeting an Immune Modulatory Receptor, as a Single Agent and in combination with a PD-1 inhibitor (Nivolumab or Pembrolizumab) in Subjects with Advanced Solid Tumors	Open	Legacy Methodist Bergan	<a href="https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03565445?term=1948-CL-0101&amp;draw=2&amp;rank=1</a>
NSCLC with documented KRAS p.G12C mutation per local testing guidelines that have exhausted standard of care options for locally advanced or metastatic disease	RMC-4630 +Sotorasib	RMC-4630-03	A Phase II, Open-Label , Multicenter Study of the Combination of RMC-4630 and Sotorasib for Non-Small Cell Lung Cancer Subjects with KRAS G12C mutation after failure of prior standard therapies	pending	Methodist Papillion Bergan Legacy	not yet available
<b>MELANOMA</b>						
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>Adjuvant Mucosal</b>						
Histological confirmation of melanoma of any mucosal site including (but not limited to) anus/rectum, vulvar/vaginal, sinonasal. NOTE: Melanomas of cutaneous origin and/or ocular origin are ineligible.	Nivolumab+ Ipilimumab	MEL 16-252 (SALVO)	Single Arm Phase II Study of Ipilimumab and Nivolumab as Adjuvant Therapy for Resected Mucosal Melanoma	Open	Legacy Methodist	<a href="https://clinicaltrials.gov/ct2/show/NCT03241186?recrs=ab&amp;cond=Single+Arm+Phase+II+Study+of+ipilimumab+and+Nivolumab+as+Adjuvant+Therapy+for+Resected+Mucosal+Melanoma&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03241186?recrs=ab&amp;cond=Single+Arm+Phase+II+Study+of+ipilimumab+and+Nivolumab+as+Adjuvant+Therapy+for+Resected+Mucosal+Melanoma&amp;rank=1</a>
<b>Adjuvant</b>						
post resection, stage IIB/C cutaneous melanoma; complete resection performed within 12 weeks of randomization	Nivolumab or placebo	CA209-76K	A Phase III, Randomized, Double-blind study of adjuvant immunotherapy with Nivolumab versus placebo after complete resection of Stage IIB/C melanoma	Open	Legacy Methodist Bergan	<a href="https://www.clinicaltrials.gov/ct2/show/study/NCT04099251?term=ca209-76&amp;draw=1&amp;rank=2&amp;show_locs=Y#locn">https://www.clinicaltrials.gov/ct2/show/study/NCT04099251?term=ca209-76&amp;draw=1&amp;rank=2&amp;show_locs=Y#locn</a>
Patients with resected melanoma (Stage IIc, IIIa, IIIB/c/d, or IV with no evidence of disease; LN metastases >1mm	Bempegaldesleukin+ Nivolumab vs Nivolumab	PIVOT-12	A Phase III, Randomized, Open-Label study of Adjuvant Immunotherapy with Bempegaldesleukin Combined with Nivolumab Versus Nivolumab After Complete Resection of Melanoma in Participants at High Risk for Recurrence (PIVOT-12)	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04410445?term=PIVOT+12&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04410445?term=PIVOT+12&amp;draw=2&amp;rank=1</a>
<b>1st line Advanced/Metastatic</b>						
First-line unresectable IIIB-D or unresectable IV metastatic melanoma; measurable disease per RECIST 1.1; ECOG 0 or 1	UV1 + Nivolumab+ Ipilimumab vs Nivolumab + Ipilimumab	UV1-202	Study Investigating the Efficacy and Safety of UV1 Vaccination in Combination with Nivolumab and Ipilimumab as First-line Treatment of Patients with Unresectable or Metastatic Melanoma (UV1-202)	Open	Legacy Methodist Bergan	not yet available
Melanoma with locally advanced, non resectable disease, which has progressed despite all standard therapies	INBRX-106	INBRX-106	An Open-Label, multicenter, First in Human, Dose Escalation, Phase I Study of INBRX-106 in Subjects with locally advanced or metastatic solid tumors	Pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04198766?term=inbrx-106&amp;draw=2&amp;rank=1</a>
<b>2nd line to 6th line Advanced/Metastatic</b>						
melanoma progression post atleast 1 prior regimen. Measurable disease per RECIST 1.1, ECOG 0 to 1	BMS-986253/placebo+ Nivolumab+Ipilimumab	CA027002	A Phase 1/2 Study of BMS-986253 in Combination with Nivolumab or Nivolumab plus Ipilimumab in Advanced Cancers	pending	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04913337?term=ngm707&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04913337?term=ngm707&amp;draw=2&amp;rank=1</a>
Stage III or IV melanoma that have had confirmed disease progression on or after anti-PD1 regimen. Patients should receive at least 1 but no more than 5 prior therapies for advanced disease. Uveal, acral, or mucosal melanoma are excluded.	BNT 111 + Cemiplimab	BNT111-01-4781	Open-Label, randomized Phase II trial with BNT 111 and Cemiplimab in combination or as single agents in patients with anti-PD-1 refractory or relapsed, unresectable Stage III or IV melanoma	Open	Legacy	<a href="https://clinicaltrials.gov/ct2/show/NCT04526899?term=bnt111&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT04526899?term=bnt111&amp;draw=2&amp;rank=1</a>
<b>BASAL CELL CARCINOMA</b>						
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>2nd Line Metastatic and beyond</b>						

