# DAVID B. RAUSHER, M.D., F.A.C.G., A.G.A.F.

2665 North Decatur Road STE #550, Decatur, Georgia 30033 | 404-296-1986

**NAME:**

David Benjamin Rausher, M.D., F.A.C.G., A.G.A.F.

**EDUCATION:**

Hamilton College 1969-1973
Clinton, New York
B.A. Conferred May 1973

State University of New York
Downstate Medical Center
Brooklyn, New York 1973-1977
M.D. Degree Conferred May 1977

**INTERNSHIP:**

Straight (Categorical) Internship in Internal Medicine
*Emory-Decatur University Hospital Systems*
*Emory University School of Medicine*
*Affiliated Hospitals Program 1977-1978*

**RESIDENCY:**

Internal Medicine
*Emory-Decatur University Hospital Systems*
*Emory University School of Medicine*
*Affiliated Hospitals Program 1978-1980*

**FELLOWSHIP**

Digestive Diseases (Gastroenterology & Hepatology)
*Emory University School of Medicine Affiliated Hospitals Program*
*Atlanta, GA 1980-1982*

**APPOINTMENTS**

- Clinical Assistant Professor of Medicine
  *Emory University School of Medicine*
- Fellow, *American College of Gastroenterology*
- Fellow, *American Gastroenterology Association*
- Chairman, Diagnostic Treatment Center
  *DeKalb Medical Center 1995-present*
- Vice-Chief, Section of Gastroenterology
  *DeKalb Medical Center 1996-1998*
- Chief, Section of Gastroenterology
  *DeKalb Medical Center 1998-present*
- President, Atlanta Center for Gastroenterology, P.C.; *1982-present*
- President, Atlanta Endoscopy Center, 1994 -*present*

**BOARD CERTIFICATION:**

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|---|---|
| National Board of Medical Examiners | 1978 |
| American Board of Internal Medicine | 1980 |
| American Board of Gastroenterology | 1982 |

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**SOCIETY MEMBERSHIPS:**

American Gastroenterology Association
American College of Gastroenterology
American Society of Gastrointestinal Endoscopy

**PUBLICATIONS:**

R.M. Baines, J.M. Wright, and D.B. Rausher, *Thalassemia phenotype caused by Inheritance Of one a-Thalassemic Gene from Each Parent, Blood,·* V.52, #5, Supp. 1, November 1978.

G.B. Sancar, D.B. Rausher, R.M. Baines and R.F. Reider *a-Thalassemia in Ashkenazi Jews: Identification of the Disorder and its Molecular Basis,·* Clin. Res. 30:557A, 1982 (Abstract).

R.F. Reider, G.B. Sancar, D.B. Rausher and B.M. Baines *a-Thalassemia in Ashkenazi Jews: Identification of the Disorder and the Studies on Its Molecular Basis:* Abstracts, 19th Congress International Soc. Hemat. P. 216 1982.

G.B. Sancar, D.B. Rausher, R.M. Baines, 0. Platica, M.M. Cedeno, l. Nawabi, R.F. Reider, *a-Thalassemia in Ashkenazi Jews.*

Gwendolyn B. Sancar, Ph.D., David B Rausher, M.D., Rosalie M. Baines, Ph.D., Marisol M. Cedeno, and Ronald F. Reider, M.D., *a-Thalassemia in Ashkenazi Jews: Identification of the Disorder and Studies on its Molecular Basis;* Submitted for publication in the British Journal of Hematology.

R.H. Dretler and David B. Rausher *Giant Esophageal Ulcer Healed with Steroid Therapy In an AIDS Patient.* Reviews of Infectious Diseases, V. 11, #5, 1989, p. 768

**CLINICAL RESEARCH:**

Principal Investigator on several Clinical Trials of Crohn's Disease, Active Ulcerative Colitis and GERD with the following sponsors: Shire, Janssen, RedHill, GenTech, Boehringer Ingelheim, Tekeda, Precision, Assembly Biosciences, F Hoffman-La Roche and Celgene.

