IMPROVE CARE

APRIL - JUNE 2020

TREAT DISEASE
IN GENERAL

Benaroya Research Institute oversees all clinical research at Virginia Mason and BRI, uniquely combining the expertise of a world-renowned biomedical research institute with the remarkable care of a healthcare quality leader.

BRI supports Virginia Mason clinical investigators in studies across a wide variety of diseases and conditions, such as cardiology and cancer, while the research led by BRI clinical investigators primarily focuses on diseases of the immune system such as type 1 diabetes, multiple sclerosis, rheumatic diseases, allergies and asthma.

The protocols listed in this booklet represent the major clinical trials approved by the Benaroya Research Institute Institutional Review Board for implementation by investigators at the Virginia Mason Medical Center. Information, protocols, consent forms and registration documents are available from these offices.

Alternatively, visit www.clinicaltrials.gov and enter the clinicaltrials.gov identifier listed for each study.

For questions, changes or additions to this booklet: Marvey Thao; (206) 342-6526 or MThao@BenaroyaResearch.org
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ANESTHESIA

Regional Versus General Anesthesia for Promoting Independence After Hip Fracture (REGAIN)

Treatment Arm(s):
A. Regional Anesthesia
B. General Anesthesia

Select Inclusion and Exclusion Criteria:
• Clinically or radiographically diagnosed intracapsular or extracapsular hip fracture
• Planned surgical treatment via hemiarthroplasty, total hip arthroplasty or appropriate fixation procedure
• Ability to walk 10 feet or across a room without human assistance before fracture
• NO Planned concurrent surgery not amenable to spinal anesthesia
• NO Absolute contraindications to spinal anesthesia
• NO Periprosthetic fracture

NIH Site: clinicaltrials.gov/ct2/show/NCT02507505
Study ID: IRB15153
PI: Wade Weigel, MD / CRC: Kelsey Yenney / (206) 287-6266
Pager: (206) 405-8786 / Kelsey.Yenney@virginiamason.org
The Allergy and Asthma Biorepository is a confidential list of people with allergies and asthma, who are willing to donate a blood sample and provide health information for scientific research. Donated samples and personal and family health information are used by scientists in the laboratory and in analysis to help us better understand the causes and long term health effects of allergies, asthma and immune-mediated diseases, as well as to explore better treatment options that can be used by physicians in patient care. All of the information gathered is kept confidential, and samples and health information used by scientists are coded with a number, not your name.

Participants are offered a $50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

**Select Inclusion Criteria:**
We are currently enrolling children and adults, one year of age and older, with physician diagnosed food and environmental allergies. We are especially looking for people with a history of severe allergies and anaphylaxis.

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy 'control' volunteer registry.

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: Allergy@BenaroyaResearch.org
The Celiac Disease Biorepository is a confidential list of people with celiac disease, who are willing to donate a blood sample and provide health information for scientific research. Donated samples and personal and family health information is used by scientists in the laboratory and in analysis to help us better understand the causes and long term health effects of gastrointestinal and immune-mediated diseases, as well as to explore better treatment options that can be used by physicians in patient care. All of the information gathered is kept confidential, and samples and health information used by scientists are coded with a number, not your name.

Participants are offered a $50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

Select Inclusion Criteria:
We are currently enrolling adults, age 18 and older, with a diagnosis of celiac disease.

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy ‘control’ volunteer registry.

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: Gastro@BenaroyaResearch.org
The Down Syndrome & Human Immunity Registry and Biorepository is a collaborative project between the BRI Translational Program and the Virginia Mason Down Syndrome Program, led by Rebecca Partridge, MD, PI, with co-investigators Bernard Khor, MD, PhD, and Jane Buckner, MD. The biorepository contains a confidential registry of individuals with and without autoimmune disease, who also have Down syndrome, and who are willing to donate biologic samples (e.g. blood).

People with Down syndrome have a significantly increased risk of getting autoimmune disease. BRI scientists are using donated samples and personal and family health information to better understand the relationship between Down syndrome and autoimmune disease. The main goal of this research is to identify new and better therapeutic targets to prevent and treat autoimmune diseases in people with Down syndrome, as well as the general population. The release of information and samples from the biorepository is governed by the BRI Institutional Review Board.

Participants are offered a $50 reimbursement for their time and effort and a parking voucher is provided for a Virginia Mason parking garage, as needed.

**Select Inclusion Criteria:**

We are currently enrolling individuals with Down syndrome who have Type 1 Diabetes and Celiac Disease, as well as those who do not have an autoimmune disease. In the coming months we will begin enrolling individuals with other autoimmune diseases.

We are also looking for friends and family members who do and do not have autoimmune disease to join one of our autoimmune disease registries, as well as our healthy ‘control’ volunteer registry.

**Contact:** Translational Registry and Biorepository  
Toll-free Line: 1-877-202-5200  
Email: DSR@BenaroyaResearch.org
Individuals, age one year and older, who do not have an autoimmune disease and are generally in good health donate a blood sample and provide health information to Benaroya Research Institute (BRI) to support scientific research. Donated samples and personal and family health information is used by scientists in the laboratory and in analysis to help us better understand the causes and long term health effects of autoimmune and other diseases, as well as to explore better treatment options that can be used by physicians in patient care. Samples also allow scientists to study how a healthy immune system works in comparison to one that has disease. All of the information gathered is kept confidential, and samples and health information used by scientists are coded with a number, not your name.

Participants are offered a $50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

*Select Inclusion Criteria:*

Individuals one year of age and older, who do not have an autoimmune disease, may be eligible to join the registry.

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: Control@BenaroyaResearch.org
Sound Life Project

This is a research study about understanding the immune system and learning why disease does and does not happen in people. We are asking healthy adults, between the ages of 25-35 and 55-65 to join this study, allowing us to observe the immune system and its responses over time. Participants are offered a $50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

Select Inclusion Criteria:

• Willing to donate blood to research
• Have personal iPhone or Android cell phone to download and use the health application
• Do NOT have any history of cancer, other than non-Melanoma skin cancers
• Do NOT have a chronic viral infection such as Hepatitis B, C, HIV/AIDS
• Have NOT had a major surgery in the past year
• NOT Anemic
• Do NOT have a first-degree relative with Rheumatoid Arthritis, Lupus, or Inflammatory Bowel Disease
• Do NOT use intravenous drugs

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: SoundLifeProject@BenaroyaResearch.org
The Infectious Diseases and Vaccines Registry and Biorepository is a collaborative project between the BRI Translational Program and Virginia Mason’s Department of Infectious Disease. The study contains a confidential registry of individuals who are willing to participate in vaccine studies, have had a viral infection, or are planning to travel to or have lived in a tropic virus risk area. Study participants provide health information and donate a blood sample. The donated samples and health information are used by scientists in the laboratory to better understand the causes and long-term health effects of infectious and bacterial diseases and how the immune system functions. The release of information and samples from the biorepository is governed by a clinical protocol that is approved and reviewed annually by the BRI Institutional Review Board.

**Select Inclusion Criteria:**

Adults age 18 years and older with no history of autoimmune disease and who:

- Are planning on getting a vaccine, such as influenza, tetanus, shingles, Yellow Fever, Japanese Encephalitis, etc.
- Have lived in a tropical virus risk area for 10 or more years, such as in India or a Southeast Asian country

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: IDR@BenaroyaResearch.org
The Inflammatory Bowel Disease Registry and Biorepository is a confidential list of people with inflammatory bowel diseases (IBD), such as Crohn’s disease and ulcerative colitis, who are willing to donate a blood sample and provide health information to support scientific research. Donated samples and personal and family health information are used by scientists in the laboratory and in analysis to help us better understand the causes and long term health effects of gastrointestinal and immune-mediated diseases, as well as to explore better treatment options that can be used by physicians in patient care. All of the information gathered is kept confidential, and samples and health information used by scientists are coded with a number, not your name.

Participants are offered a $50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

*Select Inclusion Criteria:*

We are currently enrolling adults, age 18 and older, with known or suspected history of inflammatory bowel disease.

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy ‘control’ volunteer registry.

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: Gastro@BenaroyaResearch.org
BIOREPOSITORIES

Multiple Sclerosis

The Multiple-Sclerosis – Neurological Diseases Registry and Biorepository is a collaborative project between the BRI Translational Program and the Virginia Mason Neurosciences Institute. The biorepository contains a confidential registry of individuals with multiple sclerosis (MS) or other neurologic diseases who are willing to provide personal and family health information to the registry and tissue samples (e.g., blood, CSF) to the repository. The samples and health information are used by scientists in the laboratory to better understand the causes and long-term health effects of MS and other immune-mediated neurologic diseases, as well as explore better treatment options that can be used by physicians in patient care. The release of information and samples from the biorepository is governed by a clinical protocol that is approved and reviewed annually by the BRI Institutional Review Board.

Participants are offered a $50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage as needed.

Select Inclusion Criteria:
We are currently enrolling adults, age 18 and older, with a diagnosis of multiple sclerosis who are and are not receiving immune modulating treatment.

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy ‘control’ volunteer registry.

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: Neuro@BenaroyaResearch.org
The Rheumatic Disease Registry and Biorepository is a collaborative project between the BRI Translational Program and Virginia Mason’s Department of Rheumatology. The biorepository contains a confidential registry of individuals with rheumatic diseases (e.g., rheumatoid arthritis, systemic lupus erythematosus) who are willing to provide personal and family health information to the registry and donate tissue samples (e.g., blood) to the repository. The donated samples and health information is used by scientists in the laboratory to better understand the causes and long-term health effects of rheumatic and other immune-mediated diseases, as well as explore better treatment options that can be used by physicians in patient care. The release of information and samples from the biorepository is governed by a clinical protocol that is approved and reviewed annually by the BRI Institutional Review Board.

Participants are offered a $50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

**Select Inclusion Criteria:**

Adults diagnosed with a rheumatic disease. We have a particular interest in obtaining samples from participants that are not on medication and those willing to give a sample when they are having a flare. Our current areas of study include:
- Rheumatoid Arthritis (RA)
- Systemic Lupus Erythematosus (SLE)

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy ‘control’ volunteer registry.

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**Contact:** Translational Registry and Biorepository  
Toll-free Line: 1-877-202-5200  
Email: RDR@BenaroyaResearch.org
The Diabetes Biorepository is a confidential list of people with type 1 diabetes who donate a blood sample and provide health information for scientific research. We invite you to participate in this research study to help us improve our understanding of diabetes and immune mediated diseases. The BRIDGE study was previously known as the JDRF Natural History study. The study consists of a computer registry where we store your contact, research and health information and a sample repository where we keep blood and other biologic samples for current and future use in our research.

Select Inclusion Criteria:
We are currently enrolling individuals with Type 1 Diabetes

Contact: BRI Diabetes Clinical Research Program
Toll-free Line: 1-800-888-4187
Email: Diabetes@BenaroyaResearch.org
A Cancer Registry and Specimen Repository developed to support ongoing and future research projects at Virginia Mason and BRI.

The VM BRITE Tissue Repository and Registry is designed to support ongoing studies and future studies by researchers at BRI, VM Medical Center, and their collaborators. The overall goal of these studies is to improve our knowledge of cancer using a combination of molecular, biochemical, and cellular approaches. More specifically, these studies will contribute to our understanding of the role the immune system plays in tumor development, tumor growth, and response to therapy. This research requires access to blood and/or tissue samples from people with the underlying disease(s) being studied. The release of information and samples from the biorepository is governed by a clinical protocol that is approved and reviewed annually by the BRI Institutional Review Board.

Select Inclusion Criteria:

Any tumor is a potential specimen for VM-BRITE. VM Pathology will retain adequate tissue for clinical purposes and release remaining tissue to VM-BRITE. Additionally, a blood draw (25-50 mL) will be required on the day of surgery for isolation of peripheral blood mononuclear cells and serum.

Study ID: IRB14138
PI: Flavio Rocha, MD / CRC: Jannefer Sengmany / (206) 287-6278
Pager: (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org
VM-BRI Repository For Early Detection Of Pancreas Cancer

As part of a national consortium effort to develop and test new molecular and imaging biomarkers to detect early stage PDAC and its precursor lesions and through a primary award to the Buffett Cancer Center at the University of Nebraska Medical Center (UNMC), we plan to develop a repository (the VM-BRIDPAN Registry) of serially collected, well annotated samples and selected clinical data from patients with benign and malignant diseases of the pancreas. This effort will contribute to a foundational dataset for discovery and evaluation of early detection markers for pancreas cancer.

Select Inclusion Criteria:

Age 21 and older and 1 or more of the following:

• Referral for suspected benign cystic lesions of the pancreas.
• Referral for surveillance or resection of previously diagnosed benign pancreatic neoplasms.
• Referral for suspected or confirmed pancreas cancer.
• Referral for suspected or confirmed pancreatitis.
• Referral for familial risk including familial pancreatic cancer mutations.
• NO Chemotherapy < 1 year prior to enrollment and/or sample collection
• NO Known anemia (hemoglobin < 10 g/dl)

Study ID: CRP18084
PI: Margaret Mandelson, PhD / CRC: Janet Zaltsman / (206) 287-6273
Pager: (206) 540-0704 / Janet.Zaltsman@VirginiaMason.org
This Disease Registry will collect data on patient characteristics, treatment patterns and clinical outcomes. The objective is to describe how newly diagnosed MDS, ICUS or AML patients are treated; and to build a knowledge base regarding the effectiveness and safety of front-line and subsequent treatment regimens in both community and academic settings. Enrolled patients will receive treatment and evaluations for MDS, ICUS or AML according to the standard of care and routine clinical practice at each study site. All treatments that patients receive for MDS, ICUS or AML will be recorded, including initial treatment and any subsequent therapy. Data on treatment outcomes, including response rates as measured by the treating physician, evidence of progression, survival, and patient-reported outcomes will be collected quarterly on the electronic CRF.

**Select Inclusion Criteria:**

- Newly diagnosed (confirmed diagnosis within 60 days prior to date of informed consent signature), primary or secondary Myelodysplastic Syndromes (MDS), or Acute Myeloid Leukemia (AML), or Idiopathic Cytopenia of Undetermined Significance (ICUS)
- AML patients must be at least 55 years of age at the time of informed consent signature
- MDS/ICUS patients must be at least 18 years of age at the time of informed consent signature.

