

Lynn Cancer Institute Oncology Trials

Clinical Trials – November 2022

Eugene M. and Christine E. Lynn Office of Research Administration 561.955.4800

Center for Hematology-Oncology 561.955.6400 Radiation Oncology 561.955.4111

BREAST			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Jane Skelton, MD	Agendia FLEX Registry NCT03053193	MammaPrint, Blueprint, and Full-genome Data Linked with Clinical Data to Evaluate New Gene Expression Profiles: An Adaptable Registry (FLEX Registry)	https://clinicaltrials.gov/ct2/show/NCT03053193?term=NCT03053193&draw=2&rank=1
Naomi Dempsey, MD	Alliance A011801 NCT04457596	The CompassHER2 trials (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 and placebo compared with T-DM1 and tucatinib	https://clinicaltrials.gov/ct2/results?cond=&term=NCT04457596&entry=&state=&city=&dist=
Rashmi Benda, MD	CCTG (Canadian Clinical Trials Group) MA.39 NCT03488693	TAILOR RT: A RANDOMIZED TRIAL OF REGIONAL RADIOTHERAPY IN BIOMARKER LOW RISK NODE POSITIVE AND T3N0 BREAST CANCER	https://clinicaltrials.gov/ct2/results?cond=&term=NCT03488693&entry=&state=&city=&dist=
GASTROINTESTINAL			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link

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Stephen Grabelsky, MD	Astellas 8951-CL-5201 NCT03816163	A Phase 2, Open-Label, Randomized Study to Assess the Antitumor Activity and Safety of Zolbetuximab (IMAB362) in Combination with Nab-Paclitaxel and Gemcitabine (Nab-P + GEM) as First Line Treatment in Subjects with Claudin 18.2 (CLDN18.2) Positive, Metastatic Pancreatic Adenocarcinoma	https://clinicaltrials.gov/ct2/show/NCT03816163?term=NCT03816163&draw=2&rank=1
Warren Brenner, MD	Novocure EF-27 NCT03377491	Panova-3: Pivotal, randomized, open-label study of Tumor Treating Fields (TTFields, 150kHz) concomitant with gemcitabine and nab-paclitaxel for front-line treatment of locally-advanced pancreatic adenocarcinoma	https://clinicaltrials.gov/ct2/show/NCT03377491?term=NCT03377491&draw=2&rank=1
Warren Brenner, MD	Signatera/ BESPOKE 20-041-NCP NCT04264702	BESPOKE Study of ctDNA Guided Therapy in Colorectal Cancer Open to stage I and IV as of 7/11/22. Stage II and III on hold for analysis	https://clinicaltrials.gov/ct2/show/NCT04264702?cond=NCT04264702&draw=2&rank=1
Warren Brenner, MD	Gritstone GO-010 NCT05141721	A Phase 2/3, Randomized, Open-Label Study of Maintenance GRT-C901/GRT-R902, A Neoantigen Vaccine, in Combination with Immune Checkpoint Blockade for Patients with Metastatic Colorectal Cancer	https://clinicaltrials.gov/ct2/results?cond=&term=NCT05141721&cntry=&state=&city=&dist=

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Warren Brenner, MD	Aravive AVB500-PC-005 NCT04983407	A Phase 1b/2 Randomized Study of AVB-S6-500 plus Nabpaclitaxel and Gemcitabine in Patients with Locally Advanced or Metastatic Pancreatic Adenocarcinoma On hold until opening of Phase 2	https://clinicaltrials.gov/ct2/results?cond=&term=NCT04983407&cntry=&state=&city=&dist=
HEMATOLOGY			
ANEMIA			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
MULTIPLE MYELOMA			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link

LYMPHOMA/LEUKEMIA			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Spencer Bachow, MD	LOXO-BTK-20020 NCT04666038	A Phase 3 Open-Label, Randomized Study of LOXO-305 versus Investigator’s Choice of Idelalisib plus Rituximab or Bendamustine plus Rituximab in BTK Inhibitor Pretreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BRUIN-CLL-321)	https://clinicaltrials.gov/ct2/results?cond=&term=NCT04666038&cntry=&state=&city=&dist=

