

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

DIRECTORY

Biorepositories

Mail Stop: IN-RC

Main Line 1-877-202-5200

Biorepository@BenaroyaResearch.org

Cancer Clinical Research Unit (CCRU)

Mail Stop: D4-CRP/Main Line (206) 287-6270

CancerResearch@VirginiaMason.org

Clinical Trials Unit (CTU): (Includes Allergy/Asthma, Anesthesia, Cardiology, Endocrinology, Neurology/Neurosurgery and Rheumatology)

Mail Stop: D4-CRP/Main Line (206) 287-6260

MainCTU@BenaroyaResearch.org

Digestive Diseases Research Institute

Mail Stop: D4-CRP/Main Line (206) 341-1021

DDIResearchReferral@VirginiaMason.org

Type 1 Diabetes Research Group

Mail Stop: IN-RC/ Main Line 800-888-4187

Diabetes@BenaroyaResearch.org

Urology

Mail Stop: C7-URO/ Main Line (206) 341-0896

Deborah.Sparks@VirginiaMason.org

TABLE OF CONTENTS

	Allergy/Asthma.....	4
	Anesthesia.....	5
	Biorepositories.....	6
	Cancer.....	21
	Karnofsky Performance Scale.....	57
	ECOG/ZUBROD Performance Status.....	57
	Cardiology.....	58
	Digestive Diseases.....	59
	Endocrinology.....	83
	HIV/AIDS.....	88
	Infectious Diseases.....	89
	Neurology/Neurosurgery.....	90
	Rheumatology.....	97
	Surgery.....	104
	Urology.....	107
	Research Dictation.....	109
	Sample Language For Research Dictation.....	110



ALLERGY/ASTHMA

Peanut Oral Immunotherapy Study of Early Intervention for Desensitization (POSEIDON)

Primary Objective(s):

A. AR101 powder (Peanut allergen formulation)

Subjects will be randomized to active arm of ARC005 and will be administered IP (AR101) in escalating doses for approximately 6 months.

B. Placebo powder

Subjects will be randomized to placebo arm of ARC005 and will be administered escalating doses of IP (placebo) for approximately 6 months.

Select Inclusion and Exclusion Criteria:

- Aged 1 to < 4 years at randomization.
- Written informed consent from the legal guardian/parent (or both parents where required by local authorities). Provide assent where required and as appropriate per local requirements.
- No known history of peanut ingestion and has serum IgE to peanut ≥ 5 kUA/L within 12 months before randomization.
- History of severe or life-threatening anaphylaxis anytime before the screening DBPCFC.
- Recurrent GI symptoms considered clinically significant in the opinion of the investigator.
- Mild asthma (criteria steps 1-2; NHLBI, 2007) that is uncontrolled or difficult to control based on NHLBI 2007 criteria.

NIH Site: clinicaltrials.gov/ct2/show/NCT03736447

Study ID: CRP19003

PI: David Jeong, MD / CRC: Tryniti Smith / (206) 287-6261

Tryniti.Smith@virginiamason.org



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: Ellie Fox / (206) 287-6264

Pager: (206) 405-8786 / Ellie.Fox@virginiamason.org



ANESTHESIA

Open Cardiac Surgery

Opioid-Free Anesthesia for Open Cardiac Surgery: A Prospective Randomized Controlled Trial

Primary Objective(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 traditional 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 Exclusion 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: CRP19021

PI: Adnan Alseidi, MD / CRC: Anas Najjar / (206) 287-6271

Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org



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. Opioid based anesthetic regimen
- B. Opioid free anesthetic regimen

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 Exclusion Criteria:

- Any opioid use within 4 weeks prior to surgery
- Chronic antiemetic use
- Hypersensitivity or contraindication to any study drug

Study ID: CRP19060

PI: Christine Oryhan, MD / CRC: Jannefer Sengmany / (206) 287-6278

Pager: (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org



BIOREPOSITORIES

Allergy and Asthma

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



BIOREPOSITORIES

Down Syndrome and Human Immunity

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

BIOREPOSITORIES



Healthy Volunteers without Autoimmune Disease

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



BIOREPOSITORIES

Healthy Volunteers without Autoimmune Disease

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



BIOREPOSITORIES

Inflammatory Bowel Disease

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



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



BIOREPOSITORIES

Recovered Covid Postive Study

We are enrolling participants that had tested positive for SARS-covid19, but have since recovered and are out four weeks or more from having symptoms. The study is longitudinal, but the time points may differ. Participants will be asked to donate blood and health information with a \$50 reimbursement for each blood donation visit, as with our other studies.

