

## **Open Clinical Trials**

August 2025

To refer a patient, please directly contact the disease specific nurse navigator.

Please note that in early phase studies, enrollment slots change often and may be limited.

For more information regarding trials at the University of Colorado, please visit: https://researchstudies.cuanschutz.edu/

## **Jump to Cancer Types**

- Breast
- Cutaneous
- Gastrointestinal
- Genitourinary
- Gynecologic
- Head and Neck
- Hematology
- Neuro-Oncology
- Phase 1, Expansion, Molecular Studies (POEMs)
- Radiation Oncology
- Sarcoma
- Thoracic (Lung)

## Common Eligibility Criteria for Clinical Trials

Location Key			
AMC	Anschutz Medical Campus, Anschutz Cancer Pavilion, 1665 Aurora Ct, Aurora, CO 80045		
CCMC	Cherry Creek Medical Center, 100 Cook St, Denver, CO 80206		
HRH	Highlands Ranch Hospital, 1500 Park Central Dr, Highlands Ranch, CO 80129		
LT	Lone Tree Medical Center, 9548 Park Meadows Dr, Lone Tree, CO 80124		

Satellite Site Contacts



Breast Cancer Medical Oncology Anschutz Medical Campus (AMC)				
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Metastatic Breast Cancer			
Study Name	Patients	NCT#	Sites
PRE-I-SPY Phase 1/1b Platform, PRE-Investigation of Serial Studies	Previously treated metastatic breast cancer	NCT05868226	AMC
Phase 3 trial of Saruparib plus Camizestrant vs MD choice of CDK4/6 plus endocrine therapy	ER+, HER2-, BRCA1, BRCA2 or PALB2 mutations	NCT06380751	AMC
Phase 3 Study of MK-2870 +/- pembromizumab vs physician's choice therapy	HR+/HER2-negative metastatic breast cancer	NCT06312176	AMC CCMC HRH
Phase 2 trial of nab-paclitaxel, durvalumab, tremelimumab +/- vaccine	1L metastatic TNBC	NCT03606967	AMC
Phase 2 study of tucatinib, eribulin, trastuzumab	Previously treated metastatic HER2+ breast cancer	NCT05458674	AMC
PIKture-01 Phase 1 OKI-219 (mutant selective PI3K H1047R inhibitor)	Previously treated metastatic solid tumors with PI3K H1047R mutation	NCT06239467	AMC
Phase 1 study of XMT-2056 (immune conjugate). This trial requires hospitalization and inpatient delivery of study drug for some cycles	Previously treated metastatic HER2+ breast or Gastric/GE	NCT05514717	AMC
Phase 3 CDK4/6i + fulvestrant +/- capivasertib (AKTi)	1L metastatic HR+HER2- breast cancer	NCT04862663	AMC, CCMC
Phase 1 study of STX-478 (mutant selective PI3K inhibitor)	Metastatic HR+HER2- breast cancer with PI3K mutation	NCT05768139	AMC (POEMs)
Phase 3 study OP-1250 (SERD)	Metastatic HR+HER2-	NCT06016738	AMC, HRH, CCMC, LT
Phase 3 study of zanidatamab + standard therapy v. trastuzumab + standard therapy	Previously treated metastatic HER2+ breast cancer	NCT06435429	AMC, HRH, CCMC
DYNASTY-Breast02: Phase 3 DB- 1303 (ADC) v. standard therapy	Metastatic HR+ HER2 low	NCT06018337	AMC, LT, HRH, CCMC
Phase 2 study of alisertib + endocrine therapy	Metastatic HR+HER2-	NCT06369285	AMC, HRH, CCMC
Phase 1 study of BG-C9074 (B7H4 ADC) +/- tislelizumab	Previously treated metastatic HR+HER2- or TNBC, ovarian cancer	NCT06233942	AMC (POEMs)
CDK4/6 Inhibitor Dosing Knowledge (CDK) Study	Metastatic breast cancer in older adults	NCT06377852	AMC



CANCER CENTER			
Early-Stage Breast Cancer			
ISPY2.2 Neoadjuvant study	Stage II-III Breast cancer	NCT01042379	AMC, LT, HRH, CCMC
EMBER-4: Adjuvant imlunestrant v standard therapy	High risk HR+HER2- 2-5 years endocrine therapy	NCT05514054	AMC, LT,
DARE: Phase 2 trial of ctDNA-guided treatment	High risk HR+HER2-	NCT04567420	AMC, LT, HRH, CCMC
OFSET: Phase 3 study of chemotherapy + ovarian suppression	Premenopausal HR+HER2- breast cancer	NCT05879926	AMC, LT, HRH, CCMC
OptimICE-PCR: De-escalation after pCR	TNBC with pCR to neoadjuvant therapy	NCT05812807	AMC, LT, HRH
Tailor RT: Randomized study regional RT in low-risk node+ or T3N0 breast cancer	Low-risk node+ or T3N0M0 breast cancer following surgery	NCT03488693	AMC, CCMC, HRH, LT (RT Group)
NRG-BR007: DEBRA: Phase 3 trial of de-escalation of RT in Stage I HR+HER2- breast cancer	Stage I, HR+, HER2- breast cancer with Oncotype RS ≤ 18	NCT04852887	AMC, CCMC, HRH (RT Group)
NRG-BR008: HERO: Phase 3 trial of optimized RT in low-risk HER2+ breast cancer	Early stage HER2+ breast cancer following surgery	NCT05705401	AMC, HRH (RT Group)
S2206: Phase 3 trial of Druvalumab plus chemo vs chemo alone	MammaPrint ultrahigh ER/PR+, HER2-	NCT06058377	AMC, LT, HRH, CCMC
CAMBRIA-2: Phase 3 trial of Camizestrant vs standard endocrine therapy	ER+/HER2-; intermediate- high or high risk for recurrence following definitve treatment, currently NED	NCT05952557	AMC, HRC, CCMC
A Phase 1b study of Psilocybin Assisted Psychotherapy to address fear of recurrence in patients diagnosed with early-stage breast cancer and ovarian cancer in remission	Clinical stage 1 or 2, completed primary treatment, risk of recurrence at 10 years <20%	NCT06430541	AMC



