



# Open Clinical Trials

November 2025

To refer a patient, please contact the disease specific nurse navigator directly to schedule a consultation with one of our providers.

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/>

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### [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<br>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 (24-1242)  | Previously treated metastatic breast cancer                          | <a href="#">NCT05868226</a> | AMC                |
| Phase 3 trial of Saruparib plus Camizestrant vs MD choice of CDK4/6 plus endocrine therapy (24-1711)  | ER+, HER2-, BRCA1, BRCA2 or PALB2 mutations                          | <a href="#">NCT06380751</a> | AMC                |
| Phase 3 Study of MK-2870 (Sac-TMT) +/- pembromizumab vs physician's choice therapy (24-1416)  | HR+/HER2-negative metastatic breast cancer                           | <a href="#">NCT06312176</a> | AMC<br>CCMC<br>HRH |
| Phase 2 trial of nab-paclitaxel, durvalumab, tremelimumab +/- vaccine (19-0013)   | 1L metastatic TNBC   | <a href="#">NCT03606967</a> | AMC                |
| Phase 2 study of tucatinib, eribulin, trastuzumab (22-1407)   | Previously treated metastatic HER2+ breast cancer                    | <a href="#">NCT05458674</a> | AMC                |
| PIKture-01 Phase 1 OKI-219 (mutant selective PI3K H1047R inhibitor) (24-0016)   | Previously treated metastatic solid tumors with PI3K H1047R mutation | <a href="#">NCT06239467</a> | AMC                |
| Phase 1 study of XMT-2056 (immune conjugate). <i>This trial requires hospitalization and inpatient delivery of study drug for some cycles</i> (24-1517) | Previously treated metastatic HER2+ or HER2 low breast or Gastric/GE | <a href="#">NCT05514717</a> | AMC                |
| Phase 3 CDK4/6i + fulvestrant +/- capivasertib (AKTi) (21-3077)   | 1L metastatic HR+HER2- breast cancer                                 | <a href="#">NCT04862663</a> | AMC, CCMC          |
| Phase 1 study of STX-478 (mutant selective PI3K inhibitor) (23-0200)  | Metastatic HR+HER2- breast cancer with PI3K mutation                 | <a href="#">NCT05768139</a> | AMC (POEMs)        |
| Phase 3 study OP-1250 (SERD) (23-2036)  | Metastatic HR+HER2-  | <a href="#">NCT06016738</a> | AMC, HRH, CCMC, LT |
| Phase 3 study of zanidatamab + standard therapy v. trastuzumab + standard therapy (24-1635)   | Previously treated metastatic HER2+ breast cancer                    | <a href="#">NCT06435429</a> | AMC, HRH, CCMC     |
| DYNASTY-Breast02: Phase 3 DB-1303 (ADC) v. standard therapy (24-0384)   | Metastatic HR+ HER2 low  | <a href="#">NCT06018337</a> | AMC, LT, HRH, CCMC |
| Phase 2 study of alisertib + endocrine therapy (24-1686)  | Metastatic HR+HER2-  | <a href="#">NCT06369285</a> | AMC, HRH, CCMC     |
| Phase 1 study of BG-C9074 (B7H4 ADC) +/- tislelizumab (24-1128)   | Previously treated metastatic HR+HER2- or TNBC, ovarian cancer       | <a href="#">NCT06233942</a> | AMC (POEMs)        |



|  |  |                             |                               |
|--|--|-----------------------------|-------------------------------|
| Phase 1/2 study of MBRC-101 in select advanced solid tumors (24-2430)  | Metastatic breast cancer   | <a href="#">NCT06014658</a> | AMC (POEMs)                   |
| CDK4/6 Inhibitor Dosing Knowledge (CDK) Study (24-1798)  | Metastatic breast cancer in older adults   | <a href="#">NCT06377852</a> | AMC                           |
| Phase 1/1b Study of IAM1363 (HER2/HER2 mutant TKI, CNS penetrant) (25-0333)  | Advanced Cancers Harboring HER2 tyrosine kinase domain mutations or HER2+                              | <a href="#">NCT06253871</a> | AMC (POEMs)                   |
| Phase 2 Study of Zelenectide (25-0193)   | NECTIN4 Amplified Advanced HR+ HER2- or TNBC   | <a href="#">NCT06840483</a> | AMC                           |
| Phase II Clinical Trial of Utidelone Injectable (UTD1) Plus Capecitabine (25-0715)   | HER2-negative Metastatic Breast Cancer Patients with Brain Metastases                                  | <a href="#">NCT06764940</a> | AMC                           |
| Phase 1/2 Study of ATX-559 (Oral inhibitor of Helicase DHX9) (24-2609)   | Metastatic Breast Cancer   | <a href="#">NCT06625515</a> | AMC (POEMs)                   |
| <b>Early-Stage Breast Cancer</b>   |  |                             |                               |
| ISPY2.2 Neoadjuvant study (10-0374)  | Stage II-III Breast cancer   | <a href="#">NCT01042379</a> | AMC, LT, HRH, CCMC            |
| DARE: Phase 2 trial of ctDNA-guided treatment (20-2773)  | High risk HR+HER2-   | <a href="#">NCT04567420</a> | AMC, LT, HRH, CCMC            |
| OFSET: Phase 3 study of chemotherapy + ovarian suppression (23-2461)   | Premenopausal HR+HER2-breast cancer  | <a href="#">NCT05879926</a> | AMC, LT, HRH, CCMC            |
| OptimICE-PCR: De-escalation after pCR (23-1255)  | TNBC with pCR to neoadjuvant therapy   | <a href="#">NCT05812807</a> | AMC, LT, HRH                  |
| Tailor RT: Randomized study regional RT in low-risk node+ or T3N0 breast cancer (19-0476)  | Low-risk node+ or T3N0M0 breast cancer following surgery   | <a href="#">NCT03488693</a> | AMC, CCMC, HRH, LT (RT Group) |
| NRG-BR007: DEBRA: Phase 3 trial of de-escalation of RT in Stage I HR+HER2- breast cancer (21-4582)   | Stage I, HR+, HER2- breast cancer with Oncotype RS $\leq 18$   | <a href="#">NCT04852887</a> | AMC, CCMC, HRH (RT Group)     |
| S2206: Phase 3 trial of Durvalumab plus chemo vs chemo alone (24-0401)   | MammaPrint ultrahigh ER/PR+, HER2-   | <a href="#">NCT06058377</a> | AMC, LT, HRH, CCMC            |
| CAMBRIA-2: Phase 3 trial of Camizestran vs standard endocrine therapy (24-1414)  | ER+/HER2-; intermediate-high or high risk for recurrence following definitive treatment, currently NED | <a href="#">NCT05952557</a> | 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 (24-1455) | Clinical stage 1 or 2, completed primary treatment, risk of recurrence at 10 years <20%                | <a href="#">NCT06430541</a> | AMC                           |
| A012301 LoTam: A Randomized, Phase III Clinical Trial of Low-Dose Tamoxifen (25-0681)  | Molecular Low-Risk Early-Stage Breast Cancer   | <a href="#">NCT06671912</a> | AMC<br>CCMC<br>LT<br>HRH      |