General Oncology			
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Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Genetic Registry	City of Hope National Medical Center 96144 No NCT # <i>GENETICS STUDY</i>	Molecular Genetic Studies of Cancer Patients and Their Relatives	<ul style="list-style-type: none"> Personal history or family history of cancer suggestive of presence of an inherited predisposition In a group known or suspected to have increased risk of carrying genetic alteration or of sustaining exposure that would place them at risk of cancer Willing historian to provide information or access Young age cancer diagnosis Multiple primary neoplasms in affected member Presence of rare tumor types in family Congenital malformations Any other family clustering of cancer Any other cancer-predisposing genetic disease/conditions
LUNG			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
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Matthen Mathew, MD	Merck MK7684A-003 NCT04738487	A Phase 3, Multicenter, Randomized, Double-Blind Study of MK-7684 with Pembrolizumab as a Coformulation (MK-7684A) Versus Pembrolizumab Monotherapy as First Line Treatment for Participants With PD-L1 Positive Metastatic Non-Small Cell Lung Cancer	https://clinicaltrials.gov/ct2/show/NCT04738487?cond=NCT04738487&draw=2&rank=1
Warren Brenner, MD	Biodesix BDX-00146 NCT03289780	An Observational Study Assessing the Clinical Effectiveness of VeriStrat® and Validating Immunotherapy Tests in Subjects with Non-Small Cell Lung Cancer	https://clinicaltrials.gov/ct2/show/NCT03289780?term=NCT03289780&draw=2&rank=1

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Matten Mathew, MD	Merck MK-7684A-008 NCT05224141	A Phase 3, Randomized, Double-Blind Study of MK-7684A in Combination with Etoposide and Platinum Followed by MK-7684A vs Atezolizumab in Combination with Etoposide and Platinum Followed by Atezolizumab for the First-Line Treatment of Participants with Extensive-Stage Small Cell Lung Cancer	https://clinicaltrials.gov/ct2/results?cond=&term=NCT05224141&cntry=&state=&city=&dist=&Search=Search
Matten Mathew, MD	AstraZeneca SAVANNAH D5084C00007 NCT03778229	A Phase II, Single Arm Study Assessing the Efficacy of Osimertinib in Combination with Savolitinib in Patients with EGFRm+ and MET+, Locally Advanced or Metastatic Non-Small Cell Lung Cancer who have Progressed Following Treatment with Osimertinib (The SAVANNAH Study)	https://clinicaltrials.gov/ct2/results?cond=&term=NCT03778229&cntry=&state=&city=&dist=
GENITOURINARY			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Alan Koletsky, MD	MSKCC / Pfizer C16-174 NCT03574571	DORA Trial: Phase III Trial of Docetaxel vs. Docetaxel and Radium-223 for Metastatic Castration-Resistant Prostate Cancer (mCRPC)	https://clinicaltrials.gov/ct2/show/NCT03574571?term=NCT03574571&draw=2&rank=1

Head and Neck			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link

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Head and Neck			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Michael Kasper, MD	Monopar Therapeutics MNPR-301-001 NCT04648020	A Phase 2b/3, multicenter, randomized, double-blind, placebo-controlled study comparing the efficacy and safety of clonidine mucoadhesive buccal tablet to placebo to prevent chemoradiotherapy-induced severe oral mucositis in patients with oropharyngeal cancer	https://clinicaltrials.gov/ct2/show/NCT04648020?term=NCT04648020&draw=2&rank=1