Cutaneous Oncology Anschutz Medical Campus (AMC)				
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High-Risk Resected Melanoma				
Study Name	Patients	NCT#	Sites	
Phase 2 study of pembrolizumab +/-	High-risk melanoma after	NCT03897881	AMC	
mRNA-4157 (personalized cancer	complete resection			
vaccine)				
	Advanced Melanoma			
Phase 2/3 study of LNS8801 with and	Treatment Refractory,	NCT06624644	AMC	
without Pembrolizumab	Unresectable Melanoma			
Phase 3 trial of Lifileucel (LN-144	Untreated, Unresectable or	NCT05727904	AMC	
Tumor infiltrating lymphocyte) with	metastatic melamoma			
Pembro vs Pembro monotherapy				
IGNYTE-3: Phase 3 trial of	Advanced Melanoma That	NCT06264180	AMC	
Vusolimogene Oderparepvec in	Has Progressed on an Anti-			
Combination with Nivolumab Versus	PD-1 and an Anti-CTLA-4			
Treatment of Physician's Choice	Containing Treatment			
	Regimen			
Phase 3 trial of fianlimab and	Unresectable or metastatic	NCT06246916	AMC	
cemiplimab vs reoatlimab and	melanoma			
novolumab				
PRISM-MEL-301: Phase 3 trial of	1L advanced melanoma	NCT06112314	AMC	
nivolumab +/- IMC-F106C (PRAME x	HLA-A*02:01-positive			
CD3 bispecific)				
Phase 1 study of PF-07799933 (RAFi)	Metastatic melanoma with	NCT05355701	AMC	
in advanced tumors with BRAF	BRAF V600E mutation post		(POEMs)	
alterations	BRAF/MEKi and IO			
Phase 1 study of DCSZ11 (anti-	Previously treated metastatic	NCT05785754	AMC	
CD93)+/- pembro in advanced solid	melanoma		(POEMs)	
tumors				
	Uveal Melanoma			
DAR-UM-2: Darovasertib (PKCi) +	1L HLA-A2 negative	NCT05987332	AMC	
crizotinib v. standard therapy	metastatic uveal melanoma			
	Mekel Cell Carcinoma			
			1116	
MATRiX: Phase 2 trial of ATR	Refractory Merkel cell	NCT05947500	AMC	
inhibition	Carcinoma			
	eous Malignancies in Transpla			
Phase 1B/2 study of RP1 (oncolytic IO)	Solid organ or hematopoietic	NCT04349436	AMC	
	cell transplant recipient		1	



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Gastric Gastroesonhag	eal, and Gastroesophageal Jui	action (GEJ) Cance	are
Phase 3 study of Rilvegostomig in Combination with Fluoropyrimidine and	1L HER2 Gastric Cancer	NCT06764875	AMC
Trastuzumab Deruxtecan versus			
Trastuzumab, Chemotherapy, and			
Pembrolizumab (ARTEMIDE-			
Gastric01)		11070505050	4440 11511
Phase 2 study of induction SBRT and	2L+ with homologous	NCT05379972	AMC, HRH
olaparib followed by pembrolizumab olaparib for gastric and GEJ cancers	recombination deficiency mutation		
Phase 1 study of SGN-CEACAM5C	2L+ advanced CRC, GC/GEJ	NCT06131840	AMC
advanced solid tumors including CRC,	or pancreatic cancer	110100101010	7 11 11 0
GC/GEJ, pancreatic cancer	'		
Phase 2 study of induction FLOT	Newly diagnosed, resectable	NCT04028167	AMC
followed by neoadjuvant chemoRT in	T3-4 or node+		
resectable adenocarcinoma	adenocarcinoma esophagus		
esophagus or GEJ	or GEJ	NOTOF704F07	AMC
EDDC: Phase 1 study using anti-N256-glycosylated CEACAM5/6 ADC	Select metastatic cancers including GI and NSCLC	NCT05701527	(POEMs)
(MMAE payload) +/- pembrolizumab	Including of and Noceo		(FOLIVIS)
Phase 1 study of TJ033721 in	1L metastatic gastric, GE,	NCT04900818	AMC
metastatic gastric, GE and esophageal	and esophageal adenoca		
adenocarcinoma	positive for CLDN18.2		
	y-Stage Colorectal Cancer (CR		
CIRCULATE-US: Colon adjuvant	Stage IIIA/B MSS colon	NCT05174169	AMC, LT,
chemotherapy based on evaluation of	adenocarcinoma following		HRH, CCMC
residual disease	curative resection		
Phase I trial of AWN003694 in	astatic Colorectal Cancer (CRC Refractory BRAF V600E	NCT06102902	AMC
combination with Cetuximab and	Metastatic CRC	<u>NC100102902</u>	AIVIC
Encorafenib	Wetastatio Cito		
Study of RAS (ON) inhibitors in GI	1-3L metastatic RAS-mutated	NCT06445062	AMC, LT
tumors in combination with standard	CRC, 1-2L metastatic RAS-		,
therapies	mutated pancreatic cancer		
OrigAMI-3: Phase 3 study of FOLFIRI	2L metastatic CRC	NCT06750094	AMC
+ amavantamab v	KRAS/NRAS and BRAF WT		
cetuximab/bevacizumab in metastatic			
CRC			



CANCER CENTER			
INTRINSIC: Phase 1/1b umbrella study of targeted therapies in metastatic CRC	Previously treated advanced or metastatic CRC with PIK3CA mutation +/- RAS mutation	NCT04929223	AMC
CARAPIA-1: Phase 1 study of GCC19CART in metastatic CRC. This trial requires hospitalization and inpatient delivery of study drug for some cycles	Previously treated metastatic CRC, GCC+, MSS	NCT05319314	AMC
Phase 1 study of SGN-CEACAM5C advanced solid tumors including CRC, GC/GEJ, pancreatic cancer	2L+ advanced CRC, GC/GEJ or pancreatic cancer	NCT06131840	AMC
AE2222: PUMP: Phase 3 study of systemic therapy +/- hepatic arterial infusion for unresectable CRC liver mets	Unresectable liver metastatic CRC	NCT05863195	AMC
Phase 1 study of JNJ-89402638 for metastatic CRC	3L+ unresectable metastatic CRC	NCT06663319	AMC
Phase 1 study of BI1831169 +/- ezabenlimab in advanced solid GI tumors	Advanced or metastatic GI tumors with no standard therapies	NCT05155332	AMC
Phase 1 study of INBRX-109 (DR5 ab) in metastatic solid tumors	Ewings sarcoma, CRC	NCT03715933	AMC (POEMs)
Phase 1 study of PF-07934040 (KRASi) in patients	Select advanced solid tumors with KRAS mutations	NCT06447662	AMC (POEMs)
	Liver Cancer		
Phase lb/2 study of multiple immunotherapy based treatment combinations	Locally advanced/metastatic /unresectable HCC; no priory treament	NCT04524871	AMC, HRH, CCMC
EMERALD-Y90: Phase 2 study of durvalumab + bevacizumab following transarterial radioembolization	Locoregional hepatocellular carcinoma with no extrahepatic disease	NCT06040099	AMC
Phase 1b/2 study of TTI-101 in advanced or metastatic HCC	1-3L Unresectable, locally advanced or metastatic HCC	NCT05440708	AMC
	Biliary Tract Cancer		
Phase 1/2 study of MK-2870 in combination with other anticancer agents	2L Biliary	NCT06428409	AMC, HRH, CCMC
ARTEMIDE-Biliary01: Phase 3 study of rilvegostomig + chemo as adjuvant therapy for biliary tract cancer	Adenocarcinoma of biliary tract following complete resection with curative intent	NCT04995523	AMC, HRH
Phase 2 trial of durvalumab + gemcitabine+cisplatin as neoadjuvant therapy for high-rish resectable intrahepatic cholangiocarcinoma	Intrahepatic cholangio that is considered resectable and high-risk, untreated	NCT04308174	AMC
Phase 1/2 study of M3814 + avelumab with hypofractionated radiation in metastatic hepatobiliary malignancies	2L+ metastatic or locally advanced cholangio or gallbladder carcinoma  Pancreatic Cancer	NCT04068194	AMC
Phase I/IB trial of radiotherapy in combination with TTI-101 in borderline resectable and locally advanced pancreatic ductal adenocarcinoma	Borderline resectable and locally advanced pancreatic ductal adenocarcinoma	NCT06141031	AMC