**NIH Site:** clinicaltrials.gov/ct2/show/NCT01688011

**Study ID:** IRB13104

**PI:** David Aboulafia, MD/ CRC: Anas Najjar / (206) 287-6271

**Pager:** (206) 405-9124 / Anas.Najjar@VirginiaMason.org
**Immune-Mediated Diseases and Tumor Registry and Repository**

The immune system is responsible for protecting us from infectious disease and abnormal or diseased cells. Cancer cells can be destroyed by the immune system, but many cancer cells use ways to avoid being detected, allowing their growth to go unchecked. A new class of drugs, called “immune checkpoint inhibitors,” overcomes the main defense that some cancer cells have, allowing the immune system to attack and destroy them. The Immune Checkpoint Inhibitor (ICI) Cancer Research Study is designed to look at blood samples obtained from patients who will be receiving treatment with marketed checkpoint inhibitors. Blood samples from patients receiving immune checkpoint inhibitors will be stored in the Immune-Mediated Diseases and Tumor Registry and Repository. A comparison of longitudinally obtained matched blood samples from before and after treatment and, where available, tumor tissue, will enable us to characterize the immune cells responsible for attacking the tumor and to look for associated biomarkers for cancer and response to therapy.

*Select Inclusion Criteria:*

- Patients who have a malignancy that will be treated using checkpoint inhibitors, either alone or in combination with other treatments
- Patients who are at least 18 years old
- Patients who have signed the approved informed consent

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**Study ID:** CRP17064  
**PI:** John Paul Flores, MD / **CRC:** Jannefer Sengmany / **(206) 287-6278**  
**Pager:** (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org
Phase 1 Study of VE800 and Nivolumab in Patients With Selected Types of Advanced or Metastatic Cancer

Primary Objective(s):

Subjects will receive 5 days of oral vancomycin, followed by daily VE800 in combination with Nivolumab every 4 weeks

Select Inclusion and Exclusion Criteria:

• Patients with advanced or metastatic cancer who have received no more than 3 lines of prior systemic therapy for advanced/metastatic disease
• Histologically diagnosed advanced (unresectable) or metastatic cancer with at least one measurable lesion as per RECIST 1.1
• Toxicity from prior cancer therapy should resolve to CTCAE Grade ≤ 1 (excluding alopecia and neuropathy, where up to Grade 2 residual is allowed)
• Prior treatment with immune checkpoint inhibitor (iCPI) (Note: this criterion does not apply to patients with melanoma)
• Patients must not have received a transfusion (platelets or red blood cells) within 4 weeks of the first dose of study treatment
• Patients with known active hepatitis (e.g., hepatitis B or C) NOTE: Patients with previously treated hepatitis B or C are permitted to enroll if there is evidence of documented resolution of infection.

NIH Site: clinicaltrials.gov/ct2/show/NCT04208958
Study ID: CRP19106
PI: Bruce Lin, MD / CRC: Hannah Kreinbrink (206) 347-6276
Pager: (206) 541-9318 / Hannah.Kreinbrink@VirginiaMason.org
Pembrolizumab in Treating Patients With Locally Advanced Bladder Cancer (AMBASSADOR)

**Treatment Arm(s):**

A. Observation  
B. pembrolizumab

**Select Inclusion Criteria:**

- Histologically confirmed muscle-invasive urothelial carcinoma of the bladder or upper tract; variant histology allowed as long as urothelial carcinoma is predominant
- Patient must fit into one of the following three categories:
  - Patients who received neoadjuvant chemotherapy and pathologic stage at surgical resection is >= pT2 and/or N+ OR
  - Patients that decline adjuvant cisplatin-based or other systemic chemotherapy based on an informed discussion with the physician and pathologic stage at surgical resection is >= pT3 or pN+
  - Patient must have had radical surgical resection of their bladder cancer >= 4 weeks but <= 16 weeks prior to pre-registration
- No invasive cancer at the surgical margins

NIH Site: clinicaltrials.gov/ct2/show/NCT03244384  
Study ID: CRP19006  
PI: John Paul Flores, MD / CRC: Hannah Kreinbrink / (206) 347-6276  
Pager: (206) 541-9318 / Hannah.Kreinbrink@VirginiaMason.org
A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients With Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy

Treatment Arm(s):

A. Group 1A Lumpectomy: no regional nodal XRT with WBI
B. Group 1B Mastectomy: No regional nodal or chestwall XRT
C. Group 2A lumpectomy: Regional nodal XRT with WBI
D. Group 2B Mastectomy: Regional nodal XRT and chestwall XRT

Select Inclusion and Exclusion Criteria:

- ECOG performance status of 0 or 1
- Patient must have clinically T1-3, N1 breast cancer at the time of diagnosis (before neoadjuvant therapy)
- Patient must have had pathologic confirmation of axillary nodal involvement at presentation (before neoadjuvant therapy)
- Patient must have completed a minimum of 12 weeks of standard neoadjuvant chemotherapy consisting of an anthracycline and/or taxane-based regimen
- For patients who receive adjuvant chemotherapy after surgery, a maximum of 12 weeks of intended chemotherapy may be administered but must be completed before randomization
- Patients who have undergone either a total mastectomy or a lumpectomy are eligible
- NO Definitive clinical or radiologic evidence of metastatic disease

NIH Site: clinicaltrials.gov/ct2/show/NCT01872975
Study ID: IRB16024
PI: Huong Pham, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
A Phase I/II Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK525762 in Combination With Fulvestrant in Subjects With ER+ Breast Cancer

Treatment Arm(s):

A. GSK525762 + Fulvestrant (Phase I)
B. GSK525762 + Fulvestrant (Phase II)
C. Placebo + Fulvestrant (Phase II)

Select Inclusion and Exclusion Criteria:

- Females 18 years old and greater with histologically or cytologically confirmed diagnosis of advanced or metastatic adenocarcinoma of the breast.
- History of prior therapy that satisfies one of the following criteria:
  - Disease that progressed during treatment or within 12 months of completion of adjuvant therapy with tamoxifen and/or an aromatase inhibitor (AI).
  - Disease that progressed during treatment or within 1 month after the end of treatment with prior tamoxifen, AI, or cyclin-dependent kinase (CDK) 4/6 inhibitor plus letrozole, for advanced/metastatic disease.
  - ER-positive and/or progesterone receptor (PR)-positive tumor.
  - human epidermal growth factor receptor 2 (HER2)-negative tumor.
  - NO Prior therapy with more than one line of cytotoxic chemotherapy

NIH Site: clinicaltrials.gov/ct2/show/NCT02964507
Study ID: CRP17056
PI: Meaghan O’Malley, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
Breast Cancer Conserving Therapy

A Intra-Operative Radiotherapy after breast conserving therapy in the treatment of in situ and early stage breast cancer

Treatment Arm(s):
A. IORT Administration

Select Inclusion and Exclusion Criteria:
• Have ductal carcinoma-in-situ, pleomorphic lobular carcinoma-in-situ, invasive ductal carcinoma, invasive lobular carcinoma, or other variants of invasive breast carcinoma
• Have a unifocal lesion ≤3.0 centimeters on any imaging study. Patients with lobular histology muDebrast have lesions ≤3.0 seen on MRI
• Are candidates for partial mastectomy
• Have clinically and radiographically benign-appearing lymph nodes
• ≥ 45 years of age
• No scleroderma, systemic sclerosis and active lupus
• No previous ipsilateral radiation to the thorax or breast
• No participation in an investigational drug or device study
• No multifocal breast cancer or Neoadjuvant systemic therapy
• Premenopausal patients over the age of 45, who are of pregnancy potential, will have a preoperative serum beta HCG done to ensure the patient is not pregnant

NIH Site: clinicaltrials.gov/ct2/show/NCT02266602
Study ID: IRB11143
PI: Debra Wechter, MD / CRC: Chinmaya Rajderkar / (206) 287-6262
Pager: (206) 540-0121 / Chinmaya.Rajderkar@VirginiaMason.org
Triple Negative

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

Treatment Arm(s):
A. Observation
B. Pembrolizumab

Select Inclusion and Exclusion Criteria:

• histologically confirmed estrogen receptor (ER)-, progesterone receptor (PR)- and HER2-negative with residual invasive breast cancer
• must have had neoadjuvant chemotherapy followed by surgery
• must not have had prior immunotherapy with anti-PD-L1, anti-PD-1, anti-CTLA4 or similar drugs;
• Zubrod performance status =< 2

NIH Site: clinicaltrials.gov/ct2/show/NCT02954874
Study ID: CRP18056
PI: Meaghan O’Malley, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
Elacestrant Monotherapy vs. Standard of Care for the Treatment of Patients With ER+/HER2- Advanced Breast Cancer Following CDK4/6 Inhibitor Therapy: A Phase 3 Randomized, Open-label, Active-controlled, Multicenter Trial

Treatment Arm(s):

A. Subjects in Arm 1 will receive elacestrant
B. Subjects in Arm 2 will receive Investigator’s choice of one of the Standard of Care drugs (fulvestrant, anastrozole, letrozole, or exemestane)

Select Inclusion and Exclusion Criteria:

- Subjects with proven diagnosis of adenocarcinoma of the breast with evidence of either locally advanced disease not amenable to resection or radiation therapy with curative intent or metastatic disease not amenable to curative therapy.
- Female or male subjects age ≥ 18 years; female subjects must be postmenopausal women and male subjects must not allow pregnancy with their sperm (abstain, do not donate sperm, etc).
- Prior treatment with elacestrant, GDC-0810, GDC-0927, GDC-9545, LSZ102, AZD9496, bazedoxifene, or other investigational SERD or investigational ER antagonist.
- Presence of symptomatic visceral disease as defined in protocol.

NIH Site: clinicaltrials.gov/ct2/show/NCT03778931
Study ID: CRP19061
PI: Meaghan O’Malley, MD / CRC: Rachel Dowty/ (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
PACES: A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III – Preventing Adenomas of the Colon with Eflornithine and Sulindac

Treatment Arm(s):
A. eflornithine placebo + sulindac placebo
B. eflornithine + sulindac placebo
C. eflornithine placebo + sulindac
D. eflornithine + sulindac

Select Inclusion and Exclusion Criteria:
• Patients must have a history of Stage 0, I, II or III colon cancer that has been treated with resection alone or in combination with adjuvant chemotherapy.
• Must be registered between 274-465 days of primary resection.
• Must NED by postop colonoscopy and CT scans at least 274 days after resection.
• Must not have cardiovascular risk factors including uncontrolled high blood pressure, unstable angina, or history of MI or CVA.
• Patients must not be receiving or plan to receive concomitant corticosteroids, NSAIDs, or anticoagulants on a regular basis.
• Patients must not be expecting to receive radiation or additional chemotherapy.

NIH Site: clinicaltrials.gov/ct2/show/NCT01349881
Study ID: IRB15083
PI: Bruce Lin, MD / CRC: Jannefer Sengmany / (206) 287-6278
Pager: (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org
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

Treatment Arm(s):
Patients receive oxaliplatin IV over 2 hours and leucovorin calcium IV over 2 hours on day 1, and fluorouracil IV as a bolus on day 1, then continuously over 46 hours on days 1-3. Treatment repeats every 14 days for up to 12 cycles in the absence of disease progression or unacceptable toxicity. Patients also receive atezolizumab IV over 30-60 minutes starting on day 1 of cycle 1 or 2. Treatment repeats every 14 days for up to 25 cycles in the absence of disease progression or unacceptable toxicity.

Select Inclusion and Exclusion Criteria:

- Histologically proven stage III colon adenocarcinoma (any T [Tx, T1, T2, T3, or T4], N1-2M0; includes N1C); tumors must be deemed to originate in the colon including tumors that extend into/involving the small bowel (e.g. those at the ileocecal valve)
- Patients who are known to have Lynch syndrome and have been found to carry a specific germline mutation in an MMR gene (MLH1, MSH2, MSH6, PMS2) are eligible to participate
- No prior medical therapy (chemotherapy, immunotherapy, biologic or targeted therapy) or radiation therapy for the current colon cancer except for one cycle of mFOLFOX6
- No known active hepatitis B or C

NIH Site: clinicaltrials.gov/ct2/show/NCT02912559
Study ID: CRP19009
PI: Hagen Kennecke, MD / CRC: Hannah Kreinbrink / (206) 347-6276
Pager: (206) 541-9318 / Hannah.Kreinbrink@VirginiaMason.org
Early Rectal Cancer

Neoadjuvant Chemotherapy, Excision and Observation for Early Rectal Cancer

Treatment Arm(s):

A. Chemotherapy (FOLFOX or CAPOX) followed by tumour excision

Select Inclusion and Exclusion Criteria:

- Histologically confirmed invasive well-moderately differentiated rectal adenocarcinoma diagnosed within 90 days prior to enrollment.
- Tumour stage cT1-T3abN0 based on pelvic MRI
- cN0 stage based on pelvic MRI. Any nodes ≥ 10 mm in longest dimension are considered malignant, regardless of nodal morphology. For pelvic nodes < 10 mm in longest dimension, if nodes are seen and are deemed to be morphologically benign in the opinion of the radiologist and surgeon, the patient is eligible. Patients with visible pelvic sidewall nodes are excluded
- M0 stage based on no evidence of metastatic disease by CT imaging.
- Mid to low-lying tumour eligible for local tumour excision in the opinion of the treating surgeon.
- Age of at least 18 years. ECOG Performance Status of 0 or 1

NIH Site: clinicaltrials.gov/ct2/show/NCT03259035
Study ID: IRB17113
PI: Hagen Kennecke, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
SHORT: SHOrt course Radiation and TASOX (TAS102 plus Oxaliplatin) chemotherapy in operable rectal cancer, a phase II trial.

Treatment Arm(s):

Patients are initially treated with 25 Gy in five fractions of 5 Gy conformal pelvic radiation. Radiation is to be started within 3 weeks of registration. TASOX should be commenced within 3 weeks of radiation completion. Patients are treated with 6 x 14 day cycles of TASOX. Within 4 weeks of the end of cycle #6 of TASOX patients undergo re-staging. Surgery should be performed within 4 weeks AFTER day 14, cycle#6 of TASOX, ie. 28 days after day 14, cycle 6.

Select Inclusion and Exclusion Criteria:

- Age of at least 18 years.
- Newly diagnosis of rectal adenocarcinoma.
- ECOG Performance Status (PS): 0, 1 or 2.
- Candidate for sphincter-sparing surgical resection prior to initiation of neoadjuvant therapy according to the primary surgeon.
- Clinical Stage: T1/N1, T2/N1, T3/N1, T3c/dN0.
- Absence of metastatic disease.