| <b>Cutaneous Oncology<br/>Anschutz Medical Campus (AMC)</b> |                              |  |
|---|------------------------------|--|
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| <b>High-Risk Resected Melanoma</b>  |   |                             |              |
|---|---|-----------------------------|--------------|
| <b>Study Name</b>   | <b>Patients</b>   | <b>NCT#</b>                 | <b>Sites</b> |
| Phase 2 study of pembrolizumab +/- mRNA-4157 (personalized cancer vaccine) (19-0642)  | High-risk melanoma after complete resection   | <a href="#">NCT03897881</a> | AMC          |
| <b>Advanced Melanoma</b>  |   |                             |              |
| Phase 2/3 study of LNS8801 with and without Pembrolizumab (25-0336)   | Treatment Refractory, Unresectable Melanoma   | <a href="#">NCT06624644</a> | AMC          |
| Phase 3 trial of Lifileucel (LN-144 Tumor infiltrating lymphocyte) with Pembro vs Pembro monotherapy (24-0982)                      | Untreated, Unresectable or metastatic melanoma  | <a href="#">NCT05727904</a> | AMC          |
| IGNYTE-3: Phase 3 trial of Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice (24-1672) | Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen | <a href="#">NCT06264180</a> | AMC          |
| Phase 3 trial of fianlimab and cemiplimab vs reoatlimab and novolumab (24-1713)   | Unresectable or metastatic melanoma   | <a href="#">NCT06246916</a> | AMC          |
| PRISM-MEL-301: Phase 3 trial of nivolumab +/- IMC-F106C (PRAME x CD3 bispecific) (23-2225)  | 1L advanced melanoma HLA-A*02:01-positive   | <a href="#">NCT06112314</a> | AMC          |
| Phase 1 study of PF-07799933 (RAFi) in advanced tumors with BRAF alterations (22-1125)  | Metastatic melanoma with BRAF V600E mutation post BRAF/MEKi and IO                                    | <a href="#">NCT05355701</a> | AMC (POEMs)  |
| Phase 2 Peri-operative study of Fianlimab and Cemiplimab compared with Anti-PD1 alone   | Resectable Stage 3 and 4 Melanoma   | <a href="#">NCT06190951</a> | AMC          |
| <b>Uveal Melanoma</b>   |   |                             |              |
| DAR-UM-2: Darovasertib (PKCi) + crizotinib v. standard therapy (24-0171)  | 1L HLA-A2 negative metastatic uveal melanoma  | <a href="#">NCT05987332</a> | AMC          |
| <b>Mekel Cell Carcinoma, Squamous Cell Carcinoma</b>  |   |                             |              |
| Phase 1 / 2 Study of REGN7075 (EGFRxCD28 bispecific ab) + cemiplimab (24-2232)  | Select advanced solid tumors, including cutaneous squamous cell carcinoma, CRC, HNSCC                 | <a href="#">NCT04626635</a> | AMC (POEMs)  |
| <b>Advanced Cutaneous Malignancies in Transplant Recipients</b>   |   |                             |              |
| Phase 1B/2 study of RP1 (oncolytic IO) (19-2987)  | Solid organ or hematopoietic cell transplant recipient  | <a href="#">NCT04349436</a> | AMC          |



| Gastrointestinal Oncology<br>Anschutz Medical Campus (AMC) |                                  |                     |
|--|----------------------------------|---------------------|
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| Gastric, Gastroesophageal, and Gastroesophageal Junction (GEJ) Cancers  |  |                             |                    |
|---|--|-----------------------------|--------------------|
| Phase 3 study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan versus Trastuzumab, Chemotherapy, and Pembrolizumab (ARTEMIDE-Gastric01/25-0646) (25-0646) | 1L HER2 Gastric Cancer   | <a href="#">NCT06764875</a> | AMC                |
| Phase 1 study of SGN-CEACAM5C advanced solid tumors including CRC, GC/GEJ, pancreatic cancer (23-2329)  | 2L+ advanced CRC, GC/GEJ or pancreatic cancer                                  | <a href="#">NCT06131840</a> | AMC                |
| Phase 2 study of induction FLOT followed by neoadjuvant chemoRT in resectable adenocarcinoma esophagus or GEJ (19-0376)   | Newly diagnosed, resectable T3-4 or node+ adenocarcinoma esophagus or GEJ      | <a href="#">NCT04028167</a> | AMC                |
| Phase 1 study of XMT-2056 (immune conjugate). <i>This trial requires hospitalization and inpatient delivery of study drug for some cycles</i> (24-1517)                                   | Previously treated metastatic HER2+ or HER2 low breast or Gastric/GE           | <a href="#">NCT05514717</a> | AMC                |
| Phase 1 study of TJ033721 in metastatic gastric, GE and esophageal adenocarcinoma (21-3254)   | 1L metastatic gastric, GE, and esophageal adeno ca positive for CLDN18.2       | <a href="#">NCT04900818</a> | AMC                |
| Phase 1/1b Study of IAM1363 (HER2/HER2 mutant TKI, CNS penetrant) (25-0333)   | Advanced Cancers Harboring HER2 tyrosine kinase domain mutations or HER2+      | <a href="#">NCT06253871</a> | AMC (POEMs)        |
| Early-Stage Colorectal Cancer (CRC)   |  |                             |                    |
| CIRCULATE-US: Colon adjuvant chemotherapy based on evaluation of residual disease (22-0916)   | Stage IIIA/B MSS colon adenocarcinoma following curative resection             | <a href="#">NCT05174169</a> | AMC, LT, HRH, CCMC |
| Metastatic Colorectal Cancer (CRC)  |  |                             |                    |
| Phase I trial of AWN003694 in combination with Cetuximab and Encorafenib (25-0300)  | Refractory BRAF V600E Metastatic CRC   | <a href="#">NCT06102902</a> | AMC                |
| Study of RAS (ON) inhibitors in GI tumors in combination with standard therapies (24-1326)  | 1-3L metastatic RAS-mutated CRC, 1-2L metastatic RAS-mutated pancreatic cancer | <a href="#">NCT06445062</a> | AMC, LT            |
| OrigAMI-3: Phase 3 study of FOLFIRI + amivantamab v cetuximab/bevacizumab in metastatic CRC (24-2380)   | 2L metastatic CRC KRAS/NRAS and BRAF WT  | <a href="#">NCT06750094</a> | AMC                |



|  |   |                             |                |
|--|---|-----------------------------|----------------|
| INTRINSIC: Phase 1/1b umbrella study of targeted therapies in metastatic CRC (21-3774)   | Previously treated advanced or metastatic CRC with PIK3CA mutation +/- RAS mutation   | <a href="#">NCT04929223</a> | AMC            |
| CARAPIA-1: Phase 1 study of GCC19CART in metastatic CRC. <i>This trial requires hospitalization and inpatient delivery of study drug for some cycles</i> (22-0697) | Previously treated metastatic CRC, GCC+, MSS  | <a href="#">NCT05319314</a> | AMC            |
| Phase 1 / 2 Study of REGN7075 (EGFRxCD28 bispecific ab) + cemiplimab (24-2232)   | Select advanced solid tumors, including cutaneous squamous cell carcinoma, CRC, HNSCC | <a href="#">NCT04626635</a> | AMC (POEMs)    |
| Phase 1 study of PF-07799933 (RAFi) in advanced tumors with BRAF alterations (22-1125)   | Metastatic CRC with BRAF V600E mutation   | <a href="#">NCT05355701</a> | AMC (POEMs)    |
| Phase 1 study of SGN-CEACAM5C advanced solid tumors including CRC, GC/GEJ, pancreatic cancer (23-2329)   | 2L+ advanced CRC, GC/GEJ or pancreatic cancer   | <a href="#">NCT06131840</a> | AMC            |
| AE2222: PUMP: Phase 3 study of systemic therapy +/- hepatic arterial infusion for unresectable CRC liver mets (24-0029)  | Unresectable liver metastatic CRC   | <a href="#">NCT05863195</a> | AMC            |
| Phase 1 study of JNJ-89402638 for metastatic CRC (24-1600)   | 3L+ unresectable metastatic CRC   | <a href="#">NCT06663319</a> | AMC            |
| Phase 1 study of BI1831169 +/- ezabenlimab in advanced solid GI tumors (23-2048)   | Advanced or metastatic GI tumors with no standard therapies                           | <a href="#">NCT05155332</a> | AMC            |
| Phase 1 study of PF-07934040 (KRASi) in patients (24-1423)   | Select advanced solid tumors with KRAS mutations                                      | <a href="#">NCT06447662</a> | AMC (POEMs)    |
| <b>Liver Cancer</b>  |   |                             |                |
| Phase Ib/2 study of multiple immunotherapy based treatment combinations (24-1787)  | Locally advanced/metastatic /unresectable HCC; no priory treatment                    | <a href="#">NCT04524871</a> | AMC, HRH, CCMC |
| Phase 1b/2 study of TTI-101 in advanced or metastatic HCC (22-1621)  | 1-3L Unresectable, locally advanced or metastatic HCC                                 | <a href="#">NCT05440708</a> | AMC            |
| <b>Biliary Tract Cancer</b>  |   |                             |                |
| Phase 1/2 study of M3814 + avelumab with hypofractionated radiation in metastatic hepatobiliary malignancies (23-2261)   | 2L+ metastatic or locally advanced cholangio or gallbladder carcinoma                 | <a href="#">NCT04068194</a> | AMC            |
| Phase 1/2 Study to Evaluate the Safety and Efficacy of Patritumab Deruxtecan (24-1883)   | 2L + Biliary Tract Cancer   | <a href="#">NCT06596694</a> | AMC            |
| <b>Pancreatic Cancer</b>   |   |                             |                |
| Intraperitoneal Paclitaxel for Pancreatic Ductal Adenocarcinoma (24-2111)  | Pancreatic Ductal Adenocarcinoma with Peritoneal Carcinomatosis                       | <a href="#">NCT07030283</a> | AMC            |
| Study of RAS (ON) inhibitors in GI tumors in combination with standard therapies (24-1326)   | 1-3L metastatic RAS-mutated CRC, 1-2L metastatic RAS-mutated pancreatic cancer        | <a href="#">NCT06445062</a> | AMC, LT        |
| Phase 1/2 study of M3814 + hypofractionated radiation for locally advanced pancreatic adenocarcinoma (20-2093)   | Locally advanced pancreatic adenocarcinoma following 4-6 months of neoadjuvant chemo  | <a href="#">NCT04172532</a> | AMC            |