CANCER CENTER			
Phase 3 study of Quemliclustat and	Treatment naive Metastatic	NCT06608927	AMC, HRH,
Chemotherapy Versus Placebo and	pancreatic ductal cancer		CCMC, LT
Chemotherapy			
Intraperitoneal Paclitaxel for	Pancreatic Ductal	NCT07030283	AMC
Pancreatic Ductal Adenocarcinoma	Adenocarcinoma with		
	Peritoneal Carcinamatosis		
Study of RAS (ON) inhibitors in GI	1-3L metastatic RAS-mutated	NCT06445062	AMC, LT
tumors in combination with standard	CRC, 1-2L metastatic RAS-		
therapies	mutated pancreatic cancer		
Phase 1/2 study of M3814 +	Locally advanced pancreatic	NCT04172532	AMC
hypofractionated radiation for locally	adenocarcinoma following 4-6		
advanced pancreatic adenocarcinoma	months of neoadjuvant		
'	chemo		
S2001: Phase 2 study of Olaparib +/-	Metastatic pancreatic cancer	NCT04548752	AMC, HRH
pembrolizumab maintenance in	with germline BRCA1/2		- ,
metastatic pancreatic ca with germline	mutation and prior response		
BRCA1/2 mutation	to platinum-based chemo		
Phase 1 study of SGN-CEACAM5C	2L+ advanced CRC, GC/GEJ	NCT06131840	AMC
advanced solid tumors including CRC,	or pancreatic cancer		
GC/GEJ, pancreatic cancer	'		
Phase 1 study of PF-07934040	Select advanced solid tumors	NCT06447662	AMC
(KRASi) in patients	with KRAS mutations		(POEMs)
EDDC: Phase 1 study using anti-N256-	Select metastatic cancers	NCT05701527	AMC
glycosylated CEACAM5/6 ADC	including GI and NSCLC		(POEMs)
(MMAE payload) +/- pembrolizumab			,
Phase 1b study of ATP150/2 (vaccine),	Metastatic pancreatic ductal	NCT05846516	AMC
VSV-GP154 (viral vector) and	adenocarcinoma KRAS		
ezabenlimab (ICI) in pancreatic cancer	G12D/G12V mutation		
Phase 1 study of CA-4948	2-3L metastatic or	NCT05685602	AMC
(IRAK4/FLT3i) + gemcitabine+ nab-	unresectable pancreatic		1
paclitaxel in metastatic pancreatic	ductal adeno		
cancer			
	Neuroendocrine Cancers	<u> </u>	
COMPOSE: Study of peptide receptor	Well-differentiated	NCT04919226	AMC
radionuclide therapy with lutetium	aggressive, grade 2/3,		
edotreotide v standard therapy for	SSTR+ neuroendocrine		
SSTR+ GI neuroendocrine tumors	tumors of gastroenteric or		
SSTATE STRICTION CONTROL	pancreatic origin		
NET Retreat: Phase 2 study of	Metastatic grade 1/2 midgut	NCT05773274	AMC
177Lutetium retreatment v. everolimus	neuroendocrine tumors	140100110214	/ ((V)
in metastatic midgut neuroendocrine	nodioonidoonilo tulloio		
in metastatic midgat nedroendocime		<u> </u>	



Genitourinary Oncology Anschutz Medical Campus (AMC)				
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	<b>Localized Prostate Cancer</b>		
Study Name	Patients	NCT#	Sites
Poten-C for intermediate risk	Intermediate risk prostate cancer	NCT03525262	AMC
S2210: Neoadjuvant carboplatin for patients with localized prostate cancer and germline BRCA1/2 mutations	Localized prostate cancer with germline BRCA1/2 mutation	NCT05806515	AMC
NRG GU010: Genomic risk stratification for unfavorable intermed risk localized prostate cancer	Localized prostate cancer unfavorable intermediate risk	NCT05050084	AMC (RT Group)
Pragmatic study of metformin v. lifestyle mods	Localized prostate cancer	NCT05515978	AMC
PREDICT-RT (NRG-GU009): Phase 3 trial of de-intensification for low genomic risk and intensification for high genomic risk	High-risk prostate cancer	NCT04513717	AMC, HRH (RT Group)
Phase 4 study of PYLARIFY PET/CT or PET/MRI	Newly diagnosed, favorable intermediate risk	NCT06074510	AMC
	<b>Metastatic Prostate Cancer</b>		
S1802: SST +/- surgery or radiation	Metastatic hormone sensitive prostate cancer	NCT03678025	AMC
NRG GU011:PROMETHEAN: Phase 2 trial of oligometastatic RT +/- androgen deprivation therapy	Oligometastatic hormone sensitive prostate cancer	NCT05053152	AMC, HRH (RT Group)
KEYNOTE-365: Study of pembrolizumab combinations COHORT I: Carbo/Etop +/- pembro	De novo and treatment emergent neuroendocrine/small cell prostate cancer	NCT02861573	AMC
MK-5684-003: Phase 3 study of opevesostat v. abiraterone/enzalutamide	Metastatic castration- resistant prostate cancer previously treated with hormonal agent and taxane	NCT06136624	AMC, HRH, LT
MK-5684-004: Phase 3 study of opevesostat v. abiraterone/enzalutamide	Metastatic castration- resistant prostate cancer previously treated with hormonal agent	NCT06136650	AMC, HRH, LT
JNJ-87189401 and JNJ-78278343	Metastatic hormone refractory docetaxel refractory prostate cancer	NCT06095089	AMC
Phase 1b/2a study of Pocenbrodib alone or in combination with Abiraterone Acetate, Olaparib, or 177Lu-PSMA-617	Metastatic castration- resistant Prostate Cancer	NCT06785636	AMC



