



SHAFRAN GASTROENTEROLOGY CENTER

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IRA SHAFRAN, M.D., P.A.



As a Board Certified Gastroenterologist practicing in the Orlando area since 1979, Dr. Shafran completed his Internal Medicine & GI training at Ohio State University Medical School.

During the past several years, he has been on the forefront of researching a cause & a cure for Crohn's disease. He continues to pursue ground breaking research, producing numerous publications and becoming internationally renown for his expertise using novel, successful therapies for Inflammatory Bowel Disease.

Dr. Shafran is acknowledged as one of America's "Top" Gastroenterologist in the *Guide to Top Doctors '99*, and in the *2006 through 2009 Guide to Top Physicians*. He is considered among the "Top 70 Doctors" in Central Florida according to his peers and featured in the *Orlando Magazine's* issues annually. Frequently, he can be seen on TV for newsworthy GI developments on America's Health Network and PBS *HealthWeek* and *Dr. G Medical Examiner*. As a leader in his field, Dr. Shafran lectures locally, nationally & internationally. He was featured in *Saturday Evening*

Post's May-June 2004 article, Reducing the Risk of Crohn's Disease. *The Orlando Sentinel* highlighted his ongoing work with Crohn's and a bacterial etiology in an article on the front page of their Sunday, December 2, 2007 issue, Antibiotics offer hope for Crohn's. Throughout his career, he has been an outspoken patient advocate & supporter of Patient Rights.

At the Shafran Gastroenterology Center, our associates & staff take great pride in providing our patients with the highest quality medical care in a warm & friendly way, tailoring treatment to meet each patient's specific needs.

EDUCATION

- 1967-1971** B Sc., in Zoology, cum laude; Ohio State University, Columbus, OH
- 1971-1974** M.D., cum laude; Ohio State University, Columbus, OH
- 1974-1975** Medical Internship; Ohio State University Hospital, Columbus, OH
- 1975-1977** Medical Residency; Ohio State University Hospital, Columbus, OH
- 1977-1979** Gastroenterology Fellowship; Ohio State Univ. Hospital, Columbus, OH

BOARD CERTIFICATION

- 6/1977** American Board of Internal Medicine #61873
- 6/1979** American Board of Internal Medicine, Subspecialty of Gastroenterology #61873

PROFESSIONAL EXPERIENCE

- 1975-1979** Participated in National Cooperative on Crohn's Disease
- 1979-Present** Private Practice in Gastroenterology in Winter Park, FL
Dr. Shafran performs procedures at Florida Surgery Center (180 Boston Ave., Altamonte Springs, FL)
and at Florida Surgery Center (180 Boston Avenue., Altamonte Springs, FL)
- 1979-1996** Assistant Professor-Internal Medicine/Gastroenterology-University South Florida
Assistant Professor-Internal Medicine/Gastroenterology-Florida Hospital, Orlando, FL
- 1979-1996** Active Medical Staff, Winter Park Memorial Hospital
- 1980-1990** Chairman Department of Endoscopy, Florida Hospital, Orlando, FL
- 1984-1996** Active Medical Staff, South Seminole Community Hospital
- 1992-1997** Chairman Department of Endoscopy, Florida Hospital, Orlando, FL
- 1990-Present** Risk Management Advisor, Florida Hospital, Orlando, FL
- 1990-2000** Founder, Concerned Physicians of America, Non-profit organization asserting the rights of
the Doctors and the Patients
- 1994-1998** Volunteer Physician, Health Care Clinic for the Homeless, Orlando, FL
- 1997** Special Advisor to Florida Hospital.
- 2000** Assistant Professor-College of Health & Public Affairs-University Central Florida
- 2009-Present** Volunteer Faculty-University of Central Florida Medical School

PUBLICATIONS

(separate pages)

ORGANIZATIONS & SOCIETY MEMBERSHIPS

Current

American Gastroenterologic Association (AGA)
Florida Society for Gastrointestinal Endoscopy (FMA)
American Society for Gastrointestinal Endoscopy (ASGE)
Crohn's & Colitis Foundation of America (CCFA)
National Ileitis and Colitis Foundation Member
Foundation for Excellence and Ethics in Medicine
Paratuberculosis Aggressive Research Association
Alpha Epsilon Delta Society
Phi Beta Kappa
International Paratuberculosis Association

Past

American College of Legal Medicine
American College of Physician Executives
Orange County Medical Society
Florida Society of Internal Medicine
American Society of Internal Medicine
American Association for the Study of Liver Disease
American Academy of Fellow Physicians Member
American Society of Microbiology