Principal Investigator, Protocol **PMDx039 (Project 039-15-01):** Colonoscopy, Clinical Specimen Collection Study. **ProMeddx,** 2015-2017

Principal Investigator, Protocol **BI 1311.6:** A Phase II, Multicenter, Randomized, Double-blind, Multiple Dose, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Pharmacokinetics, and Safety of BI 655066, an IL-23 p19 Antagonist Monoclonal Antibody, in Patients With Moderately to Severely Active Crohn's Disease, Who Are naïve to, or Were Previously Treated With Anti-TNF Therapy. **Boehringer-Ingelheim,** 2014 – present.

**CLINICAL RESEARCH STUDIES CONTINUED:**

Principal Investigator, Protocol **PMDx039 (Project 039-14-01):** Colonoscopy Clinical Specimen Collection Study. **ProMeddx,** 9/2014 – 5/2015.

Principal Investigator, Protocol **SP-304203-00:** A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Plecanatide (3.0 and 6.0 mg) in Patients With Chronic Idiopathic Constipation. **Synergy Pharmaceuticals, Inc.** 2/2014 – 5/2015.

Principal Investigator, Protocol **RNLC2131:** A Randomised, Double-Blind, Placebo-Controlled, Dose-Ranging, Multicenter Study to Assess the Efficacy Of Rifaximin Soluble Solid Dispersion (SSD) Tablets for the Prevention of Complications in Subjects with Early Decompensated Liver Cirrhosis.
**Salix Pharmaceuticals, Inc**., 08/2013 – 8/2015

Principal Investigator, Protocol **M14-002:** A Randomised, Double-Blind Controlled Study to Evaluate the Efficacy and Safety of the Combination of ABT-450 Ritonovir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 With and Without Ribovirin (RBV) in Treatment-Naïve Adults with Genotype 1a Chronic Hepatitis C Virus (HCV) Infection (PEARL-IV), **AbbVie,** 2013

Principal Investigator, Protocol **BI 1241.20:** A Phase III, Randomised, Partially Double-blind and Placebo-controlled study of BI 207127 in Combination With Faldaprevir and Ribavirin in Treatment-Naïve Patients with Chronic Genotype 1 HCV Infection. **Boehringer-Ingelheim,** 02/2013 – Present.

Principal Investigator, Protocol **VEN307-AF-001:** A Phase 3B, Randomized, Double-Blind, Placebo-Controlled. Parallel-Treatment Group, Multicenter Efficacy and Safety Study of Topical Diltazem Hydrochloride 2% Cream in Subjects with Anal Fissure. **Ventrus BioSciences,** 01/2013 – Present.

Principal Investigator, Protocol **A7281010 (Turnadot):** A Multicenter Open-Label Extension Study to Assess Long-Term Safety of PF-00547659 in Subjects With Ulcerative Colitis. **Pfizer, Inc.,** 01/2013 – Present.

Principal Investigator, Protocol **A7281009 (Turnadot):** A Double-Blind, Randomised, Placebo-Controlled, Parallel, Dose-Ranging Study to Evaluate the Efficacy and Safety of PF-00547659 in Subjects with Moderate to Severe Ulcerative Colitis. **Pfizer, Inc.,** 01/2013 – Present.

**CLINICAL RESEARCH STUDIES CONTINUED:**

Principal Investigator, Protocol **A-12594**: Study protocol for the Validation of the Ulcerative Colitis Patient-Reported Outcomes (UC-PRO) Instrument in Patients with Ulcerative Colitis. **United BioScouce Corporation,** 12/2012 – 11/2013.

Principal Investigator, Protocol **ZA-201**: A Phase II Double-Blinded, Randomized, Comparator-Controlled, Study of the Efficacy of Zoenasa Rectal Gel (mesalamine plus N-acetylcsteine) in Subjects with Left-side Ulcerative Colitis. **Altheus Therapeutics, Inc.,** 09/2012 – 01/2013.

