

CLINICAL TRIALS

Dr. Michael Fuchs

“Liver-specific gene knockout and gene cluster analysis in gallstone-susceptible inbred mice” - German Science Foundation (Bonn)

PI: Michael Fuchs, MD, PhD

Dr. John R. Grider

“Role of Gut Peptides in Intestinal Peristalsis”

PI: John R. Grider, Ph.D.

Dr. Douglas M. Heuman

“A phase I study of safety and antiviral efficacy of SCY-635 in patients with chronic hepatitis C”

PI: Dr. Douglas Heuman

“A phase 1/ 2 study of DENSPM (N¹, N¹¹-diethylnorspermine) in patients with unresectable hepatocellular carcinoma”

Site PI: Dr. Douglas Heuman

“Risk factors for gallstones in men with liver disease caused by chronic hepatitis C”

PI: Dr. Douglas Heuman

“Indicators of liver disease severity and prognosis”

PI: Dr. Douglas Heuman

“Efficacy of rifaximin to reduce complications requiring hospitalization in patients with advanced cirrhosis awaiting liver transplantation. A double-blind, placebo controlled trial”

PI: Dr. Douglas Heuman

“Predictors of pretransplant survival in cirrhosis”

PI: Dr. Douglas Heuman

Dr. Donald F. Kirby

“A Phase IIb, Randomized, Double-Blind, Placebo Controlled Study for the Treatment of Celiac Disease in Patients with Active Celiac Disease”

PI: Donald F. Kirby

Contact: Heather Ross 804-828-9159

“Feeding and Pancreatic Rest in Acute Pancreatitis”

PI: Donald F. Kirby, MD

Contact: 804-828-4060

Dr. John F. Kuemmerle

“Growth and function of cultured gastrointestinal muscle”

PI: Dr. JF Kuemmerle

Dr. Velimir A Luketic

“The Natural History of Primary Biliary Cirrhosis (PBC) after treatment with Methotrexate and Tacrolimus”

PI: Velimir AC Luketic, MD

Contact: Carol Sargeant 804-828-8261

“Studies of Primary Sclerosing Cholangitis (STOPSC)”

PI: Velimir AC Luketic, MD

Contact: Carol Sargeant 804-828-8261

Dr. Karnam S. Murthy

“Function of Gut Peptides in Isolated Gut Muscle Cells”

PI: Karnam S. Murthy

“Hormonal Integration of Exocrine and Endocrine Organs”

PI: Karnam S. Murthy

Dr. W. Michael Pandak

“Molecular basis of coordinate regulation of hepatic cholesterol and bile acid homeostasis”

PI: W. Michael Pandak, MD

“Lipid transporters, bile acid synthesis and cholesterol homeostasis”

PI: W. Michael Pandak, MD

Dr. Shunlin Ren

“Regulation of Cholesterol Metabolism”

PI: Shunlin Ren, PhD

Dr. Bimaljit Sandhu

“A prospective study of the natural history of pancreatitis”

PI: Bimaljit S. Sandhu, MD

Contact: Shelley Smith 804-828-7208

“A retrospective study of the natural history of pancreatitis”

PI: Bimaljit S. Sandhu, MD

Contact: Shelley Smith 804-828-7208

“Nerve growth factor in chronic pancreatitis”

PI: Bimaljit S. Sandhu, MD

Contact: Shelley Smith 804-828-7208

“Pain in Chronic Pancreatitis correlates better with NFG levels rather than Pancreatic ductal morphology”

PI: Bimaljit S. Sandhu, MD
Contact: Shelley Smith 804-828-7208

Dr. Arithi Sanjeevi

“Enterra therapy (gastric electrical stimulation) for the treatment of medically refractory gastroparesis”

PI: Arthi Sanjeevi, MD
Contact: 804-828-4060

“A Multicenter, Randomized, Placebo-controlled, Doubleblinded Study of the Efficacy and Safety of Lubiprostone in Patients with Opioid-induced Bowel Dysfunction”

PI: Arthi Sanjeevi, MD
Contact: Jolene Schlosser 804-828-9195

Dr. Arun J. Sanyal

“Activation of endogenous cannabinoid system in nonalcoholic fatty liver disease and the metabolic syndrome”

PI: Arun Sanyal, MD
Contact: Onpan Cheung, MD 804-828-8373

“The Early Use of Sanvar® with Endoscopic Treatment for the Control of Acute Variceal Bleeding Due to Portal Hypertension”

PI: Arun Sanyal, MD
Contact: Melanie White 804-827-0100

“Beta-blockers vs. Variceal Band Ligation and Beta-blockers for Primary Prophylaxis of Variceal Bleeding”