EDUCATOR

- Dedicated educator and lecturer to students, colleagues, patients, and the public
- AIDS activist, along with his wife, who is the co-founder of the HIV Awareness Program for the Florida Medical Association and both have lectured & contributed greatly to the cause of AIDS prevention.
- Preceptor
- Teacher in [flexible sigmoidoscopy](#) (certified by ASGE)
- Set up flexible sigmoidoscopy clinic in large teaching hospital, allowing hundreds of residents to learn the skills of flexible sigmoidoscopy.
- Preceptorship enables residents, students, and pharmacy reps to work with and shadow Dr. Shafran
- Instrumental in developing clinical guidelines and algorithms for a variety of internal medicine subspecialties.

QUALITY ASSURANCE

- Dr. Shafran has participated in QA and continued quality improvement issues since 1979 and has been an active leader in QA in his specialty.
- Served as an independent QA review since 1980, reviewing other gastroenterologists procedures for proctorship and re-certification.
- Participant in regular risk management issues where standard of care issues and medical-legal decision-making violations may occur.

CURRENT RESEARCH INTERESTS

- [Crohn's Disease and Mycobacterial infection](#)
 - Serologic diagnosis of inflammatory bowel disease
 - [Antibiotic treatment of Crohn's Disease.](#)
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PUBLICATIONS

Mobile and web-based application for IBD tracking

I Shafran, P Burgunder, B Shamosh

8th Annual Advances in the Inflammatory Bowel Diseases, December 3-6, 2009, P0113, Poster Session

Inflammatory Bowel Diseases, Vol 15, Number S2, December 2009

Long-term rifaximin treatment for newly diagnosed Crohn's disease

I Shafran, P Burgunder

8th Annual Advances in the Inflammatory Bowel Diseases, December 3-6, 2009 P0127, Poster Session

Inflammatory Bowel Diseases, Vol 15, Number S2, December 2009

Adalimumab therapy for patients with Crohn's disease who are unresponsive to or intolerant of infliximab

I Shafran, P Burgunder

8th Annual Advances in the Inflammatory Bowel Diseases, December 3-6, 2009 P0126, Poster Session

Inflammatory Bowel Diseases, Vol 15, Number S2, December 2009

Does combination therapy using rifaximin with adalimumab improve Crohn's disease activity and mucosal healing?

-A case series

I Shafran, P Burgunder

8th Annual Advances in the Inflammatory Bowel Diseases, December 3-6, 2009 P0017, Poster Session

Inflammatory Bowel Diseases, Vol 15, Number S2, December 2009

Rifaximin maintenance therapy for Crohn's disease.

Ira Shafran MD, P. Burgunder, ARNP, Shafran Gastroenterology Center,

ACG Annual Scientific Meeting October 23-29, 2009 P1139, Poster Session

The American Journal of Gastroenterology, Vol 104, Number S3, pg 358, September 2009

Monitoring adherence and outcomes in patients with inflammatory bowel disease

Ira Shafran MD, P. Burgunder, ARNP, Shafran Gastroenterology Center,

ACG Annual Scientific Meeting October 23-29, 2009, P707, Poster Session

The American Journal of Gastroenterology, Vol 104, Number S3, pg 481, September 2009

Evaluation of serology results from patients with inflammatory bowel disease

Ira Shafran MD, P. Burgunder, ARNP, Shafran Gastroenterology Center,

CG Annual Scientific Meeting October 23-29, 2009, P706, Poster Session

The American Journal of Gastroenterology, Vol 104, Number S3, pg 455, September 2009

Interferon beta-1a for the maintenance of remission in patients with Crohn's disease: Results of a phase II dose-finding study.

Pena Rossi C, Hanauer SB, Tomasevic R, Hunter JO, Shafran I, Graffner H.

BMC Gastroenterol. 2009 Mar 20;9(1):22.

