CURRICULUM VITAE

Sayed Saeid Khatami, M.D.

Great Lakes Gastroenterology, LLC
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Citizenship: USA

Education/ Work History:

July 2010 – Present	Great Lakes Gastroenterology, LLC, Mentor Ohio The Endoscopy Center of Lake County Board Certified Gastroenterologist and Hepatologist
Jan 2009- June 2010	Ashok V Kondru MD, Inc, Ashtabula Ohio Board Certified Gastroenterologist and Hepatologist
Jan 2006-Dec 2008	Training in Gastroenterology Fellowship, MetroHealth Med.Ctr. Cleveland, Ohio
July 2004-Dec 2005	Board Certified Internist working as Hospitalist Physician in Cleveland Clinic Health System
July 2001-June 2004	Post-graduate internal medicine residency, Cleveland Clinic Health System, Huron Hospital, Department of Medicine, Cleveland, Ohio.
Nov 2000- June 2001	Training in fundamental of research methodology. (OHEP workshop Series). Research Assistant. Karmanos Cancer Institute, Wayne State University, Detroit, Michigan.
Sep 2000-Nov 2000	Observership. Department of Pulmonary-Critical Care.VAMC. Wayne State University, Detroit, Michigan.
June 1997- Aug 2000	Volunteer Physician, Medical Assistant, and Research Assistant. Fremont, San Jose, California.
Feb 1993-May 1997	Primary Care Physician, ER Physician, Self Employed.
Feb 1986- Jan 1993	M.D., Kerman University of Medical Sciences, Kerman, Iran.
Aug 1992- Jan 1993	Internship rotations in Internal Medicine, OB-GYN, Ophthalmology, Pediatrics and Surgery. Affiliated Hospitals of Kerman University Of Medical Sciences, Kerman, Iran.
Feb 1993-Apr 1994	Primary Care Physician, Department of Public Health, Shahrekord, Iran.

May1994- May1997	Emergency Room Physician. Jesus Christ Hospital of Esfahan, Iran.
May 1995- May1997	Self-employed. Esfahan, Iran.
June 1997-Jan 1999	Medical Assistant, Phlebotomist, Ashland Medical Group. Fremont, California
Feb 1999- Aug 2000	Cardiac Technician... Washington Hospital, Fremont, California.
June 1999- May 2000	Research Assistant. California Institute of Medical Research, San Jose, California.

Honors:

Resident Competition Essay Award, First Place. Evaluating the Progression of Diffuse Esophageal Spasm (DES) to Achalasia. A prospective study. June 2004 Huron Hospital.
Honorable Mention Award, Huron Hospital.
Co-infection of Giardia lamblia and Clostridium difficile after using ranitidine. June 2002
Huron "5" Value Award, Huron Hospital, March 2002
Outstanding Volunteer Award. San Francisco General Hospital (UCSF), fall 1998, San Francisco, California.

Special GI Training:

Experienced in basic and advanced GI procedure including EGD, Colonoscopy, PEG placement, dilation, esophageal and colonic stent placements and some ERCP performance
Advanced capsule endoscopy Certificate May 2008
Rotation in Inflammatory Bowel Disease (Cleveland Clinic Oct 2008)
Hepatitis C treatment

Research Affiliations:

2012-Present		Great Lakes Gastroenterology Research, LLC 8877 Mentor Avenue, Mentor, OH 44060
	Previous Address:	9485 Mentor Avenue, Suite 105, Mentor, OH 44060
2013-Present		Great Lakes Medical Research, LLC 8877 Mentor Avenue, Mentor, OH 44060
	Previous Address:	36100 Euclid Ave., Suite 490, Willoughby, OH 44094

Research:

Nov 2007- Present	Evaluating Response to Zegerid in GERD Patients Nonresponder to delayed PPI. S.S. Khatami, S. Iduru, K. Mullen
Dec 2002-June 2003	Title: Proton Pump Inhibitors (PPI) as an independent risk factor for Increasing the number of Clostridium Difficile Colitis. A retrospective study. M. Tannous, S.S. Khatami, K. Ravakhah, M.D., M.B.A, FACP
April 2002-Jan 2004	Title: Evaluating the progression of Diffuse Esophageal Spasm (DES) to Achalasia. A prospective study. Department of Gastroenterology, Cleveland Clinic Foundation. SS. Khatami. S. Shay, Michael F. Vaezi...
Nov 2000-June 2001	Title: Polymorphism in Prostate Cancer Carcinogenesis; A case Control study of environmental and biological factors affecting Men's health. Advisor: Richard B. Everson. M.D., M.P.H. Karmanos Cancer Institute, (Wayne State University), Detroit, MI

Nov 1996-May 1997 Title: The evaluation of causes of death between 110 infants under one year old in the rural area of Esfahan province. Department of Health, Esfahan, Iran. (Principle Investigator.)

Oct 1992-Oct 1995 Title: Evaluation of Brucellosis among 250 cases; a review of clinical findings and complications. Department of Public Health Esfahan, Iran.

Abstracts/ Presentations

1) Sayed S Khatami, M. D. Milan Dodig, M. D Colonic Varices in a Patient without Portal Hypertension First year GI fellow meeting, Washington, DC June 2006
2) S.S. Khatami, S. Shay, F. Khandvala, M. Vaezi Evaluating the progression of Diffuse Esophageal Spasm (DES) to Achalasia. First prospective study. Abstract was presented at ACG meeting, Oct 2004, Orlando
3) Maxwell Larweh, S.S. Khatami, K. Ravakhah. Pneumocranium Following Nerve Block. A case report. Abstract was presented as poster at American College of Physicians (Ohio Chapter)
4) V.S. Kanan, S.S. Khatami, E. Okafor. Sarcoidosis and Amyloidosis. A case report Abstract was presented as poster at *American* College of Physicians (Ohio Chapter) 2003.
5) S.S. Khatami, A. Brobbey, M. Kamionkowski. Use of Sulindac and Anti-Estrogens in the treatment of Familial Adenomatous Polyposis (FAP) complicated by Desmoid Tumors. American College of Physicians (Ohio Chapter) 2002. (Poster)
6) A. Brobbey, S.S. Khatami, K. Ravakhah. Increased BUN/Creatinine ratio as a preliminary diagnostic tool in acute GI bleeding. American College of Physicians (Ohio Chapter) 2002.
7) S.S. Khatami, Keyvan Ravakhah, Bejeeda Mukunda. Co-infection of Giardia lamblia and Clostridium difficile after using ranitidine. Annual Experimental Biology Meeting, New Orleans, April 2002 (Poster).
8) S.S. Khatami E. Bummer, D, Stevens. The effects of macrophage colony stimulating factor) In vivo: Cytokine GM- CSF (granulocyte production by Con-A timulated spleen cells. American Society of Microbiology Meeting, LA, May 2000(Poster)
9) S.S. Khatami, The role of Immune Enhanced Diets in ICU patients. Department of Pulmonary- Critical Care (VAMC) Detroit, MI, Sep.2000 (oral presentation)
10) S.S. Khatami, The principles of Hemodynamic monitoring. Department of Pulmonary- Critical Care (VAMC) Detroit, MI Sep.2000 (oral presentation)
11) SS.Khatami, Acid-Base Disturbance. Huron Hospital, Cleveland Clinic Health System. July 2001(oral presentation)
12) SS.Khatami, Deep Vein Thrombosis (DVT) prophylaxis. Hillcrest Hospital, Cleveland Clinic Health System. Oct 2001(oral presentation)
13) SS.Khatami, Diuretic Therapy. Huron Hospital, Cleveland Clinic Health System. Nov 2001(oral presentation)
14) SS.Khatami, Approach to low back pain. Huron Hospital, Cleveland Clinic Health System. Jan 2002(oral presentation)
15) SS. Khatami, Approach to Tendonitis, Bursitis. Hillcrest Hospital, Cleveland Clinic Health System. March 2002(oral presentation)
16) SS.Khatami, Risk Assessment before surgery. Huron Hospital, Cleveland Clinic Health System. May 2002
17) SS. Khatami, Approach to Dysphagia Huron Hospital, Cleveland Clinic Health System. May 2003 (oral Presentation)
18) SS.Khatami, Management of Ductal Carcinoma in Situ South Pointe Hospital, Cleveland Clinic Health System. June2003 (oral presentation)
19) SS.Khatami, Management of GERD in pregnancy. Huron Hospital, Cleveland Clinic Health System Feb 2004 (oral presentation)
20) SS. Khatami, Management of Acute Ischemic Stroke. Huron Hospital, Cleveland Clinic Health System June 2004 (oral presentation)

