

Principal Investigator Portfolio

Erik Letko, MD
Location: Rock Creek
Area of expertise: Ophthalmology

ACTIVELY ENROLLING

Humanitarian Use Device - Keratoconus patients where a corneal transplant is the only remaining option to improve vision

Title: Correction of Myopia and Astigmatism Associated with Keratoconus Using Intacs Corneal Implants (INTACS)



Principal Investigator Portfolio

Miguel Mogyoros, MD
Location: Skyline
Area of expertise: Infectious Diseases

ACTIVELY ENROLLING

Expanded Access Program - Stamaril Yellow Fever Vaccine

Title: Expanded Access IND Program to Provide Stamaril Vaccine to Persons in the United States for Vaccination Against Yellow Fever



Principal Investigator Portfolio

Amit Sudan, MD
Location: Franklin
Area of expertise: Interventional Radiology

CLOSED TO ENROLLMENT

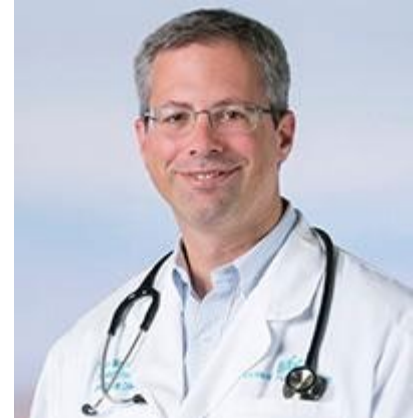
Renal Tumors

Title: Tracking Renal Tumors after Cryoablation Evaluation



Principal Investigator Portfolio

Daniel Mogyoros, MD
Location: Skyline
Area of expertise: Infectious Diseases



ACTIVELY ENROLLING

1) Expanded Access Program - Non-Tuberculosis Mycobacterial Infections

Title: Multiple Patient Program for Lamprene (clofazimine) for the treatment of Non-Tuberculous Mycobacterial (NTM) Infections (CLAM320B2002M)

CLOSED TO ENROLLMENT

1) Single Patient Use - Mycobacterial Diseases

Title: (Clofazimine SPU D.Mogyoros HKR) Single Patient Use Of Clofazimine For The Treatment Of Mycobacterial Disease

2) COVID-19

Title: Phase 3 Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of Ruxolitinib in Patients with COVID-19 Associated Cytokine Storm (RUXCOVID)

3) COVID-19

Title: An Open-Label Expanded Access Program of Ruxolitinib for the Emergency Treatment of Cytokine Storm From COVID-19 Infection (Ruxolitinib EAP)

Principal Investigator Portfolio

Rebecca Boxer, MD
Location: Waterpark III
Area of expertise: Geriatrics



CLOSED TO ENROLLMENT

Contraception

Title: A Multi-Center, Multi-National Clinical Study to Evaluate the Safety and Effectiveness of the Essure (Model ESS505) Device to Prevent Pregnancy in Women Who are Seeking Permanent Contraception

Principal Investigator Portfolio

Chris Shepela, MD
Location: Lone Tree
Area of expertise: Gastroenterology

ACTIVELY ENROLLING

Crohn's Disease

Title: A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of BMS-986165 in Subjects with Moderate-to-Severe Crohn's Disease



Principal Investigator Portfolio

Matthew Eadens, MD
Location: Franklin
Area of expertise: Oncology

CLOSED TO ENROLLMENT

Urothelial Cancer

Title: A Phase III Randomized, Controlled Clinical Trial of Pembrolizumab With or Without Platinum-Based Combination Chemotherapy Versus Chemotherapy in Subjects With Advanced or Metastatic Urothelial Carcinoma (MK-3475-361)



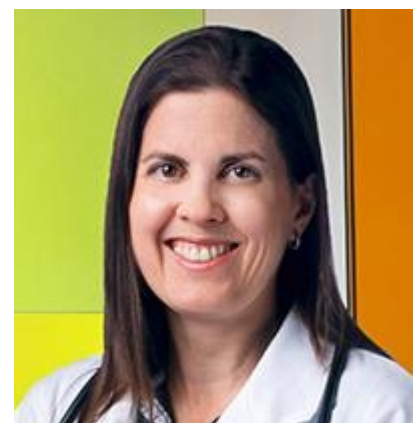
Principal Investigator Portfolio

Carla Saveli, MD
Location: Skyline
Area of expertise: Infectious Disease

CLOSED TO ENROLLMENT

COVID-19

Title: Access to Convalescent Plasma for the Treatment of Patients with COVID-19 (IND 19832)



