Oncology Clinical Trial List September 2024

Breast	
*HER2-positive- based on pre treatment biopsy, IHC score of 3+ and/or *positive by in situ hybridization (ISH). Known HR status.* **Clinical stage T1-4, N0-3 disease and residual invasive disease postop are eligible.* **Residual HR-negative, HER2 positive (+) disease in the breast and/or lymph nodes per the surgical path report are eligible; but HR+ HER2+ cancers must have node-positive residual disease per the surgical path report* **Residual disease tissue not required to be HER2-positive, eligibility based on a positive HER2 status at initial cancer diagnosis* **Micrometastases in lymph nodes after preop therapy counts as residual disease, whereas the presence of isolated tumor cells does not* **Synchronous bilateral invasive disease are eligible provided both lesions were confirmed to be HER2-positive, and at least one lesion meets criteria* **Must have received neoadjuvant chemo with one of: THP; TMP; AC-TH(P); TCH(P); FAC-TH(P), or FEC-TH(P)* **Patients are randomized to 1 of 2 arms.* ***Arm I Active Comparator: (trastuzumab emtansine, placebo): Patients receive trastuzumab emtansine (T-DM1) IV over 30-90 minutes on day 1 & placebo orally (PO) twice daily (BID) on days 1-21. Treatment repeats every 21 days for up to 14 cycles in the absence of disease progression or unacceptable toxicity.* ***Arm II Experimental: (trastuzumab emtansine, tucatinib): Patients receive T-DM1 IV over 30-90 minutes on day 1 and tucatinib PO BID on days 1-21. Treatment repeats every 21 days for up to 14 cycles in the absence of disease progression or unacceptable toxicity.* **After completion of study treatment, patients are followed up at 30 days, then every 6 months for 10 years.*	The COMPASSHER2 Trrials (Comprehensive Use of OMPREHENSIVE 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 AND PLACEBO COMPARED WITH T-DM1 AND TUCATINIB *(Quality of Life Sub-Study Closed)* **NCORP A011801** **NCT04457596** https://clinicaltrials.gov/study/NCT04457596
ER+HER2- breast cancer **Histol/cyto diagnosis of locally advanced or metastatic ER+HER2 breast cancer, must have progressed after first line (1st line depends on phase we are in)* **Documentation of ER-positive tumor (≥1% positive stained cells) based on most recent tumor biopsy* **documentation of HER2-negative tumor: determined as immunohistochemistry score 0/1+ or negative by in situ hybridization* **must be willing to undergo medically induced menopause by treatment with the approved LHRH agonist such as goserelin, leuprolide or equivalent* **at least 1 measurable lesion as defined by RECIST version 1.1 not previously irradiated.* **ECOG - PS 0 or 1* **Adequate renal, liver, and bone marrow function.* **Resolved acute effects of prior therapy to baseline severity or CTCAE Grade 1*	A Randomized, Open-label, Phase 3 Study of Adjuvant Imlunetrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endrocine Therapy for ER+, HER 2- Early Breast Cancer with an Increased Risk of Recurrence **Eli Lilly J2J-MC-JZLH** **NCT05514054** https://clinicaltrials.gov/ct2/show/NCT05514054

Breast (Continued)	
*Untreated MBC HR+ *1 or more elevated breast markers (CEA, CA15-3, CA27.29) *need at least 2 markers done *No brain mets	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 HER-2 Negative Breast Cancer **S1703 (NCORP)** **NCT03723928** https://clinicaltrials.gov/ct2/show/NCT03723928

Anal and Colorectal	
*Histologically/cytologically confirmed Stage IV CRC with BRAF V600E mutation *Prior systemic treatment in metastatic setting (considered metastatic treatment if relapse/ metastasis < 6 mos from end of adj/neoadj treatmnt *SLI: 0-1 regimens *Phase 3: None *Measurable disease (Phase 3)/ Measurable or evaluable disease (Safety Lead-in) *ECOG PS 0-1 *Adequate organ function	An Open-label, Multicenter, Randomized Phase 3 Study of First line Encorafenib Plus Cetuximab With or Without Chemotherapy Agents versus Standard of Care Therapy with a Safety Lead-in of Encorafenib and Cetuximab Plus Chemotherapy In Participants with Metastatic BRAF V600E Mutant Colorectal Cancer **Pfizer C4221015** **NCT04607421** https://clinicaltrials.gov/ct2/show/NCT04607421

Non Small Cell Lung Cancer (NSCLC)	
*Advanced stage (stages IIIB-IV) NSCLC and confirmed METex14 skipping alterations who are initiating or already treated with a systemic therapy	Disease Registry on Patients with Advanced Non-small Cell Lung Cancer (NSCLC) Harboring METex14 Skipping Alterations MOMENT (Met nOn sMall cEll caNcer registry) **EMD Serono MS200095-0050 (MOMENT)** **NCT05376891** https://clinicaltrials.gov/ct2/show/NCT05376891
*Experimental: Arm A: Durvalumab + Tremelimumab + Platinum-based Chemotherapy *Durvalumab plus tremelimumab q3w for four 21-day cycles in combination with chemotherapy *Followed by maintenance therapy (durvalumab plus pemetrexed maintenance) every 4 weeks (q4w) until disease progression or unacceptable toxicity or treatment discontinuation. *During the maintenance therapy phase, participants will receive an additional cycle of durvalumab plus tremelimumab (plus pemetrexed, where applicable) at Week 16.	A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-Squamous Histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON) **Astra Zeneca D419ML00003 (Triton)** **NCT06008093** https://classic.clinicaltrials.gov/ct2/show/NCT06008093