Publications:

September 2005 S.S. Khatami, S. Shay, F. Khandvala, M. Vaezi Does DES progress to Achalasia? Digestive Diseases and Sciences. Dig Dis Sci. 2005 Sep; 50(9):1605-10.
February 2004 S.S. Khatami, Keyvan Ravakhah, Bejeeda Mukunda. Co-infection of Giardia lamblia and Clostridium difficile after using ranitidine. 2004; 327:91-93American Journal of Medical Sceinces.
April 2001 S.S. Khatami, E. Brummer & D.A. Stevens: Effects of granulocyte-macrophage colony stimulating factor (GM-CSF) *in vivo* on cytokine production and proliferation by spleen cells. Clinical and Experimental Immunology 2001; 125:198-201.
October 1992 S.S. Khatami, S. Moradmand: Role of stress in coronary artery Disease. Graduation Thesis. University of Medical Sciences, Kerman, Iran.

Certifications/License:

Feb 1999	Telemetry- ECG-Phlebotomy
Jan 2000	California Status Letter
July 2001	Training Certificate from the State Medical Board of Ohio.
July 2001	BLS- ACLS. Valid until July 2009
Aug 2001	ECFMG Certificate. Valid indefinitely.
July 2002	Human Research Subjects Protection Training
June 2003	Sport Medicine Workshop (Cleveland Clinic Foundation)
July 2003	Ohio Medical License
Aug 2004	Internal Medicine Board (Certified)
Nov 2008	GI Board Exam (Certified)
Dec 2008	DEA

Hospital Privileges:

Lake Health System Tripoint Hospital, Concord, OH
Lake Health System West Hospital, Willoughby, OH
Euclid Hospital, Euclid, OH

Professional Membership:

American Medical Association
American Gastrointestinal Association (AGA)
American Society of Gastrointestinal Endoscopy (ASGE)
American College of Gastroenterology (ACG)
American College of Physician, American Society of Internal Medicine

Clinical Research Studies - Principal Investigator on all Studies

2014-Present	A Multicenter Randomized Parallel Group Phase III Study Comparing the Bowel Cleansing Efficacy, Safety and Tolerability of NER1006 (a Low Volume Bowel Cleansing Solution) versus a Trisulfate Bowel Cleansing Solution using a 2-Day Split-Dosing Regimen in Adults		
	NER1006	**Phase III**	**Norgene**

