UH Cancer Center Clinical Trials (AUGUST 2024)

Keywords	Trial	Official Title	Eligibility	Treatment	Contact Person	Status?	NCT
BRAIN							
Meningioma	NRG-BN003	Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma *Local PI: Richard Lee, MD*	• Newly diagnosed unifocal WHO grade II meningioma • Totally resected, Simpson Grade 1-3 • Registered within 180 days of surgery	XRT vs. Observation	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu	**Open**: QMC, TCCOH Liliha **Opt out**: HPH	NCT03180268
BREAST							
Adjuvant							
Adjuvant	ALLIANCE-A011801	**Registration to the Quality of Life (A011801-H01) Substudy is Closed to Accrual as of 07/22/2024** The CompassHER2 Trial - (Comprehensive Use of Pathologic Response Assessment to Optimize Therapy in HER2-Positive Breast Cancer) CompassHER2 Residual Disease (RD), a Double-Blinded, Phase III Randomized Trial of T-DM1 Compared With T-DM1 and Tucatinib *Local PI: Jami Fukui, MD*	• HER2+ breast cancer • cT1-4, N0-3 at initial diagnosis • Must have had THP, TMP, AC-THP, TCHP, FAC-THP or FEC-THP • No prior T-DM1 • Residual disease post-op • If HR+, residual dz must be in nodes • If HR-, breast only residual disease ok	Trastuzumab emtansine (T-DM1) ± Tucatinib	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, KMCWC, Pali Momi, Straub, QMC	NCT04457596
Adjuvant	NRG-BR007	A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER-2 Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer *Local PI: Jami Fukui, MD*	• Newly diagnosed stage 1 (pT1N0) unilateral hormone receptor positive, HER2 neg breast ca • Oncotype score <18 • Note - If pt does not have Oncotype, central testing can be covered by Genomic Health • Must've had lumpectomy. Mastectomies are not eligible	Endocrine Therapy ± Breast Radiation Therapy	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, KMCWC, Straub, QMC **XRT:** TCCOH & QMC	NCT04852887
Adjuvant	ALLIANCE-A012103	OptimICE-PCR: De-Escalation of Therapy in Early-Stage TNBC Patients Who Achieve pCR After Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy *Local PI: Jami Fukui, MD*	• Stage T1cN1-2 or T2-4N0-2 breast cancer • Must have no residual invasive disease in the breast or lymph nodes after the completion of neoadjuvant therapy. Residual DCIS is allowed. Isolated tumor cells are considered node-negative • ER and PR ≤10%; HER2-negative by ASCO/CAP guidelines • Patients must have received neoadjuvant chemotherapy in	Pembrolizumab vs. Observation	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, KMCWC, Straub, QMC	NCT05812807
Neoadjuvant	SWOG-S2212	Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study *Local PI: Jodi Kagihara, MD*	• TNBC • Must not have T4/N+, any N3, inflammatory, metastatic (M1) disease • No prior systemic therapy or radiation therapy • No previous definitive ipsilateral breast surgery • No prior therapy with anti-PD-1, anti-PD-L1, anti-PD-L2 agents, or agent directed to another stimulatory or co-inhibitory T-cell receptor	Arm 1: Usual 4 cycles of Carboplatin + Paclitaxel + Pembrolizumab 4 cycles of Doxorubicin + Cyclophosphamide + Pembrolizumab Arm 2: Shorter tx 6 cycles of Carboplatin + Docetaxel + Pembrolizumab	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, Pali Momi, Straub **Pending**: QMC	NCT05929768
Advanced / Metastatic 2nd line							
Metastatic	SWOG-S1703	Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored With Serum Tumor Marker Directed Disease Monitoring (STMDDM) Versus Usual Care in Patients With Metastatic Hormone Receptor Positive Breast Cancer *Local PI: Jeffrey Berenberg, MD*	• Stage IV, HR+, Her2- breast cancer • De-novo or recurrent disease ok • STMs at diagnosis & ± 14 days of start of 1st line treatment • CEA required, at least one of CA 15-3 & CA 27.29 • One value must be ≥ 1.5x ULN at baseline. • May be registered up to 14 days prior to first tx and up to 60 days	SoC imaging vs. Tumor Markers	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, KMCWC, QMC	NCT03723928
Symptom Management							