Skin			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Hilary Gomolin, MD	HUYA Bioscience International HBI-8000-303 NCT04674683	A Multicenter, Randomized, Double-Blind Phase 3 Study of HBI-8000 Combined with Nivolumab versus Placebo with Nivolumab in Patients with Unresectable or Metastatic Melanoma Not Previously Treated with PD-1 or PD-L1 Inhibitors	https://clinicaltrials.gov/ct2/results?cond=&term=NCT04674683&cntry=&state=&city=&dist=&Search=Search

Neurology and Neuro-Oncology			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Sajeel Chowdhary, MD	Denovo DB102-01 NCT03776071	A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Enzastaurin Added to Temozolomide During and Following Radiation Therapy in Newly Diagnosed Glioblastoma Patients Who Possess the Novel Genomic Biomarker DGM1	https://clinicaltrials.gov/ct2/show/NCT03776071?term=NCT03776071&draw=2&rank=1

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Neurology and Neuro-Oncology			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Sajeel Chowdhary, MD	National Cancer Institute/Alliance N0577 NCT00887146	Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma	https://clinicaltrials.gov/ct2/show/NCT00887146?term=NCT00887146&draw=2&rank=1
	Scripps 1R01CA229737-07 No NCT #	Clinical Translation of Precision Medicine Testing Utilizing 3 Dimensional Primary Tumor Cell Culture Enrollment paused pending revised protocol	<ul style="list-style-type: none"> • Patients scheduled to have surgery for removal of brain tumor. • Age: 18 years and older.
Sajeel Chowdhary, MD	Alliance A071701 NCT03994796	Genetic Testing in Guiding Treatment for Patients with Brain Metastases	https://clinicaltrials.gov/ct2/show/NCT03994796?term=NCT03994796&draw=2&rank=1
Sajeel Chowdhary, MD	Alliance A071401 NCT02523014	Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas With SMO/AKT/NF2/CDK sAPathway Mutations Effective 10/03/2022 abemaciclib cohort closed to accrual. AKT1, PIK3CA, PTE cohorts remain open to accrual	https://clinicaltrials.gov/ct2/results?cond=&term=NCT02523014&cntry=&state=&city=&dist=
Samuel Richter, MD	Canadian Clinical Trial Group (CCTG) CE.7 NCT03550391	A Phase III Trial of Stereotactic Radiosurgery Compared with Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) Plus Memantine for 5-15 Brain Metastases	https://clinicaltrials.gov/ct2/show/NCT03550391?term=NCT03550391&draw=2&rank=1

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Neurology and Neuro-Oncology			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Sajeel Chowdhary, MD	NRG Oncology NRG-BN010 NCT04729959	A Safety Run-in and Phase II Study Evaluating the Efficacy, Safety, and Impact on the Tumor Microenvironment of the Combination of Tocilizumab, Atezolizumab, and Fractionated Stereotactic Radiotherapy in Recurrent Glioblastoma Accrual opened to the safety run-in portion at dose level 2 (tocilizumab 8 mg/kg).	https://clinicaltrials.gov/ct2/results?cond=&term=NCT04729959&cntry=&state=&city=&dist=.
Sajeel Chowdhary, MD	Novocure EF-32 (TRIDENT) NCT04471844	A Pivotal Randomized, Open-Label Study of Optune® (TTFields, 200kHz) Concomitant with Radiation Therapy and Temozolomide for the Treatment of Newly Diagnosed Glioblastoma	https://clinicaltrials.gov/ct2/show/NCT04471844?term=NCT04471844&draw=2&rank=1

SOLID TUMORS			
Principal Investigator	Sponsor/Study ID NCT #	Protocol Description	URL Link
Warren Brenner, MD	Medicenna MDNA11-01 NCT05086692	A Phase 1/2 Open Label, Dose Escalation and Expansion Study of MDNA11, IL-2 Superkine, Administered Alone or in Combination with Immune Checkpoint Inhibitor in Patients with Advanced Solid Tumors ABILITY (A Beta-only IL-2 ImmunoTherapY) STUDY	https://clinicaltrials.gov/ct2/results?cond=&term=NCT05086692&cntry=&state=&city=&dist=&Search=Search