Comparative Analysis of IBD Serology

I Shafran, P Burgunder, T. Aplin

7th Annual Advances in the Inflammatory Bowel Diseases, December 7, 2008, Oral Presentation

Gastroenterology, Vol 134, Number 4, pg A-201, April, 2008

Tomographic Enterography With Standard Diagnostic Assessments for Detecting Active Crohn's Disease

I Shafran, P Burgunder

7th Annual Advances in the Inflammatory Bowel Diseases, December 4-7, 2008, P670, Poster Session

Inflammatory Bowel Diseases, Vol 14, Number S3, December 2008

Monitoring Treatment-Specific Adherence and Outcomes in Patients With Ulcerative Colitis
I Shafran, P Burgunder
7th Annual Advances in the Inflammatory Bowel Diseases, December 4-7, 2008, P0065, Poster Session
Inflammatory Bowel Diseases, Vol 14, Number S3, December 2008

Potential Pathogenic Role of Mycobacterium avium Subspecies paratuberculosis in Crohn's Disease
Ira Shafran, MD, Patricia Burgunder, ARNP
Inflammatory Bowel Disease, Vol 14, Number 12, pg 1753-1755 December 2008

Rifaximin Monotherapy Was Effective in Patients with Newly Diagnosed Crohn's Disease
Ira Shafran MD, P. Burgunder, ARNP, Shafran Gastroenterology Center
September 2009 ACG Annual Scientific Meeting October 3-8, 2008 Poster Session
The American Journal of Gastroenterology, Vol 104, Number S3, pg 358,

Monitoring Patients with Ulcerative Colitis in Community Based Practice to Improve Adherence
Ira Shafran, MD, P. Burgunder, ARNP, Shafran Gastroenterology Center,
ACG Annual Scientific Meeting October 3-8, 2008, P1070, Poster Session
The American Journal of Gastroenterology, Vol 103, Number S1, pg 418, September 2008

Comparison of Computed Tomographic Enterography with Standard Diagnostic Assessments for Detecting Active Crohn's Disease
Ira Shafran, MD, P. Burgunder, ARNP, Shafran Gastroenterology Center,
ACG Annual Scientific Meeting October 3-8, 2008, P1070, Poster Session
The American Journal of Gastroenterology, Vol 103, Number S1, pg 418, September 2008

Rifaximin for the treatment of newly diagnosed Crohn's disease: a case series.
Shafran I, Burgunder P.
Am J Gastroenterol. 2008 Aug;103(8):2158-60.

Anti-mycobacterials and Crohn's disease.
Chamberlin WM, Shafran I.
Aliment Pharmacol Ther. 2008 Aug 1;28(3):373-4.

Newly Diagnosed Crohn's Disease: Case Series of Rifaximin Monotherapy
I. Shafran, P. Burgunder, Presented at Crohn's & Colitis Foundation National Research & Clinical Conference
6th Annual Advances in the Inflammatory Bowel Disease, December 6-9, 2007, Poster Session
Inflammatory Bowel Diseases, Vol 14, Number S1, January 2008

Computed Tomographic Enterography as a Noninvasive Diagnostic Tool for Active Crohn's Disease
I. Shafran, P. Burgunder, Presented at Crohn's & Colitis Foundation National Research & Clinical Conference
6th Annual Advances in the Inflammatory Bowel Diseases, December 6-9, 2007, Poster Session
Inflammatory Bowel Diseases, Vol 14, Number S1, January 2008

Private Practice Experience Switching Chronic Stable Ulcerative Colitis (UC) Patients to Mesalamine MMX
J. Hilal, I. Shafran, P. Burgunder, Presented at Crohn's & Colitis Foundation National Research & Clinical Conference
6th Annual Advances in the Inflammatory Bowel Diseases, December 6-9, 2007, Poster Session
Inflammatory Bowel Diseases, Vol 14, Number S1, January 2008

Assessment of the Validity of Computed Tomographic Enterography for Diagnosing Active Crohn's Disease
I. Shafran, P. Burgunder, Presented at ACG Annual Scientific Meeting, October 12-17, 2007, Poster Session
The American Journal of Gastroenterology, Vol 102, Number 9, 635 (S264), September 2007

Rifaximin for the Treatment of Newly Diagnosed Crohn's Disease
I. Shafran, P. Burgunder
Presented at ACG Annual Scientific Meeting, October 12-17, 2007, P500, Poster Session

Interferon beta-1a for Maintenance of Remission in Patients With Crohn's Disease: Results of a Phase II Dose-Finding Study
Claudia Pena Rossi, Stephen B. Hanauer, Gregory F. Bonner, Ratko Tomasevic, John Hunter, Ira Shafran, Hans Graffner
BMC Gastroenterology (2007)

Is Monotherapy with an Oral Antibiotic Useful in Reducing Crohn's Disease Activity?