CANCER CENTER			
	Bladder Cancer		-
Phase 2 study of intravesiclar	High grade Non-muscle	NCT05085990	AMC
instillation of TARA-002	invasive bladder cancer		
EA8192 Preoperative durvalumab	Upper tract bladder cancer	NCT04628767	AMC
and/or chemo			
MODERN: A032103 risk adapted	Muscle invasive bladder	NCT05987241	AMC
adjuvant therapy - ctDNA testing and	cancer after surgery		
nivo+/- relatlimab or surveillance			
ETCTN 10144: Olaparib for DNA	2L metastatic bladder	NCT03375307	AMC
repair defect tumors	cancer		
ETCTN 10483: FGFR2/3 genetic	2L metastatic bladder	NCT04963153	AMC, LT,
alterations erdafitinib + EV	cancer		HRH
S1937: Eribulin + gemcitabine v.	3L+ metastatic bladder	NCT04579224	AMC
standard therapy	cancer post PD1i		
MoonRISe-1: Phase 3 study of TAR-	Intermediate-risk non-	NCT06319820	AMC
210 v. single agent intravesical	muscle invasive bladder		
chemotherapy for bladder cancer	cancer + FGFR alterations		
	Kidney Cancer		
SAMURAI: Phase 2 study of SABR in	Metastatic unresectable	NCT05327686	AMC, LT,
patients receiving immunotherapy	Renal Cell carcinoma		HRH, CCMC
NEOPAX: Pembrolizumab + axitinib	Neoadjuvant therapy for	NCT05969496	AMC
for RCC with IVC tumor thrombus	RCC with tumor thrombus		
ETCTN 10144: Olaparib for DNA	2L metastatic bladder	NCT03375307	AMC
repair defect tumors	cancer		
HC-7366 + belzutifan for locally	2L+ metastatic clear cell	NCT06234605	AMC
advanced or metastatic clear cell RCC	RCC		
Penile Cancer			
EA8134 InPACT: Neoadjuvant chemo	Penile cancer	NCT02305654	AMC
+ ILND v chemo +RT+ILND v ILND			



CANCER CENTER					
Gynecologic Oncology					
N. N. I	Anschutz Medical Campus (AMC)				
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		Ovarian Cancer – Front	line		
Study		Patients		NCT#	Sites
GOG-3068 HOTT HIPEC: Phe study of HIPEC + cisplatin v in HIPEC at time of cytoreductive surgery followed by niraparib	no /e	Newly diagnosed stage li ovarian, primary peritone fallopian tube cancer trea neoadj chemo	al, and	NCT05659381	AMC
III and IV ovarian cancer		 Dvarian Cancer – Mainter	nance		
COC 2072 TETON: Phase 4		1-2L platinum sensitive o		NCT04F4G447	AMC
GOG 3072 TETON: Phase 1 of ZN-c3 (Wee1i) + chemo or bevacizumab in ovarian cand	-	primary peritoneal, fallop cancer no BRCA mutatio	ian tube	NCT04516447	AIVIC
UPROAR: Phase 2 study of maintenance mirvetuximab soravtansine (ADC) and olap recurrent platinum sensitive, cancer		Recurrent platinum-sens ovarian, peritoneal, and f tube cancer		NCT05887609	AMC
		Ovarian Cancer - Recur	rent		
Phase 1/2a study of AZD533 folate receptor + TOP1i) in s tumors		Platinum-resistant or plat sensitive ovarian cancer	inum-	NCT05797168	AMC
Phase 1/2 study of VLS-1488 (KIF18Ai) in advanced high g serous ovarian cancer		Recurrent platinum-resist grade serous ovarian car ovarian carcinosarcoma, endometrial/uterine carcinosarcoma, uterine carcinoma	ncer, CN-high	NCT05902988	AMC
Phase 1 study of BG-C9074 ADC) +/- tislelizumab	(B7H4	Previously treated metas HR+HER2- or TNBC, ova cancer		NCT06233942	AMC (POEMs)
Phase I study of IMGN151 (a ADC) in ovarian cancer	inti-FRa	Recurrent endometrial or grade serous epithelial or cancer		NCT05527184	AMC
A Phase 1b study of Psilocyb Assisted Psychotherapy to ac fear of recurrence in patients diagnosed with early-stage b cancer and ovarian cancer in remission	ddress reast	Clinical stage 1 or 2, comprimary treatment, risk of recurrence at 10 years <	f 20%	NCT06430541	AMC
	Ovarian Cancer – Low Grade				
ComboMATCH: Palbociclib a binimetinib in RAS-mutant ca	ncers	Low-grade serous ovaria with RAS mutation		NCT05554367	AMC (POEMs)
Phase 2 Trial of the Combina the BET Inhibitor, ZEN00369 3694), and the PARP Inhibitor	4 (ZEN-	HRD tumors with prior Pa as immediate prior therap		NCT05327010	AMC (POEMS)

Talazoparib, in Patients with



CANCER CENTER			
Molecularly-Selected Solid Tumors (ComBET)"			
	ndometrial Cancer - Presurgical		<u>'</u>
Surgical window of opportunity study of megestrol +/- metformin for endometrial intraepithelial neoplasia	Endometrial intraepithelial neoplasia no prior therapy	NCT04576104	AMC
E	ndometrial Cancer - Frontline		
NRG GY026: Phase 2/3 study of paclitaxel/carboplatin +/- Hylecta or Phesgo in HER2+ Endometrial cancer	1L Stage I-IV endometrial serous carcinoma or carcinoma HER2+	NCT05256225	AMC, HRH, CCMC
NRG GY032: Phase 2 study of tailored adjuvant therapy in POLE-mutated p53 WT early stage endometrial cancer	1L Stage I-III endometrial cancer POLE-mutated, p53 WT, completed surgery	NCT06388018	AMC
E	ndometrial Cancer - Recurrent		
GOG 3104: Phase 3 study of sacituzumab govitecan v. standard therapy in previously treated endometrial cancer	Recurrent or persistent endometrial cancer previously treated with platinum and immunotherapy (up to 4L)	NCT06486441	AMC
Phase 1/2 study of VLS-1488 (KIF18Ai) in advanced high grade serous ovarian cancer	Recurrent platinum-resistant high grade serous ovarian cancer, ovarian carcinosarcoma, CN-high endometrial/uterine carcinosarcoma, uterine serous carcinoma	NCT05902988	AMC
GOG-3082: Phase 1b/2 basket study of ACR-368 (CHK1/2i) +/-gemcitabine in platinum-resistant ovarian, endometrial and urothelial ca based on acrivon oncosignature	Up to 4L: Recurrent, platinum- resistant ovarian cancer, endometrial adenoca, urothelial carcinoma with Acrivol Oncosignature Status	NCT05548296	AMC
Study of E7386 in combination with other anticancer drugs in solid tumors	Reurrent or persistent endometrial cancer previously treated with platinum and immunotherapy	NCT04008797	AMC
Phase I study of IMGN151 (anti-FRa ADC) in ovarian cancer	Recurrent endometrial or high- grade serous epithelial ovarian cancer	NCT05527184	AMC
Uterine Leiomyosarcoma			
GOG 3088: Phase 2 study of letrozole v. observation in uterine leiomyosarcoma	Newly diagnosed ER+ uterine leiomyosarcoma	NCT05649956	AMC, HRH
BRCA Mutation Carriers			
SOROC: Study of salpingectomy v. salpingo-oophorectomy to reduce risk of ovarian cancer in BRCA1 carriers	BRCA1 germline mutation carriers with no prior cancer diagnosis age 35-50	NCT04251052	AMC, HRH