Symptom Management	SWOG-S2010	Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Vs Patient Education Alone to Improve Persistence With Endocrine Therapy in Young Women with Stage I-III Breast Cancer (ASPEN) *Local PI: Christa Braun-Inglis, APRN*	• Stage I-III HR+ breast cancer; No distant mets • Pre- or peri- menopausal at time of breast cancer diagnosis • Must have started endocrine therapy in last 14 days or plan to start within 14 days • Pts w/ ovarian function must plan for suppression or ablation	Active Symptom Monitoring (ASM) + patient education vs. Patient Education Alone	Courtney Chun cchun@cc.hawaii.edu	**Open**: HCC, KMCWC, Straub, Pali Momi, QMC	NCT05568472
Prevention (Non Interventional)							
Exercise	FUKUI-2019-1	A Pilot Study: The Effect of Longitudinal Exercise Programming in Breast Cancer Patients *Local PI: Jami Fukui, MD*	• Stage I-III breast cancer diagnosed within 2 years • May be on adjuvant treatment • Be able to lay flat on their back for 10 minutes	Group exercise program vs. Monitoring	Matthew Toyama Mtoyama@cc.hawaii.edu	**Open**: RHOP **Pending**: HPH, QMC	NCT04013568
Surgical Procedure	NRG-CC008	A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-Oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROCk] *Local PI: Jami Fukui, MD*	• Age 35-50 • BRCA1 mutation • May be premenopausal or menopausal	Bilateral salpingectomy vs. bilateral salpingo-oophorectomy	Courtney Chun cchun@cc.hawaii.edu	**Open**: KMCWC **Opt out**: QMC	NCT04251052

Screening (Non Interventional)							
Screening	ECOG-ACRIN-EA1151-TMIST	Tomosynthesis Mammography Imaging Screening Trial Lead-in *Local PI: Ashley Marumoto, MD*	• Age 45 - 74 & scheduled for screening mammogram • No history of breast cancer • No s/s of breast disease	Digital Mammography vs. Tomosynthesis	Cheyenne Tashombe CTashombe@cc.hawaii.edu	**Open**: QMC only	NCT03233191
GASTROINTESTINAL							
Colorectal							
Adjuvant	NRG-GI008	Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (CIRCULATE-US) *Local PI: Jared Acoba, MD*	• Stage IIB, IIC, or III colon adenocarcinoma with R0 resection • No radiographic evidence of mets • No MSI-H or dMMR tumors	Cohort A: ctDNA- Chemo vs. ctDNA testing Cohort B: ctDNA+ FOLFOX/CAPOX vs mFOLFIRINOX	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, Straub, Pali Momi, QMC	NCT05174169
Adjuvant	ALLIANCE-A022004	Randomized Trial of Consolidation Targeted Adjuvant Therapy With Encorafenib and Cetuximab Versus Usual Care for Patients With Stage II/III BRAF V600E Colon Cancer *Local PI: Jared Acoba, MD*	• Stage III (any T [Tx, T1, T2, T3, or T4], N1-2M0; includes N1C) or high-risk (pT4) stage II colon adenocarcinoma • BRAF V600E mutation • MMR proficient (pMMR) or microsatellite stable (MSS) tumor • Must have received at least 3 months of adjuvant chemotherapy with either FOLFOX (minimum of 5 cycles) or CAPOX (minimum of 3	Arm 1 Encorafenib PO, Cetuximab IV Arm 2 Observation	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, Straub, Pali Momi **Pending**: QMC	NCT05710406
Neoadjuvant	ALLIANCE-A022104	The Janus Rectal Cancer Trial: A Randomized Phase II Trial Testing The Efficacy of Triplet Versus Doublet Chemotherapy to Achieve Clinical Complete Response in Patients With Locally Advanced Rectal Cancer *Local PI: Jared Acoba, MD*	• Stage II-III rectal adenocarcinoma • Tumor site rectum, ≤ 12 cm from anal verge • No prior systemic chemotherapy, targeted therapy, or immunotherapy • No radiation therapy within the past 5 years	Long-course neoadjuvant radiotherapy (LCRT), FOLFOX or CAPOX vs. LCRT, FOLFIRINOX	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, QMC	NCT05610163
Prevention	NRG-CC005	Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps (FORTE) *Local PI: Scott Kuwada, MD*	• 1st time dx of 1-2 non-advanced tubular adenomas within 4 years prior to randomization • Sessile serrated polyps/adenomas will be considered as non-advanced adenomas	5-year and 10-year surveillance colonoscopy after qualifying colonoscopy	QMC - Vanessa Rubel vrubel@cc.hawaii.edu	**Open**: QMC **Opt out**: HPH	NCT05080673
Colorectal (Non Interventional)							
Adjuvant	CASSEL-2020-2	Improving Quality of Life for Colon Cancer Patients and Their Caregivers *Local PI: Kevin Cassel, DrPH*	• Must live in Hawaii • Stage II-III Colon cancer • Less than 90 days from surgery at the time of registration • Open to all islands & has caregiver	Video & Trainings to improve QoL	Natalia Lukey 808-564-3808	**Open**: HCC, Castle, Straub, Pali Momi, Kuakini, QMC	NCT04713007