I. Shafran, P. Burgunder

5th Annual Advances in the Inflammatory Bowel Diseases, December 1-3, 2006, P082, Poster Session

The American Journal of Gastroenterology, Vol 101, Number 9, 635 (S264), September 2006

Inflammatory Bowel Disease, Vol 13, Number 5, May 2007

Adjunctive Antibiotic Therapy With Rifaximin May Help Reduce Crohn's Disease Activity

I. Shafran, P. Burgunder

5th Annual Advances in the Inflammatory Bowel Diseases, December 1-3, 2006, P081 Poster Session

Inflammatory Bowel Disease, Vol 13, Number 5, May 2007

The American Journal of Gastroenterology, Vol 101, Number 9, 1096 (S429), September 2006

A Phase 1/2A Trial of STA 5326, an Oral Interleukin-12/23 Inhibitor, in Patients with Active Moderate to Severe Crohn's Disease

R. Burakoff, CF Barish, D. Riff, R. Pruitt, WY Chey, FA Farraye, I. Shafran, S. Katz, CL Krone, M. VanderVliet,

C. Stevens, ML Sherman, E. Jacobson, R. Bleday.

Inflammatory Bowel Disease 2006 Jul;12(7):558-565

Efficacy & Tolerability of Rifaximin, a Non-Absorbable, Gut-Selective, Oral Antibiotic in the Treatment of Crohn's Disease: Results of an Open-Label Trial

I. Shafran, P. Dondelinger, L. Johnson, L. Hamm, R. Murdock, Jr.

Current Medical Research Opinion 2005 Aug;21(8):1165-9

Seroreactivities Against *Saccharomyces cerevisiae* and *Mycobacterium avium* subsp. *paratuberculosis* p35 and p36 antigens in Crohn's Disease Patients

I. Shafran, C. Piromalli, JW Decker, J. Sandoval, SA Naser, F. El-Zaatari.

Digestive Disease Science 2002 Sept;47(9):2079-81

In Situ identification of mycobacteria in Crohn's disease patient tissue using confocal scanning laser microscopy.

S.A. Naser, I. Shafran, D. Schwartz, F. El-Zaatari and J. Biggerstaff,

Molecular and Cellular Probes; 2002 Feb;16(1):41-8

[Open clinical trial of Rifabutin and Clarithromycin therapy in Crohn's Disease.](#)

I. Shafran, L. Kugler, F.A.K. El-Zaatari, S.A. Naser, J. Sandoval,

Digestive and Liver Disease; 2002 Jan; 34:22-8

[Mycobacterium avium subsp. Paratuberculosis as one cause of Crohn's Disease](#)

W. Chamberlain, D.Y. Graham, K. Hulten, H.M.T. El-Zimaity, M.R. Schwartz, S. Naser, I. Shafran, F.A.K. El-Zaatari,
Aliment Pharmacol Ther 15:000-000 (2001).

[Full text \(.pdf\)](#)

Use of Short Term Culture for Identification of *Mycobacterium avium* subsp. *Paratuberculosis* in Tissue from Crohn's Disease Patients.

D. Schwartz, I. Shafran, C. Romero, N. Naser, C. Piromalli, J. Biggerstaff, W. Chamberlain and S.A. Naser,

Clinical Microbiology and Infection. 6:1-6 (2000).

Isolation of *Mycobacterium avium* subsp. *Paratuberculosis* from Breast Milk of Crohn's Disease Patients.

S. Naser, I. Shafran, D. Schwartz.

American Journal of Gastroenterology. 95(4) 1094-1095 (2000).

[Fistula Healing in MAP Positive Crohn's Disease Patients Following Rifabutin and Macrolide Antibiotic Treatment.](#)

I. Shafran, L. Kugler, J. Sandoval

(Submitted to DDW: *Gastroenterology*).

[A Comparative Analysis of Anti-Saccharomyces Antibodies \(ASCA\) and p35 and p36 Recombinant Clones for the Diagnosis of Crohn's Disease \(CD\)](#)

I. Shafran, C. Piromalli, S. Naser,
Gastroenterology. 118(4): A697 (2000).

[Cost Analysis of Antibiotic Treatment in Crohn's Disease Patients Serologically Positive for Mycobacterium avium ss. paratuberculosis.](#)

I. Shafran, C. Piromalli and J. Davies
Gastroenterology 118(4): A5071 (2000).

[Mycobacterium Identification in Stool Cultures of IBD Patients Serologically Positive for Mycobacterium avium ss. paratuberculosis.](#)

I. Shafran M.D, C. Piromalli B.S
Gastroenterology 118(4): A6207 (2000).

[Identification of Mycobacterium avium ss. paratuberculosis in Crohn's Tissue.](#)