Head and Neck Cancer Anschutz Medical Campus (AMC)			
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Head and Neck Cancer			
Study Name	Patients	NCT#	Sites
Phase 1b/2 study of NT219 in	Recurrent or Metastatic Head	NCT06919666	AMC, HRH
combination with Pembro or	and Neck Squamous Cell		
Cetuximab	Carcinoma (HNSCC)		
FORTIFI-HN010: Phase 2/3 study of	First-Line Treatment of PD-	NCT06788990	AMC
Ficerafusp Alfa (BCA101) or Placebo	L1-positive, Recurrent or		
in Combination with Pembrolizumab	Metastatic Head and Neck		
	Squamous Cell Carcinoma		
eVOLVE-HNSCC: Phase 3 study of	Unresected locally advanced	NCT06129864	AMC, HRH
volrustomig v. observation in	head and neck squamous cell		
unresected locally advanced HNSCC	carcinoma (HNSCC) who		
	have not progressed following		
	definitive concurrent		
0: 414 4 51 4140 4 4 6	chemoRT		4140
OrigAMI-4: Phase 1b/2 study of	Recurrent or metastatic	NOTOCOOFOOO	AMC
amivantamab monotherapy + standard	HNSCC	NCT06385080	
therapy in recurrent/metastatic HNSCC Phase 1 study of BL-B01D1 in	Metastatic or unresectable		AMC
metastatic NSCLC, SCLC, Esophageal	NSCLC, SCLC, Esophageal	NCT05983432	AIVIC
SCC and HNSCC	SCC and HNSCC previously	110103903432	
SCC and Tinocc	treated		
Phase 1b study of losartan,	locoregionally recurrent	NCT06211335	AMC, HRH
pembrolizumab and SBRT in	refractory or oligometastatic	110100211000	7 7
locoregionally recurrent refractory or	HNSCC		
oligometastatic HNSCC			
NRG- HN010: Phase 2 study of	Recurrent, metastatic, or	NCT05408845	AMC, HRH
docetaxel + trastuzumab v. T-DM1 for	treatment-naïve, unresectable		·
HER2+ salivary gland cancer	HER2+ salivary gland cancer		
Phase 2 study of darolutamide +	Hormone-therapy naïve	NCT05669664	AMC
leuprolide in metastatic AR+ salivary	recurrent and/or metastatic		
gland cancer	AR+ salivary gland cancer		
Phase 3 study of BRAF-targeted	Advanced RAI-refractory	NCT06475989	AMC, HRH
therapy v. cabozantinib in RAI-	differentiated thyroid cancers		
refractory differentiated thyroid cancers	with BRAF V600 E mutation		
with BRAF V600E mutation			



Hematology Clinical Trials Unit Anschutz Medical Campus (AMC)			
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<b>Benign Heme and MPNs:</b> Brandon McMahan, MD	Brandon.mcmahon@cuanschutz.edu		

Leukemia			
Study	Patients	NCT#	Sites
22-0054: Phase I study of CD19 Directed CAR T Cells in Adult Patients with B-Cell Acute Lymphoblastic Leukemia (B-ALL) with Minimal Residual Disease (MRD) Positivity at First Complete Remission) (PI: Kamdar)	Ages ≥ 18; B-cell ALL in first complete morphologic remission; MRD positive; ECOG of ≤2	NCT05535855	AMC
24-0178: Study of Mitoxantrone for venetoclax-resistant AML (PI: Kent)	Non-APL AML by WHO criteria and have been treated with first- line venetoclax/HMA (azacitidine or decitabine)	NCT06429449	AMC
24-1444: A controlled multi-arm phase 1 umbrella study evaluating the safety and feasibility of T-cell receptor engineered donor T-cells targeting HA-1 (TSC-100) or HA-2 (TSC-101) in HLA-A*02:01 positive subjects undergoing allogeneic peripheral blood stem cell transplantation (PI: Angelos)	Undergoing allogenic HCT for the following: AML (including mixed phenotype acute leukemia), MDS, and ALL.	NCT05473910	AMC
24-0685: A multicenter, open-label, randomized, phase 2 study of venetoclax and Azacitidine plus Cusatuzumab vs. Venetoclax and Azacitidine alone in newly diagnosed AML patients who are not candidates for intensive therapy (PI: McMahon)	Diagnosis of AML according to ICC 2022 (with the exclusion of MDS/AML with 10-19% blasts). Previously untreated AML. Deemed unfit for intensive therapy.	NCT06384261	AMC
23-0273: Study of cladribine+venetoclax after failure of	Ages ≥ 18; Relapsed/Refractory AML; ECOG of ≤2	NCT06232655	AMC



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venetoclax+hypomethylating agent in			
monocytic AML (PI: McMahon)			
23-0061 KO-MEN-007: Phase 1 study of Venetoclax/Azacitidine or Venetoclax + Ziftomenib (KO-539) or Standard Induction Cytarabine/Daunorubicin (7+3) + Ziftomenib for AML (PI: McMahon)	Ages ≥ 18; documented NPM1 mutation or KMT2A rearrangement and have either newly diagnosed or relapsed/refractory AML; ECOG of ≤2	NCT05735184	AMC
20-2350: Phase 1 study of KPT-9274 in relapsed or refractory AML (PI: Pollyea)	Ages ≥ 18 years; non-APL AML who have not responded to or relapsed after at least one prior therapy and for whom no standard therapy that may provide clinical benefit is available; ECOG of ≤ 2	NCT04914845	AMC
23-2063: Expanded Access Program for SNDX-5613 in Patients with Relapsed/Refractory Acute Leukemias with Genetic Alterations Associated with HOXA Overexpression (PI: McMahon)	Acute leukemia; not eligible for participation in an ongoing clinical study and have no approved treatment options.	NCT05918913	AMC
22-1502: Dose-escalation and dose- expansion Study of UCART22 (Allogeneic Engineered T-cells Expressing Anti-CD22 Chimeric Antigen Receptor) in relapsed or refractory CD22+ B-cell Acute Lymphoblastic Leukemia (B-ALL) (PI: Schwartz)	Ages ≥ 18 years; diagnosed R/R B-ALL; B-ALL blast expressing CD22; ECOG of 0 or 1	NCT04150497	AMC
My	relodysplastic Syndrome Trials		
22-0130: A Phase 1 study of INCB057643 in Myelofibrosis and Other Advanced Myeloid Neoplasms (PI: McMahon)	Ages ≥ 18; relapsed or refractory MF, MDS, or MDS/MPN (Part 1); ECOG of ≤2	NCT04279847	AMC
24-1444: A controlled multi-arm phase 1 umbrella study evaluating the safety and feasibility of T-cell receptor engineered donor T-cells targeting HA-1 (TSC-100) or HA-2 (TSC-101) in HLA-A*02:01 positive subjects undergoing allogeneic peripheral blood stem cell transplantation (PI: Angelos)	Undergoing allogenic HCT for the following: AML (including mixed phenotype acute leukemia), MDS, and ALL.	NCT05473910	AMC
	Lymphoma		
25-0024: Randomized Phase III Study of Mosunetuzumab vs. Rituximab for Low Tumor Burden Follicular Lymphoma (PI: Kamdar)	Participants must have a histologically confirmed diagnosis of Classic Follicular Lymphoma (cFL). Involvement of no more than 3 nodal or extra nodal sites with diameter greater than 3 cm.	NCT06337318	AMC
24-0458: A Phase 1a/1b Trial in Relapsed/Refractory T-cell Non-	Ages > 18; ECOG of 0-1; diagnosed CTCL or Nodal TCL	NCT04234048	AMC