Sub-Investigator on all Studies

2009-Present	Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy and Safety of Budesonide Foam (2mg/25ml BID for 2 Weeks, Followed by 2mg/25ml QD for 4 Weeks) Versus Placebo in Subjects with Active Mild to Moderate Ulcerative Proctitis or Proctosigmoiditis.		
	# BUCF3001	**Phase 3**	**SALIX**
2009-Present	An open-label, Long-term Safety Study of Oral Linaclotide Administered to Patients with Chronic Constipation or irritable Bowel Syndrome with Constipation		
	MCP-103-305	**Phase 3**	**Ironwood**
2010-Present	A 6-Month, Phase 3, Randomized, Double-Blind, Parallel-Group, Controlled, Multi-Center Study to Evaluate the Incidence of Gastric Ulcers Following Administration of Either PA32540 or Enteric Coated Aspirin 325 mg in Subjects Who Are at Risk for Developing Aspirin-Associated Ulcers		
	PA 32540-301	**Phase 3**	**POZEN**
2010-Present	A Randomized, Double-Blind, Placebo-controlled, Parallel group, Dose-ranging, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients with Irritable Bowel Syndrome With Diarrhea.		
	27018966IBS2001	**Phase2**	**FURIEX**
2010-Present	A Non-Interventional Long-term Post-Marketing Registry of Patients Treated with Certolizumab Pegol (Cimzia) for Crohn's Disease		
	C87075	**Phase 4**	**UCB**
2010-2010	Procurement of Blood Samples from Ulcerative Colitis Subjects for Use in the development of a Gastrointestinal Disease Test		
	10IBD06	**Phase 4**	**Prometheus**
2010- 2012	RELIANCE: Research Study to Evaluate LOTRONEX® in Severe IBS-D: Analysis of Current Clinical Practice Environment		
	10LOT01	**Phase 4**	**Prometheus**
2011-2011	Procurement of Blood Samples from IBD, GI Controls and Healthy Volunteer Subjects for Use in the Development of a Gastrointestinal Disease Test		
	10IBD07	**Phase 4**	**Prometheus**
2011-Present	A Phase 3, Open Label, Multicenter Study to Assess the Safety and Tolerability of Budesonide Foam in Subjects with *Active Ulcerative Proctitis or Proctosigmoiditis*		
	BFPS 3073	**Phase 3**	**Salix**
2011-2012	A Randomized, Double-Blind, Placebo-Controlled, and Trial of Ferumoxytol for Treatment of *Iron Deficiency Anemia*.		
	AMAG-FER-IDA 301	**Phase 3**	**AMAG**
2011-2012	An Open Label Extension Trial of the Safety and Efficacy of Ferumoxytol for the Episodic Treatment of *Iron Deficiency Anemia*		
	AMAG-FER-IDA 301	**Phase 3**	**AMAG**
2011-Present	Randomized, Active Comparator, Open Label, Multicenter Study to Assess the Safety and Efficacy of OsmoPrep® Tablets versus HalfLytely® and Bisacodyl Tablet Bowel Prep Kit for *Colon Cleansing*.		
	OSBP4011	**Phase 4**	**Salix**

2011-Present Randomized, Double-Blind, Placebo-Controlled, Parallel-Treatment Group, Multicenter Efficacy and Safety Study of Intra-Anal Application of Iferanserin 10mg as a 0.5% Ointment in Subjects with Symptomatic *Internal hemorrhoids*
VEN309-Hem-SE3-001 **Phase 3** **Ventrus**

2011-Present A Double-blind Placebo-controlled Study to Evaluate Larazotide Acetate for the Treatment of *Celiac Disease*
NCTO1396213 Clin001-012 **Phase 3** **ALBA**

2011-Present A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oral Budesonide MMX® 9 mg Extended-release Tablets As Add-on Therapy in Patients with Active, *Mild or Moderate Ulcerative Colitis* not adequately controlled on a Background Oral 5-ASA Regimen
C2011-0401 **Phase3** **Santarus**

2012-Present A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Centre Study to Investigate the Safety and Efficacy of Cp-690,550 for Induction Therapy in Subjects with Moderate to Severe Crohn's Disease
A3921083 **Phase 2B** **Pfizer**

2012- Present A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Centre Study to Investigate the Safety and Efficacy of Cp-690,550 For Maintenance Therapy in Subjects with Moderate to Severe Crohn's Disease
A3921084 **Phase 2B** **Pfizer**

2012-Present An Open-Label Extension Study of Cp-690,550 as Maintenance Therapy in Patients with Crohn's Disease
A3921086 **Phase2B** **Pfizer**

2012-Present A Multicentre, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Oral Cp-690,550 as an Induction Therapy in Subjects with Moderate to Severe Ulcerative Colitis
A3921094 **Phase 3** **Pfizer**

