

### **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)



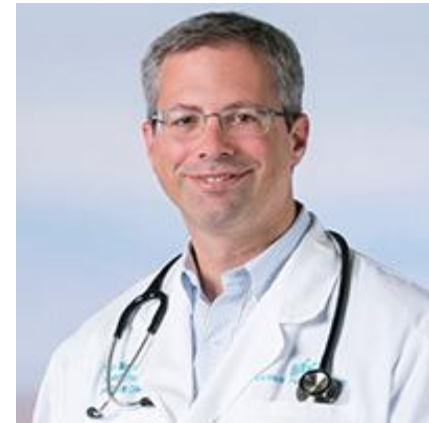
### **Principal Investigator Portfolio**

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

### **ACTIVELY ENROLLING**

**Expanded Access Program - Non-Tuberculosis Mycobacterial Infections**

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



### **Mpox Brincidofovir eIND**

Title: Emergency Use of Brincidofovir (TEMBEXA) for a Single Adult with Positive Results of Human Monkeypox Viral Testing

### **Principal Investigator Portfolio**

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

### **CLOSED TO ENROLLMENT**

### **Crohn's Disease**

Title: A Phase 4 Study Evaluating Real-World Use of CDPATH™, a Crohn's Disease Risk Prediction Tool



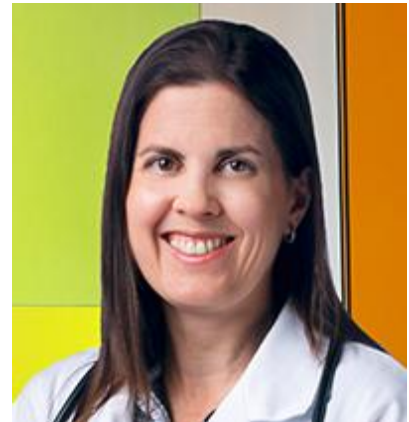
### **Principal Investigator Portfolio**

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

#### **ACTIVELY ENROLLING**

##### **TPOXX**

Title: Expanded Access IND Protocol: Use of Tecovirimat (TPOXX) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children



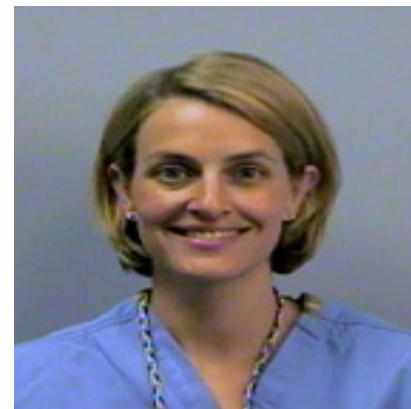
### **Principal Investigator Portfolio**

Toya Ellis, MD  
Location: East Denver  
Area of expertise: Obstetrics and Gynecology

#### **ACTIVELY ENROLLING**

##### **Genomic Markers in Menstrual Blood**

Title: Case-Control Study II of Genomic Markers in Menstrual Blood for Diagnosis of Uterine Disorders (NextGenJane)



### **Principal Investigator Portfolio**

Brittany Bastow, MD  
Location: East Denver  
Area of expertise: Obstetrics and Gynecology

#### **ACTIVELY ENROLLING**

##### **Endometriosis - HerResolve**

Title: HerResolve Clinical Performance Study



## **Principal Investigator Portfolio**

Debra Ritzwoller, PhD  
Location: Waterpark III  
Area of Expertise: Oncology (CCDR)



### **ACTIVELY ENROLLING**

#### **Metastatic Breast Cancer**

Title: (EAQ221CD) Improving Medication Adherence in Metastatic Breast Cancer using a CONnected Customized Treatment Platform (CONCURxP)

#### **CONNECT Intervention – Lung Cancer Caregivers**

Title: (WF2301CD) Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers.

#### **Health-Related Social Needs (HRSN) – Oncology Practices**

Title: (WF2303CD) Understanding and Enhancing Health-related Social Needs (HRSN) Screening Among Community Oncology Practices.