Esophageal/ GEJ							
Peri-operative	ECOG-ACRIN-EA2174	Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients With Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma *Local PI: Jared Acoba, MD*	• T1N1-3M0 or T2-3N0-2M0 adenocarcinoma (Siewert I or II) • Surgical candidate for esophagectomy • No prior immunotherapy for any malignancy	Chemo/XRT ± Nivolumab → Surgery → Nivolumab ± Ipilumumab	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu	**Temporarily Closed to Accrual as of 12/29/2022**	NCT03604991
Unresectable, metastatic	ALLIANCE-A022102	Randomized Phase III Trial of mFOLFIRINOX vs. FOLFOX With Nivolumab for First-Line Treatment of Metastatic HER2- Gastroesophageal Adenocarcinoma *Local PI: Jared Acoba, MD*	•HER2 negative, unresectable or metastatic esophagus, gasteroesophageal junction, or stomach tumors • No prior tx for unresectable or metastatic disease • Prior neoadjuvant or adjuvant cytotoxic chemotherapy or adjuvant immunotherapy allowed if completed ≥ 1 year prior to registration	Arm 1 mFOLFIRINOX ± Nivolumab Arm 2 mFOLFOX ± Nivolumab	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open:** HCC, QMC **Pending:** HPH	NCT05677490
Hepatocellular / Cholangiocarcinoma							
No prior systemic treatment	ACOBA-2017-2	Phase II study of TSR-022 (COBOLIMAB) in combination with TSR-042 (DOSTARLIMAB) for the treatment of advanced hepatocellular carcinoma *Local PI: Jared Acoba, MD*	• HCC; BCLC B or C; Child Pugh A or B7 • No prior systemic treatment, prior local therapy ok as long as there is progression or a new lesion. • Measurable disease	Cobolimab + Dostarlimab	Erin Fukaya 808-691-8577 QMC ORD 808-691-8548	**Open**: HCC, QMC, OHSU	NCT03680508
Pre-Treatment	KWEE-2021-1	Clinical Trial of Biomarkers for Predicting Immunotherapy Response in Hepatocellular Carcinoma *Local PI: Sandi Kwee, MD*	• HCC • Does not qualify for surgical resection or locoregional therapy alone or has disease that has progressed after surgical resection and/or locoregional therapy • Plan to be treated to with an immune checkpoint inhibitor • Measurable disease	FCH PET/CT scan + ctDNA genomic profiling	Tim Kelleher, RN 808-691-8582 QMC ORD 808-691-8548	All sites may refer	NCT04965454
Neuroendocrine Carcinoma (NEC)							
Neuroendocrine Carcinoma (NEC)	SWOG-S2012	Randomized Phase II/III Trial of First Line Platinum/Etoposide With or Without Atezolizumab (NSC#783608) in Patients With Advanced or Metastatic Poorly Differentiated Extrapulmonary Neuroendocrine Carcinomas (NEC) *Local PI: Elizabeth Nakasone, MD*	• Extrapulmonary poorly differentiated NEC • Unresectable or metastatic • Radiologically evaluable, measurable or non-measurable • Must not have symptomatic central nervous system metastases • Must not have had prior tx for advanced or metastatic NEC; one cycle of platinum + etoposide is allowed	Arm 1 mFOLFIRINOX ± Nivolumab Arm 2 mFOLFOX ± Nivolumab	HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, Straub, Pali Momi **Pending**: QMC	NCT05058651
Pancreatic							

Pancreatic	ALLIANCE-A022106	Phase II/III Second-Line NABPLAGEM vs. Nab-Paclitaxel/Gemcitabine in BRCA1/2 or PALB2 Mutant Metastatic Pancreatic Ductal Adenocarcinoma (PLATINUM) *Local PI: Elizabeth Nakasone, MD*	• Metastatic pancreatic adenocarcinoma. Adenosquamous carcinoma, squamous carcinoma, acinar carcinoma, and other carcinomas • Pathogenic BRAC1/2 or PALB2 mutation (somatic or germline) • Measurable disease • Clinical or radiographic progression on first-line FOLFIRINOX or	Arm 1 Nab-paclitaxel + Cisplatin + Gemcitabine Arm 2 Nab-paclitaxel + Gemcitabine	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open:** HCC, Pali Momi, Straub **Pending:** QMC	NCT06115499
GYNECOLOGICAL							
Ovarian/Fallopian/Primary Peritoneal							
Adjuvant	NRG-GY019	A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum *Local PI: Michael Carney, MD*	• Newly diagnosed stage II-IV low grade serous carcinoma • p53 wildtype • Upfront cytoreductive surgery including BSO ≤ 8 weeks ago	Carboplatin + Paclitaxel Letrozole vs. Letrozole alone	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu	**Open**: KMCWC, Pali Momi, QMC	NCT04095364