Study ID: CRP18085
PI: Hagen Kennecke, MD / Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
Temporal Variation in Exhaled Volatile Organic Compounds in Response to Therapeutic Intervention in Esophageal Cancer Patients

Primary objective(s):

A. To determine longitudinal variation in exhaled VOC concentration during intended curative therapy for esophageal cancer (EC)
B. To correlate the exhaled VOCs of EC patients to important clinical parameters

Select Inclusion Criteria:

- aged 18-90 years
- newly diagnosed, treatment naive patients with esophageal and/or gastroesophageal junctional cancer
- planning to undergo curative treatment including neoadjuvant chemoradiotherapy and surgical resection

Select Exclusion Criteria:

- pregnant females
- without malignant esophageal disease
- patients undergoing palliative treatment for esophageal cancer
- patients not receiving neoadjuvant chemoradiotherapy and surgical resection for EC
- Inability or unwillingness to provide written informed consent

Study ID: CRP19015
PI: Donald Low, MD / Chinmaya Rajderkar / (206) 287-6262
 Pager: (206) 540-0121 / Chinmaya.Rajderkar@VirginiaMason.org
Phase 2 Study of ZW25 Plus First-line Combination Chemotherapy in HER2-Expressing Gastroesophageal Adenocarcinoma (GEA)

Treatment Arm(s):
A. ZW25 plus capecitabine and cisplatin
B. ZW25 plus fluorouracil (5-FU), leucovorin, and cisplatin
C. ZW25 plus 5-FU, leucovorin, and oxaliplatin
D. ZW25 plus capecitabine and oxaliplatin

Select Inclusion Criteria:
• Disease diagnosis:
• Part 1: Unresectable, locally advanced, recurrent or metastatic HER2-expressing GEA (IHC 3+ or 2+ with or without gene amplification based upon local assessment or central assessment)
• Part 2: Unresectable, locally advanced, recurrent or metastatic HER2-high GEA (IHC 3+, or IHC 2+ and FISH+ by central review)
• Tumor measurements as per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1:
  • Part 1: Measurable or non-measurable disease
  • Part 2: Measurable disease

NIH Site: clinicaltrials.gov/ct2/show/NCT03929666
Study ID: CRP19005
PI: Bruce Lin, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
Evaluation of the Lasting Symptoms After Esophageal Resection (LASER) questionnaire in esophageal disease

Primary Objective(s):

The primary objective of this project is to improve the care for patients that are treated for diseases of the esophagus at the General and Thoracic Surgery Department at the Virginia Mason Medical Center (VMMC). Secondary aims include; increased patient involvement and satisfaction, simplified data gathering of patient related outcomes (PRO) and improved clinical research and follow up of the included conditions.

Select Inclusion Criteria:

- Any patients, ≥ 18 years old, referred to the Thoracic Surgery Department for evaluation.
- Patients undergoing endoscopic therapies who are cared for jointly by both the surgical and gastroenterology teams.

Study ID: CRP18103
PI: Bruce Lin, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
Bemarituzumab (FPA144) Combined With Modified FOLFOX6 (mFOLFOX6) in Gastric/Gastroesophageal Junction Cancer

*ON HOLD*

Treatment Arm(s):

A. bemarituzumab (FPA144)+mFOLFOX6
B. Placebo+mFOLFOX6

Select Inclusion Criteria:

- Histologically documented gastric or gastroesophageal junctional adenocarcinoma (not amenable to curative therapy)
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1
- Adequate hematological, liver and kidney function. Measurable or non-measurable, but evaluable disease using RECIST v1.1
- FGFR2b overexpression as determined by a centrally performed IHC tissue test and/or FGFR2 gene amplification as determined by a centrally performed ctDNA blood based assay
- Candidate for mFOLFOX6 chemotherapy

NIH Site: clinicaltrials.gov/ct2/show/NCT03694522
Study ID: CRP18055
PI: Bruce Lin, MD / CRC: Jannefer Sengmany / (206) 287-6278
Pager: (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org
A Study to Evaluate the Efficacy and Safety of Pemigatinib Versus Chemotherapy in Unresectable or Metastatic Cholangiocarcinoma - (FIGHT-302)

Treatment Arm(s):

A. Pemigatinib  
B. Gemcitabine + Cisplatin

Select Inclusion Criteria:

- Histologically or cytologically confirmed cholangiocarcinoma that is previously untreated and considered unresectable and/or metastatic (Stage IV per the American Joint Committee on Cancer (AJCC) Cancer Staging Manual).
- Radiographically measurable or evaluable disease by CT or MRI per RECIST v1.1 criteria.
- Eastern Cooperative Oncology Group performance status 0 to 1.
- Documented FGFR2 rearrangement.
High-Risk Liver Bile Duct Cancer

Gemcitabine, Cisplatin, and Nab-Paclitaxel Before Surgery in Patients With High-Risk Liver Bile Duct Cancer

Treatment Arm(s):

A. Gemcitabine, cisplatin, nab-paclitaxel

Select Inclusion Criteria:

- Diagnosis of intrahepatic cholangiocarcinoma
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-1.
- Absolute neutrophil count (ANC) ≥ 1,500 cells/µL
- Platelet count ≥ 100,000 cells/µL
- Hemoglobin ≥ 9 g/dL
- Serum total bilirubin ≤ 1.5 x upper limit of normal (ULN)
- Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 2.5 x ULN

NIH Site: clinicaltrials.gov/ct2/show/NCT03579771
Study ID: CRP18066
PI: Flavio Rocha, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
CANCER
Hepatobiliary Malignancies

A Randomized, Controlled Phase 3 Study of Cabozantanib (XL184) in Combination with Atezolizumab versus Sorafenib in Subjects with Advanced Hepatocellular Carcinoma Who Have Not Received Previous Systemic Anticancer Therapy

Treatment Arm(s):

A. cabozantinib 40 mg oral, qd + atezolizumab 1200 mg infusion, q3w
B. sorafenib 400 mg bid (twice a day)
C. cabozantinib 60 mg qd

Select Inclusion Criteria:

- Histological or cytological diagnosis of HCC.
- The subject has disease that is not amenable to a curative treatment approach (eg, transplant, surgery, ablation therapy) or locoregional therapy (eg, TACE).
- Measurable disease per RECIST 1.1 as determined by the Investigator.
- Barcelona Clinic Liver Cancer (BCLC) stage Category B or C.
- Child-Pugh Score of A.
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

NIH Site: clinicaltrials.gov/ct2/show/NCT03755791
Study ID: CRP19012
PI: Bruce Lin, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
Safety and Efficacy of Pembrolizumab (MK-3475) Versus Placebo as Adjuvant Therapy in Participants With Hepatocellular Carcinoma (HCC) and Complete Radiological Response After Surgical Resection or Local Ablation (MK-3475-937 / KEY-NOTE-937)

Treatment Arm(s):

A. Pembrolizumab
B. Placebo

Select Inclusion Criteria:

• Has a diagnosis of HCC by radiological criteria and/or pathological confirmation.
• Has an eligibility scan confirming complete radiological response ≥4 weeks after complete surgical resection or local ablation.
• ECOG performance status of 0 within 7 days prior to Cycle 1, Day 1.
• Has a Child-Pugh class A liver score (5 to 6 points) within 7 days prior to Cycle 1, Day 1.
• Has alpha fetoprotein concentration lower than 400 ng/mL within 28 days prior to Cycle 1, Day 1.
• Has controlled hepatitis B (Hep B).
• Has recovered adequately from toxicity and/or complications from the local intervention (surgical resection or local ablation) prior to starting study treatment.

NIH Site: clinicaltrials.gov/ct2/show/NCT03867084
Study ID: CRP19025
PI: Bruce Lin, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
Imiquimod, Fluorouracil, or Observation in Treating HIV-Positive Patients With High-Grade Anal Squamous Skin Lesions

Treatment Arm(s):
A. Intra-anal Imiquimod
B. Intra-anal fluorouracil
C. Observation (no treatments)

Select Inclusion and Exclusion Criteria:
• HIV-positive
• Biopsy-proven HSIL
• Anal HSIL lesions are visible at study entry and no lesions are suspicious for invasive cancer
• Karnofsky performance status of >= 70%
• (CD)4 count >= 200 within 120 days prior to enrollment or plasma HIV-1 (RNA) < 200 copies/mL within 120 days prior to enrollment
• NO history of anal cancer
• NO Prior intra-anal use of topical 5-fluorouracil 5% or imiquimod 2.5%, 3.75% or 5% at any point, or use of perianal imiquimod 2.5%, 3.75% or 5% or topical 5-fluorouracil 5% within 6 months prior to enrollment
• NO Extensive concurrent perianal or lower vulvar HSIL or condyloma requiring a different treatment modality than the study treatment, or treatment that cannot be deferred in observation arm, per examining provider
• NO prior history of HPV Vaccination

NIH Site: clinicaltrials.gov/ct2/show/NCT02059499
Study ID: CRP17031
PI: David Aboulafia, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
AMC-095, Nivolumab and Ipilimumab in Treating Patients With Advanced HIV Associated Solid Tumors

Treatment Arm(s):

**INDUCTION PERIOD:** Patients receive nivolumab IV over 60 minutes on days 1, 15, 29, and 43 (dose level -1 and 1) or days 1, 22, 43, and 64 (dose levels -2 and 2). Patients in dose levels -2 and 2 also receive ipilimumab IV over 90 minutes on days 1, 22, 43, and 64. Patients with an overall response of irSD, irPR, irCR, or unconfirmed irPD at the end of the Induction Period will enter the Maintenance Period.

**MAINTENANCE PERIOD:** Patients receive nivolumab IV over 60 minutes every 2 weeks for up to 42 infusions.

Select Inclusion and Exclusion Criteria:

- histologically confirmed solid tumor malignancy that is metastatic or unresectable and for which standard curative or palliative measures do not exist or are no longer effective; participants with uncontrolled Kaposi sarcoma are permitted
- HIV+
- Prior therapy for metastatic disease permitted; at least 4 weeks must have elapsed since prior chemotherapy or biological therapy, 6 weeks if the regimen included carmustine (BCNU) or mitomycin C; radiotherapy must be completed at least 28 days prior to registration
- ECOG≤1

NIH Site: clinicaltrials.gov/ct2/show/NCT02408861
Study ID: IRB15134
PI: David Aboulafia, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
A Phase II Study of sEphB4-HSA in Kaposi Sarcoma

Treatment Arm(s):
A. recombinant EphB4-HSA fusion protein (given IV)

Select Inclusion and Exclusion Criteria:

- Participants may be treatment naïve, refractory to or intolerant of one or more prior therapies, or treated with prior systemic treatment including but not limited to liposomal doxorubicin
- Participants must have biopsy-proven KS involving skin with or without visceral involvement
- If HIV-positive, any cluster of differentiation (CD)4 count will be allowed on study
- Eastern Cooperative Oncology Group (ECOG) performance status =< 2 or Karnofsky performance score (KPS) >= 60%
- Life expectancy of greater than 3 months
- If participant is HIV positive, participants must be on a stable antiretroviral regimen for at least 12 weeks prior to study enrollment
- There should be no evidence for improvement in KS in the 3 months prior to study enrollment, unless there is evidence for progression of KS in the 4 weeks immediately prior to study enrollment

NIH Site: clinicaltrials.gov/ct2/show/NCT02799485
Study ID: IRB16076
PI: David Aboulafia, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
A Pilot Study of Nelfinavir for the Treatment of Kaposi Sarcoma

Treatment Arm(s):

A. Nelfinavir 1250 mg twice daily with escalation to 3125 mg twice daily

Select Inclusion and Exclusion Criteria:

• Biopsy-proven KS involving skin (with or without visceral involvement) without need for urgent cytotoxic therapy. There should be no evidence of improvement in KS in the 4 weeks immediately prior to study enrollment and treatment.

• Known HIV-1 infection status, as documented by any nationally approved, licensed HIV rapid test performed in conjunction with screening (or enzyme-linked immunosorbent assay [ELISA] test kit), and confirmed by an approved test at each study site

• Participant may be either previously untreated for KS or refractory to or intolerant of any one or more prior KS therapies.

• ECOG performance status ≤ 2

NIH Site: clinicaltrials.gov/ct2/show/NCT03077451
Study ID: IRB16077
PI: David Aboulafia, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
Phase I and Dose-Expansion Study of Ibrutinib and R-da-EPOCH for Front Line Treatment of AIDS-Related Lymphomas

Treatment Arm(s):
A. R-da-EPOCH

Select Inclusion and Exclusion Criteria:
- Histologically documented CD20 positive or negative diffuse large B-cell lymphoma (DLBCL)
- Known HIV-1 infection status, as documented by any nationally approved, licensed HIV rapid test performed in conjunction with screening (or enzymelinked immunosorbent assay [ELISA] test kit), and confirmed by an approved test at each study site
- HIV-Positive
- Only participants whose lymphoma is untreated are allowed for the dose-finding portion
- ECOG performance status ≤ 2
- CD4 count >= 100
- No chemotherapy other than R-EPOCH or R-CHOP, or radiotherapy other than palliative within the last 4 weeks
- No Prior cytotoxic chemotherapy or radiotherapy for this lymphoma

NIH Site: clinicaltrials.gov/ct2/show/NCT03220022
Study ID: CRP17077
PI: David Aboulafia, MD / CRC: Rachel Dowty/ (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
DLBCL

A Randomized Phase 3 Study to Evaluate the Efficacy and Safety of Enzastaurin Plus R-CHOP Versus R-CHOP in Treatment-Naive Subjects With High-Risk Diffuse Large B-Cell Lymphoma Who Possess the Novel Genomic Biomarker DGM1™

Treatment Arm(s):
A. R-CHOP + enzastaurin hydrochloride
B. R-CHOP + placebo

Select Inclusion and Exclusion Criteria:

• histologically-confirmed diagnosis of CD20-positive DLBCL based on the WHO classification. The diagnosis must be confirmed at the enrolling site. Subjects with history of indolent lymphoma or follicular Grade 3 lymphoma are not eligible.
• ECOG score of 0, 1 or 2
• IPI score of at least 3
• estimated life expectancy of at least 12 weeks

NIH Site: clinicaltrials.gov/ct2/show/NCT03263026
Study ID: CRP17095
PI: David Aboulafia, MD / CRC: Anas Najjar/ (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
Post-Authorization Long-Term Safety Study of LUTATHERA (SALUS)

Treatment Arm(s):
   A. Lutathera

Select Inclusion Criteria:
   • patients with unresectable or metastatic, well-differentiated, somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours treated with LUTATHERA

Select Exclusion Criteria:
   • hypersensitivity to LUTATHERA (active substance or any of the excipients)
   • pregnancy (established, suspected, or when not excluded)
   • kidney failure with creatinine clearance < 30 mL/min

NIH Site: clinicaltrials.gov/ct2/show/NCT03691064
Study ID: IRB18067
PI: Hagen Kennecke, MD / CRC: Janet Zaltsman / (206) 287-6273
Pager: (206) 540-0704 / Janet.Zaltsman@VirginiaMason.org
A prospective, randomised, Controlled, Open-label, Multicentre phase III study to evaluate efficacy and safety of (PRRT) with 177Lu-Edotreotide compared to Everolimus in patients with inoperable, progressive, (SSTR+), (GEP-NET)