### **CLOSED TO ENROLLMENT**

#### **Cancer-Related Financial Hardship (Financial Navigation Intervention)**

Title: (S1912CD) A Randomized-Trial Addressing Cancer-Related Financial Hardship through Delivery of a Proactive Financial Navigation Intervention (CREDIT)

## **Principal Investigator Portfolio**

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



### **ACTIVELY ENROLLING**

#### **1) Stage IB-IIIa Non-Small Cell Lung Cancer**

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

#### **2) 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)

#### **3) Pain Management for Cancer Survivors**

Title: Internet-delivered Management of Pain Among Cancer Treatment Survivors (WF-1901)

#### **4) Cancer Related Fatigue (Breast Cancer)**

Title: Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue (URCC-18007)

#### **5) Resected Non-Small Cell Lung Cancer (NSCLC)**

Title: (A081801) Integration of Immunotherapy Into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO)

#### **6) Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)**

Title: (EA5182) Randomized Phase III Study of Combination Osimertinib (AZD9291) and Bevacizumab Versus Osimertinib (AZD9291) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)

#### **7) Colon Adjuvant Chemotherapy**

Title: (NRG-GI008) Colon Adjuvant Chemotherapy based on Evaluation of Residual Disease (CIRCULATE – US)

#### **8) Squamous Cell Carcinoma of Head and Neck**

Title: (NRG-HN009) Randomized Phase II/III Trial of Radiation with High-Dose Cisplatin (100 mg/m<sup>2</sup>) Every Three Weeks versus Radiation with Low-Dose Weekly Cisplatin (40 mg/m<sup>2</sup>) for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)

Updated on 1/15/2025

## **9) Immune Checkpoint Inhibitor: Anti-PD-1/Anti-PD-L1 Immunotherapy**

Title: (URCC-21038) Disparities in Results of Immune Checkpoint Inhibitor Treatment with anti-PD-1/anti-PD-L1 Immunotherapy in a Community Oncology Setting (DiRECT)

## **10) Lung MAP Screening – Non Small Cell Lung Cancer**

Title: A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)

## **11) Anti-PD-1 Therapy – Advanced Melanoma**

Title: (EA6192) A Phase II Study of Biomarker Driven Early Discontinuation of Anti-PD-1 Therapy in Patients with Advanced Melanoma (PET-Stop)

## **12) Behavioral Therapy – Randomized Control Trial**

Title: (URCC-19185) Multicenter Randomized Controlled Trial comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL).

## **13) FORTE – Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps**

Title: (NRG-CC005) FORTE – Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps

## **14) Multiple Myeloma**

Title: Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study) (S1803)

## **15) Triple-Negative Breast Cancer (TNBC)**

Title: (A012103) OptimICE-pCR: De-Escalation of Therapy in Early-Stage TNBC Patients Who Achieve pCR After Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy

## **16) Optimizing Endocrine Therapy (Breast Cancer)**

Title: Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions (A191901)

## **17) 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 (EA6141)

## **18) Immune Checkpoint Inhibitor Toxicity**

Immune Checkpoint Inhibitor Toxicity (I-CHECHIT): A Prospective Observational Study (S2013)

### **CLOSED TO ENROLLMENT**

#### **1) 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))

#### **2) 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)

#### **3) High-Risk Anal Cancer**

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

#### **4) 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*) (EA5142)

#### **5) 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)

#### **6) 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 ( $\geq 65$  Years of Age) with Chronic Lymphocytic Leukemia (CLL) (A041202)

#### **7) 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 (E1A11)

## **8) 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) (E1411)

## **9) Melanoma**

Title: A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon alfa-2b for Resected High-Risk Melanoma (E1609)

## **10) 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) (E1912)

## **11) 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 (E5103)

## **12) ALK Rearrangements/Translocation**

Title: Crizotinib in Patients with Tumors (other Than Adenocarcinoma of Lung or ALCL) with ALK Rearrangements (MATCH Substudy F) (EAY131)