Chemo-naive / Non-recurrent	NRG-GY026	**Registration to Stage I and Stage II is Temporarily Closed to Accrual as of 04/29/2024, Stage III or IV open** A Phase II/III Study of Paclitaxel/Carboplatin Alone or Combined With Either Trastuzumab and Hyaluronidase-oysk (HERCEPTIN HYLECTA) or Pertuzumab, Trastuzumab, and Hyaluronidase-zzxf (PHESGO) in HER2 Positive, Stage I-IV Endometrial Serous Carcinoma or Carcinosarcoma *Local PI: Michael Carney, MD*	• Stage IA-IVB, non-recurrent, chemotherapy-naive, HER2+ endometrial serous carcinoma or endometrial carcinosarcoma/metastatic HER2+ and HER2 low/null endometrial carcinoma • Within 8 weeks of primary surgery at registration • For uterine-confined (stage I) disease, tumor must be invasive into the myometrium • ECOG 0-2	Arm 1 Paclitaxel, Carboplatin Arm 2 Paclitaxel, Carboplatin, Herceptin Hylecta (Trastuzumab/Hyaluronidase-oysk) Arm 3 Paclitaxel, Carboplatin, Phesgo (Pertuzumab/Trastuzumab/Hyaluronidase-zzxf)	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu	**Open**: KMCWC, QMC	NCT05256225
Advanced / Recurrent	DB-1303-O-1001	A Phase 1/2a, Multicenter, Open-Label, Non-Randomized First in Human Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of DB-1303 in Patients with Advanced/Metastatic Solid Tumors *Local PI: Michael Carney, MD*	• Recurrent/metastatic HER2+ and HER2 low/null endometrial carcinoma • Progressed on or after at least 1 line of systemic treatment including platinum-based therapy • Must have exposure to immune checkpoint inhibitor • No more than 3 lines of therapy	DB 1303 Monotherapy	Robyn Morse 808-212-3440	**Open**: KMCWC only	NCT05150691
ComboMATCH	ECOG-ACRIN-EAY191-N4	A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients With Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers: A ComboMATCH Treatment Trial *Local PI: Michael Carney, MD*	• Must be enrolled on the ComboMATCH Master Registration Trial EAY191 • Must have RAS pathway mutant ovarian (primary peritoneal, fallopian tube) or endometrial cancer • Patients with ovarian cancer is not eligible for further platinum-	Regimen 1 Selumetinib + Olaparib PO Regimen 2 Selumetinib PO	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu	**Open:** KMCWC, QMC	NCT05554328
HEAD & NECK							
Oropharyngeal							
Newly Dx	NRG-HN005	A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients With Early-Stage, P16-Positive, Non-smoking Associated Oropharyngeal Cancer *Local PI: Richard Lee, MD*	• p16 positive oropharynx squamous cell carcinoma • Smoker (≥10 pack years): T1-2N2-3 or T3-4N0-3 • Non-smoker (<10 pack years): T4N0-3 or T1-3N2-3 • No prior treatment	Arm 1 70Gy XRT + Cisplatin Arm 2 60 Gy XRT + Cisplatin Arm 3 60 Gy XRT + Nivolumab	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu	**Temporarily Closed to Accrual as of 11/08/2023**	NCT03952585
Head & Neck							
Advanced / Recurrent	ECOG-ACRIN-EA3202	A Phase II/III Trial of Chemotherapy + Cetuximab vs Chemotherapy + Bevacizumab vs Atezolizumab + Bevacizumab Following Progression on Immune Checkpoint Inhibition in Recurrent/Metastatic Head and Neck Cancers *Local PI: David Saito, MD*	• HNSCC (excluding SCC of salivary glands, EBV-associated nasopharynx and skin) • Disease progression after at least 6 weeks of immune checkpoint inhibitor (ICI) tx in the first-line setting for recurrent/metastatic disease • Patient must not have a history of ≥ grade 3 immune-related adverse event on prior ICI therapy	Phase II Arm A Cetuximab, Docetaxel, Cisplatin, Carboplatin Phase II Arm B Docetaxel, Cisplatin/Carboplatin, Bevacizumab Phase II Arm C Bevacizumab, Atezolizumab Phase III Arm A Cetuximab, Docetaxel, Cisplatin/Carboplatin Phase III Arm B Chemotherapy, Bevacizumab, Atezolizumab	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, QMC **Opt out**: HPH	NCT05063552