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: Biorepository@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.

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: RDR@BenaroyaResearch.org



BIOREPOSITORIES

Type 1 Diabetes

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



BIOREPOSITORIES

VM-BRIDPAN

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**



Connect® MDS/AML Disease Registry

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



BIOREPOSITORIES

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

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: Jannefer Sengmany / (206) 287-6278

Pager: (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org



CANCER

Bladder

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 \geq 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 \geq pT3 or pN+
- Patient must have had radical surgical resection of their bladder cancer \geq 4 weeks but \leq 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: Karolina Rauch / (206) 287-6279

Pager: (206) 314-0118 / Karolina.Rauch@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



CANCER

Breast

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: Tryniti Smith / (206) 287-6265

Tryniti.Smith@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



CANCER

Colorectal

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/involve 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: Jannefer Sengmany / (206) 287-6278

Pager: (206) 541-4635 / Jannefer.Sengmany@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



CANCER

Colorectal

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 / Karolina Rauch / (206) 287-6279

Pager: (206) 314-0118 / Karolina.Rauch@VirginiaMason.org



CANCER

Esophageal

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: Karolina Rauch / (206) 287-6279

Pager: (206) 314-0118 / Karolina.Rauch@VirginiaMason.org



A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab Versus Temozolomide in Patients With Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma

Treatment Arm(s):

- A. Arm I (radiation therapy, temozolomide)
Patients undergo radiation therapy over 30 fractions for 5 days per week (Monday-Friday) and receive temozolomide PO daily for 6 weeks. After radiation, patients may wear the Optune device at the discretion of the patient and their treating physician. Beginning 1 month after radiation therapy, patients receive temozolomide on days 1-5. Treatment repeats every 28 days for up to 12 cycles at the discretion of the treating investigator in the absence of disease progression or unacceptable toxicity.
- B. Arm II (radiation therapy, ipilimumab, nivolumab)
Patients undergo radiation therapy over 30 fractions for 5 days per week (Monday-Friday) for 6 weeks. Starting on the first day of radiation, patients also receive ipilimumab IV over 90 minutes Q4W for 4 doses and nivolumab IV over 30 minutes every 2 weeks until disease progression.

Select Inclusion Criteria:

- No known IDH mutation.
- Availability of formalin-fixed paraffin-embedded (FFPE) tumor tissue block and hematoxylin & eosin (H&E) stained slide to be sent for central pathology review for confirmation of histology and MGMT promoter methylation status.
- Contrast-enhanced brain MRI within 72 hours after surgery

NIH Site: clinicaltrials.gov/ct2/show/NCT04396860

Study ID: CRP20076

PI: John Paul Flores, MD / CRC: Rachel Dowty / (206) 287-6275

Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org



CANCER

Hepatobiliary Malignancies

Biliary Tract Cancer

A Single Arm Phase Ib/II Multi-Center Study of Nivolumab in Combination With Nanoliposomal-Irinotecan, 5-Fluorouracil, and Leucovorin as Second Line Therapy for Patients With Advanced Biliary Tract Cancer

Treatment Arm(s):

- A. Nivolumab
- B. Nanoliposomal-Irinotecan
- C. 5-Fluorouracil
- D. Leucovorin

Select Inclusion Criteria:

- Patients must have a pathologically confirmed carcinoma of the biliary tract (intra-hepatic, extra-hepatic (hilar, distal) or gall bladder) that is not eligible for curative resection, transplantation, or ablative therapies. Tumors with mixed hepatocellular and cholangiocarcinoma histology are excluded
- Age ≥ 18 years
- Child-Pugh score of less than 7
- ECOG performance status of 0-1
- Must be able to tolerate CT and/or MRI with contrast

NIH Site: clinicaltrials.gov/ct2/show/NCT03785873

Study ID: CRP20040

PI: Bruce Lin, MD / **CRC:** Joanne Chung / (206) 287-6277

Pager: (206) 540-0147 / Joanne.Chung@VirginiaMason.org



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) $\geq 1,500$ cells/ μL
- Platelet count $\geq 100,000$ 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 Cabozantinib (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



CANCER

HIV/AIDS Malignancies

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 $\geq 70\%$
- (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 \leq 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



CANCER

HIV/AIDS Malignancies

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) $\geq 60\%$
- 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 enzymelinked 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



CANCER

HIV/AIDS Malignancies

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 DLB-CL 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 LU-TATHERA (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



CANCER

Pancreas

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

PI: 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



CANCER

Pancreas

PANOVA-3: Effect of Tumor Treating Fields (TTFields, 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