PI: Arun Sanyal, MD
Contact: 804-828-4060

“The role of endogenous cannabinoids in the physiologic dysfunction associated with cirrhosis and spontaneous bacterial peritonitis”

PI: Arun Sanyal, MD
Contact: Onpan Cheung, MD 804-828-8373

“De Novo Lipogenesis and Racial Susceptibility to Nonalcoholic Fatty Liver Disease”

PI: Arun Sanyal, MD
Contact: 804-828-4060

“A study of the activation of endoplasmic reticulum stress and differential expression of MicroRNA in both disease progression and efficacy of anti-viral therapy in patients with chronic hepatitis C”

PI: Arun Sanyal, MD
Contact: Onpan Cheung, MD 804-828-8373

“The Metabolomic Basis for Nonalcoholic Fatty Liver Disease”

PI: Arun Sanyal, MD
Contact: Onpan Cheung, MD 804-828-8373

“The Role of Midodrine in Cirrhosis with Severe Arterial Vasodilation”
PI: Arun Sanyal, MD
Contact: Carol Sargeant 804-828-8261

“The Natural History of Nonalcoholic Fatty Liver Disease”
PI: Arun Sanyal, MD
Contact: Carol Sargeant 804-828-8261

“A multicenter, randomized double-blind, placebo-controlled trial to evaluate the efficacy, safety and tolerability of Rifaximin 550 mg BID for 6 months in preventing hepatic encephalopathy”
PI: Arun Sanyal, MD
Contact: Jolene Schlosser 804-828-9195

“A Multicenter, Open-label Trial to Evaluate the Long-term Safety and Tolerability of Rifaximin 550 mg BID in Subjects with a History of Hepatic Encephalopathy”
PI: Arun Sanyal, MD
Contact: Jolene Schlosser 804-828-9195

“Satavaptan Cirrhotic Ascites Treatment Study: a double-blind, randomized, parallel-group comparison of treatment with satavaptan at 5 to 10 mg daily versus placebo on top of conventional treatment in patients with ascites due to cirrhosis of the liver (CATS)”
PI: Arun Sanyal, MD
Contact: Jolene Schlosser 804-828-9195

Dr. Mitchell Schubert

“Regulation of gastric endocrine and exocrine section”
PI: Mitchell Schubert, MD

Dr. Mitchell L. Shiffman

“Relationship of Alpha One Antitrypsin Heterozygosity to Graft Failure in Hepatitis C and Non-Hepatitis C Liver Transplant”
PI: Mitchell L. Shiffman, MD
Contact: Charlotte Hofmann 804-828-9154

“Identifying Single Nucleotide Polymorphisms (SNPS) and RNA Expression Signatures in Genes Associated With Differential Fibrosis Progression and Response to Interferon Therapy in Patients with Hepatitis C Virus Infection”
PI: Mitchell L. Shiffman, MD
Contact: Charlotte Hofmann 804-828-9154

“The impact of peginterferon alfa-2a maintenance therapy on portal hypertension in patients with chronic hepatitis C virus infection and advanced fibrosis and cirrhosis enrolled in the HALT-C trial”

PI: Mitchell L. Shiffman, MD

Contact: Charlotte Hofmann 804-828-9154

“A Cross Sectional and Retrospective Evaluation in HBeAg-Positive of HBeAg-Negative Chronic Hepatitis B (CHB) Patients with Evidence of HBV Replication and Normal or Minimally Elevated Liver Transaminases (The MELT Study)”

PI: Mitchell L. Shiffman, MD

Contact: Denice Shelton 804-675-6923

“Prevention of the recurrence of Hepatitis B Virus with the combination tonofovir and of emtricitabine (Truvada) in liver transplant recipients”

PI: Mitchell L. Shiffman, MD

Contact: Charlotte Hofmann 804-828-9154

“A Phase 3, Randomized, Multi-Center Study to Evaluate the Efficacy and Safety of Albumin Interferon Alfa-2b (alb-IFN) in Combination with Ribavirin Compared with Peginterferon Alfa-2a (PEGASYS® or PEG-IFN α 2a) in Combination with Ribavirin in Interferon Alfa Naïve Subjects with Chronic Hepatitis C Genotype 1”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“An Open-Label, Randomized Study to Assess the Safety and Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Efficacy of Two Doses of Locteron™ (PolyActive™ – Interferon Alpha 2b) given every 2 weeks for 12 weeks compared to PEG-Intron given weekly for 12 weeks to African-American Subjects with Chronic Hepatitis C (treatment naïve, Genotype 1) on Co-Medication with weight-based Ribavirin”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“A Study to Describe the Antiviral Effect of Entecavir (ETV) in Blacks/African Americans and Hispanics with Chronic Hepatitis B Virus (HBV) Infection who are Nucleoside/tide-Naïve”