## **13) 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)

## **14) 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)

## **15) 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)

## **16) 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)

## **17) 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)

## **18) NF2 Inactivating Mutation**

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

## **19) AKT Mutation**

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

## **20) 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 (GY004)

## **21) 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 (S1207)

## **22) High Risk Resected 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 (S1404)

## **23) 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  $\geq 1$  CM Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy (S1418)

## **24) 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)



### **25) 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)

### **26) HER2-Positive Metastatic Breast Cancer**

Title: A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer (NRG-BR004)

### **27) Advanced Refractory Cancers/Lymphomas/Multiple Myeloma**

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

### **28) Metastatic Untreated Colorectal Cancer**

Title: Randomized Double-Blind Phase III Trials of Vitamin D3 Supplementation in Patients with previously Untreated Metastatic Colorectal Cancer (SOLARIS) (A021703)

### **29) 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)

### **30) Chronic Lymphocytic Leukemia (CLL)**

Title: A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients ( $\geq$  70 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (A041702)

### **31) 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)

### **32) 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)

### **33) Rare Tumors**

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

### **34) Non-Small Cell Lung Cancer (NSCLC)**

Title: INSIGNA A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-Driven Analysis (EA5163)

### **35) 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)

### **36) Metastatic Untreated Renal Cell Cancer**

Title: PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab Vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated REnal Cell CancEr [PDIGREE] (A031704)

### **37) Peripheral Neuropathy**

Title: Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study (A221805)

### **38) Non-Small Cell Lung Cancer (NSCLC)**

Title: A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC (S1914)

### **39) PRAGMATICA – Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer**

Title: (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.

### **40) Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL) (EPCORE DLBCL -2)**

Title: (M20-621) 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)

### **Principal Investigator Portfolio**

Anuradha Gudavalli, MD

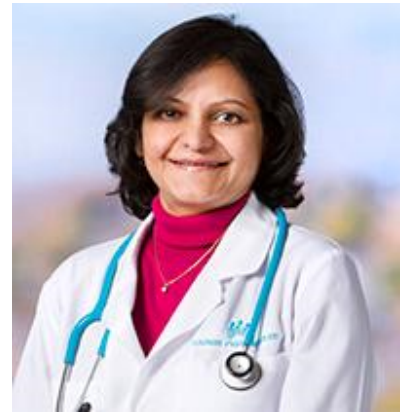
Location: Intermountain Health/Rock Creek

Area of expertise: Cardiology

### **ACTIVELY ENROLLING**

#### **Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial (CLASP II TR)**

Title: A prospective, multicenter, randomized, controlled pivotal trial to evaluate the safety and effectiveness of transcatheter tricuspid valve repair with the Edwards PASCAL Transcatheter Valve Repair System and optimal medical therapy (OMT) compared to OMT alone in patients with tricuspid regurgitation



#### **Surgical Mitral Valve Repair (REPAIR MR)**

Title: Percutaneous MitraClip™ Device or Surgical Mitral Valve REpair in PATients with PrlmaRy Mitral Regurgitation who are Candidates for Surgery

### **Principal Investigator Portfolio**

Shankar Perumal, MD

Location: Skyline

Area of Expertise: Neurology

### **ACTIVELY ENROLLING**

#### **Refractoy Focal Onset Epilepsy**

Title: A Phase 2/3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Study to Evaluate the Efficacy, Safety and Tolerability of BHV-7000 in Subjects with Refractory Focal Onset Epilepsy



## **Principal Investigator Portfolio**

Jill Gersh, MD

Location: Skyline/Lone Tree

Area of Expertise: Infectious Disease

### **ACTIVELY ENROLLING**

#### **Mpox JYNNEOS Vaccine EUA**

Title: Expanded Access IND Protocol: Use of Vaccinia Immune Globulin Intravenous (VIGIV, CNJ-016) for Treatment of Human Orthopoxvirus