Ages 18-80; ECOG of 0, 1, or 2; Previously untreated participants with CD-20 positive Large B-cell Lymphoma	NCT06047080	AMC	
Ages ≥ 18; diagnosed aggressive or indolent B-cell malignancies; ECOG of ≤2	NCT05458297	AMC	
Ages ≥ 18; ECOG of ≤2	NCT05169515	AMC	
Ages ≥ 18; relapsed or refractory follicular lymphoma (FL) (Grade 1, 2 or 3a) or marginal zone lymphoma (MZL) histologically confirmed < 6 mos of screening, by local pathology; FL: Received at least 1 prior line; MZL: received 2+ prior lines; ECOG of 0 or 1	NCT04245839	AMC	
Ages ≥ 16; Relapsed or refractory aggressive B-cell NHL; ECOG of 0 or 1	NCT05098613	AMC	
Multiple Myeloma			
Ages ≥ 18; Diagnosed MM and evidence of PD based on IMWG criteria; ECOG of ≤1	NCT05722418	AMC	
Benign Heme			
Ages ≥ 18; Diagnosed polycythemia vera; ECOG of ≤2	NCT05210790	AMC	
	with CD-20 positive Large B-cell Lymphoma  Ages ≥ 18; diagnosed aggressive or indolent B-cell malignancies; ECOG of ≤2  Ages ≥ 18; Felapsed or refractory follicular lymphoma (FL) (Grade 1, 2 or 3a) or marginal zone lymphoma (MZL) histologically confirmed < 6 mos of screening, by local pathology; FL: Received at least 1 prior line; MZL: received 2+ prior lines; ECOG of 0 or 1  Ages ≥ 16; Relapsed or refractory aggressive B-cell NHL; ECOG of 0 or 1  Multiple Myeloma  Ages ≥ 18; Diagnosed MM and evidence of PD based on IMWG criteria; ECOG of ≤1	Previously untreated participants with CD-20 positive Large B-cell Lymphoma  Ages ≥ 18; diagnosed aggressive or indolent B-cell malignancies; ECOG of ≤2  Ages ≥ 18; Felapsed or refractory follicular lymphoma (FL) (Grade 1, 2 or 3a) or marginal zone lymphoma (MZL) histologically confirmed < 6 mos of screening, by local pathology; FL: Received at least 1 prior line; MZL: received 2+ prior lines; ECOG of 0 or 1  Ages ≥ 18; Relapsed or refractory follicular lymphoma (MZL) histologically confirmed < 6 mos of screening, by local pathology; FL: Received at least 1 prior line; MZL: received 2+ prior lines; ECOG of 0 or 1  Ages ≥ 16; Relapsed or refractory aggressive B-cell NHL; ECOG of 0 or 1  Multiple Myeloma  Ages ≥ 18; Diagnosed MM and evidence of PD based on IMWG criteria; ECOG of ≤1  Benign Heme  Ages ≥ 18; Diagnosed NCT05210790	



22-0130: A Phase 1 study of INCB057643 in Myelofibrosis and Other Advanced Myeloid Neoplasms (PI: McMahon)	Ages ≥ 18; relapsed or refractory MF, MDS, or MDS/MPN (Part 1); ECOG of ≤2	NCT04279847	AMC
	Allo Transplant/GVHD		
24-1138: A Phase 2, Open-Label, Randomized, Multicenter Study to Evaluate the Safety and Efficacy of Axatilimab in Combination With Ruxolitinib in Participants With Newly Diagnosed Chronic Graft-Versus-Host Disease (PI: Schwartz)	New-onset moderate or severe cGVHD, as defined by the 2014 NIH Consensus Development Project Criteria for Clinical Trials in cGVHD, requiring systemic therapy (Jagasia et al 2015).	NCT06388564	AMC



Neuro-Oncology Anschutz Medical Campus (AMC)			
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Neuro-Oncology			
Study	Patients	NCT#	Sites
Phase I Study of [177Lu] Lu-NeoB in Combination with Radiotherapy and Temozolomide in newly Diagnosed Glioblastoma and as a Single Agent in Recurrent Glioblastoma	Newly diagnosed and recurent GMB	NCT05739942	AMC
Phase 1 study of perioperative vorasidenib (IDH1/2i) + pembrolizumab in recurrent or progressive enhancing IDH-1 mutant astrocytomas	IDH1 mutant astrocytomas/oligodendrogliomas recurrent or progressive enhancing	NCT05484622	AMC
GBM AGILE: Phase 2/3 platform trial evaluating multiple regimens for glioblastoma	Newly diagnosed and recurrent GBM	NCT03970447	AMC,
Phase 1/2 trial of Selinexor (XPO1i) + temozolomide in recurrent glioblastoma	Recurrent GBM	NCT05432804	AMC
Study of SonoCloud-9 + carboplatin v. standard of care in first recurrence GBM	1 <sup>st</sup> Recurrent GBM	NCT05902169	AMC
Phase 1/2 study of nivolumab +/- ipilimumab + multifraction SRS in recurrent high grade radiation- relapsed meningioma	Recurrent grade II/III radiation- relapsed meningioma	NCT03604978	AMC
A071401 Phase 2 study of SMO/AKT/NF2 inhibitors in progressive meningiomas	Progressive meningiomas with AKT1, PIK3CA or PTEN mutations	NCT02523014	AMC
Phase 2 study of tirabrutinib (BTKi) in primary CNS lymphoma	Newly diagnosed CNS lymphoma	NCT04947319	AMC



Phase 1, Expansion, Molecular Studies (POEMs) Anschutz Medical Campus (AMC)			
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Contact Disease Site Speci	Contact Disease Site Specific Nurse Navigator (ie Breast Cancer, GI, GU, etc.)		
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POEMs Studies			
Study	Patients	NCT#	Sites
Phase 1/2 study of ATX-559	Locally advanced or metastatic solid tumors and molecularly defined tumors	NCT06625515	AMC
Phase 1 study of LY4050784 (selective SMARCA2/BRM inhibitor)	Advanced solid tumors with SMARCA4/BRG1 Alterations	NCT06561685	AMC
Phase 1 study of INBRX-109 (DR5 ab) in metastatic solid tumors	Ewings sarcoma, CRC	NCT03715933	AMC
Phase 1 study of PF-07799933 (RAFi) in advanced tumors with BRAF alterations	Metastatic melanoma with BRAF V600E mutation post BRAF/MEKi and IO	NCT05355701	AMC
Phase 1 study of mRNA-4359 + pembrolizumab in advanced solid tumors	1L NSCLC PD-L1 TPS > 50%	NCT05533697	AMC
ComBET: Phase 2 trial of ZEN- 3694 (BETi) + talazoparib in advanced solid tumors	Advanced solid tumor prior PARPi +/-DDR (not PARP1/2) mutation	NCT05327010	AMC
Phase 1 study of STX-478 (mutant selective PI3K inhibitor)	Metastatic HR+HER2- breast cancer with PI3K mutation	NCT05768139	AMC
Phase 1 study of DCSZ11 (anti- CD93) as monotherapy and combo in advanced solid tumors	Melanoma and others	NCT05785754	AMC
ComboMATCH: Palbociclib and binimetinib in RAS-mutant cancers	Low-grade serous ovarian cancer with RAS mutation	NCT05554367	AMC
Phase 1 study of RMC-6291 (KRAS G12Ci) + RMC-6236 (KRASi) in KRAS G12C mutant solid tumors	Previously treated metastatic NSCLC with KRAS G12C mutation	NCT06128551	AMC
Phase 1 study of BG-C9074 (B7H4 ADC) +/- tislelizumab	Metastatic breast and ovarian cancer	NCT06233942	AMC
Medilink: Phase 1 study of YL211 (cMET ADC with Topo-1 payload)	Select advanced solid tumors	NCT06384352	AMC
Phase 1 study of PF-07934040 (KRASi) in patients	Select advanced solid tumors with KRAS mutations	NCT06447662	AMC
Phase 1 study of NX-1607 (CBL-2i)	Select advanced solid tumors	NCT05107674	AMC