Advanced	SWOG-S2101	Biomarker Stratified CaboZantinib (NSC#761968) and NivOlumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Participants With Advanced Solid Tumors (IO Refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers - an immunoMATCH Pilot Study *Local PI: David Saito, MD*	• Stage III or IV unresectable, recurrent, or metastatic non-uveal melanoma • Squamous cell carcinoma of the head and neck (HNSCC) that is either locally recurrent and nonamendable to curative therapy (e.g., radiation, surgery) or metastatic • Documented progression within 12 weeks after the last dose of PD-1 checkpoint inhibition-based therapy	Nivolumab and cabozantinib	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Temporarily Closed to Accrual as of 08/15/2024**	NCT05136196
Head & Neck Survivorship							
HN-STAR	WF-1805CD	Implementation and Effectiveness Trial of HN-STAR *Local PI: Christa Braun-Inglis, APRN*	• Primary or locoregionally recurrent H&N squamous cell carcinoma • Completed chemotherapy and/or radiation therapy with curative	HN-STAR survivorship tool vs. usual care	QMC - Erin Fukaya Efukaya@cc.hawaii.edu	**Open**: QMC only	NCT04208490
HEMATOLOGIC							
Leukemias							
Newly Dx	ECOG-ACRIN-EA9181	A Phase III Randomized Trial of Steroids + Tyrosine Kinase Inhibitor Induction With Chemotherapy or Blinatumomab for Newly Diagnosed BCR-ABL-Positive Acute Lymphoblastic Leukemia in Adults Local PI: *Craig Boddy, MD*	• Newly diagnosed B-ALL - BCR-ABL1 positive • Ph+ ALL determined locally • Ages 18-75 • No prior chemo for B-ALL; May be on steroids or TKI prior to step 1 registration to reduce disease burden	Prednisone + TKI ⍰ HyperCVAD + Sterioids + TKI vs. Blinatumomab + TKI	HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, Straub, Pali Momi **Opt out**: QMC	NCT04530565
Precursor B-Cell ALL	ALLIANCE-A041501	A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) With Newly Diagnosed Precursor B-Cell ALL *Local PI: Craig Boddy, MD*	• Newly diagnosed CD-22 positive B-cell acute lymphoblastic leukemia • Burkitts & BCR-ABL fusion not eligible. • No prior treatment; Limited corticosterioids ok • Age ≥ 18 years and < 40 years. • Patients with Down Syndrome excluded d/t excessive toxicities	SoC vs. SoC + Inotuzumab Ozogamicin	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu	**Temporarily Closed to Accrual as of 05/24/2022**	NCT03150693
Lymphomas							
Lymphoma (DLBCL)	SWOG-S1918	A Phase II/III Randomized Study of R-MiniCHOP With or Without CC-486 (Oral Azacitidine) in Patients Age 75 Years or Older With Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIB Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-Cell Lymphomas With MYC and BCL2 and/or BCL6 Rearrangements *Local PI: Craig Boddy, MD*	• DLBCL, Ann Arbor Stage IIX (bulky), III or IV; transformed dz ok • No prior treatment for DLBCL; Prior therapy for indolent lymphoma allowed. • Patients Age ≥ 75 Years • ECOG 0-2; Creatinine clearance ≥ 30	Reduced Dose Rituximab-Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-miniCHOP) vs. R-miniCHOP + Azacitidine	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, Straub, Pali Momi, QMC	NCT04799275
Lymphoma (DLBCL)	Abbvie-M20-621 (Protocol not available)	A Phase 3, Randomized, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with R-CHOP Compared to R-CHOP in Subjects with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL) (EPCORE DLBCL-2) *Local PI: Craig Boddy, MD*	• Newly diagnosed, histologicall confirmed CD20+ DLBCL • No prior hx of systemic anti-lymphoma tx for DLBCL other than corticosteroids with or without vincristine during pre-phase treatment, or non-curative intent palliative radiotherapy with the stipulation that radiated lesions cannot be selected as target lesion for response assessment	R-CHOP + Epcoritamab vs. R-CHOP + Rituximab	HPH - Robyn Morse robyn.morse@hawaiipacifichealth.org	**Open**: Straub	NCT05578976
LUNG							
Adjuvant							
Adjuvant	ALLIANCE-A151216	ALCHEMIST - Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial *Local PI: Jeffrey Berenberg, MD*	• Stage IB - IIIA; Resected • If Stage IB, Tumor must be ≥ 4 cm • No prior treatment; Planned adjuvant treatment ok	A081801 or E4512 (E4512 closed to accrual as of 05/10/2024)	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: TCCOH, HCC, Hawaii Oncology, KMCWC, Straub, Pali Momi, Kuakini, QMC	NCT02194738