NIH Site: clinicaltrials.gov/ct2/show/NCT03377491

Study ID: CRP18024

PI: Vincent Picozzi, MD / **CRC:** Janet Zaltsman / (206) 287-6273

Pager: (206) 540-0704 / Janet.Zaltsman@VirginiaMason.org



**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 $\geq 50\%$
- FDG-PET SUVmax decrease by $\geq 30\%$ 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 adenocarcinoma
- 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



CANCER

Pancreas

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 \geq 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



Phase III IGRT and SBRT vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer

Treatment Arm(s):

- A. Intensity-Modulated Radiation Therapy (IMRT):
Patients undergo Intensity-Modulated Radiation Therapy (IMRT) once daily 5 fractions per week for 28 fractions over less than 32 business days.
- B. Stereotactic Body Radiation Therapy (SBRT):
Patients undergo Stereotactic Body Radiation Therapy (SBRT) at least every other day for 2-3 fractions per week for 5 fractions over less than 12 business days.

Select Inclusion and Exclusion Criteria:

- History and physical including a digital rectal exam 60 days prior to registration
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1 60 days prior to registration
- MRI of the prostate and pelvis (compliant with PIRADSV2.1 guidelines) within 1 year prior to registration
- Prior or current invasive malignancy with current evidence of active disease within the past 2 years
- Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields

NIH Site: clinicaltrials.gov/ct2/show/NCT03367702

Study ID: CRP20022

PI: Andrew Suen, MD / CRC: Jannefer Sengmany / (206) 287-6278

Pager: (206) 541-4635 / Jannefer.Sengmany@VirginiaMason.org



CANCER

Prostate

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 \geq 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 \leq 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: Marina Jovic / (206) 287-6282

Marina.Jovic@VirginiaMason.org



CANCER

Solid Tumors

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



CANCER

Urothelial Carcinoma

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 health-care 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

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

KARNOFKSY PERFORMANCE SCALE

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

ECOG/ZUBROD PERFORMANCE STATUS

0	Fully active; able to carry on all pre-disease activities without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
2	Ambulatory & capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited self-care; confined to bed or chair 50% or more of waking hours
4	Completely disabled; cannot carry on any self-care and totally confined to bed or chair
5	Death



CARDIOLOGY

Coronary Artery Disease

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: Kate Duran / (206) 287-6268

Pager: (206) 540-8924 / Kate.Duran@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



DIGESTIVE DISEASES

Endoscopy

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: 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/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/show/NCT02476279

Study ID: CRP18061

PI: Andrew Ross, MD / CRC: Tida Tangwongchai (206) 341-1416

Tida.Tangwongchai@VirginiaMason.org



DIGESTIVE DISEASES

Endoscopy

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



DIGESTIVE DISEASES

General Gastroenterology

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 symptoms (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 $< 500/\text{mm}^3$, 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/show/NCT04095663

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 (\geq) 18 years and less than or equal to (\leq) 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



DIGESTIVE DISEASES

IBD

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 Gelinias / (206) 341-1992

Pager: (206) 797-0393 / Katharyn.Gelinias@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



DIGESTIVE DISEASES

IBD

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 Gelinias / (206) 341-1992

Pager: (206) 797-0393 / Katharyn.Gelinias@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



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.

NIH Site: clinicaltrials.gov/ct2/show/NCT02394028

Study ID: IRB15018

PI: Michael Chiorean, MD / **CRC:** Katie Gelinias / (206) 341-1992

Pager: (206) 797-0393 / Katharyn.Gelinias@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 ≥ 220 but ≤ 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



DIGESTIVE DISEASES

IBD

Moderately to Severely Active Ulcerative Colitis

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



DIGESTIVE DISEASES

IBD

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) \geq 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 Chiorean, MD / CRC: Cheryl Shaw / (206) 341-1786

Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org



DIGESTIVE DISEASES

IBD

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



DIGESTIVE DISEASES

IBD

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

*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 Gelinas / (206) 341-1992

Pager: (206) 797-0393 / Katharyn.Gelinas@VirginiaMason.org



DIGESTIVE DISEASES

Liver Disease

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 Part1 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 Gelinias / (206) 341-1786

Pager: (206) 797-0393/ Katharyn.Gelinias@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/show/NCT03059446

Study ID: CRP17012

PI: Asma Siddique, MD / CRC: Cheryl Shaw / (206) 341-1786

Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org



DIGESTIVE DISEASES

Liver Disease

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. Cilofexor
- 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 $\geq 150,000/\text{mm}^3$
 - 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