## Cancer Center

NCI-DESIGNATED COMPREHENSIVE  
CANCER CENTER

|   |  |                             |             |
|---|--|-----------------------------|-------------|
| Phase 1 study of SGN-CEACAM5C advanced solid tumors including CRC, GC/GEJ, pancreatic cancer (23-2329)  | 2L+ advanced CRC, GC/GEJ or pancreatic cancer  | <a href="#">NCT06131840</a> | AMC         |
| Phase 1 study of PF-07934040 (KRASi) in patients (24-1423)  | Select advanced solid tumors with KRAS mutations   | <a href="#">NCT06447662</a> | AMC (POEMs) |
| Phase 1b study of ATP150/2 (vaccine), VSV-GP154 (viral vector) and ezabenlimab (ICI) in pancreatic cancer (23-1329)                               | Metastatic pancreatic ductal adenocarcinoma KRAS G12D/G12V mutation  | <a href="#">NCT05846516</a> | AMC         |
| Phase 1 study of CA-4948 (IRAK4/FLT3i) + gemcitabine+ nab-paclitaxel in metastatic pancreatic cancer (23-0613)                                    | 2-3L metastatic or unresectable pancreatic ductal adeno  | <a href="#">NCT05685602</a> | AMC         |
| <b>Neuroendocrine Cancers</b>   |  |                             |             |
| COMPOSE: Study of peptide receptor radionuclide therapy with lutetium edotreotide v standard therapy for SSTR+ GI neuroendocrine tumors (21-3552) | Well-differentiated aggressive, grade 2/3, SSTR+ neuroendocrine tumors of gastroenteric or pancreatic origin | <a href="#">NCT04919226</a> | AMC         |
| NET Retreat: Phase 2 study of 177Lutetium retreatment v. everolimus in metastatic midgut neuroendocrine (23-1917)                                 | Metastatic grade 1/2 midgut neuroendocrine tumors  | <a href="#">NCT05773274</a> | AMC         |



| Genitourinary Oncology<br>Anschutz Medical Campus (AMC) |                                  |  |
|---|----------------------------------|--|
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| Elizabeth Kessler, MD                                   | Elizabeth.kessler@cuanschutz.edu |  |

| Localized Prostate Cancer   |   |                             |                          |
|---|---|-----------------------------|--------------------------|
| Study Name  | Patients  | NCT#                        | Sites                    |
| Poten-C for intermediate risk (18-2209)   | Intermediate risk prostate cancer   | <a href="#">NCT03525262</a> | AMC                      |
| S2210: Neoadjuvant carboplatin for patients with localized prostate cancer and germline BRCA1/2 mutations (23-2420)                           | Localized prostate cancer with germline BRCA1/2 mutation  | <a href="#">NCT05806515</a> | AMC                      |
| NRG GU010: Genomic risk stratification for unfavorable intermediate risk localized prostate cancer (22-0175)                                  | Localized prostate cancer unfavorable intermediate risk   | <a href="#">NCT05050084</a> | AMC (RT Group)           |
| Pragmatic study of metformin v. lifestyle mods (19-1536)  | Localized prostate cancer   | <a href="#">NCT05515978</a> | AMC                      |
| Metastatic Prostate Cancer  |   |                             |                          |
| S1802: SST +/- surgery or radiation (18-2252)   | Metastatic hormone sensitive prostate cancer  | <a href="#">NCT03678025</a> | AMC                      |
| NRG GU011:PROMETHEAN: Phase 2 trial of oligometastatic RT +/- androgen deprivation therapy (22-0504)  | Oligometastatic hormone sensitive prostate cancer   | <a href="#">NCT05053152</a> | AMC, HRH (RT Group)      |
| KEYNOTE-365: Study of pembrolizumab combinations<br>COHORT I: Carbo/Etop +/- pembro (21-3724)   | De novo and treatment emergent neuroendocrine/small cell prostate cancer                          | <a href="#">NCT02861573</a> | AMC                      |
| MK-5684-003: Phase 3 study of opevesostat v. abiraterone/enzalutamide (24-0350)   | Metastatic castration-resistant prostate cancer previously treated with hormonal agent and taxane | <a href="#">NCT06136624</a> | AMC, HRH, LT             |
| MK-5684-004: Phase 3 study of opevesostat v. abiraterone/enzalutamide (24-0742)   | Metastatic castration-resistant prostate cancer previously treated with hormonal agent            | <a href="#">NCT06136650</a> | AMC, HRH, LT             |
| JNJ-87189401 and JNJ-78278343 (23-1990)   | Metastatic castration-resistant prostate cancer   | <a href="#">NCT06095089</a> | AMC                      |
| Phase 1b/2a study of Pocenbrodib alone or in combination with Abiraterone Acetate, Olaparib, or 177Lu-PSMA-617 (24-2278)                      | Metastatic castration-resistant Prostate Cancer   | <a href="#">NCT06785636</a> | AMC                      |
| CCTG-PR26 - Randomized phase 3 clinical trial for the addition of docetaxel to androgen receptor pathway inhibitors (TRIPLE-SWITCH) (25-0680) | Metastatic Castration Sensitive Prostate Cancer and Suboptimal PSA Response                       | <a href="#">NCT06592924</a> | AMC<br>CCMC<br>LT<br>HRH |
| Bladder Cancer  |   |                             |                          |





|   |   |                             |                          |
|---|---|-----------------------------|--------------------------|
| Phase 2 study of intravesicular instillation of TARA-002 (24-1264)  | High grade Non-muscle invasive bladder cancer                                 | <a href="#">NCT05085990</a> | AMC                      |
| EA8192 Preoperative durvalumab and/or chemo (21-3855)   | Upper tract urothelial cancer   | <a href="#">NCT04628767</a> | AMC                      |
| MODERN: A032103 risk adapted adjuvant therapy - ctDNA testing and nivo+/- relatlimab or surveillance (24-0700)                      | Muscle invasive bladder cancer or upper tract urothelial cancer after surgery | <a href="#">NCT05987241</a> | AMC                      |
| ETCTN 10144: Olaparib for DNA repair defect tumors (18-1651)  | 2L metastatic bladder cancer  | <a href="#">NCT03375307</a> | AMC                      |
| S1937: Eribulin + gemcitabine v. standard therapy (22-0927)   | 3L+ metastatic bladder cancer post PD1i                                       | <a href="#">NCT04579224</a> | AMC                      |
| <b>Kidney Cancer</b>  |   |                             |                          |
| SAMURAI: Phase 2 study of SABR in patients receiving immunotherapy (24-2480)  | Metastatic unresectable Renal Cell carcinoma                                  | <a href="#">NCT05327686</a> | AMC, LT, HRH, CCMC       |
| NEOPAX: Pembrolizumab + axitinib for RCC with IVC tumor thrombus (22-1669)  | Neoadjuvant therapy for RCC with tumor thrombus                               | <a href="#">NCT05969496</a> | AMC                      |
| ETCTN 10144: Olaparib for DNA repair defect tumors (18-1651)  | 2L metastatic bladder cancer  | <a href="#">NCT03375307</a> | AMC                      |
| HC-7366 + belzutifan for locally advanced or metastatic clear cell RCC (24-0745)  | 2L+ metastatic clear cell RCC   | <a href="#">NCT06234605</a> | AMC                      |
| STRIKE/A032201: Study of short term Intensified Pembrolizumab (Keytruda) and Tivozanib for High-risk renal cell carcinoma (25-0682) | Clear cell RCC following complete resection                                   | <a href="#">NCT06661720</a> | AMC<br>HRH<br>CCMC<br>LT |
| <b>Penile Cancer</b>  |   |                             |                          |
| EA8134 InPACT: Neoadjuvant chemo + ILND v chemo +RT+ILND v ILND (17-1515)   | Penile cancer   | <a href="#">NCT02305654</a> | AMC                      |