PI: Mitchell Shiffman

Contact: Denice Shelton 804-675-6923

“A Phase 2, Randomized, Double-Blind Study Exploring the Efficacy, Safety and Tolerability of Tenofovir Disoproxil Fumarate (DF) Monotherapy Versus Emtricitabine plus Tenofovir DF Fixed-Dose Combination Therapy in Subjects Currently Being Treated with Adefovir Dipivoxil for Chronic Hepatitis B and having Persistent Viral Replication”

PI: Mitchell Shiffman

Contact: Denice Shelton 804-675-6923

“A Randomized, Double-Blind, Controlled Evaluation of Tenofovir DF versus Adefovir Dipivoxil for the Treatment of HbeAg Positive Chronic Hepatitis B”

PI: Mitchell Shiffman

Contact: Denice Shelton 804-675-6923

“A Double-Blind, Randomized, Placebo-Controlled Multi-Center, Phase II Parallel Dose-Ranging Study to Assess the Antifibrotic Activity of GI262570 in Chronic Hepatitis C Subjects with Hepatic Fibrosis who Have Failed Prior Antiviral Therapy”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“LENS – Long-term Eltrombopag ObservatioNal Study - A Long Term Observational Ocular Safety Follow-up Study in Adults Who Have Received Study Medication (SB-497115-GR / Eltrombopag Olamine or Placebo) in a Phase II or III Clinical Study Evaluating Eltrombopag”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“A double-blind, randomized, placebo-controlled, multi-centre, dose-ranging, parallel group, phase II study to assess efficacy, safety/tolerability, and pharmacokinetics of a thrombopoietin receptor agonist, SB-497115-GR, when administered as 30, 50, and 75 mg once daily for 12 weeks in subjects with chronic hepatitis C–related thrombocytopenia who are potential candidates for antiviral treatment with pegylated interferon and ribavirin”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“Randomized, placebo-controlled, multi-centre study to assess the efficacy and safety of eltrombopag in thrombocytopenic subjects with hepatitis C virus (HCV) infection who are otherwise eligible to initiate antiviral therapy (peginterferon alfa-2a plus ribavirin) ENABLE 1 (Eltrombopag to INitiate and Maintain Interferon Antiviral Treatment to Benefit Subjects with Hepatitis C related Liver Disease)”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“Comparison of PEG-Intron 1.5 ug/kg/wk Plus REBETOL vs. PEG-Intron 1 ug/kg/wk Plus REBETOL vs. PEGASYS 180 ug/wk Plus Copegus in Previously Untreated Adult Subjects With Chronic Hepatitis C Infected With Genotype 1”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“A Phase 3, Randomized, Open-Label Study of the Safety and Efficacy of Two Dose Levels of Daily Interferon Alfacon-1 plus Ribavirin in Hepatitis C Infected Patients Who Failed to Achieve Virologic Response After Previous Pegylated Interferon Alfa plus Ribavirin Therapy and During at Least 24 Weeks of No Treatment in IRHC-001”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and Safety of Clevudine Compared with Adefovir at Weeks 48 and 96 in Nucleoside Treatment-Naive Patients with HBeAg Negative Chronic Hepatitis due to Hepatitis B Virus”

PI: Mitchell Shiffman

Contact: Denice Shelton 804-675-6923

“A Phase IV, 2x2 Factorial, Double Blind Study of 24 Versus 48 Weeks and 90 Versus 180 mcg Doses of Pegylated Interferon alfa-2a 40KD (PEG-IFN, Ro 25-8310) in Adult Subjects with HBeAg Positive Chronic Hepatitis B”