Radiation Oncology Anschutz Medical Campus (AMC)		
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Radiation Oncology-Breast Cancer			
Study	Patients	NCT#	Sites
Tailor RT: Randomized study regional RT in low-risk node+ or T3N0 breast cancer	Low-risk node+ or T3N0M0 breast cancer following surgery	NCT03488693	AMC, CCMC, HRH, LT
DEBRA (BR007): Phase 3 trial of de- escalation of RT in Stage I HR+HER2- breast cancer	Stage I, HR+, HER2- breast cancer with Oncotype RS ≤ 18	NCT04852887	AMC, CCMC, HRH
Radiatio	on Oncology- Genitourinary Ca	ncer	
NRG GU011:PROMETHEAN: Phase 2 trial of oligometastatic RT +/- androgen deprivation therapy	Oligometastatic hormone sensitive prostate cancer	NCT05053152	AMC, HRH
NRG GU010: Genomic risk stratification for unfavorable intermed risk localized prostate cancer	Localized prostate cancer unfavorable intermediate risk	NCT05050084	AMC
Rac	liation Oncology -Lung Cancer		
MAVERICK (S1827): MRI brain surveillance +/- cranial irradiation small-cell lung	Small-Cell Lung Cancer	NCT04155034	AMC, HRH
NRG-LU008: Phase 3 trial of primary lung SBRT followed by mediastinal chemo-RT locally advanced NSCLC	Locally advanced NSCLC	NCT05624996	AMC, LT, HRH
Radia	tion Oncology-Pancreatic Can	cer	
Phase I/IB trial of radiotherapy in combination with TTI-101 in borderline resectable and locally advanced pancreatic ductal adenocarcinoma	Borderline resectable and locally advanced pancreatic ductal adenocarcinoma	NCT06141031	AMC
Radia	tion Oncology –Neuro Oncolo	gy	
Phase I Study of [177Lu] Lu-NeoB in Combination with Radiotherapy and Temozolomide in newly Diagnosed Glioblastoma and as a Single Agent in Recurrent Glioblastoma	Newly diagnosed and recurent GMB	NCT05739942	AMC
Radiation Oncology-Multiple Cancer Types			
NRG-BN013: PHASE 3 study of single fraction SRS for versus FSRS for intact brain metastases	Non-small cell lung cancer Melanoma Breast cancer Renal cell carcinoma Gastrointestinal cancer at least 1 and up to 8 total intact brain metastases and at least 1 of the up to 8	NCT06500455	AMC



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	lesions must be a lesion with	
	a maximum diameter of >/=	
	1.0 cm and = 3.0 cm</td <td></td>	



Sarcoma Anschutz Medical Campus (AMC)		
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	Sarcoma		
Study	Patients	NCT#	Sites
Phase 1 study of Peposertib (M3814) and Low-Dose Liposomal Doxorubicin	Metastatic Leiomyosarcoma and Other Soft Tissue Sarcomas	NCT05711615	AMC
STRASS 2 (EA7211): Phase 3 study of neoadjuvant chemo followed by surgery v surgery alone high-risk retroperitoneal sarcoma	High risk retroperitoneal sarcoma (LPS/LMS)	NCT04031677	AMC
EA7222: Phase 3 trial of doxorubicin +/- pembrolizumab undifferentiated pleomorphic sarcoma	Undifferentiated pleomorphic sarcoma and related poorly differentiated sarcomas	NCT06422806	AMC
A randomized blinded placebo- controlled phase 2 study of inbrx-109 in unresectable or metastatic conventional chondrosarcoma	Unresectable Metastatic Convention Chondrosarcoma	NCT04950075	AMC
Phase 1/2 st udy of ADI-PEG 20 or placebo plus gemcitabine and docetaxel in previously treated subjects with leiomyosarcoma	Leiomyosarcoma	NCT05712694	AMC
Phase 3 double blind randomized placebo-controlled study of ivosidenib in pts over 18 yo with locally advanced or metastatic conventional chondrosarcoma with an IDH1 mutation, untreated or previously treated with 1 systemic treatment regimen	Locally advanced or metastatic conventional chondrosarcoma with IDH1 mutation	NCT06127407	AMC
A Phase I/Ib Study of Losartan in Combination with Sunitinib in the Treatment of Pediatric and Adult Patients with Relapsed or Refractory Osteosarcoma	Osteosarcoma	NCT03900793	CHCO, AMC



Thoracic (Lung) Oncology Anschutz Medical Campus (AMC)				
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Erin Schenk, MD, PhD	Erin.schenk@cuanschutz.edu	-		

Early-Stage NSCLC			
Study	Patients	NCT#	Sites
NAUTIKA-1: Phase 2 study of neoadjuvant and adjuvant biomarker-selected therapy for NSCLC.	Stage IB-III NSCLC ALK fusion, ROS1 fusion, NTRK1/2/3 fusion or KRAS G12C (Neoadjuvant TKIs x 8 w), PD-L1+ > 1% (atezo + SBRT)	NCT04302025	AMC
NRG-LU008: Phase 3 trial of primary lung SBRT followed by mediastinal chemo-RT locally advanced NSCLC	Locally advanced NSCLC	NCT05624996	AMC, LT, HRH (RT Group)
•	1 <sup>st</sup> Line Metastatic NSCLC		
Phase 3 study of vonescimab Versus Pembrolizumab	First line Metastatic NSCLC with High PD-L1 expression	NCT06767514	AMC
Phase 1b/2 study of Telisotuzumab Adizutecan in Combination with Budigalimab	Advanced or Metastatic Non- Squamous NSCLC with No Prior Treatment for Advanced Disease and No Actionable Genomic Alterations (AndroMETa-Lung-536)	NCT06772623	AMC
Study of Response of Bony Metatstases for patients on TKI or systemic treatment	NSCLC with completed molecular testing; receiving standard of care TKI or systemic therapy for actionable driver	NCT03958565	AMC, LT
Phase 1 study of mRNA-4359 + pembrolizumab in advanced solid tumors	1L NSCLC PD-L1 TPS ≥ 50%	NCT05533697	AMC (POEMS)
	EGFR mutant NSCLC		
LungMAP S1900G: Phase 2 study of osimertinib + capmatinib +/-ramucirumab in	Metastatic NSCLC EGFR mutant with MET amplification as resistance	NCT05642572	AMC
Systimmune: Phase 1 study of BL- B01D1 (EGFR-HER3 bispecific ADC topoisomerase payload) in metastatic NSCLC	Metastatic NSCLC with EGFR mutation	NCT05983432	AMC
Immunocore: Phase 1 study of a bispecific T-cell engager to PRAME (HLA-A*02:01) and CD3 + osimertinib	Metastatic NSCLC with EGFR mutation Note: This trial requires hospitalization and inpatient delivery of study drug for some cycles	NCT04262466	AMC