| <b>Gynecologic Oncology<br/>Anschutz Medical Campus (AMC)</b> |                             |                     |
|---|-----------------------------|---------------------|
| <b>Nurse Navigator</b>  | <b>Email</b>                | <b>Phone</b>        |
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| <b>Ovarian Cancer - Frontline</b>  |   |                             |                    |
|--|---|-----------------------------|--------------------|
| <b>Study</b>   | <b>Patients</b>   | <b>NCT#</b>                 | <b>Sites</b>       |
| GOG-3068 HOTT HIPEC: Phase 3 study of HIPEC + cisplatin v no HIPEC at time of cytoreductive surgery followed by niraparib in stage III and IV ovarian cancer (23-2189)             | Newly diagnosed stage III/IV ovarian, primary peritoneal, and fallopian tube cancer treated with neoadj chemo   | <a href="#">NCT05659381</a> | AMC                |
| <b>Ovarian Cancer - Maintenance</b>  |   |                             |                    |
| GOG 3072 TETON: Phase 1b study of ZN-c3 (Wee1i) + chemo or bevacizumab in ovarian cancer (22-0890)   | 1-2L platinum sensitive ovarian, primary peritoneal, fallopian tube cancer no BRCA mutation   | <a href="#">NCT04516447</a> | AMC                |
| UPROAR: Phase 2 study of maintenance mirvetuximab soravtansine (ADC) and olaparib in recurrent platinum sensitive, ovarian cancer (22-0384)  | Recurrent platinum-sensitive ovarian, peritoneal, and fallopian tube cancer   | <a href="#">NCT05887609</a> | AMC                |
| NRG-GY036: A Phase III Trial of One vs. Two Years of Maintenance Olaparib, with or without Bevacizumab (25-0399)   | BRCA1/2 Mutated or Homologous Recombination Deficient (HRD+) Ovarian Cancer Following Response to First Line Platinum-Based Chemotherapy                    | <a href="#">NCT06580314</a> | AMC<br>CCMC<br>HRH |
| <b>Ovarian Cancer - Recurrent</b>  |   |                             |                    |
| FONTANA: Phase 1/2a study of AZD5335 (ADC folate receptor + TOP1i) in solid tumors (23-2128)   | Platinum-resistant or platinum-sensitive ovarian cancer   | <a href="#">NCT05797168</a> | AMC                |
| VOLASTRA: Phase 1/2 study of VLS-1488 (KIF18Ai) in advanced high grade serous ovarian cancer (23-1991)   | Recurrent platinum-resistant high grade serous ovarian cancer, ovarian carcinosarcoma, CN-high endometrial/uterine carcinosarcoma, uterine serous carcinoma | <a href="#">NCT05902988</a> | AMC                |
| Phase 1 study of BG-C9074 (B7H4 ADC) +/- tislelizumab (24-1128)  | Previously treated metastatic HR+HER2- or TNBC, endometrial, or ovarian cancer  | <a href="#">NCT06233942</a> | AMC<br>(POEMs)     |
| 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 (23-1455) | Clinical stage 1 or 2, completed primary treatment, risk of recurrence at 10 years <20%   | <a href="#">NCT06430541</a> | AMC                |
| GCT1184-02 (GOG-3107): A Phase 3 Randomized, Open-label Study of Rinatibart Sesutecan (Rina-S) versus  | Platinum Resistant Ovarian Cancer   | <a href="#">NCT06619236</a> | AMC                |

|  |  |                             |                |
|--|--|-----------------------------|----------------|
| Treatment of Investigator's Choice (IC) (25-0457)  |  |                             |                |
| Phase I Evaluation of combination CLK/DYRK (Cirtuvivint) inhibition with PARP inhibition (Olaparib) in BRCA/HRD platinum resistant ovarian cancer (24-1749)                            | Platinum Resistant Ovarian Cancer with 1-3 prior lines of therapy. BRCA or HRD + with prior parp inhibitor.  | <a href="#">NCT06856499</a> | AMC            |
| <b>Ovarian Cancer – Low Grade</b>  |  |                             |                |
| Phase 2 Trial of the Combination of the BET Inhibitor, ZEN003694 (ZEN-3694), and the PARP Inhibitor Talazoparib, in Patients with Molecularly-Selected Solid Tumors (ComBET) (23-0145) | HRD tumors with prior PARPi use as immediate prior therapy   | <a href="#">NCT05327010</a> | AMC (POEMs)    |
| <b>Endometrial Cancer - Presurgical</b>  |  |                             |                |
| No active trials at this time  |  |                             |                |
| <b>Endometrial Cancer - Frontline</b>  |  |                             |                |
| NRG GY026: Phase 2/3 study of paclitaxel/carboplatin +/- Hylecta or Phesgo in HER2+ Endometrial cancer (22-1764)   | 1L Stage I-IV endometrial serous carcinoma, carcinosarcoma, or other histology HER2+   | <a href="#">NCT05256225</a> | AMC, HRH, CCMC |
| NRG GY032: Phase 2 study of tailored adjuvant therapy in POLE-mutated p53 WT early stage endometrial cancer (24-1417)  | 1L Stage I-III endometrial cancer POLE-mutated, p53 WT, completed surgery  | <a href="#">NCT06388018</a> | AMC            |
| <b>Endometrial Cancer - Recurrent</b>  |  |                             |                |
| GOG 3104: Phase 3 study of sacituzumab govitecan v. standard therapy in previously treated endometrial cancer (24-1498)  | Recurrent or persistent endometrial cancer previously treated with platinum and immunotherapy (up to 3 prior lines)                                      | <a href="#">NCT06486441</a> | 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 (23-0115)            | Up to 2L in recurrent setting: Recurrent, platinum-resistant ovarian cancer, endometrial adenoca, urothelial carcinoma with Acrivol Oncosignature Status | <a href="#">NCT05548296</a> | AMC            |
| Phase 1 study of BG-C9074 (B7H4 ADC) +/- tislelizumab (24-1128)  | Previously treated metastatic HR+HER2- or TNBC, endometrial, or ovarian cancer   | <a href="#">NCT06233942</a> | AMC (POEMs)    |
| Study of E7386 in combination with other anticancer drugs in solid tumors (22-2245)  | Recurrent or persistent endometrial cancer previously treated with platinum and immunotherapy  | <a href="#">NCT04008797</a> | AMC            |
| Phase I study of IMGN151 (anti-FRa ADC) in ovarian cancer (22-1835)  | Recurrent endometrial or high-grade serous epithelial ovarian cancer (up to 3 prior lines)   | <a href="#">NCT05527184</a> | AMC            |
| <b>Uterine Leiomyosarcoma</b>  |  |                             |                |
| GOG 3088: Phase 2 study of letrozole v. observation in uterine leiomyosarcoma (24-0041)  | Newly diagnosed ER+ uterine leiomyosarcoma   | <a href="#">NCT05649956</a> | AMC, HRH       |