Principal Investigator, Protocol **ML27900**: Non-investigational, Prospective Cohort Study of the Effectiveness, Safety, and Utilization of Two Approved Pegylated Interferon-Based Direct Acting Antiviral Triple Therapies in the Management of Genotype 1 Chronic Hepatitis C in Routine Clinical Practice in the USA. **F.Hoffman-LaRoche Ltd, Genentech,** 09/2012 – Present.

Principal Investigator, Protocol **A3921139 (Octave)**: A Multi-Centre, Open-Label Study of CP-690, 550 in Subjects with Moderate to Severe Ulcerative Colitis. **Pfizer, Inc.,** 07/2012 – Present.

Principal Investigator, Protocol **A3921096 (Octave)**: A Multi-Centre, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of oral CP-690,500 As a Maintenance Therapy in Subjects with Ulcerative Colitis. **Pfizer, Inc.,** 07/2012 – Present.

Principal Investigator, Protocol **A3921095 (Octave)**: A Multi-Centre, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of oral CP-690,500 As an Induction Therapy in Subjects with Moderate to Severe Ulcerative Colitis. **Pfizer, Inc.,** 07/2012 – Present.

Principal Investigator, Protocol **C2011-0401**: A randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oral Budesonide MMX 9mg 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. **Santarus Inc.,** 03/2012 – 08/2013.

Principal Investigator, Protocol **1220.48**: A Phase III, open-label study of once Daily BI 201335 240mg for 24 weeks in combination with pegylated interferon-a (PegIFN) and ribavirin (RBV) in patients with genotype 1 chronic hepatitis C Infection who failed a prior PegIFN / RBV treatment. **Boehringer-Ingelheim,** 10/2011 – Present.

**CLINICAL RESEARCH STUDIES CONTINUED:**

Principal Investigator, Protocol **1220.47**: A Phase III, randomized, double-blind and placebo-controlled study of once Daily BI 201335 120mg for 24 weeks and BI 201335 240mg for 12 weeks in combination with pegylated interferon-a and Ribavirin in Treatment-Naïve Patients with Genotype 1 Chronic Hepatitis C Infection. **Boehringer-Ingelheim,** 05/2011 – Present.

Principal Investigator, Protocol **B0151005**: A Multicenter Open-Label Extension Study for subjects who participated in the Study B0150013 (ANDANTE II). **Pfizer, Inc.,** 11/2011 – Present.

Principal Investigator, Protocol **B0151003**: A Double-Blind, Randomized Placebo-Controlled, Dose-Ranging study to Evaluate the Efficacy and Safety of PF-04236921 In subjects with Crohn's Disease who are Anti-TNF Inadequate Responders. (ANDANTE) **Pfizer, Inc.,** 04/2011 – Present.

Principal Investigator, Protocol **ASMP3001**: A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study of Asimadoline in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome. **Tioga Pharmaceuticals, Inc.,** 04/2010 – 02/2013.

Principal Investigator, **COLO CP-01-US** Chemoprevention of Colorectal Adenomas an international, multicenter, randomized, Parallel-group, prospective, double-blind placebo-controlled clinical trial evaluating the efficacy and safety of a combination treatment administered over 3 years in patients at risk of experiencing recurrence of colorectal adenomas. **ColoTech AS,** 10/2008 – 03/2011.

Principal Investigator **E3810-G000-301:** Randomized, double-blind parallel study of Rabeprazole Extended Release 50mg versus Esomeprazole 40mg for healing and symptomatic relief of moderate to severe erosive gastroesophageal reflux disease (GERD) **Eisai Medical Research,** 09/2008 – Present.

Principal Investigator **E3810-G000-303:** Randomized, double-blind parallel study of Rabeprazole Extended Release 50mg versus Esomeprazole 40mg for healing and symptomatic relief of mild to moderate erosive gastroesophageal reflux disease (GERD) **Eisai Medical Research,** 09/2008 – 06/2009.