I. Shafran, C. Piromalli, C. Romero, D. Schwartz and S. Naser
Gastroenterology 118(4): A1767 (2000).

[Rifabutin and Macrolide Antibiotic Treatment in Crohn's Patients Identified Serologically Positive for Mycobacterium avium ss. paratuberculosis.](#)

I. Shafran, C. Piromalli, S. Naser
Gastroenterology 118(4): A4182 (2000).

Specific seroreactivity of Crohn's disease patients against p35 and p36 antigens of M. avium subsp. paratuberculosis.
Naser SA, Hulten K, Shafran I, Graham DY, El-Zaatari FA
Vet Microbiol 2000 Dec 20;77(3-4):497-504

[Comparison of Serologic Markers for the Diagnosis of Crohn's Disease.](#)

I. Shafran, M.D., C. Piromalli, F. El-Zaatari, Ph.D
Am J of Gastroenterol. 94, 2761 (1999).

[Serum sickness-like illness in Crohn's Disease Patients Treated With Antibiotics.](#)

I. Shafran M.D. and C. Piromalli
Am J of Gastroenterol. 94, 2737 (1999).

[Treatment of Crohn's Disease with Rifabutin and Macrolide Antibiotics.](#)

I. Shafran, C. Piromalli
Am J of Gastroenterol 94, 2761 (1999).

[Mycobacterium Avium, SS Paratuberculosis, in Crohn's Disease is an Affirmative.](#)

D. Schwartz, D. Campbell, C. Romero, I. Shafran, S. Naser
presented at the *American Society of Microbiology Meeting, 99th meeting, Chicago, May of 1999*, poster session.

[In Vitro Evaluation of Anti-Tuberculous Drugs Against M. Avium, Subspecies Paratuberculosis, for Treatment of Crohn's' Disease.](#)

D. Campbell, D. Schwartz, C. Romero, I. Shafran, S. Naser
presented at the *American Society of Microbiology 99th Meeting, May of 1999*, poster session.

[Endoscopic Healing of Crohn's Disease After Antibiotic Treatment.](#)

I. Shafran, C. Piromalli, S. Naser
Gastroenterology, A-929 (1999).

[Humeral Immune Response of Crohn's Patients for Mycobacterium Avium, Subspecies Paratuberculosis.](#)

I. Shafran, W. Fenster, C. Piromalli, C. Romero, D. Schwartz, D. Campbell, F. El-Zaatari
Gastroenterology, A-929 (1999).

[In Vitro Evaluation of Anti-Tuberculous Drugs Against Mycobacterium Avium Subspecies Paratuberculosis for Treatment of Crohn's Disease.](#)

S.A. Naser, W. Fenster, C. Romero, D. Schwartz, C. Piromalli, I. Shafran
Gastroenterology, A-783 (1999).

[Rapid Culturing and PCR Detection of Mycobacterium Avium, SS. Paratuberculosis, from Crohn's Disease Tissue.](#)

S. Naser, W. Fenster, C. Romero, D. Schwartz, C. Campbell, C. Piromalli, I. Shafran
Gastroenterology, A-782 (1999).

[Mycobacterium avium subsp. Paratuberculosis in Crohn's Disease Is Serologically Positive](#)

S. Naser, I. Shafran
Clinical and Diagnostic Laboratory Immunology, 6: 282 (1999).

Specific Seroreactivity of Crohn's Disease Patients Against P 35 and P 36 Antigens of M. Avium Subspecies Paratuberculosis, S.A. Naser, K. Hulten, I. Shafran, D.Y. Graham, F. El-Zaatari, presented at the 1999 6th International Colloquium on Paratuberculosis in Melbourne, Australia.

The Use of Combined Antigens for Specific Diagnosis of Crohn' Disease.

I. Shafran, W. Fenster, S. Ishak, F. El-Zaatari, S. Naser
presented at the *American Society of Microbiology, 98th General Meeting*, in Atlanta, Georgia, May of 1998.