Cancer Center

NCI-DESIGNATED COMPREHENSIVE  
CANCER CENTER

| BRCA Mutation Carriers  |   |                             |          |
|---|---|-----------------------------|----------|
| SOROC: Study of salpingectomy v. salpingo-oophorectomy to reduce risk of ovarian cancer in BRCA1 carriers (20-2079) | BRCA1 germline mutation carriers with no prior cancer diagnosis age 35-50 | <a href="#">NCT04251052</a> | AMC, HRH |



| Head and Neck Cancer<br>Anschutz Medical Campus (AMC) |  |                     |
|---|--|---------------------|
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| Head and Neck Cancer   |   |   |             |
|--|---|---|-------------|
| Study Name   | Patients  | NCT#  | Sites       |
| Phase 1b/2 study of NT219 in combination with Pembro or Cetuximab (24-0689)  | Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC)   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06919666">NCT06919666</a> | AMC, HRH    |
| Phase 1 / 2 Study of REGN7075 (EGFRxCD28 bispecific ab) + cemiplimab (24-2232)   | Select advanced solid tumors, including cutaneous squamous cell carcinoma, CRC, HNSCC   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT04626635">NCT04626635</a> | AMC (POEMs) |
| FORTIFI-HN010: Phase 2/3 study of Ficerafusp Alfa (BCA101) or Placebo in Combination with Pembrolizumab (25-0122)                                  | First-Line Treatment of PD-L1-positive, Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma                                     | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06788990">NCT06788990</a> | AMC         |
| eOLVE-HNSCC: Phase 3 study of volrustomig v. observation in unresected locally advanced HNSCC (23-2332)  | Unresected locally advanced head and neck squamous cell carcinoma (HNSCC) who have not progressed following definitive concurrent chemoRT | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06129864">NCT06129864</a> | AMC, HRH    |
| OrigAMI-4: Phase 1b/2 study of amivantamab monotherapy + standard therapy in recurrent/metastatic HNSCC (24-0472)                                  | Recurrent or metastatic HNSCC   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06385080">NCT06385080</a> | AMC         |
| Phase 1b study of losartan, pembrolizumab and SBRT in locoregionally recurrent refractory or oligometastatic HNSCC (24-1630)                       | Locoregionally recurrent refractory or oligometastatic HNSCC  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06211335">NCT06211335</a> | AMC, HRH    |
| NRG- HN010: Phase 2 study of docetaxel + trastuzumab v. T-DM1 for HER2+ salivary gland cancer (22-2363)  | Recurrent, metastatic, or treatment-naïve, unresectable HER2+ salivary gland cancer   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05408845">NCT05408845</a> | AMC, HRH    |
| Phase 2 study of darolutamide + leuprolide in metastatic AR+ salivary gland cancer (23-0845)   | Hormone-therapy naïve recurrent and/or metastatic AR+ salivary gland cancer   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05669664">NCT05669664</a> | AMC         |
| EA3231: Phase 3 study of BRAF-targeted therapy v. cabozantinib in RAI-refractory differentiated thyroid cancers with BRAF V600E mutation (24-2273) | Advanced RAI-refractory differentiated thyroid cancers with BRAF V600E mutation   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06475989">NCT06475989</a> | AMC, HRH    |



| Hematology Clinical Trials Unit<br>Anschutz Medical Campus (AMC) |  |                              |
|--|--|------------------------------|
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| <b>Doc Line Phone:</b> 720-848-2628 (doc line)                   |  |                              |
| <b>Physician</b>   | <b>Email</b>   |                              |
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| <b>Cell Therapy/Stem Cell Transplant:</b> Jon Gutman, MD         | Jonathan.gutman@cuanschutz.edu   |                              |
| <b>Lymphoma:</b> Manali Kamdar, MD                               | Manali.kamdar@cuanschutz.edu   |                              |
| <b>Multiple Myeloma:</b> Dan Sherbenou, MD, PhD                  | Daniel.sherbenou@cuanschutz.edu  |                              |
| <b>Benign Heme and MPNs:</b> Brandon McMahon, MD                 | Brandon.mcmahon@cuanschutz.edu   |                              |

| Leukemia   |  |   |       |
|--|--|---|-------|
| Study  | Patients   | NCT#  | Sites |
| 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: Schwartz/22-0054)  | Ages $\geq 18$ ; B-cell ALL in first complete morphologic remission; MRD positive; ECOG of $\leq 2$  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05535855">NCT05535855</a> | AMC   |
| Study of Mitoxantrone for venetoclax-resistant AML (PI: Kent/24-0178)  | Non-APL AML by WHO criteria and have been treated with first-line venetoclax/HMA (azacitidine or decitabine)   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06429449">NCT06429449</a> | AMC   |
| 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/24-1444) | Undergoing allogeneic HCT for the following: AML (including mixed phenotype acute leukemia), MDS, and ALL.   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05473910">NCT05473910</a> | AMC   |
| 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/24-0685)  | 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. | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06384261">NCT06384261</a> | AMC   |
| Study of cladribine+venetoclax after failure of venetoclax+hypomethylating agent in monocytic AML (PI: McMahon/23-0273)  | Ages $\geq 18$ ; Relapsed/Refractory AML; ECOG of $\leq 2$   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06232655">NCT06232655</a> | AMC   |
| KO-MEN-007: Phase 1 study of Venetoclax/Azacitidine or Venetoclax + Ziftomenib (KO-539) or Standard Induction  | Ages $\geq 18$ ; documented NPM1 mutation or KMT2A rearrangement and have either newly diagnosed or  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05735184">NCT05735184</a> | AMC   |





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|--|---|-----------------------------|-----|
| Cytarabine/Daunorubicin (7+3) + Ziftomenib for AML (PI: McMahon/23-0061)   | relapsed/refractory AML; ECOG of $\leq 2$   |                             |     |
| MO-TRANS) Phase III study to evaluate the efficacy and safety of Mocravimod as an adjunctive and maintenance treatment (24-0936)   | acute myeloid leukemia (AML) patients undergoing allogeneic hematopoietic cell transplantation (HCT)  | <a href="#">NCT05429632</a> | AMC |
| <b>Myelodysplastic Syndrome Trials</b>   |   |                             |     |
| 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/24-1444) | Undergoing allogeneic HCT for the following: AML (including mixed phenotype acute leukemia), MDS, and ALL.  | <a href="#">NCT05473910</a> | AMC |
| <b>Lymphoma</b>  |   |                             |     |
| S2308: Randomized Phase III Study of Mosunetuzumab vs. Rituximab for Low Tumor Burden Follicular Lymphoma (PI: Kamdar/ 25-0024))   | 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.   | <a href="#">NCT06337318</a> | AMC |
| A Phase 1a/1b Trial in Relapsed/Refractory T-cell Non-Hodgkin Lymphoma to Determine the Safety Profile, Pharmacology, and Maximum Tolerated Dose of ST-001, a fenretinide phospholipid suspension (12.5 mg/mL) for Intravenous Infusion (PI: Haverkos/24-0458)                                     | Ages > 18; ECOG of 0-1; diagnosed CTCL or Nodal TCL   | <a href="#">NCT04234048</a> | AMC |
| Phase 2 basket study of MK-2140 as monotherapy and in combination in aggressive and indolent B-cell malignancies (waveLINE-006) (PI: Bair/22-1252)   | Ages $\geq 18$ ; diagnosed aggressive or indolent B-cell malignancies; ECOG of $\leq 2$   | <a href="#">NCT05458297</a> | AMC |
| Phase 1b Study of mosunetuzumab or glofitamab + CC-220 and CC-99282 in B-Cell Non-Hodgkin Lymphoma (PI: Kamdar/22-0939)  | Ages $\geq 18$ ; ECOG of $\leq 2$   | <a href="#">NCT05169515</a> | AMC |
| Phase 2 study of JCAR017 in adults with relapsed or refractory indolent B-cell non-Hodgkin Lymphoma (NHL) (PI: Kamdar/19-3011)   | Ages $\geq 18$ ; 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 | <a href="#">NCT04245839</a> | AMC |
| Phase 1/1b study of bispecific CD19 and CD22 chimeric antigen receptorCo-expressing T cells (CD19x22 CAR T) in adolescent  | Ages $\geq 16$ ; Relapsed or refractory aggressive B-cell NHL; ECOG of 0 or 1   | <a href="#">NCT05098613</a> | AMC |