Adjuvant	ALLIANCE-A081801	Integration of Immunotherapy Into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO *Local PI: Jeffrey Berenberg, MD*	ALCHEMIST Sub-Study • EGFR & ALK negative • Eligible for adjuvant treatment 30-77 days from surgery • Candidate for adjuvant platinum-doublet therapy	Platinum ± Keytruda ⍰ Maintenance Keytruda	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, Straub, Pali Momi, QMC	NCT04267848
Advanced / Metastatic 2nd line							
Advanced/ Recurrent	SWOG-LUNGMAP	LUNGMAP: A Master Protocol to Evaluate Biomarker-driven Therapies and Immunotherapies in Previously Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study) *Local PI: Jeffrey Berenberg, MD*	• Stage IV or Recurrent NSCLC • Must have had one line of therapy for any stage of disease • If prior therapy was for stage IV, must have had platinum • If prior therapy was for stage I-III, must be < 1 year ago • May be screened while on current therapy or at progression	Tissue to be evaluated for substudies	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, TCCOH, KMCWC, Straub, Pali Momi, QMC	NCT03851445

Advanced/ Recurrent	SWOG-S1900E	**Cohort 1 closed to accrual as of 12/13/2023 Cohort 2 will be closed to accrual as of 08/15/2024, Cohort 3 open** A Phase II Study of AMG 510 in Participants With Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LUNG-MAP SUB-STUDY) *Local PI: Jeffrey Berenberg, MD*	LUNGMAP Sub-Study • KRAS mutation found by LUNGMAP protocol • Non-squamous histology • Measurable disease • No active brain mets or spinal cord compression	Sotorasib (AMG 510) Monotherapy	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, Straub, Pali Momi, QMC	NCT04625647
Advanced/ Recurrent	SWOG-S1900G	A Randomized Phase II Study of INC280 (Capmatinib) Plus Osimertinib With or Without Ramucirumab in Participants With EGFR-Mutant, MET-Amplified Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study) *Local PI: Nicolas Villanueva, MD*	LUNGMAP Sub-Study • NSCLC with a sensitizing EGFR mutation and have radiologically or clinically progressed on osimertinib, alone or in combination with other agent(s), as their most recent line of therapy • MET amplification determined by tissue-based or blood-based	Arm A Capmatinib, osimertinib, ramucirumab Arm B Capmatinib, osimertinib	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, QMC **Opt out**: HPH	NCT05642572
Recurrent	SWOG-S2302	Pragmatica-Lung: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) Plus Pembrolizumab (MK-3475; NSC 776864) Versus Standard of Care for Participants Previously Treated With Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer *Local PI: Nicolas Villanueva, MD*	• Stage IV or Recurrent NSCLC • Must have had one line of therapy for any stage of disease • Must have received platinum-based chemotherapy and experienced disease progression • Anti-PD-1/PD-L1 may have been given alone or in combination with other therapy; must have experienced disease progression ≥ 84 days from most recent anti-PD-1/PD-L1 therapy	Arm A Standard of Care with chemotherapy Arm B Ramucirumab + Pembrolizumab	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, QMC, Straub, Pali Momi	NCT05633602
Advanced	NRG-LU008	Phase III Prospective Randomized Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed by Concurrent Mediastinal Chemoradiation for Locally Advanced Non-Small Cell Lung Cancer *Local PI: Michael Roach, MD*	• Stage II or III (AJCC Eighth Edition) non-small cell lung cancer (NSCLC) with known PD-L1 status • No evidence of distant metastases based on FDG PET/CT scan obtained within 60 days of registration	Arm A Radiation with concurrent chemotherapy Arm B SBRT with concurrent chemotherapy	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, QMC **XRT**: QMC **Opt out**: HPH	NCT05624996
Small Cell							
Post-adjuvant	SWOG-S1827	A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer *Local PI: Michael Roach, MD*	• Any stage small cell lung cancer • No brain mets • Completed platinum based chemotherapy • Must have responded to first line treatment	MRI brain surveillance + Prophylactic brain radiation	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: TCCOH, HCC, Kuakini, Straub, Pali Momi, QMC	NCT04155034
OTHER - Includes CCDR, Screening, Symptom mangement, etc.							