2012-Present A Multicentre, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Oral Cp-690,550 as a Maintenance Therapy in Subjects with Ulcerative Colitis
A3921096 **Phase 3** **Pfizer**

2012-Present A Multi-Center, Open-Label Study of Cp-690,550 in Subjects with Moderate to Severe Ulcerative Colitis
A3921139 **Phase3** **Pfizer**

2012-Present A Randomized, 12-Week, Double-Blind, Placebo-Controlled, Repeat-Dose, Oral, Dose-Ranging Study to Assess the Safety and Efficacy of Plecanatide in Patients with Chronic Idiopathic Constipation
P304-20210 **Phase 2B** **Synergy**

2012-Present A Phase 2, Multi-Center, Randomized, Double Blind, Placebo-Controlled, Multiple-Dose Study to Determine the Safety and Efficacy of Orally Administered LX1033 in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome
LX1033.1-201-IBS **Phase 2** **Lexicon**

2012-Present A Study to Assess Repeat Treatment Efficacy and Safety of Rifaximin 550 mg TID in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)
RFIB3053 **Phase 3** **Salix**

2012-Present A Phase II Study to Evaluate the Efficacy and Safety Of 12 Weeks Of Treatment with Oral Cndo 201 Trichuris Suis Ova Suspension (Tso) As Compared to Placebo, Followed by A 12 Week Open-Label Treatment Period In Patients with Moderately to Severely Active Crohn's Disease
CNDO-201-003 **Phase 2** **Coronado**

2012-Present A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial of Linaclotide Administered Orally for 12 Weeks to Patients With Chronic Constipation and Prominent Abdominal Bloating at Baseline
LIN-MD-04 **Phase 3** **Forest**

2012-Present A Randomized, Double-blind, Multiple Dose Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of AMG 181 in Subjects with Moderate to Severe Ulcerative Colitis
20110166 **Phase 2** **Amgen**

2012-Present A Randomized, Double-blind, Multiple Dose Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of AMG 181 in Subjects with Moderate to Severe Crohn's Disease
20110232 **Phase 2** **Amgen**

2012-Present A Randomized, Double-Blinded, Active-Controlled Study Of Cb-183,315 In Patients With Clostridium Difficile Associated Diarrhea
LCD-CDAD-10-07 **Phase 3** **Cubist**

2012-Present A Randomized, Double-Blind, Placebo-Controlled, Adaptive DesignStudy Of The Efficacy, Safety, And Tolerability Of A Single Infusion Of MK- 3415 (Human Monoclonal Antibody To Clostridium Difficile Toxin A), MK-6072 (Human Monoclonal Antibody To Clostridium Difficile Toxin B), And MK-3415A (Human Monoclonal Antibodies To Clostridium Difficile Toxin A And Toxin B) In Patients Receiving Antibiotic Therapy For Clostridium Difficile Infection
MK-3415A PN001 **Phase 3** **Merck**

2012-Present A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-Term Safety and Tolerability of Cb-5945 for the Treatment of Opioid-Induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain
5945-OIC-12-05 **Phase 3** **Cubist**

2012-2013 A 12-Week, Randomized, Double-Blind,Placebo-Controlled Study Of asimadoline In Subjects With Diarrhea-Predominant Irritable Bowel Syndrome
ASMP3001 **Phase 3** **Tioga**

2012-Present Oral Budesonide Suspension (OBS) in Adolescent and Young Adult Subjects (12-25 Years of Age) with Eosinophilic Esophagitis: A Phase II, Randomized, Double-Blind, Placebo-Controlled Study with an Open-Label Extension
MPI-101-06 **Phase 2** **Meritage**

2013-Present A Randomized, Double-Blind, Placebo-Controlled Dose-Ranging Study of the Efficacy and Safety of ALV003 Treatment in Symptomatic Celiac Disease Patients Maintained on a Gluten-Free Diet
ALV003-1221 **Phase 2B** **Alvine**