Clinical Clinical Algorithms in Gastroenterology

Shafran, I.
1996 [submitted for publication]

Mastering Flexible Sigmoidoscopy and Primer of Flexible Sigmoidoscopy for the Clinician: a CD-ROM

Shafran, I.
1996 [submitted for publication]

H. Pylori, An Overview

Shafran, I.
Internet Publication for the ASIM Web Page, 1996

Absence of Helicobacter Pylori in Gastric Carcinoma

Shafran, I. Apter, M.N., Sprung, D.J.
Gastrointestinal Oncology, A597, April, 1996

Gut Digest-Clinical Practice Patient Information Brochures

Encompassing over 16 different GI issues
Shafran, I. 1995-Present

Incidence of Adenocarcinoma in Barrett's Esophagus-A Community- Based Study

Sprung, D.J., Shafran, I., Apter, M.N.
Am J of Gastroenterology, Vol. 90, No 9, Pg 1572, (76) Sept, 1995

Prevalence of Adenocarcinoma of the Esophagus-A Community-Based Study

Sprung, D.J., Shafran, I., Apter, M.N.
Am J of Gastroenterology, Vol. 90, No 9, Pg 1572, (76) Sept, 1995

Reasons for Exclusion of Patients in Treatment of NANB Hepatitis

Shafran, I. Apter, M.N., Sprung, D.J.
Gastroenterology, Vol. 108, No.4, Pg. 1167, April 1995

Drug Treatment for Esophageal Spasm

Shafran, I.

Gastroenterology, Pg 1334, December, 1982

Segmental Esophageal Spasm, A Variant of Diffuse Esophageal Spasm

Shafran, I., Ellison, C.E., Fromkes, J.

Gastroenterology, Vol. 80, 1979

Esophageal Spasm with Normally Relaxing Hypertensive Lower Esophageal Sphincter

Ellison, C.E., Shafran, I., Fromkes, J., Thomas, F. Carey, L.C.

Current Surgery, 36 (5) Pg 362-364, Sept 1979

Nutmeg Toxicology

Shafran, I.

New England Journal of Medicine, Vol. 296:694, 1977

Prostaglandins and Crohn's Disease

Shafran, I., Mauer, W., Thomas, F.B.

New England Journal of Medicine, Vol. 296:694, 1977

Nutmeg and Medullary Carcinoma of the Thyroid

Shafran, I., McCrone, D.

New England Journal of Medicine, Vol. 293:1266, 1975

RESEARCH EXPERIENCE

- A Randomized, Double-Blind, Multi-Center Comparison Study of Medroxyprogesterone in a Subset of Subjects With Mild to Moderate Ulcerative Colitis Who Previously Failed High-Dose Mesalamine Therapy
- A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction of Clinical Remission in Patients with Crohn's Disease
- A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Maintenance of Clinical Remission in Patients with Crohn's Disease
- A Crohn's Therapy Resource, Evaluation and Assessment Tool (TREAT) Registry
- Safety and Efficacy of Two Dose Regimens of XXX in Patients with Active Crohn's Disease: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial
- Crohn's Disease Seropositive to *Mycobacteria paratuberculosis* Treated with Rifabutin & Macrolide Antibiotics
- Molecular, Microbiologic, Immunologic investigation of the *Mycobacterium paratuberculosis* Role in Crohn's Disease Etiology
- A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of Orally Administered Mesalamine MMX in Patients with Mild to Moderate Ulcerative Colitis
- A Phase III, Randomized, Multi-Center, Open-Label, 12 to 14 Month Extension Study to Evaluate the Safety and Tolerability of Mesalamine MMX (mesalazine) Given Once Daily vs. Twice Daily for the Maintenance of Ulcerative Colitis in Remission
- A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Mesalamine MMX (mesalazine) Given Twice Daily (2.4g/day) Versus SPD476 Given as a Single Dose (4.8g/day) in Subjects with Acute Mild to Moderate Ulcerative Colitis
- Phase 2, Double-Blinded, Controlled Study of Four Dosing Regimens of Alicaforen Enema, and Antisense Inhibitor of ICAM-1, for the Treatment of Patients with Mild to Moderate Active Ulcerative Colitis
- A Phase III, Multicenter, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Intravenous Antegren in Subjects with Moderately to Severely Active Crohn's Disease with Elevated C-Reactive Protein
- A Randomized, Double-Blind, Placebo-Controlled, Multicenter Evaluation of the Efficacy and Safety of Zelnorm (6mg BID) Administered Orally for 12 Weeks, in Male Patients with Chronic Constipation
- A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy and Safety of Zelnorm (6mg BID) and Placebo in Female Patients with Dyspepsia
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of Nicotine Administered as an Enema for Treatment of Active Mild-to-Moderate Ulcerative Colitis
- A Phase III, Multicenter, Open-Label, Long-Term Study of the Safety, Tolerability, And Efficacy of Intravenous Antegren in Crohn's Disease Subjects Who Have Previously Participated in CD307 Crohn's Disease Studies
- Randomized, Stratified, Double-Blind, Placebo-Controlled Phase 2 Study of the Steroid-Sparing Properties of Sagomostim Therapy in Patients with Corticosteroid-Dependent Crohn's Disease
- Open-Label Trial of Sagomostim, A Recombinant Human Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF), in Active Crohn's Disease