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Phase 1b/2 study of BG-60366 (EGFR	Metastatic NSCLC with	NCT06685718	AMC
CDAC protein degrader) for EGFRm	EGFR mutation		
NSCLC patients			
ALK,	ROS1, or RET rearranged NSC	LC	
NVL-655 EAP: Expanded access	Metastatic NSCLC with ALK	NCT05384626	AMC
program for NVL-665 (novel ALK TKI)			
NVL-520: Expanded access program	Metastatic NSCLC with ROS1	NCT05118789	AMC
for NVL-520 (novel ROS1 TKI)	William Woold Will Wool	110100110700	7 (1010
Phase 1/2 study of amivantamab in	Previously treated advanced	NCT05845671	AMC
metastatic NSCLC with ALK, ROS1 or		<u>INC 10304307 1</u>	AIVIC
1	NSCLC with ALK, ROS1, or		
RET gene fusions	RET gene fusions		
	MET or HER2 altered NSCLC	NOT00004000	1 4 4 4 0
SWOG S1900K: Phase 2 study of	MET exon skip metastatic	NCT06031688	AMC
tepotinib +/- ramucirumab for MET	NSCLC		
exon 14 skip NSCLC			
SystImmune: Phase 1 study of BL-	HER2 Exon 20 mutated	NCT05983432	AMC
B01D1 (EGFR-HER3 bispecific ADC	metastatic NSCLC		
topoi payload) metastatic NSCLC			
· · · · · · · · · · · · · · · · · · ·	RAS or BRAF altered NSCLC		
Rev Med: Phase 1 study of RMC-6291	Previously treated metastatic	NCT06128551	AMC
(KRAS G12Ci) + RMC-6236 (KRASi)	NSCLC with KRAS G12C	110100120001	(POEMs)
in KRAS G12C mutant solid tumors	mutation		(I OLIVIS)
Phase 1 study of PF-07934040	Select advanced solid tumors	NCT06447662	AMC
(KRASi) in patients	with KRAS mutations		(POEMs)
	Metastatic NSCLC: ADCs, cyto		
Medilink: Phase 1 study of YL211	Select advanced solid tumors	NCT06384352	AMC
(cMET ADC with Topo-1 payload)			(POEMs)
EDDC: Phase 1 study (all-comers)	Select metastatic cancers	NCT05701527	AMC
using anti-N256-glycosylated	including GI and NSCLC		(POEMs)
CEACAM5/6 ADC (MMAE payload) +/-			, ,
pembrolizumab			
	tic NSCLC: Immunotherapy ag	ents and Small Mole	ecules
Immunocore: Phase 1/2 study of IMC-	HLA-A*02:01-positive		AMC
F106C as single agent and in	patients with PRAME-positive	NCT04262466	7 (1010
combination with IO in HLA-A*02:01-	cancers including NSCLC	110104202400	
positive patients with PRAME-positive	adeno or squamous		
Cancers	Description of all all at a 121	NOTOGEOGOG	AMC
Zymeworks: Phase 1 study of ZW171,	Previously treated select solid	NCT06523803	AMC
mesothelin-CD3 bispecific T cell	tumors		
engager, in solid tumors. <i>This trial</i>			
requires hospitalization and inpatient			
delivery of study drug for some cycles.			
	Small Cell Lung Cancer		
MAVERICK (S1827): MRI brain	Small-Cell Lung Cancer	NCT04155034	AMC, HRH
surveillance +/- cranial irradiation			
small-cell lung			
Harpoon: Phase 1 / 2 study of	Metastatic SCLC	NCT04471727	AMC
HPN328-4001, Trispecific T-cell			
activating construct to CD3, HAS, and			
DLL3. This trial requires hospitalization			
and inpatient delivery of study drug for			
some cycles	<u> </u>		j



Systlmmune: Phase 1 study of BL- B01D1 (EGFR-HER3 bispecific ADC topoi payload) metastatic NSCLC	HER2 Exon 20 mutated metastatic NSCLC and SCLC	NCT05983432	AMC
Mesoti	helioma and Thymic Malignand	ies	
AZ Evolve: Phase 3 study of volrustomig (PD1/CTLA4 bispecific) + chemotherapy vs investigators choice	unresectable, untreated mesothelioma	NCT06097728	AMC
Zymeworks: Phase 1 study of ZW171, mesothelin-CD3 bispecific T cell engager, in solid tumors. This trial requires hospitalization and inpatient delivery of study drug for some cycles.	Previously treated select solid tumors	NCT06523803	AMC



	Satellite Site Contacts		
	Physician Leads	Nurse Navigators	
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LT	Corbin Eule, MD	Crystal Stribling (CrystalD.Stribling@uchealth.org)	
	(Corbin.Eule@CUAnschutz.edu)		

Common Eligibility Criteria for Clinical Trials	
Performance Status	ECOG 0-1
	Karnofsky Performance Status ≥ 60
Age	Age ≥ 18 years (ask for sarcoma trials)
Measurable disease	Lesions that can be accurately measured in at least one dimension
	with a minimum size requirement:
	For CT or MRI scans:
	o The lesion must be <b>≥10 mm</b> in its longest diameter.
	<ul> <li>o For lymph nodes, the short axis must be ≥15 mm to be considered measurable.</li> </ul>
	For physical exam or clinical measurement:
	o The lesion must be ≥10 mm in its longest dimension and
	should be measurable with a caliper or ruler.
	For ultrasound:
	<ul> <li>Lesions can only be considered measurable if they are confirmed by CT or MRI measurements.</li> </ul>
	Non-Measurable Lesions:
	<ul> <li>Lesions that do not meet the criteria above are classified as non- measurable.</li> </ul>
	Please note that bone lesions (unless there is soft tissue)
	extension), pleural effusions, or ascites are <b>not</b> considered measurable disease.
Adequate organ and bone	<b>Bone marrow:</b> ANC ≥ 1.5, Hgb ≥ 9.0 (without recent transfusion),
marrow function	platelets ≥ 100 (without recent transfusion).
	<b>Hepatic:</b> AST and ALT < 2 x ULN, bilirubin < 2.0.
	Renal: CrCl ≥ 50 ml/min.
	Cardiovascular: No symptomatic congestive heart failure; no MI, CVA, or
	unstable angina in the past 6 months.
	Pulmonary: History of ILD requiring steroids (protocol dependent).
	Neurologic: If brain metastases are present, they must have been
	treated and not progressing.