CURRICULUM VITAE

Don Brinberg, M.D.

Great Lakes Gastroenterology, LLC
Great Lakes Gastroenterology Research, LLC
Great Lakes Medical Research, LLC
8877 Mentor Avenue
Mentor, OH 44060

Great Lakes Gastroenterology, LLC
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36100 Euclid Avenue, Suite 490
Willoughby, Ohio 44094

The Endoscopy Center of Lake County
9614 Old Johnnycake Ridge Road
Mentor, OH 44060
(440) 205-1225

Board Certification

Diplomat American Board of Internal Medicine, 1985
Diplomat American Board of Gastroenterology, 1988

Education

1978	John Hopkins University, Baltimore, MD Bachelor of Arts
1982	Harvard Medical School, Cambridge, MA Doctor of Medicine
1982-1983	Brigham and Women's Hospital, Boston, MA Internship in Internal Medicine
1983-1985	Brigham and Women's Hospital, Boston, MA Residency in Internal Medicine
1985	West Roxbury V.A. Medical Center, Boston, MA Chief Resident, April - June 1985
1985-1987	Columbia-Presbyterian Medical Center, New York, NY

Private Practice

1987-2012	Consultants in Gastroenterology, Inc Mayfield Hts, Ohio
2012-Present	Great Lakes Gastroenterology, LLC Mentor, Ohio

Hospital Privileges

1987-Present Lake West Hospital & Tripoint Hospital, Lake Health System
1987-Present Hillcrest Hospital, Cleveland Clinic
2009-Present UHHS Geauga Hospital

Awards and Honors

1973	National Merit Scholarship Letter of Commendation
1974	Regents Scholarship
1977	Phi Beta Kappa
1978	Valedictorian John Hopkins Univers·
1978-1982	Cecil Hayes Scholarship Winner
1999	Physician of the Year Lake Hospital System

Appointments

1982-1985	Fellow in Medicine Harvard Medical School
1989-2005	Assistant Clinical Professor of Medicine Case Western Reserve School of Medicine

	1989	Chief, Section of Hepatobiliary Disease Division of Gastroenterology Mount Sinai Medical Center
	1998-2001	Chairman, Department of Medicine Lake Hospital System
	2001-2008	Member, Board of Trustees Lake Hospital System

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 Activities	1975 - 1977	Baltimore Cancer Research Center Purification and Characterization of human liver ribonuclease
	1975-1977	Harvard Medical School, Department of Physiology Immunoreactive neurotensin content in the rat ileum: increase following dietary fat consumption
	1985 to 1987	Columbia University Department of Medicine Atrial Natriuretic factor and gastrointestinal transport
	1988-1990	Haas Fund Grant, Mount Sinai Medical Center Retrospective evaluation of GI bleeding at Mount Sinai Hospital

Publications:

1. Brinberg D, Molin C, Brinberg DL, Michel, D., Kaline M. Surgical Endoscopy: A Conflict of Interest? Abstract Gastroenterology May 1990
2. Kahlam S, Brinberg D, Stefaneson T, Grecius F., Portal Vein Thrombosis in Crohn's Disease. Submitted for publication Amer Journal of Gastroenterology Feb. 1990
3. Brinberg D, Berkeley B, Crohn's Disease: A comprehensive approach to management. Postgraduate Medicine, October 1989 V.86
4. Brinberg D, Carr M, Premkumar A, Stein J, Green P, Isolated Ventral Pancreatitis in an Alcoholic with Pancreas Divisum. Gastrointestinal Radiology 13: 323-326 1988
5. Simchon S, Manger WM, Carlin R, Peeter LL, Jan KM, Brown T, Brinberg D, Chien S. Mechanism of salt induced hypertension in S-Dahl rats. Abstract Hypertension meetings New Orleans, Fall 1987
6. Brinberg D, Musch M, Wang YL, Field M APIII does not affect Na+ transport in rabbit or rat jejunum. Abstract The American Society of Hypertension, May 1987
7. Brinberg D, Berkeley B, Nash I A Fatal Arrhythmia in an Intensive Care Unit, Annals oflnternal Medicine, Feb. 1987
8. Brinberg D, Green PHR, Lebwohl 0, Estrogen Therapy for Bleeding Gastrointestinal Telangectasias. Annals of Internal Medicine, 1986, Sept 105 (3) 462-3
9. Brinberg D, Stein J. Mallory-Weiss Tear with Colonic Lavage, Annals of Internal Medicine 1986. June 104 (6) 894-5
10. Scolnick B, Brinberg D, Diltiazem and Generalized Lymphadenopathy. Annals of Internal Medicine, 1985, April 102 (4) 558

Clinical Research Studies - Principal Investigator on the following studies:

2014-2016 A Phase 2b, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of RM-131 Administered to Patients with Vomiting Symptoms and Moderate to Severe Diabetic Gastroparesis
RM-131-009 Phase 2b Rhythm

2014-2016 Randomized, double blind, prospective trial investigating the efficacy of Methotrexate in induction and maintenance of steroid free remission in ulcerative colitis (Methotrexate Response In Treatment of UC)
UC Merit University of N.C.

2016-Present An Open-Label, Long-Term Safety and Tolerability Study of Plecanatide in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)
SP304203-06 Phase III **Synergy**

Clinical Research Studies - Sub- Investigator on the following studies;

2011-Present An, Open Label, Multicenter Study to Assess the Safety and Tolerability of Budesonide Foam in Subjects with *Active Ulcerative Proctitis*
BFPS 3073 Phase 3 Salix

2011- 2013 A Double-blind Placebo-controlled Study to Evaluate Larazotide Acetate for the Treatment of *Celiac Disease*
NCT01396213 ClinOOl-012 Phase 3 ALBA

2011- 2012 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 28 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 28 Synergy

2012-2013 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 (IBS-D)
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- 2013 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
CND0-201-003 **Phase 2** **Coronado**

2012- 2013 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 Design Study 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 PNOOl **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
5945-0IC-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 (lbs-D)
ON0-2952POU004 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 iquivalence of Lubiprostore 24 mcgCapsules (Dr. Reddy's Laboratories Ltd.) with AMITIZA@ (Lubiprostone) 24 mcg Capsules in the Treatment of Chronic Idiopathic Constipation
DRL-USGOI-Ll20l2 Phase 3 Sucampo Pharmaceuticals

2013-2015 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

2013-2016 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 Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects with Moderately to Severely Active Crohn's Disease (UNITl-2)
CNT01275CRD3002: 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

2014-2016 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 10 mg once daily in female patients with irritable bowel syndrome with diarrhea (rBS-D).
NAK-07 Phase 3 Menarini

2014 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

2014-2015 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

2014-2016 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

2014-2016 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 Naiive to TNF Inhibitors
GA28949 Phase 3 Genentech

2014-Present Phase III, Double Blind, Placebo Controlled, MultCenter 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

2014-2017 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

2015-2017 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

2015-2017 Combined Phase !VIII, Double-blind, Randomized, Placebo-Controlled, Induction and Maintenance Study Evaluating the Safety and Efficacy of GS-5745 m 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
CNT01275UC03001 **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**

2015-2016 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**

2015-2016 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**

2015-2016 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**

2015-2016 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 wtih Irritable Bowel Syndrome with Constipation **MCP-103-204**
Phase 2b **Ironwood**

2016 Clinical Validation Study to Evaluate Presence of H. pylori with l3C-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**