PI: Mitchell Shiffman

Contact: Denice Shelton 804-675-6923

“An Extension Protocol to Evaluate the Long-term Effects of Treatment with Peginterferon alfa-2a (PEG-IFN)- or Interferon- Based Therapies for Patients with Chronic Hepatitis C (Protocol NV15908B)”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“A Phase II, Randomized, Double-Blinded, Multicenter, Dose Finding Study Evaluating the Efficacy and Safety of the HCV Polymerase Inhibitor Prodrug (RO4588161) When Given In Combination with Pegasys® and Copegus® Versus the Currently Approved Combination of Pegasys® and Copegus® in Treatment-Naive Patients with Chronic Hepatitis C Genotype 1 Virus Infection”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“A Phase II, Randomized, Multicenter, Double-Blinded Study Evaluating the Safety and Tolerability of the HCV Polymerase Inhibitor Prodrug (RO4588161) When Given In Combination with Pegasys® With or Without Copegus® Versus the Currently Approved Combination of Pegasys and Copegus in Treatment-Naive Patients with Chronic Hepatitis C Genotype 1 Virus Infection. Protocol PV18369”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“Randomized, Multicenter, Double-Blinded, Phase IV Study Evaluating the Efficacy (as Measured by Sustained Virological Response) and Safety of 360 µg Induction Dosing of Pegasys® in Combination with Higher Copegus® Doses in Treatment-naïve Patients with Chronic Hepatitis C Genotype 1 Virus Infection of High Viral Titer and Baseline Body Weight Greater than or Equal to 85 kg”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“Long-Term Follow-Up of Subjects in a Phase 2 or 3 Clinical Trial in Which SCH 503034 Was Administered for the Treatment of Chronic Hepatitis C”

PI: Mitchell Shiffman

Contact: Jennifer Salvatori 804-675-6924

“A Safety and Efficacy Study of SCH 503034 in Previously Untreated Subjects With Chronic Hepatitis C Infected With Genotype 1”

PI: Mitchell Shiffman

Contact: Kim Williams 804-675-6848

“PEG-Intron/Rebetol vs PEG-Intron/SCH 503034 With and Without Ribavirin in Chronic Hepatitis C HCV 1 Peginterferon alfa/Ribavirin Nonresponders: A SCH 503034 Dose Finding Phase 2 Study”

PI: Mitchell Shiffman

Contact: Kim Williams 804-675-6848

“Efficacy and Safety of Daily Infergen/Ribavirin in Patients with Chronic Hepatitis C Virus Infection Who Were Partial Responders after Peginterferon alfa/Ribavirin Therapy”

PI: Mitchell Shiffman

Contact: Kim Williams 804-675-6848

“Comparison of Weight-based Doses of Taribavirin Combined With Peginterferon Alfa-2b Versus Ribavirin Combined With Peginterferon Alfa-2b in Therapy-naïve Patients With Chronic Hepatitis C Virus Genotype 1 Infection”

PI: Mitchell Shiffman

Contact: Kim Williams 804-675-6848

“A Phase 2 Study of VX-950 in Combination with Peginterferon alfa-2a (Pegasys®) With Ribavirin (Copegus®) in Subjects with Genotype 1 Hepatitis C who Have not Received Prior Treatment”

PI: Mitchell Shiffman

Contact: Kim Williams 804-675-6848

“A Phase 2 Study of Telaprevir (VX-950) in Combination with Peginterferon α -2a (Pegasys®), and Ribavirin (Copegus®) in Subjects with Genotype 1 Hepatitis C Who Have Not Achieved Sustained Viral Response with a Prior Course of Interferon-Based Therapy”

PI: Mitchell Shiffman

Contact: Denice Shelton 804-675-6923

“A phase 2, randomized, open-label study of the safety, antiviral activity, and pharmacokinetics of HCV-796 administered in combination with peginterferon alfa-2b (PEG-Intron) plus ribavirin (REBETOL) versus PEG-Intron plus REBETOL in subjects with hepatitis C virus genotype 1 infection”

PI: Mitchell Shiffman

Contact: Denice Shelton 804-675-6923

Dr. Richard K. Sterling

“Pharmacokinetics of Efavirenz During Treatment of HIV-Infected Subjects with Hepatic Impairment”

PI: Richard K. Sterling, MD

Contact: Paula Smith 804-828-2988

“Evaluation and Treatment of Chronic Hepatitis C in the Inmate Population”

PI: Richard Sterling, MD

Contact: Paula Smith 804-828-2988

“A Randomized, Multicenter, Double Blinded, Phase IV Study Comparing the Safety and Efficacy of Pegasys® 180 µg plus Copegus® 1000/1200 mg to the Currently Approved Combination of Pegasys® 180 µg plus Copegus® 800 mg in Interferon-naïve Patients with Chronic Hepatitis C Genotype 1 Virus Infection Coinfected with Human Immunodeficiency Virus (HIV-1)”

PI: Richard Sterling, MD

Contact: Paula Smith 804-828-9195

“The Spectrum of Liver Disease in Patients Living with Human Immunodeficiency Virus (HIV)”

PI: Richard Sterling, MD

Contact: Paula Smith 804-828-9195