*Treatment Arm(s):*

A. 177Lu-edotreotide

B. Everolimus

*Select Inclusion Criteria:*

- Histologically and clinically confirmed diagnosis of well-differentiated neuro-endocrine tumour of non-functional gastroenteric origin (GE-NET) or both functional or non-functional pancreatic origin (P-NET)

*Select Exclusion Criteria:*

- Known hypersensitivity to edotreotide or everolimus
- Prior exposure to any peptide receptor radionuclide therapy (PRRT)
- Serious non-malignant disease
- Prior therapy with mTor inhibitors

NIH Site: clinicaltrials.gov/ct2/show/NCT03049189
Study ID: CRP19081
PI: Hagen Kennecke, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
Alternating neoadjuvant Gemcitabine-Nab-Paclitaxel and na1-IRI with 5-Fluorouracil and folinic acid (Leucovorin) regimens in resectable and borderline resectable pancreatic cancer, A Pilot Study

*Only borderline resectable pancreatic cancer is open at this time*

Primary Objective(s):
Safety, tolerability, and feasibility of gemcitabine-nab paclitaxel alternating with na1-IRI/5FU/leucovorin (NAPOLI) in borderline resectable pancreatic cancer

Select Inclusion Criteria:
- Pathologically proven pancreatic cancer
- Borderline resectable pancreatic cancer per NCCN guidelines
- Age ≥18
- ECOG PS 0/1
- Adequate hematologic/hepatic and renal function by standard parameters

Select Exclusion Criteria:
- Prior definitive resection of pancreatic cancer
- Prior chemotherapy or radiation therapy for pancreatic cancer
- Neuropathy > grade 1
- Any other basis for study exclusion per investigator discretion
- Unable or unwilling to provide written signed informed consent

NIH Site: clinicaltrials.gov/ct2/show/NCT03703063
Study ID: CRP17118
Pl: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
Gemcitabine and nab-paclitaxel in pancreatic adenocarcinoma with positive peritoneal cytology as a sole metastatic site

Primary Objective(s):
A. Cytological Conversion

Select Inclusion Criteria:
• Pathologically proven pancreatic cancer
• Localized with positive peritoneal cytology as a sole metastatic site
• Age >18
• ECOG PS 0/1
• Signed informed consent

NIH Site: clinicaltrials.gov/ct2/show/NCT03703089
Study ID: CRP17130
PI: Vincent Picozzi, MD / CRC: Janet Zaltsman / (206) 287-6273
Pager: (206) 540-0704 / Janet.Zaltsman@VirginiaMason.org
PANOVA-3: Effect of Tumor Treating Fields (TTFFields, 150 kHz) as Front-Line Treatment of Locally-advanced Pancreatic Adenocarcinoma Concomitant With Gemcitabine and Nab-paclitaxel

Treatment Arm(s):
A. NovoTTF-100L(P)
B. Best standard of care

Select Inclusion Criteria:
- 18 years of age and older
- Life expectancy of ≥ 3 months
- Histological/cytological diagnosis of de novo adenocarcinoma of the pancreas
- Unresectable, locally advanced stage disease
- ECOG score 0-2
- Amenable and assigned by the investigator to receive therapy with gemcitabine and nab-paclitaxel
- Able to operate the NovoTTF-100L(P) System independently or with the help of a caregiver
- NO Prior palliative treatment (e.g. surgery, radiation) to the tumor
Distal Pancreatectomy, Minimally Invasive Or Open, For Malignancy (DIPLOMA): A Randomized Controlled, Multicenter, Non-Inferiority Trial

Treatment Arm(s):
A. MIDP
B. ODP

Select Inclusion Criteria:
• ≥ 18 years
• Elective indication for distal pancreatectomy for proven or suspected PDAC
• Upfront (without induction / down-sizing radio- or chemotherapy) resectable PDAC in the pancreatic body or tail
• The tumor can be radically resected via both minimally invasive or open surgery according to the local treating team

Study ID: CRP18049
PI: Adnan Alseidi, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
CANCER
Pancreas

Locally advanced, unresectable

A Phase 3, Randomized, Double-Blind Study of Pamrevlumab or Placebo in combination with Gemcitabine Plus Nab-paclitaxel as Neoadjuvant Treatment in Patients with Locally Advanced, Unresectable Pancreatic Cancer

Treatment Arm(s):
A. Pamrevlumab + G/NP
B. Placebo + G/NP

Select Inclusion Criteria:
• Reduction in CA19-9 level ≥ 50%
• FDG-PET SUVmax decrease by ≥ 30% at EOT when compared to baseline
• Partial response [PR], complete response [CR], or stable disease [SD] per RECIST
• 1.1 at EOT
• Meet the definition of resectable or borderline resectable per NCCN®

NIH Site: clinicaltrials.gov/ct2/show/NCT03941093
Study ID: CRP18119
PI: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
A Randomized Phase 2/3 Multi-Center Study of SM-88 in Subjects With Pancreatic Cancer Whose Disease Has Progressed or Recurred

Treatment Arm(s):
A. (Part 1 enrollment complete) SM-88 used with MPS (methoxsalen, phenytoin and sirolimus)
(Part 2 actively enrolling) SM-88 (920 mg per day) used with MPS (methoxsalen, phenytoin and sirolimus) will be administered to 125 evaluable subjects until unacceptable toxicity, disease progression, or any of the treatment discontinuation criteria are met

Select Inclusion Criteria:
- Subjects have received two (2) and not more than two (2) previous systemic regimens for the treatment of pancreatic adenocarcinom
- Subjects must have completed any investigational cancer therapy at least 30 days prior to first dose
- ≥18 years of age
- ECOG PS ≤2
- All acute toxic effects of any prior antitumor therapy resolved to Grade ≤ 1 before baseline, with the exception of alopecia and neurotoxicity (CTCAE Grade 1 or 2 permitted)

NIH Site: clinicaltrials.gov/ct2/show/NCT03512756
Study ID: CRP18032
PI: Vincent Picozzi, MD / CRC: Janet Zaltsman / (206) 287-6273
Pager: (206) 540-0704 / Janet.Zaltsman@VirginiaMason.org
Precision Promise Platform Trial For Metastatic Pancreatic Cancer

*Treatment Arm(s):*
- A. Active Comparator: Enzalutamide
- B. Experimental: I-131-1095 in combination with enzalutamide

*Select Inclusion and Exclusion Criteria:*
- Age ≥ 18 years
- Histologically or cytologically confirmed metastatic pancreatic adenocarcinoma
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
- Adequate organ function (lab results must be obtained within the 28-day window prior to randomization)
- Consent to provide protocol-mandated tissue and blood samples for diagnostic and research purposes
- Received any therapy within 28 days (or 5 half-lives, whichever is shorter,) prior to randomization
- History of allergy or hypersensitivity to any of the study treatments or any of their excipients
- Known history of hepatitis B, HIV or active hepatitis C infection
- Receiving immunosuppressive or myelosuppressive medications that would, in the opinion of the Investigator, increase the risk of serious neutropenic complications

Study ID: CRP19086
PI: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
A Multicenter, Randomized, Controlled Phase 2 Study: Efficacy and Safety of I-131-1095 Radiotherapy in Combination With Enzalutamide in Metastatic Castration-resistant Prostate Cancer (mCRPC) Patients Who Are 18F-DCFPyL Prostate-specific Membrane Antigen (PSMA)-Avid, Chemotherapy-naive, and Progressed on Abiraterone

Treatment Arm(s):
A. Active Comparator: Enzalutamide
B. Experimental: I-131-1095 in combination with enzalutamide

Select Inclusion and Exclusion Criteria:

- Male ≥ 18 years of age
- Histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features at initial diagnosis
- Castration-resistant prostate cancer, with serum testosterone ≤ 50 ng/dL at Screening
- Radiographic evidence of metastatic disease prior to Randomization or up to 21 days prior to Screening
- Received any anti-tumor therapy within 4 weeks of Randomization, with the exception of abiraterone, GnRH therapy and non-radioactive bone-targeted agents
- Active malignancy other than prostate cancer, with the exception of curatively treated non-melanoma skin cancer, carcinoma in situ, or non-muscle invasive bladder/urothelial cancer

NIH Site: clinicaltrials.gov/ct2/show/NCT03939689
Study ID: CRP19092
PI: John Paul Flores, MD / CRC: Jannefer Sengmany / (206) 287-6278
Pager: (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org
Does the Use of a Post-Operative Pedometer Affect Rate of Return of Bowel Function and Narcotic Use Following Radical Prostatectomy?

Treatment Arm(s):
This study will evaluate whether use of pedometer with progressing step-count goals following radical prostatectomy decreases post-operative narcotic use and decreases the time before return of bowel function.

Select Inclusion and Exclusion Criteria:
- Male between 18 and 75 years of age undergoing robot-assisted laparoscopic radical prostatectomy for prostate cancer at Virginia Mason Medical Center
- Long-term, opioid use, defined by the CDC as use of opioids on most days for more than 3 months
- History of inflammatory bowel disease
- Prior abdominopelvic radiation
- Concurrent surgery during radical prostatectomy
- Inability to ambulate
- Gastroparesis or other baseline bowel dysmotility issues
- Inability or unwillingness of subject or legal guardian/representative to give written informed consent

Study ID: CRP19098
PI: John Corman, MD / CRC: Hannah Kreinbrink / (206) 347-6276
Pager: (206) 541-9318 / Hannah.Kreinbrink@VirginiaMason.org
Efficacy and Safety of Olaparib (MK-7339) in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer (MK-7339-002)

Treatment Arm(s):
A. Olaparib

Select Inclusion Criteria:

- Has a histologically- or cytologically-confirmed advanced (metastatic and/or unresectable) solid tumor (except breast or ovarian cancers whose tumor has a germline or somatic BRCA mutation) that is not eligible for curative treatment and for which standard of care therapy has failed. Participants must have progressed on or be intolerant to standard of care therapies that are known to provide clinical benefit. There is no limit on the number of prior treatment regimens.
- Has either centrally-confirmed known or suspected deleterious mutations in at least 1 of the genes involved in HRR or centrally-confirmed HRD.

NIH Site: clinicaltrials.gov/ct2/show/NCT03742895
Study ID: CRP18120
PI: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org
A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

*Treatment Arm(s):*

A. NGM120 Subcutaneous Injection Doses 1-6
B. Placebo

*Select Inclusion and Exclusion Criteria:*

- Have histologically confirmed advanced or metastatic castration-resistant prostate cancer, bladder cancer, melanoma, non-small cell lung cancer, pancreatic cancer, colorectal cancer, gastric cancer, esophageal cancer, ovarian cancer, and head neck squamous cell carcinoma.
- Have not received any approved chemotherapy, except in the adjuvant setting.
- Subject was using immunosuppressive medications within 14 days before Screening with the exception of topical (intranasal, inhaled, and local injection), systemic (prednisone equivalent 10 mg/day or less), or as needed for hypersensitivity reactions such as computed tomography (CT) scan premedication.
- Subject has active infections or other serious underlying significant medical illness, abnormal and clinically significant laboratory findings or psychiatric illness/social situation.

NIH Site: clinicaltrials.gov/ct2/show/NCT04068896
Study ID: CRP19071
PI: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271
Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org

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A Prospective, Non-Interventional Study to Assess the Prevalence of PD-L1 Expression in the First-Line Setting of Locally Advanced/Unresectable or Metastatic Urothelial Carcinoma

**Primary Objective(s):**

The primary objective is to assess the prevalence of pre-treatment tumor tissue PD-L1 high expression in the 1L setting in advanced UC patients (locally advanced/unresectable or metastatic) using the Ventana SP263 assay.

**Select Inclusion and Exclusion Criteria:**

- Age ≥18 years old
- Patients with histologically-confirmed diagnosis of UC and healthcare provider (HCP)-confirmed advanced UC prior to or during 1L therapy (primary histology UC; mixed histologies are allowed).
- Patients with available tumor tissue sample (fresh or archival – up to 3 years old) that was collected as part of SoC any time prior to 1L treatment for advanced UC with a target of 18 slides available for biomarker testing (PD-L1 and tTMB).
- Patients with history of non-urothelial active malignancy that completed therapy within 2 years from study enrollment except:
  - Any resected in situ carcinoma or non-melanoma skin cancer
  - Localized (early stage) cancer treated with curative intent (with out evidence of recurrence and intent for further therapy) and in which no systemic therapy was

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NIH Site: clinicaltrials.gov/ct2/show/NCT03788746
Study ID: CRP19051
PI: John Paul Flores, MD / CRC: Karolina Rauch / (206) 287-6279
Pager: (206) 314-0118 / Karolina.Rauch@VirginiaMason.org
**Karnofsky Performance Scale**

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>Normal, no complaints, no signs of disease</td>
</tr>
<tr>
<td>90%</td>
<td>Capable of normal activity, few symptoms or signs of disease</td>
</tr>
<tr>
<td>80%</td>
<td>Normal activity with some difficulty, some symptoms or signs</td>
</tr>
<tr>
<td>70%</td>
<td>Caring for self, not capable of normal activity or work</td>
</tr>
<tr>
<td>60%</td>
<td>Requiring some help, can take care of most personal requirements</td>
</tr>
<tr>
<td>50%</td>
<td>Requires help often, requires frequent medical care</td>
</tr>
<tr>
<td>40%</td>
<td>Disabled, requires special care and help</td>
</tr>
<tr>
<td>30%</td>
<td>Severely disabled, hospital admission indicated but no risk of death</td>
</tr>
<tr>
<td>20%</td>
<td>Very ill, urgently requiring admission, requires supportive measures or treatment</td>
</tr>
<tr>
<td>10%</td>
<td>Moribund, rapidly progressive fatal disease processes</td>
</tr>
<tr>
<td>0%</td>
<td>Death</td>
</tr>
</tbody>
</table>

**ECOG/Zubrod Performance Status**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Fully active; able to carry on all pre-disease activities without restriction</td>
</tr>
<tr>
<td>1</td>
<td>Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature</td>
</tr>
<tr>
<td>2</td>
<td>Ambulatory &amp; capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours</td>
</tr>
<tr>
<td>3</td>
<td>Capable of only limited self-care; confined to bed or chair 50% or more of waking hours</td>
</tr>
<tr>
<td>4</td>
<td>Completely disabled; cannot carry on any self-care and totally confined to bed or chair</td>
</tr>
<tr>
<td>5</td>
<td>Death</td>
</tr>
</tbody>
</table>
ECLIPSE: Evaluation Of Treatment Strategies For Severe Calcific Coronary Arteries: Orbital Atherectomy Vs. Conventional Angioplasty Technique Prior To Implantation Of Drug-Eluting Stents

Treatment Arm(s):
A. Orbital Atherectomy (OA)
B. Conventional Balloon Angioplasty

Select Inclusion Criteria:
- Stable ischemic heart disease or
- acute coronary syndrome (NSTEMI or unstable angina), or
- stabilized recent STEMI (>48 hours prior to randomization procedure)