Supportive Care							
Educate, Nurture, Advise, Before Life Ends (ENABLE)	URCC-18110CD	Implementing Palliative Care: Learning Collaborative vs. Technical Assistance *Local PI: Christa Braun-Inglis, APRN*	• Diagnosed within the last 90 days with an advanced cancer (newly diagnosed stage III/IV, recurrence, or progressive solid tumor cancer) • Expected survival of at least 6 months	Virtual Learning Collaborative vs. Technical Assistance	Courtney Chun cchun@cc.hawaii.edu	**Open**: QMC	NCT04062552
Parent-Child, Survivorship	FUKUI-2022-1	Enhancing Connections-Palliative Care: A Cancer Parenting Program for Patients With Advanced Cancer and Their Children *Local PI: Jami Fukui, MD*	• Parents with any late-stage, non-curable cancer • All therapies allowed • Age restriction, parent age 23-68 with a child age 5-17 living at home at least 50% of the time and residential with non-ill parent or	ECPC vs. Informational Intervention	The Enhancing Connections Research Office at: 206-685-0837	All sites may refer	NCT05477784
Chemotherapy-Induced Peripheral Neuropathy	URCC-19075	Multi-Center Randomized Controlled Phase II Trial of Exercise to Treat Chemotherapy-Induced Peripheral Neuropathy (CIPN) *Local PI: Christa Braun-Inglis, APRN*	• Cancer diagnosis • Received neurotoxic chemotherapy within the past 9 months • At least one CIPN symptoms • ECOG PS 0-1	Exercise intervention vs. Standard care	Courtney Chun cchun@cc.hawaii.edu	**Open**: HCC, KMCWC, Straub, Pali Momi **Opt out**: QMC	NCT04888988
Prevention, Chemotherapy-Induced Peripheral Neuropathy	SWOG-S2205	Ice Compress: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy *Local PI: Christa Braun-Inglis, APRN*	• Cancer diagnosis • Must be planning to begin neoadjuvant or adjuvant tx (protocol-specified chemotherapy regimens) for a solid tumor malignancy within 3 days after randomization • Must not have a history of Raynaud's phenomenon, cold agglutinin	Cryocompression vs. Continuous compression vs. Low cyclic compression	Courtney Chun cchun@cc.hawaii.edu	**Open**: KMCWC only	NCT05642611
Anorexia	ALLIANCE-A222004	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia *Local PI: Ashley Springer, APRN*	• Diagnosis of advanced cancer • 2-month weight loss of at least 5 pounds (patient report) or caloric intacke of less than 20 cal/kg of body weight per day (physician-estimated)	Olanzapine vs. Megestrol Acetate	Courtney Chun cchun@cc.hawaii.edu	**Open**: HCC, KMCWC, Straub, Pali **Pending**: QMC	NCT04939090
Symptom Management							
Fatigue	URCC-18007	Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue *Local PI: Jami Fukui, MD*	• Any cancer; Stable disease or NED • Worst level of fatigue in past week moderate to severe (≥ 4) • Completed therapy > 2 months prior	Bupropion vs. Placebo	Courtney Chun cchun@cc.hawaii.edu	**Open**: HCC, KMCWC, QMC	NCT03996265

Insomnia	URCC-19185	Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL) *Local PI: Christa Braun-Inglis, APRN*	• Any cancer with life expectancy of at least 12 months • Currently receiving any cancer treatment (surgery alone excluded) • Report sleep disturbance of 3 or greater on sleep disturbance question • No clinical diagnosis of obstructive sleep apnea or restless leg	Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) vs. Healthy Eating Education Learning (HEAL)	Courtney Chun cchun@cc.hawaii.edu	**Open**: HCC, KMCWC, Straub, Pali Momi, TCCOH **Opt out**: QMC	NCT04829539
Pain	WF-1901	Internet-delivered Management of Pain Among Cancer Treatment Survivors *Local PI: Christa Braun-Inglis, APRN*	• Diagnosis of invasive cancer • Pain of ≥ 4 on "Most days" • May be off treatment or receiving treatment in adjuvant or maintenance setting • If on analgesics, must be on stable dose	painTRAINER® vs. Enhanced Usual Care	Courtney Chun cchun@cc.hawaii.edu	**Open**: HCC, KMCWC, Straub, Pali Momi, QMC, FHP (Guam), TCCOH	NCT04462302
Survey							