\* STAR Trial  
2021

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## Nebraska Cancer Specialists Research Trials

mBCC, histologic confirmation of distant BCC metastasis (e.g., lung, liver, lymph nodes, or bone), with metastatic disease that is RECIST measurable using CT or MRI	CX-4945	18014	A Phase I, Multi-Center, Open-Label, Treatment Duration Increment, Expansion, Safety, and PK study of CX-4945 administered twice daily to patients with advanced basal cell carcinoma	Available*	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03897036?term=NCT03897036&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03897036?term=NCT03897036&amp;draw=2&amp;rank=1</a>
<b>OVARIAN</b>						
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>2nd Line Metastatic and beyond</b>						
Histology proven LGSOC (ovarian, peritoneal); <b>KRAS mutation</b> (part A) Measurable disease per RECIST 1.1	VS-6766 vs VS-6766 + Defactinib	20298	A Phase II Study of VS-6766 Alone and in Combination with Defactinib in Recurrent Low-Grade Serous Ovarian Cancer	Available*	Legacy Methodist Papillion	<a href="https://www.clinicaltrials.gov/ct2/show/NCT04625270?term=NCT04625270&amp;draw=2&amp;rank=1">https://www.clinicaltrials.gov/ct2/show/NCT04625270?term=NCT04625270&amp;draw=2&amp;rank=1</a>
<b>Non Interventional</b>						
<b>Patient Population</b>	<b>Treatment</b>	<b>Trial</b>	<b>Title</b>	<b>Status</b>	<b>Location(s)</b>	<b>Trial Information</b>
<b>Blood Collection Trial</b>						
IV NSCLC, SCLC, Breast or Colorectal (can be a new diagnosis, persistent, or recurrent disease). Has measurable disease. After imaging to determine RECIST meets one of the following: planned initiation of a new systemic first or second line treatment or planned continuation of the current line of therapy after a cycle of therapy and prior to initiation of the next cycle	N/A	CADEX-001	Development and Validation of a Multiplex qPCR Short Fragment Cell Free DNA Assay as a potential biomarker for predicting Early Non-Response to therapy in Metastatic Cancer	Hold	Legacy Methodist Bergan Papillion	N/A
diagnosis of metastatic (Stage IV) PC, confirmed by either biopsy of a metastatic tumor site or history of localized disease supported by metastatic disease on imaging studies (ie, clearly noted in hospital/clinical records)	N/A	19144	Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer (64091742PCR002)	Open	Legacy Methodist Papillion	<a href="https://clinicaltrials.gov/ct2/show/NCT03871816?term=64091742PCR002&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03871816?term=64091742PCR002&amp;draw=2&amp;rank=1</a>