- Phase 3 Randomized, Double-Blind, Placebo-Controlled Multicenter Retreatment Study of Sagomostim in Patients with Active Crohn's Disease and Prior Treatment Response to 308180
- A Phase I/IIa Trial of STA5326 in Crohn's Disease Patients with CDAI Scores of 220-400
- A Multi-Centered, Randomized, Double-Blind, Placebo-Controlled Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction of Clinical Remission in Subjects with Moderate to Severe Crohn's Disease who Have Lost Response or are Intolerant to Infliximab
- A Multi-Centered, Open-Label Study of the Human Anti-TNF Monoclonal Antibody Adalimumab to Evaluate the Long-term Safety and Tolerability of Repeated Administration of Adalimumab in Subjects with Crohn's Disease
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Use of Mesalamine Pellet Formulation 1.6G QD to Maintain Remission from Mild to Moderate Ulcerative Colitis
- Multicenter, Randomized, Double-Blind, Active-Controlled Trial Comparing REMICADE (infliximab) and REMICADE plus Azathioprine to Azathioprine in the Treatment of Patients with Crohn's Disease Naïve to both Immunomodulators and Biologic Therapy (Study of Biologic and Immunomodulator Naïve Patients in Crohn's Disease) SONIC
- A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-arm Study of the Efficacy and Safety of OPC6535 Tablets in the Treatment of Subjects With Active Ulcerative Colitis
- A Phase 3, Multicenter, 52-Week, Open-Label, Extension Study of the Safety and Efficacy of 25mg or 50mg of OPC6535 Oral Tablets in the Treatment of Subjects With Ulcerative Colitis
- A Randomized, Double-Blind, Placebo-Controlled Clinical Study of the Oral Anti-Interleuken 12 Inhibitor, STA-5326 for the Induction of Clinical Response in Patients with Crohn's Disease
- A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Three Different Doses (275, 550, 1100 mg) of Rifaxamin Administered BID for either Two or Four Weeks in the Treatment of Patients with Diarrhea-Associated Irritable Bowel Syndrome
- A Phase III, Multicenter, Randomized, Double-Blind, Actively Controlled Trial to Evaluate the Safety and Efficacy of a New Tablet Fornation and Dosing of Balsalazide Sodium 3.3 G BID vs Asacol 0.8 G TID in Mildly to Moderately Active Ulcerative Colitis.
- A Phase IIIb Multi-Center, Double Blind, Placebo-Controlled, Randomized Trial to Examine the Corticosteroid Sparing Effect of Certilizumab pegol in Patients with Moderate to Severe Crohn's Disease.
- A Multi-Center, Open Label Treatment Protocol of the Human Anti-TNF Monoclonal Antibody adalimumab in patients with Moderate to Severe Crohn's Disease with Previous Exposure to Infliximab.
- A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction and Maintenance of Clinical Remission in Subjects with Moderately to Severely Active Ulcerative Colitis.
- A Phase III, Multi-Center, Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with Abatacept in Subjects with Active Crohn's Disease who have had Inadequate Clinical Response and or Intolerance to Medical Therapy.
- Clinical Efficacy and Safety of Mesalamine (MAX-002) vs Canasa in the Treatment of Mild to Moderate Ulcerative Proctitis: A Multi-Center, Open-Label, Randomized, Parallel Group, Non-Inferiority Study