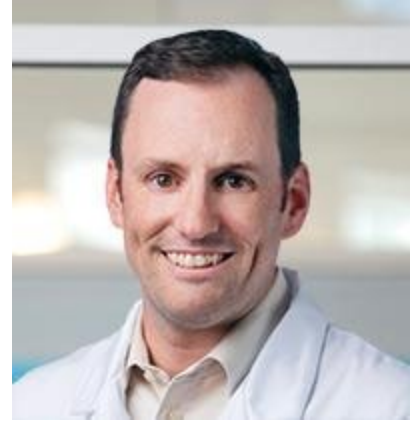
Principal Investigator Portfolio

Joshua Klopper, MD
Location: Skyline
Area of expertise: Endocrinology

CLOSED TO ENROLLMENT

Differentiated Thyroid Cancer (DTC)

Title: Clinical Performance Evaluation of a New Thyroglobulin Assay in Subjects with Differentiated Thyroid Cancer (TG II assay)



Principal Investigator Portfolio

Lanny Dunham Jr, MD
Location: Lone Tree
Area of expertise: General surgery

ACTIVELY ENROLLING

Pulmonary Nodule Resection Surgery

Title: Intraoperative, Percutaneous Localization of Peripheral Pulmonary Nodules for Resection: a Prospective, Open-Label, Multi-Center Registry Study of Thoracic Surgery Outcomes (PLOTS REGISTRY)



Principal Investigator Portfolio

Alex Menter, MD
Location: Lone Tree
Area of expertise: Oncology



ACTIVELY ENROLLING

1) High-Risk Anal Cancer

Title: A Randomized Phase II Study of Nivolumab after Combined Modality Therapy (CMT) in High Risk Anal Cancer (EA2165)

2) Breast Cancer

Title: Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women With Early Breast Cancer (A011401 (BWEL))

3) Stage III Colon Cancer & DNA Repair Disorder

Title: Randomized Trial of Standard Chemotherapy Alone or Combined With Atezolizumab as Adjuvant Therapy for Patients With Stage III Colon Cancer and Deficient DNA Mismatch Repair (A021502)

4) Stage II and III Bladder Urothelial Cancer

Title: Phase III Randomized Adjuvant Study of MK-3475 (Pembrolizumab) in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation (A031501)

5) Chronic Lymphocytic Leukemia (CLL)

Title: A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (≥ 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL)

6) Stage IB-III A Non-Small Cell Lung Cancer

Title: Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) (A151216)

7) Stage IB-III A Non-Small Cell Lung Cancer + ALK gene mutation

Title: A Randomized Phase III Trial for Surgically Resected Early Stage Non-small Cell Lung Cancer: Crizotinib Versus Observation for Patients With Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein (*Daughter study of ALCHEMIST*) (E4512)

8) Chronic Lymphocytic Leukemia (CLL)

Title: A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab Versus Ibrutinib and Obinutuzumab in Untreated Younger Patients With Chronic Lymphocytic Leukemia (CLL) (EA9161)

9) Triple-Negative Breast Cancer

Title: A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel With or Without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer (NRG-BR003)

10) Cancer Disparities in Trials

Title: Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (DCP-001)

11) Advanced Refractory Cancers/Lymphomas/Multiple Myeloma

Title: Molecular Analysis for Therapy Choice (MATCH)
Arms: After screening, patients assigned to 1 of 30 subprotocols

12) Solid Tumors; EGFR Activating Mutation

Title: Phase II Trial of Afatinib in Patients with Solid Tumors (Other Than Small Cell and Non-Small Cell Lung Cancer) or Lymphomas, That Have Activating Mutations of EGFR and Have Progressed After Standard Treatment (MATCH Substudy A)

13) EGFR T790M Mutation or Rare Activating Mutations of EGFR

Title: AZD9291 in Patients with Tumors Having EGFR T790M Mutations (Except Non-Small Cell Lung Cancer) or Rare Activating Mutations of EGFR (MATCH Substudy E)