ENDOCRINOLOGY

Diabetes Mellitus, Type 1

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

Study ID: 19091

PI: Carla Greenbaum, MD

1 (800) 888-4187 / Diabetes@BenaroyaResearch.org



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



ENDOCRINOLOGY

Diabetes Mellitus, Type 1

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

Study ID: 18044

PI: Carla Greenbaum, MD

1 (800) 888-4187 / Diabetes@BenaroyaResearch.org

*Diabetes Translational Research Project*

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



HIV/AIDS

Anal Cancer Prevention

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



A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of MSTT1041A or UTTR1147A in Patients With Severe COVID-19

Treatment Arm(s):

- A. Experimental: MSTT1041A
- B. Placebo Comparator: MSTT1041A-matched Placebo
- C. Experimental: UTTR1147A
- D. Placebo Comparator: UTTR1147A-matched Placebo

Select Inclusion Criteria:

- Hospitalized with COVID-19 pneumonia confirmed per WHO criteria (including a positive PCR of any specimen; e.g., respiratory, blood, urine, stool, other bodily fluid) and evidenced by chest X-ray or CT scan
- Peripheral capillary oxygen saturation (SpO₂) ≤93% (on room air or supplemental oxygen) or partial pressure of oxygen (PaO₂)/fraction of inspired oxygen (FIO₂) ≤300 millimetres of mercury (mmHg) or requiring supplemental oxygen to maintain SpO₂ >93% or requirement for supplemental oxygen to maintain SpO₂ at an acceptable level per local standard of care

Select Exclusion Criteria:

- Pregnant or breastfeeding, or positive pregnancy test at screening
- Participating in another clinical drug trial
- ALT or AST >10 times the upper limit of normal (ULN) at screening

NIH Site: clinicaltrials.gov/ct2/show/NCT04386616

Study ID: CRP20044

PI: Uma Malhotra, MD / CRC: Kate Duran / (206) 287-6268

Pager: (206) 540-8924 / Kate.Duran@VirginiaMason.org



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: Tryniti Smith / (206) 287-6261

Tryniti.Smith@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 Farrokh, MD / CRC: Chinmaya Rajderkar / (206) 287-6262

Pager: (206) 540-0121 / Chinmaya.Rajderkar@VirginiaMason.org



NEUROLOGY/NEUROSURGERY

Neurosurgery

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

Study ID: IRB12151

PI: Farrokh Farrokhi, MD / CRC: Chimaya Rajderkar / (206) 287-6262

Pager: (206) 540-0121 / Chinmaya.Rajderkar@VirginiaMason.org



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 S2AI 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 S2AI 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 ≥ 20 and ≤ 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 ≥ 6
- Presenting GCS ≥ 5 and ≤ 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: Tryniti Smith / (206) 287-6261

Tryniti.Smith@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.

NIH Site: clinicaltrials.gov/ct2/show/NCT03812653

Study ID: CRP19014

PI: Fatima Milfred, MD / CRC: Tryniti Smith / (206) 287-6261

Tryniti.Smith@VirginiaMason.org



Anticoagulation in Intracerebral Hemorrhage (ICH) Survivors for Stroke Prevention and Recovery

Treatment Arm(s):

- A. Apixaban 5mg once in the morning and evening
- B. Aspirin 81mg once daily

Select Inclusion Criteria:

- Intracerebral hemorrhage (ICH) (including primary intraventricular hemorrhage) confirmed by brain CT or MRI
- Can be randomized within 14-120 days after ICH onset
- CHA2DS2-VASc score ≥ 2
- or females of reproductive potential: use of highly effective contraception

Select Exclusion Criteria:

- History of ICH before index event
- Active infective endocarditis
- Lobar ICH with cerebral amyloid angiopathy
- Clear indication for anticoagulant drugs (e.g., requires anticoagulation for deep vein thrombosis or pulmonary embolism) or antiplatelet drugs (e.g., requires aspirin or clopidogrel for recent MI).
- Serum creatinine ≥ 2.5 mg/dL

NIH Site: clinicaltrials.gov/ct2/show/NCT03907046

Study ID: CRP20018

PI: Steven O'Donnell, MD / CRC: Kelly Robertson / (206) 287-6263

Pager: (206) 314-0414 / Kelly.Robertson@VirginiaMason.org



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:

- Systemic 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



RHEUMATOLOGY

dcSSc or SSc-PAH

A Phase 2, Randomized, Placebo-controlled, Double-blind, Open-label Extension Multicenter Study to Evaluate the Efficacy and Safety of KD025 in Subjects With Diffuse Cutaneous Systemic Sclerosis

Treatment Arm(s):

- A. KD025 200 mg daily, double-blinded for the first 28 weeks. Subjects will then will be unblinded, and continue on the same KD025 dose for the remaining 24 weeks.
- B. matched placebo, double-blinded for the first 28 weeks. Subjects will then will be unblinded, and re-randomized to one of the KD025 doses (200 mg daily or 200 twice a day) in a 1:1 fashion.