2013-Present A Randomized, 12-Week, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Assess the Safety and Efficacy of Plecanatide in Patients with Irritable Bowel Syndrome with Constipation (IBS-C).
SP304-20212: **Phase 3** **Synergy**

2013-Present A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Ono-2952 in Female Subjects with Diarrhea-Predominant Irritable Bowel Syndrome (Ibs-D)
ONO-2952POU004 **Phase 3** **ONO**

2013-Present A Phase 3b, Randomized, Double-Blind, Placebo-Controlled, Parallel-Treatment Group, Multicenter Efficacy and Safety Study of Topical Diltiazem Hydrochloride 2% Cream in Subjects with Anal Fissure
VEN307-AF-001 **Phase 3b** **Ventrus**

2013-Present A Randomized, Double-blind, Double-dummy, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Clinical equivalence of Lubiprostore 24 mcg Capsules (Dr. Reddy's Laboratories Ltd.) with AMITIZA@ (Lubiprostone) 24 mcg Capsules in the Treatment of Chronic Idiopathic Constipation
DRL-USGOl-Ll20l2 **Phase 3** **Sucampo Pharmaceuticals**

2013-Present Randomized, Multi-Centre, Double-Blind, Placebo-Controlled Trial of HMPL-004 in Patients with Mild to Moderate Active Ulcerative Colitis (NATRUL-3)
HMPL-004-03 & 04 **Phase 3** **Hutchinson**

2013-Present A Randomized, Double-Blind, Placebo-Controlled, Dose-ranging, Multicenter Study to Assess the Efficacy and Safety of Rifaximin Soluble Solid Dispersion (SSD) Tablets for the Prevention of Complications in Subjects with Compensated Liver Cirrhosis "
RNLC2131 **Phase 2** **Salix**

2013-Present A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of AZD1722 for the Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)
D5612C00001 **Phase 3** **Ardelyx**

2013-Present A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Studyto Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects with Moderately to Severely Active Crohn's Disease (UNITI-2)
CNTO1275CRD3002: **Phase 3** **Janssen**

2014-Present A Randomized, Double Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Fixed-dose Combination RHB-104 in Subjects with Moderately to Severely Active Crohn's Disease.
RHB-104-01 **Phase 3** **Redhill**

2014-Present A 52-week, double-blind, randomized, placebo-controlled, parallel-group phase III study with re-randomization at week 25 to evaluate the efficacy and safety of oral ibodutant l0 mg once daily in female patients with irritable bowel syndrome with diarrhea (IBS-D)
NAK-07 **Phase 3** **Menarini**

2014-Present A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of Metoclopramide Nasal Spray in Women with Symptoms Associated with Diabetic Gastroparesis.
METO-IN-003 **Phase 3** **Evoke**

2014-Present A Randomized, Double-Blind, Placebo-Controlled Phase II Study to Evaluate the Effect of 12 weeks of Once-Daily Dosing of the Oral Motilin Receptor Agonist Camicinal, on Gastroparesis Symptoms in Type 1 and 2 Diabetic Subjects with Gastroparesis"

MOT201159 **Phase 2** **GSK**

2014-Present A Phase 3, International, Multicenter, Randomized, Double-blind, Placebo controlled, Parallel-group Efficacy and Safety Trial of Linaclotide Administered Orally for 12 Weeks to Patients with Irritable Bowel Syndrome with Constipation (IBS-C)"

ICP-103-307 **Phase 3** **Ironwood**

2014-Present A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group Trial of Linaclotide (72 ug or 145 ug) Administered Orally for 12 Weeks to Patients with Chronic Idiopathic Constipation

MCP-103-309 **Phase 3** **Ironwood**

2014-Present Phase III, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy for (Induction of Remission) and Safety of Etrolizumab Compared with Placebo in Patients with Moderate to Severe Ulcerative Colitis Who are Naive to TNF Inhibitors