Breast Cancer, Rural Time to Treatment Initiation	OKADO-2023-1	Improving time to treatment initiation for breast cancer patients in rural Hawaii *Local PI: Izumi Okado, PhD*	• 18 years or older • Reside in Hawaii • Have started first treatment for invasive breast cancer after 01/01/23 • Have treatment for invasive breast cancer for at least 2 months	None	Izumi Okado iokado@cc.hawaii.edu Care Coordination Study Team 808-356-5772	All sites may refer	—
Geriatrics							
Geriatric Survivorship health education	URCC-19178	Optimizing Functional Outcomes of Older Cancer Survivors after Chemotherapy The GEM-S Study *Local PI: Valerie Ferguson, APRN*	• 65 years of age or older • Completed/will complete curative chemotherapy for any solid tumor in last 6 months • Have surgery planned within six months of informed consent	Geriatric Evaluation and Management Survivorship Tool vs. Usual Care	Courtney Chun cchun@cc.hawaii.edu	**Open**: KMCWC, Straub, Pali Momi **Opt out**: QMC	NCT05006482
Financial Toxicity							
Metastatic / CCDR	SWOG-S1912CD (CREDIT)	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT) *Local PI: Christa Braun-Inglis, APRN*	• Metastatic solid tumor or hematologic malignancy • Recurrent tumors ok if first presentation of mets • Registered within 120 days from diagnosis • Must be willing to provide credit information including SSN • Spouse/Caregiver must also participate	Financial literacy training ± Financial counseling with Consumer Education and Training Services	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Open**: HCC, KMCWC, Pali Momi, Straub, QMC, FHP (Guam)	NCT04960787
Immune Checkpoint Inhibitor Toxicity							
Immune Checkpoint Inhibitor Toxicity	SWOG-S2013	Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study *Local PI: Judy Ko, APRN*	• Must plan to receive ICI-based therapy for a solid tumor malignancy within 7 calendar days after registration • If had prior ICI-based therapy, must have completed ICI-based therapy at least 180 days prior to registration	Observational: Biospecimen collection and questionnaire	HPH - James Tom James@cc.hawaii.edu HCC - Jasmine Chow jchow@cc.hawaii.edu	**Temporarily Closed to Accrual as of 05/06/2024**	NCT04871542
Genomic Tumor Board							
Genomic Tumor Board	SWOG-S2108CD	A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) in Intervention to Usual Practice to Increase Evidence-based Genome-informed Therapy *Local PI: Jami Fukui, MD*	• Solid tumor malignancy that is either recurrent, relapsed, refractory, metastatic, or newly dx Stage III-IV • May have started anti-cancer treatment for the current diagnosis. • MD anticipates pt will start new anticancer treatment within 6 months • Must have a genomic tumor test (GTT) ordered prior to registration with results pending	UHCC randomized to Group 1 - No intervention	QMC - Erin Fukaya Efukaya@cc.hawaii.edu HPH - James Tom James@cc.hawaii.edu HCC - Emily Kurth ekurth@cc.hawaii.edu	**Open**: HCC, KMCWC, Straub, Pali Momi, QMC	NCT05455606
Master Protocols							
ComboMATCH	ECOG-ACRIN-EAY191	Molecular Analysis for Combination Therapy Choice (ComboMATCH) *Local PI: Jeffrey Berenberg, MD*	• Measureable disease • Locally advanced or advanced histologically documented solid tumors requiring therapy	-	Jeffrey Berenberg, MD	**Open:** HCC, KMCWC, Straub, Pali Momi, QMC	NCT05564377
Division of Cancer Prevention Studies							
Screening	DCP-001	Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP) *Local PI: Jeffrey Berenberg, MD*	• Studies marked with • Meets study's eligibility and is approached for study participation	Verbal QoL	Jeffrey Berenberg, MD	**Open**: HCC, TCCOH, Castle, KMCWC, Straub, Pali Momi, QMC, TAMC, FHP (Guam)	—

Early onset malignancy	DCP-002	Early Onset Malignancies Initiative (EOMI): Molecular Profiling of Breast, Colorectal, Kidney, Liver, Prostate, and Multiple Myeloma among Racially and Ethnically Diverse Populations
		Local PI: Jeffrey Berenberg, MD
			• Patients with the following
			  • Breast cancer ≤ 45
			  • Kidney cancer & Myeloma ≤ 50
			  • Colon, Liver & Prostate cancer ≤ 55
			• Hispanic, non-Hispanic Black & White, American Indian, & Alaska
				Tumor tissue & blood collection	Jeffrey Berenberg, MD	**Temporarily Closed to Accrual as of 03/01/2024**	NCT04955808