DNA Evaluation, Liquid Biopsy, Gene Sequencing	
***Cohort B - No Cancer - no cancer diagnosis or stable nodule for at least 1 year by chest CT scan. (~70% no nodules and ~30% stable nodules anticipated)* ***Cohort C - Cancer, Non-Lung primary - pathologic diagnosis of non-lung cancer inclusive of TNM Stage, originating from: esophagus (upper), colon or rectum, pancreas, stomach (including lower esophagus), head & neck, bladder, kidney, or liver.*	DNA Evaluation of Fragments for Early Interception - - Lung Cancer Training Study **DELFI-L101** **(Cohort A closed to enrollment)** **NCT04825834** https://clinicaltrials.gov/ct2/show/NCT04825834
**Baseline blood draw before initial treatment* **Longitudinal blood draws every month to assess DNA changes* **No samples will be tested until sufficient samples have been collected study wide* **Physicians will not receive results* **However, patients can have blood tested up to 3 times free of charge on commercially available Guardant 360*	SIBYL: obServation of therapy response with lIquid BiopsY evaluation **Guardant 06-MX-001 (SYBIL)** **Not listed in NCT**

DNA Evaluation, Liquid Biopsy, Gene Sequencing (Cont'd)	
**Must have had/will have at least one dose of anti-PD-1/PD-L1 immunono* **Must have had/will have tumor biopsy prior to anti-PD-1/PD-L1 treatment* **Must have had/will have CT or MRI of tumor prior to anti-PD-1/PD-L1 immunotherapy* **Must have enough tissue available for protocol needs* *CANCERS* **Head and neck squamous cell carcinoma (HNSCC)* **Non-small-cell lung cancer (NSCLC) - *Small cell lung cancer (SCLC)* **Urothelial carcinoma (UCC) - *Cervical cancer* **Gastric or gastroesophageal junction adenocarcinoma* **Esophageal squamous cell carcinoma (ESCC)* **Triple-negative breast cancer (TNBC) - *Hepatocellular carcinoma (HCC)* **Renal cell carcinoma (RCC) - *Colorectal cancer (CRC)*	A Multicenter Cancer Biospecimen Collection Study **Cofactor Genomics, Inc. PREDAPT-2** **NCT04510129** https://clinicaltrials.gov/ct2/show/NCT04510129
Patients who are having surgery, or have had surgery with preserved specimens.* ****Breast, DCIS, Ovarian, Liver, Renal Cell Carcinoma, and Gastric cancer* ***must be newly diagnosed and have histologically confirmed cancer* ****Ovarian, Esophageal, Gastric, Liver, and Pancreatic cancer*** ***must be 35 to 80 years old* ***must be newly diagnosed/treatment naïve at time of collection* ***must be pre-therapy AND pre-surgery*	Cancer Tissue, Adjacent Normal Tissue, Urine and Peripheral Whole Blood Translational Oncology: Discovery and Evaluation of Biomarkers/Pharmacogenomics for the Diagnosis and Personalized Management of the Oncology Patient **MT Group MTG-015 Biospecimen** **(No NCT)**

Precision Medicine Basket Trials	
Screening: Large 1B; IIA or IIB; NSCLC Squamous Stage IB – IIIA; Free testing for EGFR, ALK and PD-L1	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) **A151216 (NCORP)** **NCT02194738** https://clinicaltrials.gov/ct2/show/NCT02194738

Smoldering Multiple Myeloma	
**ECOG PS 0-2, and adequate lab values, Measurable disease* **Asymptomatic high-risk smoldering multiple myeloma (SMM) within past 12 months* **Bone marrow aspirate &/or biopsy w/in 42 days of randomization and demonstrate 10-59% clonal plasma cells* **No lytic lesions, plasmacytoma, or unexplained hypercalcemia* **No known COPD or moderate-severe asthma* **No prior/concurrent systemic or radiation therapy for myeloma; *No contraindication to DVT prophylaxis/aspirin* **Not more than 1 focal marrow lesion on MRI of pelvis or spine* **No concurrent use of erythropoietin* **No prior glucocorticosteroid therapy for MML (but other glucocorti-costeroid use is permitted per protocol)* **No active, uncontrolled seizure disorder, or uncontrolled intercurrent illness* **No monoclonal gammopathy of undetermined significance* **No Gr 2 or higher peripheral neuropath* **No active, uncontrolled infection* **History of current/previous DVT or PE allowed but must take anti-coagulation* **No baseline NYHA classification III/IV heart failure* **HIV, HBV, HCV patients are eligible*	Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) **NCORP EAA173** **NCT03937635** https://clinicaltrials.gov/ct2/show/NCT03937635

Rollover Studies	
**Previously enrolled in a Pembrolizumab Study*	A Multicenter, Open label, Phase III Extension Trial to Study the Long-term Safety and Efficacy in Participants w/Advanced Tumors Who Are Currently on Treatment or in F/up in a Pembrolizumab Trial. **Merck MK-3475-587-00** **NCT03486873** https://clinicaltrials.gov/ct2/show/NCT03486873
**Previously enrolled in Tolmar2506A study*	Open-label, Safety Extension Study for Subjects with Hormone-Receptor-Positive (HR+), Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Breast Cancer Who Have Completed the OVarian Suppression Evaluating Subcutaneous Leuprolide Acetate in Breast Cancer (OVELIA) Study **Tolmar** **TOL2506A-EXT Extension Safety Study** **NCT05645536** https://clinicaltrials.gov/study/NCT05645536

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