14) Tumors with cKIT Exon 9, 11, 13, or 14 Mutation

Title: Phase II Study of Sunitinib in Patients with Tumors with cKIT Mutations (Excluding GIST, Renal Cell Carcinoma or Pancreatic Neuroendocrine Tumor) (MATCH Substudy V)

15) Recurrent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Title: A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (NRG-GY009)

16) Triple-Negative Breast Cancer

Title: A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer With ≥ 1 CM Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy (S1418)

17) Rare Tumors

Title: DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (S1609)

18) Stage III-IV High-Risk Melanoma

Title: A Phase II Randomized Study of Adjuvant vs. Neoadjuvant MK-3475 (Pembrolizumab) for Clinically Detectable Stage III-IV High-Risk Melanoma (S1801)

19) Cancer Treatment based on Molecular Alterations

Title: Profiling Biospecimens From Cancer Patients to Screen for Molecular Alterations Related to Treatment Selection (STRATA)

20) Breast Cancer Survivors with Cognitive Impairment after Chemotherapy Exposure

Title: A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors With Cognitive Impairment (WF-97116)

TEMPORARILY CLOSED TO ENROLLMENT

1) Non-Small Cell Lung Cancer

Title: Randomized Study of Erlotinib vs Observation in Patients With Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC) (*Daughter study of ALCHEMIST*) (A081105)

CLOSED TO ENROLLMENT

1) Node Positive HER2 Negative Breast Cancer

Title: A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for HER2 Negative Breast Cancer: The ABC Trial (A011502)

2) Stage IB-III A Non-Small Cell Lung Cancer

Title: Adjuvant Nivolumab in Resected Lung Cancers (ANVIL) - A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung (*Daughter study of ALCHEMIST*)

3) Castration-Resistant Metastatic Prostate Cancer

Title: Phase III Trial of Enzalutamide Versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer

4) Untreated Chronic Lymphocytic Leukemia

Title: A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)

5) Glioblastoma Multiforme

Title: A Phase II/III Randomized Trial Of Veliparib Or Placebo In Combination With Adjuvant Temozolomide In Newly Diagnosed Glioblastoma With MGMT Promoter Hypermethylation

6) Breast Cancer

Title: A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients With HER2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy

7) High risk HER2 Negative Breast Cancer + Germline BRCA 1/2 Mutation

Title: A Randomised, Double-blind, Parallel Group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients With gBRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

8) Advanced Transitional Cell Urinary Tract Cancer

Title: A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients With Advanced Transitional Cell Carcinoma

9) Metastatic Colon Cancer

Title: A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients With Resected Stage III Colon Cancer

10) Plasma Cell Myeloma/Multiple Myeloma

Title: Randomized Phase III Trial of Bortezomib, Lenalidomide, and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide, and Dexamethasone (CRd) Followed by Limited or Indefinite Duration Lenalidomide Maintenance in Patients With Newly Diagnosed Symptomatic Multiple Myeloma

11) Mantle Cell Lymphoma

Title: Intergroup Randomized Phase II Four Arm Study in Patients With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab + Bendamustine Followed By Rituximab Consolidation (RB → R); Arm B = Rituximab + Bendamustine + Bortezomib Followed By Rituximab Consolidation (RBV → R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB → LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV → LR)

12) Diffuse Large B Cell Lymphoma

Title: Randomized Phase II Open Label Study of Lenalidomide RCHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma

13) Melanoma

Title: A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon alfa-2b for Resected High-Risk Melanoma

14) Chronic Lymphocytic Leukemia or small lymphocytic lymphoma

Title: A Randomized Phase III Study of Ibrutinib (PCI-32765)-Based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients With Chronic Lymphocytic Leukemia (CLL)

15) Breast Cancer

Title: A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel With Bevacizumab or Placebo in Patients With Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer

16) Stage III and IV Melanoma

Title: Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma

17) Tumor Testing for Genetic Mutations

Title: COMET - Communication and Education in Tumor Profiling: A Randomized Study of Pre-disclosure Genetic Education v. Usual Care in Tumor Profiling for Advanced Cancer