Select Exclusion Criteria:
- Any prior PCI in the target vessel or its branches 12 months prior to randomization.
- Subject has undergone a PCI procedure that is unsuccessful or with complications within 30 days prior to randomization, including during the randomization procedure.
- Any cardiac intervention or surgery planned within 12 months post randomization procedure aside from a potential planned staged PCI as part of the randomized treatment strategy.
- Subject has received a heart transplant.
- Evidence of heart failure

NIH Site: clinicaltrials.gov/ct2/show/NCT03108456
Study ID: CRP18090
PI: Drew Baldwin, MD / CRC: Kelsey Yenney / (206) 287-6266
Pager: (206) 405-8786 / Kelsey.Yenney@VirginiaMason.org
DETERMINE-preserved - Dapagliflozin Effect on Exercise Capacity Using a 6-minute Walk Test in Patients With Heart Failure With Preserved Ejection Fraction

*Treatment Arm(s):*
A. Oral Dapagliflozin  
B. Placebo

*Select Inclusion Criteria:*
- Male or female, aged ≥40 years  
- Established documented diagnosis of symptomatic HFpEF (NYHA functional class II-IV), which has been present for at least 8 weeks  
- LVEF>40% and evidence of structural heart disease  
- Elevated NT-proBNP levels  
- Patients should receive background standard of care as described below: All patients will be treated according to locally recognised guidelines on standard of care treatment for patients with HFpEF. Therapy should have been individually optimised and stable for ≥4 weeks (this does not apply to diuretics) and include (unless contraindicated or not tolerated) treatment of co morbidities (including high blood pressure, ischaemic heart disease, atrial fibrillation).  
- 6MWD≥100 metres and ≤425 metres at enrolment and randomization

NIH Site: clinicaltrials.gov/ct2/show/NCT03877224  
Study ID: CRP19047  
PI: Sarah Weiss, MD / CRC: Ellie Fox / (206) 287-6264  
Pager: (206) 540-0074 / Ellie.Fox@VirginiaMason.org
Chronic Pancreatitis

Fully Covered Self Expanding Metal Stents (FCSEMS) for Pancreatic Duct Strictures in Patients with Chronic Pancreatitis

Treatment Arm(s):
Stents selected for use in this study:
• Diameter: 6 mm, 8 mm
• Length: 4cm, 5cm, 6cm
• Type: Soft
• Delivery system: Rapid Exchange

Select Inclusion Criteria:
• Chronic pancreatitis induced stricture of Cremer Type IV, namely distal dominant stricture with upstream ductal dilation.

NIH Site: clinicaltrials.gov/ct2/show/NCT02802020
Study ID: IRB16050
PI: Richard Kozarek, MD / CRC: Katie Gelinas / (206) 341-1992
Pager: (206) 797-0393 / Katharyn.Gelinas@VirginiaMason.org
Chronic Pancreatitis

A Phase 1, Single Dose PK and Safety Study with NI-03 Followed by a Phase 2, Randomized, Double-Blind, Parallel-Group Dose-Ranging Study to Evaluate the Safety and Efficacy of NI-03 Compared to Placebo in Subjects with Chronic Pancreatitis

Treatment Arm(s):
Stents selected for use in this study:
• Diameter: 6 mm, 8 mm
• Length: 4 cm, 5 cm, 6 cm
• Type: Soft
• Delivery system: Rapid Exchange

Select Inclusion Criteria:
• Chronic pancreatitis induced stricture of Cremer Type IV, namely distal dominant stricture with upstream ductal dilation.

NIH Site: clinicaltrials.gov/ct2/show/NCT02693093
Study ID: IRB16032
PI: Richard Kozarek, MD / CRC: Cheryl Shaw / (206) 341-1786
Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org
Pancreatitis

Stent vs. Indomethacin for Preventing Post-ERCP Pancreatitis

Treatment Arm(s):
A. Indomethacin alone
B. Indomethacin + pancreatic stent

Select Inclusion Criteria:
Clinical suspicion of or known sphincter of Oddi dysfunction
• History of post-ERCP pancreatitis
• Pancreatic sphincterotomy
• Pre-cut (access) sphincterotomy (freehand pre-cut and septotomy)
• Difficult cannulation:
• Short-duration (≤ 1 min) balloon dilation of an intact biliary sphincter.

Or has at least 2 of the following:
• Age < 50 years old & female gender
• History of recurrent pancreatitis (at least 2 episodes)
• ≥3 pancreatic injections
• Pancreatic acinarization
• Pancreatic brush cytology

NIH Site: clinicaltrials.gov/ct2/showNCT02476279
Study ID: CRP18061
PI: Andrew Ross, MD / CRC: Tida Tangwongchai (206) 341-1416
Tida.Tangwongchai@VirginiaMason.org
Recurrent Pancreatitis

SpHincterotomy for Acute Recurrent Pancreatitis (SHARP)

Treatment Arm(s):
A. EUS + Sham
B. EUS + ERCP with miES

Select Inclusion Criteria:
• >18 years
• Two or more episodes of acute pancreatitis, with each episode meeting two of the following three criteria:
  • abdominal pain consistent with acute pancreatitis (acute onset of a persistent, severe, epigastric pain often radiating to the back)
  • serum lipase activity (or amylase activity) at least three times greater than the upper limit of normal
  • characteristic findings of acute pancreatitis on CECT, MRI or transabdominal ultrasonography
• At least one episode of acute pancreatitis within 24 months of enrollment
• Pancreas divisum confirmed by prior MRCP that is reviewed by an abdominal radiologist at the recruiting site.
• By physician assessment, there is no certain explanation for recurrent acute pancreatitis.

NIH Site: clinicaltrials.gov/ct2/show/NCT03609944
Study ID: CRP18078
PI: Andrew Ross, MD / CRC: Kat Magbitang (206) 341-1406
Pager: (206) 405-5800 / KatrinaAnn.Magbitang@VirginiaMason.org
Acute Cholecystitis

A Multicenter, Prospective Study of EUS-Guided Transluminal Gallbladder Drainage in Patients With Acute Cholecystitis as an Alternative to Percutaneous Gallbladder Drainage

Treatment Arm(s):
A. AXIOS(TM) Stent and Electrocautery Enhanced Delivery System: Patients who are at high risk or unsuitable for surgery will receive an AXIOS stent under EUS guidance for treatment of acute cholecystitis.

Select Inclusion Criteria:
- History of post-ERCP pancreatitis
- Pancreatic sphincterotomy
- Pre-cut (access) sphincterotomy (freehand pre-cut and septotomy)
- Difficult cannulation:
- Short-duration (≤ 1 min) balloon dilation of an intact biliary sphincter.
Or has at least 2 of the following:
- Age < 50 years old & female gender
- History of recurrent pancreatitis (at least 2 episodes)
- ≥3 pancreatic injections

NIH Site: clinicaltrials.gov/ct2/show/NCT03767881
Study ID: CRP18118
PI: Shayan Irani, MD / CRC: Kate Beck / (206) 341-1312
Pager: (206) 341-1465 / Kate.Beck@VirginiaMason.org
Diverticulitis

Institutional Database for medical and surgical management of diverticulitis

**Treatment Arm(s):**
- A. Partial Colectomy
- B. Medical Management

**Select Inclusion Criteria:**
- Adults ≥18 years
- At least one episode of diverticulitis confirmed by CT scan in last 5 years and a colonoscopy to rule out or screen for other colon pathology concordant with screening guidelines; AND A. History of recurrent uncomplicated diverticulitis without current symp-toms (AUD in remission) over the prior 5 years; OR B. Persistent signs, symptoms, and concerns related to diverticular disease ≥3 months after recovery from an episode of AUD (e.g., excluding irritable bowel syndrome and other conditions in coordination with gastroenterologist)

**Select Inclusion Criteria:**
- Previous operation for diverticulitis
- Current diagnosis or previous endoscopic or surgical interventions for bleeding, fistula, stricture related to diverticular disease
- Actively undergoing chemotherapy or radiation for malignancy
- Immunodeficiency (e.g., absolute neutrophil count <500/mm³, chronic immunosuppressive drugs (e.g., oral corticosteroids, anti-TNF agents), or known AIDS [i.e., recent CD4 count <200 ] assessed by patient history)

NIH Site: clinicaltrials.gov/ct2/showNCT04095663
Study ID: CRP19057
PI: Val Simianu, MD / CRC: Kat Magbitang / 206-341-1406
Pager: (206) 405-5800 / KatrinaAnn.Magbitang@VirginiaMason.org
Crohn’s Disease
A Phase-III, Randomized, Double-blind, Parallel-group, Placebo-controlled, International, Multicentre Study to Assess Efficacy and Safety of Cx601, Adult Allogeneic Expanded Adipose-derived Stem Cells (eASC) for the Treatment of Complex Perianal Fistula(s) in Patients With Crohn’s Disease Over a Period of 24 Weeks and a Follow-up Period up to 52 Weeks

Treatment Arm(s):
A. Cx601 eASCs 120 million cells (5 million cells per milliliter [mL]) will be administered once by intralesional injection
B. CX601 placebo-matching eASCs cells will be administered once by intralesional administration

Select Inclusion Criteria:
- Participants of either gender greater than or equal to (>=) 18 years and less than or equal to (<=) 75 years of age
- Participants with CD diagnosed at least 6 months prior to Screening visit in accordance with accepted clinical, endoscopic, histological and/or radiological criteria

Select Exclusion Criteria:
- Concomitant rectovaginal or rectovesical fistula(s)
- Severe rectal and/or anal stenosis and/or severe proctitis (defined as the presence of large >0.5 cm ulcers in the rectum) that make impossible to follow the surgery procedure manual
- Any major surgery of the GI tract (including one or more segments of the colon or terminal ileum) within 6 months prior the screening or any minor surgery of the GI tract within 3 months prior to screening

NIH Site: clinicaltrials.gov/ct2/show/NCT03279081
Study ID: CRP18046
PI: Michael Chiorean, MD / CRC: Cheryl Shaw / (206) 341-1786
Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org
Chron’s Disease

A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study of the Efficacy and Safety of Risankizumab in Subjects With Moderately to Severely Active Crohn’s Disease

Treatment Arm(s):
A. Risankizumab, administered by IV infusion
B. Placebo, administered by IV infusion

Select Inclusion Criteria:
• Male or female aged >=18 to <= 80 years, or minimum age of adult consent according to local regulations, at the Baseline Visit. Where locally permissible, subjects 16 to < 18 years of age who meet the definition of Tanner stage 5 for development at the Baseline Visit
• Diagnosis of CD for at least 3 months prior to Baseline
• Demonstrated intolerance or inadequate response to conventional or to biologic therapy for CD
• Subject with a current diagnosis of ulcerative colitis or indeterminate colitis
• Receipt of Crohn’s disease approved biologic agents (infliximab, adalimumab, certolizumab, vedolizumab, natalizumab within 8 weeks prior to Baseline or ustekinumab within 12 weeks prior to Baseline), or any investigational biologic or other agent or procedure within 35 days or 5 half-lives prior to Baseline, whichever is longer.

NIH Site: clinicaltrials.gov/ct2/show/NCT03105128
Study ID: CRP18087
PI: Michael Chiorean, MD / CRC: Katie Gelinas / (206) 341-1992
Pager: (206) 797-0393 / Katharyn.Gelinas@VirginiaMason.org
Crohn’s Disease

Open-Label Extension and Safety Study for Patients With Crohn’s Disease Previously Enrolled in the Etrolizumab Phase III Study GA29144

Treatment Arm(s):
A. etrolizumab
B. Safety monitoring

Select Inclusion Criteria:

Part 1 Open-label Extension:
• Patients previously enrolled in etrolizumab Phase III study GA29144 who meet the eligibility criteria for open-label etrolizumab as described in the protocol

Part 2 Safety Monitoring:
• Patients who participated in etrolizumab Phase III study GA29144 and are not eligible or choose not to enter Part 1
• Patients who transfer from Part 1
• Completion of the 12-week safety follow-up period prior to entering

NIH Site: clinicaltrials.gov/ct2/show/NCT02403323
Study ID: IRB15043
PI: Michael Chiorean, MD / CRC: Katie Gelinas / (206) 341-1992
Pager: (206) 797-0393 / Katharyn.Gelinas@VirginiaMason.org
Crohn’s Disease

A Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects With Moderately to Severely Active Crohn’s Disease Who Have Inadequately Responded to or Are Intolerant to Biologic Therapy

Treatment Arm(s):
A. upadacitinib dose A for 12 weeks
B. open-label upadacitinib dose A for 12 weeks
C. placebo for 12 weeks

Select Inclusion Criteria:
- Confirmed diagnosis of CD for at least 3 months prior to Baseline.
- Confirmed diagnosis of moderate to severe CD as assessed by stool frequency (SF), abdominal pain (AP) score.
- Evidence of mucosal inflammation based on the Simplified Endoscopic Score for Crohn’s disease (SES-CD) on an endoscopy confirmed by a central reader.
- Demonstrated an inadequate response or intolerance to any biologic therapy for infliximab, adalimumab, certolizumab pegol, vedolizumab, and ustekinumab.

NIH Site: clinicaltrials.gov/ct2/show/NCT03345836
Study ID: CRP17099
PI: Michael Chiorean, MD / CRC: Katie Gelinas / (206) 341-1992
Pager: (206) 797-0393 / Katharyn.Gelinas@VirginiaMason.org
Crohn’s Disease

A Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects With Moderately to Severely Active Crohn’s Disease Who Have Inadequately Responded to or Are Intolerant to Conventional Therapies But Have Not Failed Biologic Therapy

Treatment Arm(s):
- Group A: upadacitinib dose A for 12 weeks
- Group B: placebo for 12 weeks

Select Inclusion Criteria:
- Confirmed diagnosis of CD for at least 3 months prior to Baseline.
- Confirmed diagnosis of moderate to severe CD as assessed by stool frequency (SF), abdominal pain (AP) score.
- Evidence of mucosal inflammation based on the Simplified Endoscopic Score for Crohn’s disease (SES-CD) on an endoscopy confirmed by a central reader.
- Demonstrated an inadequate response or intolerance to conventional therapies (Oral locally acting steroids, Intravenous or oral corticosteroids, Immunosuppressants), in the opinion of the investigator.