|  |  |                             |     |
|--|--|-----------------------------|-----|
| and adult patients with relapsed and/or refractory B-NHL (PI: Kamdar/21-2578)  |  |                             |     |
| Phase 3 Study Comparing the Combination of Beleodaq-CHOP or Folutyn-COP to the CHOP Regimen Alone (24-2331)  | Newly Diagnosed Patients with Peripheral T-Cell Lymphoma   | <a href="#">NCT06072131</a> | AMC |
| <b>Multiple Myeloma</b>  |  |                             |     |
| A Phase 1, Multicenter, Open-Label Study of CB-011, a CRISPR-Edited Allogeneic anti-BCMA CAR-T Cell Therapy in Patients with Relapsed/Refractory Multiple Myeloma (CaMMouflage Trial) (PI: Sherbenou/23-0376)                        | Ages $\geq 18$ ; Diagnosed MM and evidence of PD based on IMWG criteria; ECOG of $\leq 1$  | <a href="#">NCT05722418</a> | AMC |
| A phase 1b/2, open-label, multicenter study of GC012F (AZD0120), a CD19/BCMA dual CART-cell therapy, in adult subjects with relapsed/refractory Multiple Myeloma Remission) (PI: Monge Urrea/24-2523)                                | Ages $\geq 18$ ; Received at least three prior MM treatment lines of therapy; Have received as part of their previous therapy a PI and IMiD and an antiCD38 antibody                 | <a href="#">NCT05850234</a> | AMC |
| <b>Benign Heme</b>   |  |                             |     |
| Phase 3, Study to Evaluate the Safety and Efficacy of Bomedemstat (MK-3543/IMG-7289) versus Best Available Therapy (BAT) (24-2052)   | Essential Thrombocythemia who have an Inadequate Response to or are Intolerant of Hydroxyurea  | <a href="#">NCT06079879</a> | AMC |
| <b>Allo Transplant/GVHD</b>  |  |                             |     |
| 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/24-1138) | 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). | <a href="#">NCT06388564</a> | AMC |



| Neuro-Oncology<br>Anschutz Medical Campus (AMC) |  |                     |
|---|--|---------------------|
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| Physician                                       | Email  |                     |
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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 (24-0082) | Newly diagnosed and recurrent GMB  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05739942">NCT05739942</a> | AMC   |
| Phase 1 study of perioperative vorasidenib (IDH1/2i) + pembrolizumab in recurrent or progressive enhancing IDH-1 mutant astrocytomas (24-0020)                               | IDH1 mutant astrocytomas/oligodendrogliomas recurrent or progressive enhancing | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05484622">NCT05484622</a> | AMC   |
| GBM AGILE: Phase 2/3 platform trial evaluating multiple regimens for glioblastoma (19-0744)  | Newly diagnosed and recurrent GBM  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT03970447">NCT03970447</a> | AMC,  |
| A071401 Phase 2 study of SMO/AKT/NF2 inhibitors in progressive meningiomas (15-1747)   | Progressive meningiomas with AKT1, PIK3CA or PTEN mutations                    | <a href="https://clinicaltrials.gov/ct2/show/study/NCT02523014">NCT02523014</a> | AMC   |

| Phase 1, Expansion, Molecular Studies (POEMs)<br>Anschutz Medical Campus (AMC) |                                 |       |
|--|---------------------------------|-------|
| Nurse Navigator  | Email                           | Phone |
| Contact Disease Site Specific Nurse Navigator (ie Breast Cancer, GI, GU, etc.) |                                 |       |
| Physician  | Email                           |       |
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| Antonio Jimeno, MD, PhD  | Antonio.jimeno@cuanschutz.edu   |       |

| POEMs Studies   |   |                             |             |
|---|---|-----------------------------|-------------|
| Study   | Patients  | NCT#                        | Sites       |
| Phase 1/2 study of ATX-559 (24-2609)  | Locally advanced or metastatic solid tumors and molecularly defined tumors            | <a href="#">NCT06625515</a> | AMC (POEMs) |
| Phase 1 study of LY4050784 (selective SMARCA2/BRM inhibitor) (24-1841)  | Advanced solid tumors with SMARCA4/BRG1 Alterations Priority NSCLC                    | <a href="#">NCT06561685</a> | AMC (POEMs) |
| Phase 1 study of INBRX-109 (DR5 ab) in metastatic solid tumors (18-1672)  | Ewings sarcoma  | <a href="#">NCT03715933</a> | AMC (POEMs) |
| Phase 1 study of R07502175 (CCR8i)+ pembrolizumab (22-1245)   | NSCLC PD-L1 $\geq$ 50%, CPI naive   | <a href="#">NCT05581004</a> | AMC (POEMs) |
| Phase 1 study of PF-07799933 (RAFi) in advanced tumors with BRAF alterations (22-1125)  | Metastatic CRC with BRAF V600E mutation   | <a href="#">NCT05355701</a> | AMC (POEMs) |
| Phase 1 study of mRNA-4359 + pembrolizumab in advanced solid tumors (22-1490)   | 1L NSCLC PD-L1 TPS $\geq$ 50%   | <a href="#">NCT05533697</a> | AMC (POEMs) |
| ComBET: Phase 2 trial of ZEN-3694 (BETi) + talazoparib in advanced solid tumors (23-0145)   | Advanced solid tumor prior PARPi +/- DDR (not BRCA1/2) mutation                       | <a href="#">NCT05327010</a> | AMC (POEMs) |
| Phase 1 study of STX-478 (mutant selective PI3K inhibitor) (23-0200)  | Metastatic HR+HER2- breast cancer with PIK3CA kinase and helical mutations            | <a href="#">NCT05768139</a> | AMC (POEMs) |
| Phase 1/2 study of MBRC-101 in select advanced solid tumors (23-2430)   | Metastatic breast cancer, NSCLC (adeno and Sq Cell)                                   | <a href="#">NCT06014658</a> | AMC (POEMs) |
| Phase 1 study of BG-C9074 (B7H4 ADC) +/- tislelizumab (24-1128)   | Metastatic breast, endometrial and platinum resistant ovarian                         | <a href="#">NCT06233942</a> | AMC (POEMs) |
| Medilink: Phase 1 study of YL211 (cMET ADC with Topo-1 payload) (24-1562)   | Part 2 Backfill: nsq-NSCLC and sq-NSCLC EGFR WT                                       | <a href="#">NCT06384352</a> | AMC (POEMs) |
| Phase 1 study of PF-07934040 (KRASi) in patients (24-1423)  | Select advanced solid tumors with KRAS mutations NSCLC G12D/V only                    | <a href="#">NCT06447662</a> | AMC (POEMs) |
| Phase 1 study of ATG-031 (CD24 ab) (23-1892) <i>This trial requires hospitalization and inpatient delivery of study drug first several cycles</i> | Advanced solid tumors   | <a href="#">NCT06028373</a> | AMC (POEMs) |
| Phase 1 / 2 Study of REGN7075 (EGFRxCD28 bispecific ab) + cemiplimab (24-2232)  | Select advanced solid tumors, including cutaneous squamous cell carcinoma, CRC, HNSCC | <a href="#">NCT04626635</a> | AMC (POEMs) |
| Phase 1/1b Study of IAM1363 (HER2/HER2 mutant TKI, CNS penetrant) (25-0333)   | Advanced Cancers Harboring HER2 tyrosine kinase domain mutations or HER2+             | <a href="#">NCT06253871</a> | AMC (POEMs) |