GA28949 **Phase 3** **Genentech**

2014-Present Phase III, Double Blind, Placebo Controlled, Multicenter Study of the Efficacy and Safety of Etrolizumab During Induction and Maintenance in Patients with Moderate to Severe Active Ulcerative Colitis Who are Refractory of TNF Inhibitors

GA28950 **Phase 3** **Genentech**

2014-Present An Open-Label Extension and Safety Monitoring Study of Moderate to Severe Ulcerative Colitis Patients Previously Enrolled in Etrolizumab Phase III Studies

GA28951 **Phase 3** **Genentech**

2014-Present A Multi-Center, Randomized, Open-label, Controlled Study to Investigate the Treatment Response of Intravenous Injectafer (Ferric Carboxymaltose) vs. Oral Iron to Baseline Hepcidin Levels in Patients with Iron Deficiency Anemia (IDA) secondary to Inflammatory Bowel Disease (IBD)

1VIT13035 **Phase IV** **Luitopold**

2014-Present Phase 2, Multi-Center, Randomized, Double-Blind, Placebo Controlled, Parallel Group Clinical Trial to Evaluate the Efficacy and Safety of RPC4046 in Adult Subjects with Eosinophilic Esophagitis

RPC-201 **Phase 2** **Receptos**

2014-Present A multi-center, randomized, double-blind study to compare the efficacy and safety of cadazolid versus vancomycin in subjects with Clostridium difficile-associated diarrhea (CDAD)

AC-061A302 **Phase 3** **Actelion**

2015-Present A Phase 2, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of GS-5745 In Subjects with Moderately to Severely Active Crohn's Disease

GS-US-395-1663 **Phase 2** **Gilead**

2015-Present Combined Phase II/III, Double-blind, Randomized, Placebo-Controlled, Induction and Maintenance Study Evaluating the Safety and Efficacy of GS-5745 in Subjects with Moderately to Severely Active Ulcerative Colitis
GS-US-395-1100 Phase 2 /3 Gilead

2015-Present Clinical Study of the fCAL ELISA as an aid in the differentiation between IBD from IBS
ALPCal-01 Buhlmann

2015-Present Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, and Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis
CNTO1275UCO3001 Phase 3 Janssen

2015-Present 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.
GA29144 Phase 3 Genentech

2015-Present An Open-Label Extension and Safety Monitoring Study of Patients with Moderately to Severely Active Crohn's Disease Previously Enrolled in The Etrolizumab Phase III Protocol GA29144.
GA29145 Phase 3 Genentech

2015-Present A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study with a 4-Week Randomized Withdrawal Period to Evaluate the Efficacy and Safety of Tenapanor for the Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)
TEN-301 Phase 3 Ardelyx

2015-Present A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Investigating the Efficacy and Safety of Mesalamine 4 g Extended Release Granules (Sachet) for the Induction of Clinical and Endoscopic Remission in Active, Mild to Moderate Ulcerative Colitis
000174 Phase 3 Ferring

2015-Present A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Investigating the Efficacy and Safety of Mesalamine 2 g Extended Release Granules (Sachet) for Maintenance of Clinical and Endoscopic Remission in Ulcerative Colitis
000175 Phase 3 Ferring

2015-**P**resent Phase 2b, randomized, double-blind, double-dummy, placebo-controlled, parallel group, dose-range-finding study of two delayed release formulations of linaclotide administered orally for 12 weeks to patients with Irritable Bowel Syndrome with Constipation
MCP-103-204 Phase 2b Ironwood

2016-Present Clinical Validation Study to Evaluate Presence of H. pylori with 13C-Urea Breath test using the BreathID® Hp Lab System Compared to biopsy Results
Protocol No. DM2-HP -0715 Phase 3 Exalenz

2016-Present Oral Budesonide Suspension (OBS) in Adolescent and Adult Subjects (11 to 55 Years of Age, Inclusive) with Eosinophilic Esophagitis: A Phase 3 Randomized, Double-blind, Placebo-controlled Study
SHP621-301 Phase 3 Shire