

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)



Principal Investigator Portfolio

Claudia Steiner, MD
Location: Waterpark III
Area of expertise: Internal Medicine

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

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



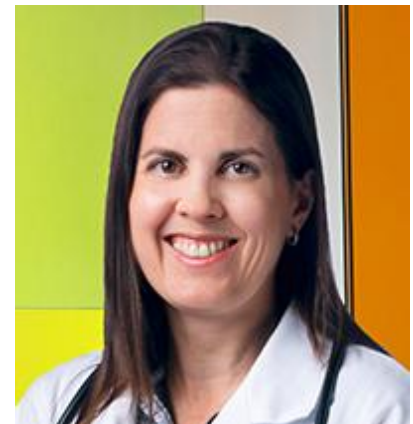
CLOSED TO ENROLLMENT

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



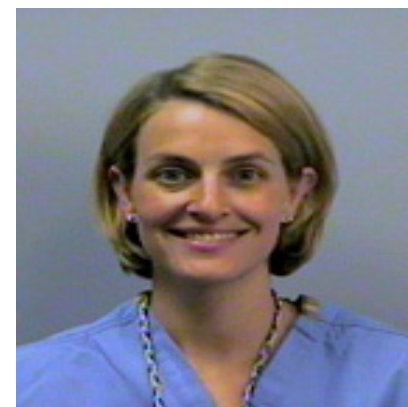
ACTIVELY ENROLLING

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

Adam Hebb, MD
Location: SCL/ Franklin
Area of Expertise: Neurological Surgery

ACTIVELY ENROLLING

DBS Dystonia Therapy

Title: Medtronic Activa Dystonia Therapy



Principal Investigator Portfolio

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

ACTIVELY ENROLLING

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)



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: (WF2300CD) Practice Survey for Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers

Principal Investigator Portfolio

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



ACTIVELY ENROLLING

1) Stage IB-III A 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) 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)

4) Pain Management for Cancer Survivors

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

5) Cancer Related Fatigue (Breast Cancer)

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

6) Resected Non-Small Cell Lung Cancer (NSCLC)

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

7) 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)

8) Colon Adjuvant Chemotherapy

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

9) Squamous Cell Carcinoma of Head and Neck

Title: (NRG-HN009) Randomized Phase II/III Trial of Radiation with High-Dose Cisplatin (100 mg/m²) Every Three Weeks versus Radiation with Low-Dose Weekly Cisplatin (40 mg/m²) for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)

10) 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)

11) 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)

12) 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)

13) 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).

14) 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

15) 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

16) 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)

17) 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)

18) 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

19) Optimizing Endocrine Therapy (Breast Cancer)

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

20) 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)

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) 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)

4) High-Risk Anal Cancer

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

5) 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)

6) 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)

7) 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) (A041202)

8) 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 (A071102)

9) 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 (B-50-I)

10) 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 (B-55)

11) 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)

12) 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 =

Updated on 07/05/2024

Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV → LR) (E1411)

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 (E1609)

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) (E1912)

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 (E5103)

16) ALK Rearrangements/Translocation

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

17) 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)

18) 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)

19) 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)

20) 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)

21) 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)

22) NF2 Inactivating Mutation

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

23) AKT Mutation

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

24) 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)

25) 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)

26) Advanced Squamous Cell Lung Cancer

Title: A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP) (S1400)

27) 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) (S1400I)

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)

28) Recurrent Bladder Urothelial Cancer

Title: Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (S1605)

29) 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)

30) 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)

31) 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)

32) 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)

33) 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)

34) 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)

35) 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)

36) Advanced Refractory Cancers/Lymphomas/Multiple Myeloma

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

37) 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)

38) 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)

39) 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)

40) 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) (A041702)

41) 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)

42) 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)

43) Rare Tumors

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

44) 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)

45) 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)

Updated on 07/05/2024

46) 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)

55) Immune Checkpoint Inhibitor Toxicity

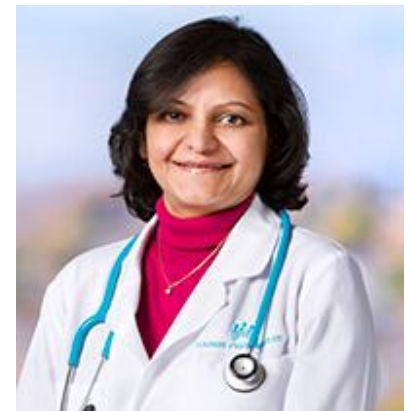
Title: Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A prospective observational study (S2013).

56) 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)

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