Select Inclusion Criteria:

- Male and female subjects ≥ 18 years old with the diagnosis of dcSSc according to the 2013 American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) criteria
- Must have disease duration (defined as interval from first non-Raynaud disease manifestation) of ≤ 5 years
- Must have mRSS of ≥ 15 but ≤ 35
- Male Subjects must not donate sperm for three (3) months after last dose of study drug.

NIH Site: clinicaltrials.gov/ct2/show/NCT03919799

Study ID: CRP20019

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 Upadacitinib
- C. Placebo for ABBV-105 and Placebo for Upadacitinib

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 \geq 1:80)
 - anti-dsDNA+
 - anti-Smith+
- SLEDAI-2K \geq 6 as reported and independently adjudicated
- Physician's Global Assessment (PhGA) \geq 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



RHEUMATOLOGY

Lupus

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



A Multicenter, Longitudinal, Open-Label, Single-Arm Study Describing Cognitive Processing Speed Changes in Relapsing Multiple Sclerosis Subjects Treated With Ozanimod (RPC-1063)

Treatment Arm(s):

- A. Patients with relapsing MS will receive RPC-1063 orally

Select Inclusion Criteria:

- Subject is male or female 18 to 65 years of age (inclusive) at the time of signing of the ICF.
- Subject has a diagnosis of MS according to the 2010 or 2017 Revised McDonald criteria.
- Subjects has ≤ 5 years since time of RMS diagnosis.
- Subject has ≤ 1 approved RMS DMT at time of study entry.

Select Exclusion Criteria:

- Subject has a visual or other sensorimotor impairment likely to confound test performance.
- Subject has a presence of > 10 GdE lesions on the Baseline brain MRI scan.
- Subject has a history of developmental disorder (eg, attention-deficit/hyperactivity disorder [ADHD], learning disability).

NIH Site: clinicaltrials.gov/ct2/show/NCT04140305

Study ID: CRP20009

PI: Lucas McCarthy, MD / CRC: Tryniti Smith / (206) 287-6261

Tryniti.Smith@VirginiaMason.org



RHEUMATOLOGY

Rheumatoid Arthritis

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:** Kelly Robertson / (206) 287-6263

Pager: (206) 314-0414 / Kelly.Robertson@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 intolerance (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



SURGERY

Autogenic splenic implantation in distal pancreatectomy with Splenectomy 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 laparoscopic procedure
- Fit to undergo distal pancreatectomy (American society of anaesthesiologist (ASA) classification ≤ 3 , see appendix)

Study ID: CRP19021

PI: Adnan Alseidi, MD / CRC: Anas Najjar / (206) 287-6271

Pager: (206) 405-9124 / Anas.Najjar@VirginiaMason.org



Neuspera's Implantable Sacral Neuromodulation (SNS) System in patients with symptoms of overactive bladder (OAB)

Select Inclusion Criteria:

- 22 years of age and older
- BMI between 18 and 35
- 6 months' history of urinary urgency incontinence diagnosis
- Failed conservative therapy and second-line drug therapy and is not a candidate for additional conservative or second-line therapy

Select Exclusion Criteria:

- Current urinary tract mechanical obstruction (e.g. benign prostatic hypertrophy, prostate cancer or urethral stricture)
- Has a predominance of stress urinary incontinence
- Any neurological condition that could interfere with normal bladder function, including stroke, epilepsy, multiple sclerosis, Parkinson's disease, or spinal cord injury
- Pelvic organ prolapse stage 3 or higher
- Previously implanted with a sacral neuromodulation device
- Any other active implanted devices (e.g. drug delivery pumps, pacemaker, ICD) whether turned on or off.
- Treatment of urinary symptoms with Botox within 12 months

NIH Site: clinicaltrials.gov/ct2/show/NCT04232696

Study ID: CRP19101

PI: Alvaro Lucioni, MD / CRC: Debbie Sparks / (206) 341-0896

Pager: (206) 663-9768 / Deborah.Sparks@VirginiaMason.org



UROLOGY

Stress urinary incontinence

CELLEBRATE: 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 \geq 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