| Radiation Oncology<br>Anschutz Medical Campus (AMC) |  |  |
|---|--|--|
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| Physician   | Email  |  |
| Christine Fisher, MD                                | <a href="mailto:Christine.fisher@cuanschutz.edu">Christine.fisher@cuanschutz.edu</a>     |  |
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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 (19-0476)  | Low-risk node+ or T3N0M0 breast cancer following surgery   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT03488693">NCT03488693</a> | AMC, CCMC, HRH, LT |
| DEBRA (BR007): Phase 3 trial of de-escalation of RT in Stage I HR+HER2- breast cancer (21-4582)  | Stage I, HR+, HER2- breast cancer with Oncotype RS $\leq$ 18   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT04852887">NCT04852887</a> | AMC, CCMC, HRH     |
| Radiation Oncology- Genitourinary Cancer   |  |   |                    |
| NRG GU011:PROMETHEAN: Phase 2 trial of oligometastatic RT +/- androgen deprivation therapy (22-0504)   | Oligometastatic hormone sensitive prostate cancer  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05053152">NCT05053152</a> | AMC, HRH           |
| NRG GU010: Genomic risk stratification for unfavorable intermed risk localized prostate cancer (22-0175)   | Localized prostate cancer unfavorable intermediate risk  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05050084">NCT05050084</a> | AMC                |
| Radiation Oncology -Lung Cancer  |  |   |                    |
| MAVERICK (S1827): MRI brain surveillance +/- cranial irradiation small-cell lung (20-0359)   | Small-Cell Lung Cancer   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT04155034">NCT04155034</a> | AMC, HRH           |
| NRG-LU008: Phase 3 trial of primary lung SBRT followed by mediastinal chemo-RT locally advanced NSCLC (23-1258)  | Locally advanced NSCLC   | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05624996">NCT05624996</a> | AMC, LT, HRH       |
| DURABLE: Delayed or Upfront brain Radiotherapy (24-1615)   | naïve lung cancer patients with asymptomatic or minimally symptomatic Brain metastases and ALK rEarrangement | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05987644">NCT05987644</a> | AMC                |
| Radiation Oncology-Pancreatic Cancer   |  |   |                    |
| No active trials at this time  |  |   |                    |
| Radiation Oncology –Neuro Oncology   |  |   |                    |
| 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 (24-0082) | Newly diagnosed and recurrent GMB  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT05739942">NCT05739942</a> | AMC                |
| Radiation Oncology-Multiple Cancer Types   |  |   |                    |
| NRG-BN013: PHASE 3 study of single fraction SRS for versus FSRS for intact brain metastases (24-2477)  | Non-small cell lung cancer<br>Melanoma<br>Breast cancer  | <a href="https://clinicaltrials.gov/ct2/show/study/NCT06500455">NCT06500455</a> | AMC                |



## Cancer Center

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|  |   |  |  |
|--|---|--|--|
|  | Renal cell carcinoma<br>Gastrointestinal cancer<br>at least 1 and up to 8 total intact brain<br>metastases and at least 1 of the up to<br>8 lesions must be a lesion with a<br>maximum diameter of $\geq 1.0$ cm and<br>$\leq 3.0$ cm |  |  |
|--|---|--|--|





| Sarcoma<br>Anschutz Medical Campus (AMC) |                              |  |
|--|------------------------------|--|
| Nurse Navigator                          | Email                        | Phone                                    |
| Erica Becker, PA-C                       | Erica.becker@cuanschutz.edu  | Phone: 720-848-9395<br>Fax: 720-848-5245 |
| Sarah Reynolds, ONN-CG, RN               | Sarah.Reynolds2@uchealth.org | Phone: 720-848-0201<br>Fax: 720-848-0160 |
| Physician                                | Email                        |  |
| Breelyn Wilky, MD                        | Breelyn.wilky@cuanschutz.edu |  |

| Sarcoma   |   |                             |             |
|---|---|-----------------------------|-------------|
| Study   | Patients  | NCT#                        | Sites       |
| Phase 1 study of Peposertib (M3814) and Low-Dose Liposomal Doxorubicin (25-0217)  | Metastatic Leiomyosarcoma and Other Soft Tissue Sarcomas                        | <a href="#">NCT05711615</a> | AMC         |
| STRASS 2 (EA7211): Phase 3 study of neoadjuvant chemo followed by surgery v surgery alone high-risk retroperitoneal sarcoma (23-1625)   | High risk retroperitoneal sarcoma (LPS/LMS)                                     | <a href="#">NCT04031677</a> | AMC         |
| EA7222: Phase 3 trial of doxorubicin +/- pembrolizumab undifferentiated pleomorphic sarcoma (24-2043)   | Undifferentiated pleomorphic sarcoma and related poorly differentiated sarcomas | <a href="#">NCT06422806</a> | AMC         |
| Phase 1/2 study of ADI-PEG 20 or placebo plus gemcitabine and docetaxel in previously treated subjects with leiomyosarcoma (23-1728)  | Leiomyosarcoma  | <a href="#">NCT05712694</a> | 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 (23-1378) | Locally advanced or metastatic conventional chondrosarcoma with IDH1 mutation   | <a href="#">NCT06127407</a> | 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 (18-2740)  | Osteosarcoma  | <a href="#">NCT03900793</a> | CHCO, AMC   |
| Phase 1 study of INBRX-109 (DR5 ab) in metastatic solid tumors (18-1672)  | Ewings sarcoma  | <a href="#">NCT03715933</a> | AMC (POEMs) |
| A phase II Study on Efficacy and Tolerability of Weekly Doxorubicin in Elderly Patients (24-0118)   | Advanced or Metastatic Leiomyosarcoma of Soft Tissue                            | <a href="#">NCT07125183</a> | AMC         |
| Phase 1/2, Open-label, Dose Escalation and Expansion Study of ADCE-D01, a Humanized Anti-human uPARAP Antibody Linked to a Topoisomerase I Inhibitor (24-2281)  | Metastatic and/or Unresectable Soft Tissue Sarcoma                              | <a href="#">NCT06797999</a> | AMC         |
| Multi-cohort, Open-label, Phase 1/2 Study of DCC-3009 in Participants With Gastrointestinal Stromal Tumors (GIST) (24-2282)   | GIST  | <a href="#">NCT06630234</a> | AMC         |



| Thoracic (Lung) Oncology<br>Anschutz Medical Campus (AMC) |                              |  |
|---|------------------------------|--|
| Nurse Navigator   | Email                        | Phone                                    |
| Courtney Sorensen, RN                                     | Courtney.thoutt@uchealth.org | Phone: 720-848-2962<br>Fax: 720-848-0360 |
| Physician   | Email                        |  |
| Tejas Patil, MD   | Tejas.patil@cuanschutz.edu   |  |
| 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 (22-1484)                  | 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)                    | <a href="#">NCT04302025</a> | AMC                     |
| NRG-LU008: Phase 3 trial of primary lung SBRT followed by mediastinal chemo-RT locally advanced NSCLC (23-1258)      | Locally advanced NSCLC  | <a href="#">NCT05624996</a> | AMC, LT, HRH (RT Group) |
| 1 <sup>st</sup> Line Metastatic NSCLC  |   |                             |                         |
| Phase 3 study of vonescimab Versus Pembrolizumab (25-0500)   | First line Metastatic NSCLC with High PD-L1 expression  | <a href="#">NCT06767514</a> | AMC                     |
| Phase 1b/2 study of Telisotuzumab Adizutecan in Combination with Pembro (25-0149)                                    | Advanced or Metastatic Non-Squamous NSCLC with No Prior Treatment for Advanced Disease and No Actionable Genomic Alterations (AndroMETa-Lung-536) | <a href="#">NCT06772623</a> | AMC                     |
| Study of Response of Bony Metastases for patients on TKI or systemic treatment (19-0392)                             | NSCLC with completed molecular testing; receiving standard of care TKI or systemic therapy for actionable driver                                  | <a href="#">NCT03958565</a> | AMC, LT                 |
| Phase 1 study of R07502175 (CCR8i) + pembrolizumab (22-1245)   | NSCLC PD-L1 $\geq$ 50%, CPI naive   | <a href="#">NCT05581004</a> | AMC (POEMS)             |
| Phase 1 study of mRNA-4359 + pembrolizumab in advanced solid tumors (22-1490)  | 1L NSCLC PD-L1 TPS $\geq$ 50%   | <a href="#">NCT05533697</a> | AMC (POEMS)             |
| Phase 1 / 2 Study of REGN7075 (EGFRxCD28 COSTIMULATORY BISPECIFIC ANTIBODY) IN COMBINATION WITH Cemiplimab (24-2232) |   | <a href="#">NCT04626635</a> | AMC (POEMS)             |
| EGFR mutant NSCLC  |   |                             |                         |
| LungMAP S1900G: Phase 2 study of osimertinib + capmatinib +/- ramucirumab (23-0936)                                  | Metastatic NSCLC EGFR mutant with MET amplification as resistance   | <a href="#">NCT05642572</a> | AMC                     |
| Systimmune: Phase 1 study of BL-B01D1 (EGFR-HER3 bispecific ADC topoisomerase payload) in metastatic NSCLC (23-2288) | Metastatic NSCLC with EGFR mutation   | <a href="#">NCT05983432</a> | AMC                     |