NIH Site: clinicaltrials.gov/ct2/show/NCT03345849
Study ID: CRP17100
PI: Michael Chiorean, MD / CRC: Katie Gelinás / (206) 341-1992
Pager: (206) 797-0393 / Katharyn.Gelinás@VirginiaMason.org
Crohn’s Disease

A Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects With Crohn’s Disease Who Completed the Studies M14-431 or M14-433

Treatment Arm(s):
- Group A arm A: Upadacitinib dose B
- Group A arm B: Upadacitinib dose C
- Group A arm C: Placebo for Upadacitinib
- Group B arm A: Long term extension, Upadacitinib dose B
- Group B arm B: Long term extension, Upadacitinib dose C
- Group B arm C: Long term extension, Upadacitinib

Select Inclusion Criteria:
- For Substudy 1: Participant who receive double-blind treatment in Study M14-431 or Study M14-433 and achieve clinical response. Participant completes study procedures in the parent study.
- For Substudy 2: Participant completes Substudy 1. Participant who receive open-label upadacitinib Dose B in Study M14-431 and achieve clinical response. Participant completes study procedures in the parent study/substudy.

NIH Site: clinicaltrials.gov/ct2/show/NCT03345823
Study ID: CRP17098
PI: Michael Chiorean, MD / CRC: Katie Gelinas / (206) 341-1992
Pager: (206) 797-0393 / Katharyn.Gelinas@VirginiaMason.org
Crohn’s Disease

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Assess the Efficacy and Safety of Risankizumab in Subjects With Moderately to Severely Active Crohn’s Disease Who Failed Prior Biologic Treatment

Treatment Arm(s):
A. Risankizumab
B. Placebo

Select Inclusion Criteria:
- Male or female aged >=18 to <= 80 years, or minimum age of adult consent according to local regulations, at the Baseline Visit
- Diagnosis of CD for at least 3 months prior to Baseline
- Confirmed diagnosis of moderate to severe CD as assessed by stool frequency (SF), abdominal pain (AP) score, and Simple Endoscopic Score for Crohn’s Disease (SES-CD)
- Demonstrated intolerance or inadequate response to biologic therapy for CD

Select Exclusion Criteria:
- Subjects with unstable doses of concomitant Crohn’s disease therapy
- Receipt of Crohn’s disease approved biologic agents (infliximab, adalimumab, certolizumab, vedolizumab, natalizumab within 8 weeks prior to Baseline or ustekinumab within 12 weeks prior to Baseline), or any investigational biologic or other agent or procedure within minimally 35 days or 5 half-lives prior to Baseline, whichever is longer

NIH Site: clinicaltrials.gov/ct2/show/NCT03104413
Study ID: CRP18086
PI: Michael Chiorean, MD / CRC: Tida Tangwongchai / (206) 341-1416
Tida.Tangwongchai@VirginiaMason.org
**DIGESTIVE DISEASES**  
**IBD**

*Moderately to Severely Active Crohn’s Disease*

**GA29144:** A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Etrolizumab as an Induction and Maintenance Treatment for Patients with Moderately to Severely Active Crohn’s Disease

*Treatment Arm(s):*

- **A.** Etrolizumab 105 mg Q4W in Induction and Maintenance Arms
- **B.** Etrolizumab 210 mg Weeks 0,2,4,8 and 12 in Induction Arm only
- **C.** Placebo

*Select Inclusion Criteria:*

- Moderately to severely active CD based on clinical, histopathological and endoscopic evidence > 3 months prior to screening.
- Intolerant, refractory or no response to at least one of the following therapies within the last 5 years: CS therapy, IS therapy, Anti-TNF Therapy.

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**NIH Site:** clinicaltrials.gov/ct2/show/NCT02394028  
**Study ID:** IRB15018  
**PI:** Michael Chiorean, MD / CRC: Katie Gelinas / (206) 341-1992  
**Pager:** (206) 797-0393 / Katharyn.Gelinas@VirginiaMason.org
**Moderately to Severely Active Crohn’s Disease**

**Safety and Efficacy Study of JNJ-64304500 in Participants With Moderately to Severely Active Crohn’s Disease (TRIDENT)**

**Treatment Arm(s):**
- Experimental Part I: Placebo
- Experimental Part I: JNJ-64304500
- Experimental Part II: Placebo
- Experimental Part II: JNJ-64304500 High Dose
- Experimental Part II: JNJ-64304500 Middle Dose
- Experimental Part II: JNJ-64304500 Low Dose
- Experimental Part II: Ustekinumab

**Select Inclusion Criteria:**
- Have Crohn’s disease or fistulizing Crohn’s disease of at least 3 months’ duration, with colitis, ileitis, or ileocolitis, confirmed at any time in the past by radiography, histology, and/or endoscopy
- Crohn’s Disease Activity Index (CDAI) score of \( \geq 220 \) but \( \leq 450 \)

**NIH Site:** clinicaltrials.gov/ct2/show/NCT02877134  
**Study ID:** IRB16082  
**PI:** Michael Chiorean, MD / CRC: Kate Beck / (206) 341-1312  
**Pager:** (206) 314-1465 / Kate.Beck@VirginiaMason.org
A Study to Evaluate the Safety and Efficacy of ABT-494 for Induction and Maintenance Therapy in Subjects With Moderately to Severely Active Ulcerative Colitis

Treatment Arm(s):
A. ABT-494
B. Placebo

Select Inclusion Criteria:
• Diagnosis of ulcerative colitis for 90 days or greater prior to Baseline, confirmed by colonoscopy during the Screening Period, with exclusion of current infection, colonic dysplasia and/or malignancy. Appropriate documentation of biopsy results consistent with the diagnosis of UC, in the assessment of the Investigator, must be available.

• Active ulcerative colitis with an Adapted Mayo score of 5 to 9 points and endoscopic sub score of 2 to 3 (confirmed by central reader).

• Demonstrated an inadequate response to, loss of response to, or intolerance to corticosteroids, immunosuppressants, and/or biologic therapies.

NIH Site: clinicaltrials.gov/ct2/show/NCT02819635
Study ID: IRB17010
PI: Michael Chiorean, MD / CRC: Cheryl Shaw / (206) 341-1786
Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org
Ulcerative Colitis
An Open-Label Extension Study of Etrasimod in Subjects With Moderately to Severely Active Ulcerative Colitis

Treatment Arm(s):
A. Etrasimod 2 mg

Select Inclusion Criteria:
Must have met the eligibility criteria and have been enrolled in one of the two parent studies (APD334-301 or APD334-302) and also meet the following additional criteria:
- Participants previously enrolled in Study APD334-301 must have completed the Week 12 visit and have been assessed to have active UC that had deteriorated from baseline or completed the Week 52 visit
- Participants previously enrolled in APD334 302 must have completed the Week 12 visit

Select Exclusion Criteria:
- If Investigator considers the participant to be unsuitable for any reason to participate in the Open-Label Extension study
- Experienced an adverse event that led to discontinuation from one of the parent studies

NIH Site: clinicaltrials.gov/ct2/show/NCT03950232
Study ID: CRP19017
PI: Michael Chiorean, MD / CRC: Kate Beck / (206) 341-1786
Pager: (206) 341-1465 / Kate.Beck@VirginiaMason.org
Ulcerative Colitis

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, 52-Week Study to Assess the Efficacy and Safety of Etrasimod in Subjects with Moderately to Severely Active Ulcerative Colitis

Treatment Arm(s):
A. Placebo
B. Etrasimod 2 mg

Select Inclusion Criteria:
- Diagnosed with ulcerative colitis (UC) ≥ 3 months prior to screening
- Active UC confirmed by endoscopy

Select Exclusion Criteria:
- Severe extensive colitis
- Diagnosis of Crohn’s disease (CD) or indeterminate colitis or the presence or history of a fistula consistent with CD
- Diagnosis of microscopic colitis, ischemic colitis, or infectious colitis

NIH Site: clinicaltrials.gov/ct2/show/NCT03945188
Study ID: CRP19016
PI: Michael Chiorean, MD / CRC: Cheryl Shaw / (206) 341-1786
Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org
Ulcerative Colitis

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Evaluate the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects With Moderately to Severely Active Ulcerative Colitis

Treatment Arm(s):
A. Upadacitinib administered orally, once daily
B. Placebo administered orally, once daily

Select Inclusion Criteria:
• Male or female participants >= 16 and <=75 years of age at Baseline
• Diagnosis of Ulcerative Colitis (UC) for 90 days or greater prior to Baseline, confirmed by colonoscopy during the Screening Period, with exclusion of current infection, colonic dysplasia and/or malignancy. Appropriate documentation of biopsy results consistent with the diagnosis of UC, in the assessment of the Investigator, must be available.
• If female, participant must meet the contraception recommendation criteria.

Select Exclusion Criteria:
• Participant with current diagnosis of Crohn’s disease (CD) or diagnosis of indeterminate colitis (IC)
• Participant who received azathioprine or 6-mercaptopurine (6-MP) within 10 days of Baseline

NIH Site: clinicaltrials.gov/ct2/show/NCT03653026
Study ID: CRP18071
PI: Michael Chioorean, MD / CRC: Cheryl Shaw / (206) 341-1786
Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org
Ulcerative Disease

A Phase 2a Randomized, Double-blind, Active-controlled, Parallel-group, Multicenter, Proof-of-concept Clinical Study to Evaluate the Efficacy and Safety of Combination Therapy With Guselkumab and Golimumab in Participants With Moderately to Severely Active Ulcerative Colitis

Treatment Arm(s):
A. Participants will receive guselkumab Dose 1 as intravenous (IV) infusion and Dose 2 as subcutaneous (SC) injection; and golimumab Dose 1 and Dose 2 as SC injection and placebo to maintain the blind.
B. Participants will receive guselkumab Dose 1 as IV infusion, Dose 2 as SC injection and placebo to maintain the blind.
C. Participants will receive golimumab Dose 1 and Dose 2 as SC injection and placebo to maintain the blind.

Select Inclusion Criteria:
• Confirmed diagnosis of CD for at least 3 months prior to Baseline.
• Moderately to severely active UC as defined by Mayo score
• History of inadequate response to or failure to tolerate conventional therapy
• Has screening laboratory test results within the study protocol defined parameters

NIH Site: clinicaltrials.gov/ct2/show/NCT03662542
Study ID: CRP19036
PI: Michael Chiorean, MD / CRC: Kat Magbitang / 206-341-1406
Pager: (206) 405-5800 / KatrinaAnn.Magbitang@VirginiaMason.org
Ulcerative Colitis

A Study to Assess the Efficacy and Safety of Risankizumab in Subjects With Ulcerative Colitis Who Responded to Induction Treatment in M16-067 or M16-065

Treatment Arm(s):
  A. Risankizumab
  B. Placebo

Select Inclusion Criteria:
  • Subjects who have completed Study M16-065 or Study M16-067 and have achieved clinical response

Select Exclusion Criteria:
  • Subjects who have a known hypersensitivity to risankizumab or the excipients of any of the study drugs or the ingredients of Chinese hamster ovary (CHO) or had an adverse event (AE) during Studies M16-065 or M16-067 that in the investigator’s judgment makes the subject unsuitable for this study

NIH Site: clinicaltrials.gov/ct2/show/NCT03398135
Study ID: CRP18016
PI: Michael Chiorean, MD / CRC: Tida Tangwongchai 206-341-1416
Tida.Tangwongchai@VirginiaMason.org
Ulcerative Colitis

A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Subjects With Moderately to Severely Active Ulcerative Colitis Who Have Failed Prior Biologic Therapy

Treatment Arm(s):
A. Risankizumab
B. Placebo

Select Inclusion Criteria:
• Male or female aged >=18 to <= 80 years at the Baseline Visit. Where locally permissible, subjects 16 to < 18 years of age who meet the definition of Tanner stage 5 for development at the Baseline Visit
• Confirmed diagnosis of ulcerative colitis (UC) for at least 3 months prior to Baseline.
• Active UC as assessed by adapted Mayo Score
• Demonstrated intolerance or inadequate response to one or more biologic therapies
• Females must be postmenopausal for more than 2 years or surgically sterile or practicing specific forms of birth control.

NIH Site: clinicaltrials.gov/ct2/show/NCT03398148
Study ID: CRP18017
PI: Michael Chiorean, MD / CRC: Tida Tangwongchai 206-341-1416
Tida.Tangwongchai@VirginiaMason.org

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Ulcerative Colitis
A Phase 3 Multicenter, Long-Term Extension Study to Evaluate the Safety and Efficacy of Upadacitinib (ABT-494) in Subjects With Ulcerative Colitis

Treatment Arm(s):
A. Upadacitinib
B. Placebo

Select Inclusion Criteria:
• Participant has not achieved clinical response at the end of the induction period (Week 8) in Study M14-234 Substudy 1, has had loss of response during the maintenance period of Study M14-234 Substudy 3, or has successfully completed Study M14-234 Substudy 3

Select Exclusion Criteria:
• Participant with a poorly controlled medical condition, such as uncontrolled diabetes, unstable ischemic heart disease, moderate or severe congestive heart failure (New York Heart Association class III or IV), recent cerebrovascular accidents and any other condition which, in the opinion of the investigator or sponsor, would put the subject at risk by participation in this study
• Current evidence of active or untreated latent tuberculosis

NIH Site: clinicaltrials.gov/ct2/show/NCT03006068
Study ID: CRP17021
PI: Michael Chiorean, MD / CRC: Katie Gelnas / (206) 341-1992
Pager: (206) 797-0393 / Katharyn.Gelnas@VirginiaMason.org
Hepatitis C Screening
City Wide Hepatitis C Screening and Linkage to Care

Primary Objective(s):
1. Assess the overall prevalence of chronic HCV by utilizing ED based screening for chronic HCV in three major Seattle-metropolitan hospitals in individuals age >18 years. We hypothesize 7% will be HCV-antibody positive with 80% of these having HCV RNA.

2. Assess the overall linkage to care of patients with detectable HCV viral load to care/treatment. We hypothesize an approximate 65% linkage to care rate and a 50% of the entire cohort being treated.

Select Inclusion Criteria:
- Any individual registered in the ED over age 18
- Willing to receive HCV screening testing along with standard of care diagnostic testing if not already documented
- Subject has a reliable means of contact

Select Inclusion Criteria:
- Non-English speaking
- Admitted to the ED for sexual assault
- Currently enrolled or expected to enroll in another clinical study which excludes co-enrollment

Study ID: CRP17068
PI: Blaire Burman, MD / CRC: Kat Magbitang / (206) 341-1406
Pager: (206) 405-5800 / KatrinaAnn.Magbitang@VirginiaMason.org
Non-alcoholic Steatohepatitis

AURORA: A Phase 3 Study to Evaluate the Efficacy and Safety of Cenicriviroc for the Treatment of Liver Fibrosis in Adult Subjects With Nonalcoholic Steatohepatitis

Treatment Arm(s):
A. Cenicriviroc 150mg
B. Placebo

Select Inclusion Criteria:
• Male and female subjects aged between 18-75 years
• Histological evidence of NASH based on central reading of the Screening biopsy
• Subjects included in Part 1 must have histopathological evidence of Stage 2 or 3 liver fibrosis per the NASH CRN System based on central reading of the Screening biopsy slides. Subjects newly randomized in Part 2 must have histological evidence of Stage 3 liver fibrosis per the NASH CRN System, based on central reading of the Screening period biopsy slides. Historical biopsy can be used, provided the criteria listed on Item 3a above are fulfilled

Select Exclusion Criteria:
• Inability to undergo a liver biopsy
• Alcohol consumption greater than 21 units/week for males or 14 units/week for females
• Prior or planned liver transplantation

NIH Site: clinicaltrials.gov/ct2/show/NCT03028740
Study ID: CRP17020
PI: Asma Siddique, MD / CRC: Katie Gelinis / (206) 341-1786
Pager: (206) 797-0393/ Katharyn.Gelinas@VirginiaMason.org
Non-alcoholic Steatohepatitis

Open-label Rollover Study of Cenicriviroc for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis (NASH)

Treatment Arm(s):
A. Cenicriviroc (CVC) 150 mg tablet once daily in the morning with food until CVC is commercially available or the study is terminated.