- A Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Study Efficacy, and Pharmacokinetics of Multiple Doses of Basiliximab, with Concomitant Corticosteroids, in Steroid Refractory Ulcerative Colitis
- A 52 Week, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled Study to Assess the Safety and Efficacy of a 12-Week Treatment of Acute Diverticulitis with Asacol 2.4g/day, Followed by a 9 Month Treatment-Free Observation Period
- A Double-Blind, Randomized, Placebo-Controlled Multicenter Study to Assess the Safety and Efficacy of AST120 in Mild to Moderately Active Crohn's Patients with Fistulas
- Double-Blind, Randomized, Multi-Center, Placebo-Controlled Phase II Study of Efficacy and Safety of HPML004 in Subjects with Active Moderate Crohn's Disease
- A Phase III, Multi-Center, Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with (IV Administered) Abtacept in Subjects with Active Ulcerative Colitis (UC) Who Have Had an Inadequate Clinical Response and/or Intolerance to Medical Therapy.
- Procurement of Fasting Blood Samples for Use in the Development of a Gastrointestinal Disease Test Panel
- A Multi-Center, Investigator-Blinded, Randomized, 12-month, Parallel-Group, Non-Inferiority Study to Compare the Efficacy of 1.6 to 2.4 g Asacol Therapy QD vs Divided Dose BID in the Maintenance of Remission of Ulcerative Colitis
- A 5 Year Registry Study of Humira in Subjects with Moderately to Severely Active Crohn's Disease
- A Phase III, Multi-Center, Placebo-Controlled, Randomized, Double-Blind, Durability, and Retreatment Study to Evaluate the Safety and Efficacy of Prochymal (ex vivo cultured adult human mesenchymal stem cells) Intravenous Infusion for the Maintenance and Re-Induction of Clinical Benefit and Remission in Subjects Experiencing Treatment Refractory Moderate to Severe Crohn's Disease
- A 52 Week, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled Study to Assess the Safety and Efficacy of a 12-Week Treatment of Acute Diverticulitis with Asacol 2.4 g/day (400mg Mesalamine Tablet), followed by a 9 Month Treatment-free Observation Period
- A Phase I-II, Double-Blind, Randomized, Placebo-Controlled, Dose-Ranging Study of the Safety, Tolerance, Pharmacokinetics and Activity of HE3286 when administered orally to patients with active mild to moderate Ulcerative Colitis.
- A Multicenter, Open-Label Study of the Human Anti-TNF Monoclonal Antibody Adalimumab to Evaluate the Long term Safety and Tolerability of Repeated Administration of Adalimumab in Subjects With Ulcerative Colitis
- A Phase IIb, Multi-Center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose Ranging Study Comparing the Efficacy, Safety, and Pharmacokinetics of Intravenous Infusions of ABT-874 vs. Placebo in Subjects with Moderately to Severely Active Crohn's Disease.
- A Phase IIIb, Multinational, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Efficacy and Safety of Certolizumab Pegol, a Pegylated Fab' Fragment of a Humanized Anti-TNF-Alpha Monoclonal Antibody, Administered Subcutaneously at Weeks 0, 2 and 4 in Subjects with Moderately to Severely Active Crohn's disease.
- A Phase IIIb, Multinational, Open-Label, Follow-On Trial to C87085 Designed to Assess the Long-Term Safety of Certolizumab Pegol, a Pegylated Fab' Fragment of a Humanized Anti-TNF-Alpha Monoclonal Antibody, Administered Subcutaneously at Weeks 0, 2 and 4, and Then Every 4 Weeks Thereafter, in Subjects with Moderately to Severely Active Crohn's Disease Who Have Participated in C87085.
- A Phase 2/3 Multicenter, Randomized, Placebo Controlled, Double-Blind, Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis.

- A Phase III, Multicenter, Randomized, Placebo Controlled, Double-Blind, Study to Evaluate the Safety and Efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis.
- A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of Rifaxamin 550 mg in the Treatment of Subjects With Non-Constipation Irritable Bowel.
- A Phase II, Randomized, Multi-Centre, Double-Blind, Placebo-Controlled Trial of HMPL-004 in Patients with Mild to Moderate Active Ulcerative Colitis with or without Mesalamine.
- Phase III Study of the Efficacy and Safety of New Oral Budesonide-MMX (CB-01-02) 6mg and 9mg Extended Release Tablet Formulations in Patients with Mild or Moderate, Active Ulcerative Colitis. A Multi-Center, Randomized, Double-Blind, Double-Dummy Comparative Study Versus Placebo, with an Additional Reference Arm Evaluating Asacol 2400mg.
- A Phase IIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-group Study to Evaluate the Efficacy, and Safety of Ustekinumab Therapy in Subjects with Moderately to Severely Active Crohn's Disease Previously Treated with TNF Antagonist Therapy.
- A Phase III, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by Vedolizumab (MLN0002) in Patients with Moderate to Severe Ulcerative Colitis.
- A Phase III, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by Vedolizumab (MLN0002) in Patients with Moderate to Severe Crohn's Disease.
- A Phase III, Open Label Study to Determine the Long-term Safety and Efficacy of Vedolizumab (MLN0002) in Patients with Ulcerative Colitis and Crohn's Disease.

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