|   |   |                             |             |
|---|---|-----------------------------|-------------|
| Phase 1b/2 study of BG-60366 (EGFR CDAC protein degrader) for EGFRm NSCLC patients (25-0436)  | Metastatic NSCLC with EGFR mutation   | <a href="#">NCT06685718</a> | AMC         |
| <b>ALK, ROS1, or RET rearranged NSCLC</b>   |   |                             |             |
| NVL-655 EAP: Expanded access program for NVL-665 (novel ALK TKI) (22-0814)  | Metastatic NSCLC with ALK   | <a href="#">NCT05384626</a> | AMC         |
| Phase 1/2 study of amivantamab in metastatic NSCLC with ALK, ROS1 or RET gene fusions (22-1450)   | Previously treated advanced NSCLC with ALK, ROS1, or RET gene fusions                       | <a href="#">NCT05845671</a> | AMC         |
| Expanded Access Treatment of Zidesantinib (NVL-520) (25-0792)   | Advanced ROS1+ NSCLC or Other ROS1+ Solid Tumors  | <a href="#">NCT06797362</a> | AMC         |
| <b>MET or HER2 altered NSCLC</b>  |   |                             |             |
| SWOG S1900K: Phase 2 study of tepotinib +/- ramucirumab for MET exon 14 skip NSCLC (24-0486)  | MET exon skip metastatic NSCLC  | <a href="#">NCT06031688</a> | AMC         |
| SystImmune: Phase 1 study of BL-B01D1 (EGFR-HER3 bispecific ADC topoi payload) metastatic NSCLC (23-2288)   | HER2 Exon 20 mutated metastatic NSCLC   | <a href="#">NCT05983432</a> | AMC         |
| Phase 1/1b Study of IAM1363 (HER2/HER2 mutant TKI, CNS penetrant) (25-0333)   | Advanced Cancers Harboring HER2 tyrosine kinase domain mutations or HER2+                   | <a href="#">NCT06253871</a> | AMC (POEMs) |
| <b>KRAS or BRAF altered NSCLC</b>   |   |                             |             |
| Phase 1 study of PF-07934040 (KRASi) in patients (24-1423)  | Select advanced solid tumors with KRAS mutations, NSCLC G12D/V                              | <a href="#">NCT06447662</a> | AMC (POEMs) |
| <b>2<sup>nd</sup> Line and Beyond Metastatic NSCLC: ADCs, cytotoxics, radiation</b>   |   |                             |             |
| Medilink: Phase 1 study of YL211 (cMET ADC with Topo-1 payload) (24-1562)   | NSCLC EGFR WT   | <a href="#">NCT06384352</a> | AMC (POEMs) |
| Phase 1/2 study of MBRC-101 in select advanced solid tumors (24-2430)   | Metastatic NSCLC (adeno and SCC)  | <a href="#">NCT06014658</a> | AMC (POEMs) |
| <b>2<sup>nd</sup> Line and Beyond Metastatic NSCLC: Immunotherapy agents and Small Molecules</b>  |   |                             |             |
| Immunocore: Phase 1/2 study of IMC-F106C as single agent and in combination with IO in HLA-A*02:01-positive patients with PRAME-positive cancers (22-1394)  | HLA-A*02:01-positive patients with PRAME-positive cancers including NSCLC adeno or squamous | <a href="#">NCT04262466</a> | AMC         |
| Phase 1 study of LY4050784 (selective SMARCA2/BRM inhibitor) (24-1841)  | Advanced solid tumors with SMARCA4/BRG1 Alterations   | <a href="#">NCT06561685</a> | AMC (POEMs) |
| <b>Small Cell Lung Cancer</b>   |   |                             |             |
| MAVERICK (S1827): MRI brain surveillance +/- cranial irradiation small-cell lung (20-0359)  | Small-Cell Lung Cancer  | <a href="#">NCT04155034</a> | AMC, HRH    |
| Harpoon: Phase 1 / 2 study of HPN328-4001, Trispecific T-cell activating construct to CD3, HAS, and DLL3. <i>This trial requires hospitalization and inpatient delivery of study drug for some cycles</i> (21-2992) | Metastatic SCLC   | <a href="#">NCT04471727</a> | AMC         |
| SystImmune: Phase 1 study of BL-B01D1 (EGFR-HER3 bispecific ADC topoi payload) metastatic NSCLC (23-2288)   | HER2 Exon 20 mutated metastatic NSCLC and SCLC  | <a href="#">NCT05983432</a> | AMC         |



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| Mesothelioma and Thymic Malignancies  |                                      |                             |     |
|---|--------------------------------------|-----------------------------|-----|
| AZ Evolve: Phase 3 study of volrustomig (PD1/CTLA4 bispecific) + chemotherapy vs investigators choice (24-0442) | unresectable, untreated mesothelioma | <a href="#">NCT06097728</a> | AMC |



| Satellite Site Contacts |   |   |
|-------------------------|---|---|
|                         | Physician Leads   | Nurse Navigators  |
| CCMC                    | Scott Kono, MD,<br>( <a href="mailto:Scott.Kono@CUAnschutz.edu">Scott.Kono@CUAnschutz.edu</a> )   | Lanie Wolff ( <a href="mailto:lanie.wolff@uchealth.org">lanie.wolff@uchealth.org</a> )<br>720-516-9254  |
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| LT                      | Corbin Eule, MD<br>( <a href="mailto:Corbin.Eule@CUAnschutz.edu">Corbin.Eule@CUAnschutz.edu</a> ) | Crystal Stribling ( <a href="mailto:CrystalD.Stribling@uchealth.org">CrystalD.Stribling@uchealth.org</a> )  |

| Common Eligibility Criteria for Clinical Trials |  |
|---|--|
| <b>Performance Status</b>                       | ECOG 0-1<br>Karnofsky Performance Status $\geq$ 60   |
| <b>Age</b>                                      | Age $\geq$ 18 years (ask for sarcoma trials)   |
| <b>Measurable disease</b>                       | <p><b>Lesions that can be accurately measured in at least one dimension</b> with a minimum size requirement:</p> <ul style="list-style-type: none"> <li>• <b>For CT or MRI scans:</b> <ul style="list-style-type: none"> <li>○ The lesion must be <math>\geq 10</math> mm in its longest diameter.</li> <li>○ For lymph nodes, the short axis must be <math>\geq 15</math> mm to be considered measurable.</li> </ul> </li> <li>• <b>For physical exam or clinical measurement:</b> <ul style="list-style-type: none"> <li>○ The lesion must be <math>\geq 10</math> mm in its longest dimension and should be measurable with a caliper or ruler.</li> </ul> </li> <li>• <b>For ultrasound:</b> <ul style="list-style-type: none"> <li>○ Lesions can only be considered measurable if they are confirmed by CT or MRI measurements.</li> </ul> </li> </ul> <p><b>Non-Measurable Lesions:</b></p> <ul style="list-style-type: none"> <li>• Lesions that do not meet the criteria above are classified as <b>non-measurable</b>.</li> <li>• Please note that bone lesions (unless there is soft tissue extension), pleural effusions, or ascites are <b>not</b> considered measurable disease.</li> </ul> |
| <b>Adequate organ and bone marrow function</b>  | <p><b>Bone marrow:</b> ANC <math>\geq</math> 1.5, Hgb <math>\geq</math> 9.0 (without recent transfusion), platelets <math>\geq</math> 100 (without recent transfusion).<br/> <b>Hepatic:</b> AST and ALT <math>&lt;</math> 2 x ULN, bilirubin <math>&lt;</math> 2.0.<br/> <b>Renal:</b> CrCl <math>\geq</math> 50 ml/min.<br/> <b>Cardiovascular:</b> No symptomatic congestive heart failure; no MI, CVA, or unstable angina in the past 6 months.<br/> <b>Pulmonary:</b> History of ILD requiring steroids (protocol dependent).<br/> <b>Neurologic:</b> If brain metastases are present, they must have been treated and not progressing.</p>   |