Select Inclusion Criteria:
• Successful completion of both Treatment Period 1 and Treatment Period 2, of the CENTAUR Study (652-2-203), including a Year 2 liver biopsy

Select Exclusion Criteria:
• Prior or planned liver transplantation
• Other known causes of chronic liver disease such as: Alcoholic liver disease, Primary biliary cirrhosis, Primary sclerosing cholangitis, Autoimmune hepatitis, Wilson’s disease, hemochromatosis, or iron overload, or Alpha-1-antitrypsin (A1AT) deficiency.

NIH Site: clinicaltrials.gov/ct2/showNCT03059446
Study ID: CRP17012
PI: Asma Siddique, MD / CRC: Cheryl Shaw / (206) 341-1786
Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org
Primary Sclerosing Cholangitis

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety, Tolerability, and Efficacy of Cilofexor in Non-Cirrhotic Subjects With Primary Sclerosing Cholangitis

Treatment Arm(s):
- A. Cliofexor
- B. Placebo

Select Inclusion Criteria:
- Diagnosis of large duct PSC
- Liver biopsy at screening that is deemed acceptable for interpretation and demonstrates stage F0 - F3 fibrosis in the opinion of the central reader
- Individual has the following laboratory parameters at the screening visit, as determined by the central laboratory:
  - Platelet count ≥ 150,000/mm^3
  - Estimated glomerular filtration rate (eGFR) ≥ 30 milliliter/minute (mL/min), as calculated by the Cockcroft-Gault equation
  - ALT ≤ 8 x upper limit of the normal range (ULN)
  - Total bilirubin < 2 mg/dL, unless the individual is known to have Gilbert’s syndrome or hemolytic anemia
  - International normalized ratio (INR) ≤ 1.4, unless due to therapeutic anticoagulation
  - Negative anti-mitochondrial antibody

NIH Site: clinicaltrials.gov/ct2/show/NCT03890120
Study ID: CRP19018
PI: Asma Siddique, MD / CRC: Kat Magbitang / (206) 341-1406
Pager: (206) 405-5800 / KatrinaAnn.Magbitang@VirginiaMason.org
“Pathway to Prevention” TrialNet Risk Screening - This study is designed to enhance our understanding of characteristics in individuals at risk for developing type 1 diabetes mellitus (T1D). Relatives of people with T1D have a 15 times greater chance of developing the disease than the general population. This study screens relatives for the presence of antibodies. Those who are found to be at risk can receive close monitoring for the development of diabetes or qualify for other prevention studies.

Study Type:

A. Observational - Screening and Monitoring visits.

Select Inclusion Criteria:

- Individuals 2.5 to 45 years of age who have an immediate family member with type 1 diabetes (i.e. child, parent, or sibling).
- Individuals 2.5 – 20 years old who have an extended family member with type 1 diabetes (i.e. cousin, niece, nephew, aunt, uncle, grandchildren, or half-sibling).

Select Exclusion Criteria:

- Eligible participants should NOT have diabetes already.
- No previous history of being treated with insulin or oral diabetes medications.
- Not currently using systemic immunosuppressive agents (topical and inhaled agents are acceptable).

NIH Site: clinicaltrials.gov/ct2/show/NCT00097292
Study ID: 10102
PI: Carla Greenbaum, MD
1 (800) 888–4187 / Diabetes@BenaroyaResearch.org
DREAMT Study - Early Markers of Disease and Response to Therapy

“DREAMT” In earlier studies, abatacept was shown to slow down beta cell destruction and preserve insulin secretion in people after diagnosis of type 1 diabetes. Abatacept seemed to work better in some people than in others. This study seeks to identify markers that predict how effective abatacept will be in individuals newly diagnosed with type 1 diabetes.

Select Inclusion Criteria:

- Diagnosed with type 1 diabetes within the last six months
- Age 6-45 years
- Positive for at least one diabetes-related autoantibody
- In good general health, and
- live or work in the Seattle area
PROTECT study - In a recent landmark prevention study, teplizumab was found to delay type 1 diabetes diagnosis in high-risk individuals for a median of two years. This study investigates the safety, tolerability, and efficacy in preserving insulin secretion in children and adolescents with newly diagnosed type 1 diabetes (T1D).

Treatment Arm(s):

A. Teplizumab IV infusion
B. Placebo

Select Inclusion Criteria:

• Parents must contact Benaroya Research Institute within 10 days of the child’s diagnosis
• Age 8-17 years
• In good general health

Study ID: 971
PI: Carla Greenbaum, MD
1 (800) 888–4187 / Diabetes@BenaroyaResearch.org
Targeting Beta Cell Dysfunction in Longstanding T1D

“Waking Beta Cells” - The study’s purpose is to test whether two months of treatment with golimumab (SIMPONI®) can transiently improve insulin secretion in people with long-standing T1D who no longer produce insulin.

Select Inclusion Criteria:

- Diagnosed with type 1 diabetes at least three years ago
- Age 18 through 50 years
- Reside or work in the Seattle area
BRIDge – A study aiming to improve understanding of diabetes and immune mediated disease. Participants agree to share contact, research, and health information with Benaroya Research Institute. Participation in this study is voluntary and consists of visiting Benaroya Research Institute to give blood samples and answer questions about personal and family medical history. Samples will be used to investigate genetic markers associated with autoimmune disease and to study measures of autoimmunity, such as antibodies and immune system activity.

Study Type:

• Observational

Select Inclusion Criteria:

• Individuals diagnosed with type 1 diabetes within the past 30 years
• Participants 55 years of age or younger

Study ID: IRB10024
PI: Carla Greenbaum, MD
1 (800) 888 – 4187 / diabetes@benaroyaresearch.org
Phase 2, Multicenter, Double-blind (Sponsor-unblinded), Randomized, Placebo-Controlled Study of the Safety and Efficacy of Elagolix in Women with Polycystic Ovary Syndrome

Treatment Arm(s):
A. Experimental: various doses of Elagolix plus matching placebo

Select Inclusion Criteria:
• Participants with clinical diagnosis of Polycystic Ovary Syndrome (PCOS)
• Participants with a Body Mass Index (BMI) of 18.5 to 38kg/m² at time of Screening

Select Exclusion Criteria:
• Participants with newly diagnosed medical condition requiring intervention that has not been stabilized at least 30 days prior to Baseline
• Participants with an unstable medical condition (including, but not limited to, uncontrolled hypertension, epilepsy requiring anti-epileptic medicine, unstable angina, confirmed inflammatory bowel disease)
• Participants with surgical history of hysterectomy, unilateral or bilateral oophorectomy, bilateral tubal ligation, bilateral tubal occlusion, or bilateral salpingectomy

NIH Site: clinicaltrials.gov/ct2/show/NCT03951077
Study ID: CRP19042
PI: Linda Mihalov, MD / Chinmaya Rajderkar / (206) 287-6262
Pager: (206) 540-0121 / Chinmaya.Rajderkar@VirginiaMason.org
ANCHOR Study: Topical or Ablative Treatment in Preventing Anal Cancer in Patients With HIV and Anal High-Grade Squamous Intraepithelial Lesions

Treatment Arm(s):
   A. Patients are directed to receive either topical or ablative treatment at the discretion of the clinician including: imiquimod, fluorouracil or trichloroacetic acid, infrared coagulation, hyfrecation/electrocautery, or laser. Patients may also undergo excision under anesthesia
   B. Active monitoring

Select Inclusion and Exclusion Criteria:
   • HIV-1 infection
   • No HSIL treatments in past 6 months
   • No history of anal cancer or signs of anal cancer at baseline, and no history of penile, vulvar, vaginal or cervical cancer
   • Biopsy-proven HSIL at baseline
   • At least one focus of HSIL must be identified that is not within a condyloma that may be treated after enrollment into the study

NIH Site: clinicaltrials.gov/ct2/show/NCT02135419
Study ID: IRB14114
PI: David Aboulafia, MD / CRC: Rachel Dowty / (206) 287-6275
Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org
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Prospective Evaluation of DVT Incidence and Risk Factors in Patients with ALS: A Pilot Study

Treatment Arm(s):
In this study, we aim to prospectively quantify the incidence and additional risk factors of VTE in our ALS population. Our secondary objective is to characterize the accuracy of D-dimer testing for exclusion of VTE.

Select Inclusion Criteria:
- Patients 18 years or older who are seeking or receiving care of ALS at the Neuroscience Institute.
- Patients who are, by the clinical judgement of the investigator, are at high risk for developing a DVT (i.e. reduced mobility, extremity weakness, etc.)

Select Exclusion Criteria:
- symptomatic VTE at enrollment
- acute stroke within the previous 3 months prior to enrollment
- For subjects who are on anticoagulation therapy, the dose must be stable for at least 3 months before enrolling in the trial. Bulbar-onset disease.
- concomitant cognitive disorders

Study ID: CRP17109
PI: Justin Stahl, MD / CRC: Ellie Fox / (206) 287-6264
Pager: (206) 540-0074 / Ellie.Fox@VirginiaMason.org
RAD-PD: Registry for the Advancement of Deep Brain Stimulation in Parkinson’s Disease

*Treatment Arm(s):*
A. Individuals diagnosed with idiopathic PD
B. Candidate for DBS treatment of PD as determined by the site investigator(s)

*Select Inclusion Criteria:*
• Individuals diagnosed with idiopathic PD
• Candidate for DBS treatment of PD as determined by the site investigator(s)

*Select Exclusion Criteria:*
• Individuals with prior history of DBS or lesion surgery
• Individuals who are unwilling or unable to participate in serial follow-up assessments as desired in the schedule of activities
• Individuals who are unable or unwilling to engage in completion of patient reported outcome measures, even with the assistance of a care provider

Study ID: CRP19039
PI: Farrokh Farrokhi, MD / CRC: Chinmaya Rajderkar / (206) 287-6262
Pager: (206) 540-0121 / Chinmaya.Rajderkar@VirginiaMason.org
Medtronic Product Surveillance Registry

Primary objective:
The purpose of the Registry is to provide continuing evaluation and periodic reporting of safety and effectiveness of Medtronic market-released products. The Registry data is intended to benefit and support interests of patients, hospitals, clinicians, regulatory bodies, payers, and industry by streamlining the clinical surveillance process and facilitating leading edge performance assessment via the least burdensome approach.

Select Inclusion Criteria:
- Patient or legally authorized representative provides written authorization and/or consent per institution and geographical requirements
- Patient has or is intended to receive or be treated with an eligible Medtronic product
- Patient within enrollment window relative to therapy initiation or meets criteria for retrospective enrollment

Select Exclusion Criteria:
- Patient who is, or will be, inaccessible for follow-up
- Patient with exclusion criteria required by local law
- Patient is currently enrolled in or plans to enroll in any concurrent drug and/or device study that may confound results

NIH Site: clinicaltrials.gov/ct2/show/NCT01524276
Study ID: IRB12147
PI: Farrokh Farrokhi, MD / CRC: Ellie Fox / (206) 287-6264
PAGER: (206) 540-0074 / Ellie.Fox@VirginiaMason.org
Medtronic® Deep Brain Stimulation (DBS™) Therapy for Dystonia - HUD

Primary objective:
Medtronic DBS Therapy for Dystonia delivers electrical stimulation to areas of your brain to help control symptoms of various movement disorders. Medtronic DBS Therapy for Dystonia may help control your symptoms, but it is not a cure. When you turn on the brain stimulation, it will deliver stimulation that may decrease some or all of your symptoms. Your symptoms will return when the system is turned off.

Select Inclusion Criteria:
• Diagnosis of chronic, intractable (drug refractory) primary dystonia, including generalized and segmental dystonia, hemidystonia, and cervical dystonia (torticollis)
• Must be 7 years of age or older
SIJ Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial

Treatment Arm(s):
A. Multilevel Lumbar Fusion Surgery with additional placement of iFuse 3-D in a trajectory parallel to the S2Al screw

Select Inclusion Criteria:
• Age 21-75 at time of screening
• Patient scheduled for multilevel (>3 levels) spinal fusion surgery with planned fixation to the pelvis using S2Al screws
• Patient has signed study-specific informed consent form
• Patient has the necessary mental capacity to participate and is physically able to comply with study protocol requirements

Select Exclusion Criteria:
• Prior sacroiliac joint fusion/fixation on either side
• Any known sacral or iliac pathology
• Severe osteoporosis
• Known allergy to titanium or titanium alloys
• Patient currently receiving or seeking short- or long-term worker’s compensation and/or currently involved in injury litigation related to the SI joint or low back pain.
• Currently pregnant or planning pregnancy in the next 2 years

NIH Site: clinicaltrials.gov/ct2/show/NCT04062630
Study ID: CRP19118
PI: Jean-Christophe Leveque, MD / CRC: Kate Duran / (206) 287-6268
Pager: (206) 540-8924 / Kate.Duran@virginiamason.org
MIND: Artemis in the Removal of Intracerebral Hemorrhage

Treatment Arm(s):

A. Artemis + Medical Management (MIS)
B. Best Medical Management Alone (MM)

Select Inclusion Criteria:

• Supratentorial ICH of volume $\geq 20$ and $\leq 80$ cc (measured using A x B x C/2 method)
• Hemostasis (hemorrhage increase of $< 5$ cc as confirmed by 2 CT/MR taken a minimum of 6 hours apart)
• NIHSS $\geq 6$
• Presenting GCS $\geq 5$ and $\leq 15$
• Historical mRS 0 or 1
• Symptom onset $< 24$ hours prior to initial CT
• MIS must be initiated within 72 hours of ictus/bleed
• SBP must be $< 180$ mmHg and controlled at this level for

NIH Site: clinicaltrials.gov/ct2/show/NCT03342664
Study ID: CRP17117
PI: Robert Ryan, MD / CRC: Chinmaya Rajderkar / (206) 287-6262
Pager: (206) 540-0121 / Chinmaya.Rajderkar@VirginiaMason.org
Sleep for Stroke Management and Recovery Trial (Sleep SMART)