18) ALK Rearrangements/Translocation

Title: Crizotinib in Patients with Tumors (other Than Adenocarcinoma of Lung or ALCL) with ALK Rearrangements (MATCH Substudy F)

19) ROS1 Translocation or Inversion

Title: Phase II Study of Crizotinib in Patients with ROS1 Translocations (Other Than Patients with Non-Small Cell Lung Cancer) (MATCH Substudy G)

20) BRAF V600E or V600K Mutations

Title: Phase II Study of Dabrafenib and Trametinib in Patients with Tumors with BRAF V600E or V600K Mutations (Excluding Melanoma, Thyroid Cancer, Colorectal Adenocarcinoma, and Non-Small Cell Lung Cancer) (MATCH Substudy H)

21) PIK3CA Mutation

Title: GDC-0032 (taselisib) in Patients with Tumors (other than breast cancer) with PIK3CA Mutation but without KRAS Mutation or PTEN Loss (MATCH Substudy I)

22) HER2 Amplification

Title: Ado-trastuzumab Emtansine in Patients with Tumors with HER2 Amplification (Except Breast and Gastric/Gastro-Esophageal Junction (GEJ) Adenocarcinomas) (MATCH Substudy Q)

23) BRAF Fusion or BRAF Non-V600 Mutation

Title: Phase II Study of Trametinib in Patients with BRAF Fusions, or with Non-V600E, Non-V600K BRAF Mutations (MATCH Substudy R)

24) NF2 Inactivating Mutation

Title: VS-6063 (defactinib) in Patients with Tumors with NF2 Loss (MATCH Substudy U)

25) AKT Mutation

Title: AZD5363 in Patients with Tumors with AKT Mutations (MATCH Substudy Y)

26) Stage III or IV Ovarian Cancer

Title: Veliparib With Carboplatin and Paclitaxel and as Continuation Maintenance Therapy in Subjects With Newly Diagnosed Stage III or IV, High-grade Serous, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

27) Breast Cancer

Title: A Phase III Randomized Trial of Metformin Versus Placebo on Recurrence and Survival in Early Stage Breast Cancer

28) Multiple Myeloma

Title: A Prospective, Longitudinal, Observational Study in Newly Diagnosed Multiple Myeloma (MM) Patients to Assess the Relationship between Patient Outcomes, Treatment Regimens and Molecular Profiles

29) Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Title: A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

30) Multiple Myeloma

Title: A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma Without an Intent for Immediate Autologous Stem Cell Transplant

31) Newly Diagnosed Cancer

Title: A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients

32) High-risk, Hormone Receptor Positive, HER2 Negative Breast Cancer

Title: Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients With High-Risk, Hormone Receptor-Positive and HER2/Neu Negative Breast Cancer

33) Stage III or IV Unresectable BRAF Mutant Melanoma

Title: A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAF V600E/K Mutant Melanoma

34) Advanced Squamous Cell Lung Cancer

Title: A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP)

35) Stage IV Squamous Cell Lung Cancer

Title: A Phase III Randomized Study of Nivolumab Plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (Lung-Map Sub-Study)

36) High-risk melanoma

Title: A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma

37) Metastatic pancreatic cancer

Title: Randomized Phase II Study of 2nd Line FOLFIRI Versus Modified FOLFIRI with PARP Inhibitor ABT-888 (Veliparib) (NSC-737664) in Metastatic Pancreatic Cancer

38) Recurrent Bladder Urothelial Cancer

Title: Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

39) Stage I, II, or III Colorectal Cancer

Title: Longitudinal Assessment of Financial Burden in Patients With Colon or Rectal Cancer Treated With Curative Intent (EAQ162CD)

40) Stage I, II, or III Breast or Gynecological Cancer

Title: Phase II Double Blind Dose Finding Trial of Bupropion Versus Placebo for Sexual Desire in Women With Breast or Gynecologic Cancer (NRG-CC004)

41) Non-Small Cell Lung Cancer

Title: A Randomized, Double-Blind, Placebo-Controlled Pilot Study of an Oral, Selective Peripheral Opioid Receptor Antagonist in Advanced Non-Small Cell Lung Cancer (A221504)

42) Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube or Primary Peritoneal Cancer

Title: A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS) (NRG-GY005)