Treatment Arm(s):

A. 6 months of CPAP plus usual medical therapy.
B. 6 months of usual medical therapy alone.

Select Inclusion Criteria:

• TIA with ABCD2 ≥4 or ischemic stroke, within the prior 14 days.
Oral Ifetroban to Treat Diffuse Cutaneous Systemic Sclerosis (SSc) or SSc-associated Pulmonary Arterial Hypertension

Treatment Arm(s):
A. oral ifetroban or oral placebo daily for 365 days

Select Inclusion Criteria:
• Systematic Sclerosis (SSc), as defined using the 2013 American College of Rheumatology/ European Union League Against Rheumatism Classification Criteria and dcSSc within 7 years following initial diagnosis as defined by the onset of the first non-Raynaud symptom.
• SSc-PAH Criteria:
  • Adults fulfilling the 2013 American College of Rheumatology/ European Union League Against Rheumatism Classification Criteria with confirmed SSc-PAH (limited or dcSSc) confirmed via previous cardiac catheterization
  • Stable oral therapy for PAH for at least 30 days (monotherapy or combination)
  • New York Heart Association (NYHA) Class I-III Heart Failure

NIH Site: clinicaltrials.gov/ct2/show/NCT02682511
Study ID: CRP19055
PI: Jeffrey Carlin, MD / CRC: Kelly Robertson / (206) 287-6263
Pager: (206) 314-0414 / Kelly.Robertson@virginiamason.org
A Study to Investigate the Safety and Efficacy of ABBV-105 and Upadacitinib Given Alone or in Combination in Participants With Moderately to Severely Active Systemic Lupus Erythematosus

Treatment Arm(s):

A. Upadacitinib and ABBV-105  
B. ABBV-105 and Placebo for Updadacitinib  
C. Placebo for ABBV-105 and Placebo for Updadacitinib

Select Inclusion Criteria:

- Clinical diagnosis of SLE at least 24 weeks prior to screening  
- At Screening, must have at least one of the following:  
  - antinuclear antibody(ANA)+ (titer >= 1:80)  
  - anti-dsDNA+  
  - anti-Smith+  
- SLEDAI-2K >= 6 as reported and independently adjudicated  
- Physician’s Global Assessment (PhGA) >= 1 during screening period  
- Background treatment, stable for 30 days, at Baseline with prednisone, antimalarials, azathioprine, mycophenolate, leflunomide cyclosporine, tacrolimus, and/or methotrexate (MTX).

NIH Site: clinicaltrials.gov/ct2/show/NCT03978520  
Study ID: CRP19053  
PI: Jeffrey Carlin, MD / CRC: Kate Duran / (206) 287-6268  
Pager: (206) 540-8924 / Kate.Duran@VirginiaMason.org
A Study of Baricitinib in Participants With Systemic Lupus Erythematosus (BRAVE II)

Treatment Arm(s):

A. Baricitinib High Dose
B. Baricitinib Low Dose
C. Placebo Group

Select Inclusion Criteria:

• A clinical diagnosis of SLE at least 24 weeks prior to screening.
• Have a positive ANA (titer ≥1:80) and/or a positive anti-dsDNA, and/or a positive anti-Sm during screening.
• Have a total SLEDAI-2K score ≥6 during screening.
• Have a clinical SLEDAI-2K score ≥4 at randomization.
• Have at least 1 British Isles Lupus Assessment Group (BILAG) A score or 2 BILAG B scores during screening.
• Are receiving at least one of the following standard of care medications for SLE:
  • A single antimalarial at a stable dose for at least 8 weeks prior to screening
  • A single immunosuppressant at a stable dose for at least 8 weeks prior to screening
  • An oral corticosteroid, initiated at least 4 weeks prior to screening, at a stable dose ≤40 milligrams/day prednisone (or equivalent) for at least 2 weeks prior to screening.
A Phase 2, Randomized, Double-blind, Placebo-controlled Evaluation of the Safety and Efficacy of BMS-986165 With Background Treatment in Subjects With Lupus Nephritis

Treatment Arm(s):
A. Placebo
B. BMS-986165

Select Inclusion Criteria:
• Meets the Systemic Lupus Erythematosus International Collaborating Clinics (SLICC) criteria for SLE
• Renal biopsy confirming a histologic diagnosis of active LN: International Society of Nephrology/Renal Pathology Society (ISN/RPS) Classes III (A or A/C), IV-S (A or A/C), or IV-G (A or A/C); or Class V (in combination with Class III or IV)
• Urine protein:creatinine ratio (UPCR) ≥1.5 mg/mg

Select Exclusion Criteria:
• Pure ISN/RPS Class V membranous LN
• Screening estimated glomerular filtration rate (eGFR; calculated using the Modification of Diet in Renal Disease [MDRD] equation) ≤30 mL/min/1.73 m2
• Dialysis within 12 months before screening or plans for dialysis within 6 months after enrollment in the study

NIH Site: clinicaltrials.gov/ct2/show/NCT03943147
Study ID: CRP19080
PI: Jeffrey Carlin, MD / CRC: Kelly Robertson / (206) 287-6268
Pager: (206) 314-0414 / Kelly.Robertson@VirginiaMason.org
Strategy to Prevent the Onset of Clinically-Apparent Rheumatoid Arthritis

Treatment Arm(s):
A. Hydroxychloroquine Group  
B. Placebo Group

Select Inclusion Criteria:
• Elevation of autoantibody anti-cyclic citrullinated peptide-3 (anti-CCP3) defined by result of anti-CCP3 ≥40 units, at screening.

Select Exclusion Criteria:
• Evidence of significant retinal disease that, in the opinion of the examiner, would make identification of potential future retinal toxicity from hydroxychloroquine difficult to evaluate;  
• A medical history of inflammatory arthritis (IA) of any type and/or rheumatic disease and immunologic disease(s) that may be associated with IA  
• Prior or current systemic treatment with disease modifying anti-rheumatic agents, immunomodulatory agents, or glucocorticoids for IA, other rheumatic diseases, or other immunologic diseases

NIH Site: clinicaltrials.gov/ct2/show/NCT02603146
Study ID: CRP18063  
PI: Jeffrey Carlin, MD / CRC: Kelsey Yenney / (206) 287-6266  
Pager: (206) 405-8786 / Kelsey.Yenney@VirginiaMason.org
A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Phase 3 Study Evaluating the Safety and Efficacy of Intravenous Iloprost in Subjects With Systemic Sclerosis Experiencing Symptomatic Digital Ischemic Episodes (AURORA Study)

Treatment Arm(s):
- A. Placebo
- B. Iloprost Injection, for intravenous use

Select Inclusion Criteria:
- Subjects must be greater than or equal to 18 years of age
- Subjects must have a diagnosis of Systemic Sclerosis as defined by the 2013 American College of Rheumatology criteria/EULAR criteria
- Subjects must be willing and able to comply with the study requirements and give informed consent for participation in the study

Select Exclusion Criteria:
- Female subjects who are pregnant or breastfeeding
- Subjects with systolic blood pressure <85 mmHg
- Subjects with a history of major trauma or hemorrhage within 30 days of screening
- Subjects with any history of acetaminophen intolerability (eg, allergic reaction to acetaminophen)

NIH Site: clinicaltrials.gov/ct2/show/NCT04040322
Study ID: CRP19070
PI: Jeffrey Carlin, MD / CRC: Kate Duran / (206) 287-6268
Pager: (206) 540-8924 / Kate.Duran@VirginiaMason.org
Opioid-Free Anesthesia for Open Cardiac Surgery: A Prospective Randomized Controlled Trial

Primary Objectvie(s):
To compare the opioid consumption in the first 24-postoperative hours between subjects who have received an opioid-free anesthetic with those that have received a tradtional opioid heavy anesthetic for open cardiac surgery.

Select Inclusion Criteria:
• Male or female ≥ 18 years of age at the time of consent
• Undergoing elective midline sternotomy for CABG, aortic aneurysm repair, single valve repair/replacement, or CABG in combination with single valve repair/replacement
• Diagnosis of coronary artery disease, mitral valve stenosis or regurgitation or aortic stenosis or regurgitation requiring open cardiac surgery

Select Inclusion Criteria:
• Any opioid use within 4 weeks prior to surgery
• End stage renal disease requiring dialysis
• Severe pulmonary hypertension (PASP>2/3 SBP)
• Hypersensitivity or contraindication to any of the study medications

Study ID: CRP19041
PI: Sarah Bain, MD
Contact: (206) 223-6980
The effect of an opioid-free anesthetic on post-operative opioid consumption after laparoscopic bariatric surgery: a prospective, double-blinded, randomized controlled trial

**Treatment Arm(s):**
- A. Autogenic splenic implant
- B. Distal pancreatectomy with splenectomy
- C. Spleen-preserving distal pancreatectomy

**Select Inclusion Criteria:**
- Adult (>18 years old)
- Patients undergoing elective laparoscopic gastric bariatric surgery (i.e. laparoscopic roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy)
- Able to provide informed consent

**Select Inclusion Criteria:**
- Any opioid use within 4 weeks prior to surgery
- Chronic antiemetic use
- Hypersensitivity or contraindication to any study drug
- Non-English speaking subjects

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Study ID: CRP19060
PI: Christine Oryhan, MD / CRC: Jannefer Sengmany / (206) 287-6278
Pager: (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org
Autogenic splenic implantation in distal pancREatec-tomy with SplencTomy for benign lesiOns of the distal pancREas (RESTORE) : A multi-center, randomized, open labelled trial

Treatment Arm(s):
A. Autogenic splenic implant
B. Distal pancreatectomy with splenectomy
C. Spleen-preserving distal pancreatectomy

Select Inclusion Criteria:
• ≥ 18 years
• Indication for elective DP for suspected benign or low grade malignant lesion of the pancreatic body or tail
• Either preoperatively determined DPS or SPDP where splenic preservation appears not feasible intraoperatively
• Either open or laparascopic procedure
• Fit to undergo distal pancreatectomy (American societ of anaesthesiologist (ASA) classification ≤ 3, see appendix)
A phase 2, multicenter, randomized, double blind, placebo-controlled, single-treatment, 2-stage, dose finding study evaluating the efficacy and safety of BOTOX® intravesical instillation in participants with overactive bladder and urinary incontinence

**Select Inclusion Criteria:**
- Age 18 – 75 years
- Symptoms of overactive bladder with urgency urinary incontinence for > 6 months
- Has not been adequately managed with ≥ 1 pharmacologic therapies for treatment of their OAB symptoms

**Select Exclusion Criteria:**
- Has symptoms of OAB due to any known neurological condition
- Has a predominance of stress urinary incontinence
- Has a history of ≥ 2 UTIs within 3 months or is taking prophylactic antibiotics to prevent chronic UTIs
- Uses CIC or indwelling catheter to manage their urinary incontinence
- Has had previous or current botulinum toxin serotype for any non-urological condition within 12 weeks of randomization

NIH Site: clinicaltrials.gov/ct2/show/NCT03320850
Study ID: CRP17074
PI: Kathleen Kobashi, MD / CRC: Debbie Sparks / (206) 341-0896
Pager: (206) 663-9768 / Deborah.Sparks@VirginiaMason.org
CELEBRATE: An Adaptive, Two Stage, Double-Blind, Stratified, Randomized Controlled Comparing the Safety and Efficacy of AMDC-USR with Placebo in Female Subjects with Stress Urinary Incontinence

**Select Inclusion Criteria:**

- 50 to 75 years of age with primary and moderate-to-severe symptoms of stress urinary incontinence
- 6 months’ history of stress urinary incontinence diagnosis
- Has a history of inefficient, insufficient, or refused pelvic floor muscle training (PFMT)

**Select Exclusion Criteria:**

- BMI ≥ 35
- A medical diagnosis of fibromyalgia, uncontrolled diabetes (hemoglobin A1c >7%), requires prophylactic antibiotics for chronic UTI’s, cystitis or urethritis
- History of cancer in pelvic organs, ureters, or kidneys
- Systemic neuromuscular disorder (e.g. multiple sclerosis, Parkinson’s disease
- Actively undergoing treatment with stimulation neuromodulation system within the last 6 months
- Surgical intervention in the pelvic area within the last 6 months

NIH Site: clinicaltrials.gov/ct2/show/NCT03104517
Study ID: CRP17058
PI: Una Lee, MD / CRC: Debbie Sparks / (206) 341-0896
Pager: (206) 663-9768 / Deborah.Sparks@VirginiaMason.org
**SAMPLE LANGUAGE FOR RESEARCH DICTATION**

**Initial Informed Consent**
“Subject has been verbally informed of the study specifics and has been given the opportunity to ask questions. All questions were answered to the subject’s satisfaction. It was clearly stated that the study was voluntary and that they could withdraw anytime. The subject agreed to participate in the ‘xxxx’ study and signed the Consent Form prior to any study specific procedures on ‘dd/mmm/yyyy’. A copy of the signed and dated consent form was given to the subject.”

**Inclusion/Exclusion**
“Subject has met inclusion, exclusion criteria. All related study procedures have been completed.” Document performance status, as needed.

**Establish Therapy**
“Subject has been randomized to ‘study arm/control group X’.”
“Subject has been scheduled to begin study therapy on ‘dd/mmm/yyyy’.” “Study therapy ‘X’ will be given to subject every ‘xxxx’.”

**Interim Evaluation**
“Subject was restaged on ‘dd/mmm/yyyy’ and remains stable. Subject will continue on study therapy receiving ‘xxxx + frequency’. Next restaging will occur in ‘x period’.” List also any therapy-related Serious Adverse Events or other significant experiences.

**Final Evaluation**
“Subject is going off-study for ‘x reason’. The last day of study therapy was ‘dd/mmm/yyyy’ Study follow-up will occur ‘x frequency’ as per the protocol.”
RESEARCH DICTATION

Maintaining clear and complete records of each stage of a subject's research participation is a requirement for both the safety of our patients and for continuing research compliance.

1. **Screening or Study Discussion**
   a. Study points discussed
   b. Alternatives discussed
   c. Other Specifics

2. **Consenting**
   a. Study points discussed (coordinator may supplement)
   b. Allowed to ask questions & had any answered to their satisfaction
   c. Agreed to participate
   d. Signed and dated the consent form prior to any study specific procedures completed.
   e. Copy of the signed and dated consent was given to subject

3. **Therapy**
   a. Therapy or study arm subject was randomized to
   b. Frequency of visits and/or follow-up

4. **Dosing/Device Modifications**
   a. Any changes
   b. Why?

5. **Adverse Events (details can be in study chart)**
   a. Start/Stop dates
   b. ConMeds
   c. Severity (incl. any grading)
   d. Causality

6. **Progression/Crossover/Off Study**