**CLINICAL RESEARCH STUDIES CONTINUED:**

Principal Investigator **E3810-A001-307:** A multicenter, randomized Double-Blind study to compare the efficacy, safety and tolerability of Rabeprazole ER 50mg with placebo in subjects with symptomatic gastroesophageal reflux disease (sGERD) **Eisai Medical Research,** 09/2008 – 05/2009.

Principal Investigator, Protocol **C13006**: a Phase 3, 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. **Millennium Pharmaceuticals,** 09/2008 – Present.

Principal Investigator, Protocol **C13007**: a Phase 3, 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. **Millennium Pharmaceuticals,** 09/2008 – Present.

Principal Investigator, Protocol **C13008**: a Phase 3, Open-label study to Determine the Long-Term Safety and Efficacy of Vedolizumab (MLN0002) in Patients with Ulcerative Colitis Crohn's Disease. **Millennium Pharmaceuticals,** 09/2008 – Present.

Principal Investigator, Protocol **R97-023** Intron-A-Retrovirus for treatment of patients with Chronic Hepatitis C, not previously treated with Interferon, **Schering Corp.**

Principal Investigator: A double-blind study to compare the efficacy and safety of **SB-207366A** (5mg) with placebo in patients with Irritable Bowel Syndrome for **Smith Kline Beechem, Inc.**

Principal Investigator: Protocol **S3B30020**: A 24-week Randomized, open-label study of health care resource use, quality of life productivity with Alosetron 1mg, twice daily, versus traditional therapy in females with non-constipated Irritable Bowel Syndrome for **Glaxo-Wellcome Inc.**

Principal Investigator: Protocol **DPM03-01** Dipentum (olsalazine soldium) in the Management of Ulcerative Colitis in Remission: a multicenter, open-label, post-marketing Clinical Experience Study.

Principal Investigator, **Protocol GA28949:** 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 Naïve to TNF Inhibitors. **F Hoffman-La Roche**. 2014 – Present

Principal Investigator**, Protocol GA29144**: Phase III, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Etrolizumab as an Induction and Maintenance Treatment with Moderately to Severely Acute Crohn's Disease. **F Hoffman-La Roche** 2015- Present.

Principal Investigator, **Protocol SHP647-302:** A Phase 3 Randomized, Double-blind, Placebocontrolled, Parallel-group Efficacy and Safety Study of SHP647 as Induction Therapy in Subjects with Moderate to Severe Ulcerative Colitis. **Shire**, 2017 – present.

Principal Investigator, **Protocol SHP647-306:** A Phase 3 Randomized, Double-blind, Placebocontrolled, Parallel-group Efficacy and Safety Study of SHP647 as Induction Therapy in Subjects with Moderate to Severe Crohn's Disease. **Shire** 2018- Present.

Principal Investigator, **Protocol CNTO1959CRD3001**: A Phase 2/3, Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn's Disease. **Janssen**, 2018- Present.

Principal Investigator, **Protocol RPC01-3202:** Induction Study #2- A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Oral Ozanimod as Induction Therapy for Moderately to Severely Active Crohn's Disease. **Celgene** 2018 – Present.

Principal Investigator, **Protocol PR-100-10**: A Study to Determine the Genotype Frequency of TNFSF15-Pathway Associated Risk Haplotype in Subjects with Diagnosis of Crohn's Disease. **Precision** 2018 – Present.

Principal Investigator, Protocol **VEDDOLIZUMAD-4014:** A Phase 4 Open-Label Study to Evaluate Vedolizumab IV Dose Optimization on Treatment Outcomes In Nonresponders With Moderately to Severely Active Ulcerative Colitis. **Takeda** 2018 - Present.

Principal Investigator, **Protocol 1368-0005:** A Phase II/III Randomized, Double-blind, Placebocontrolled, Multicenter Study to Evaluate the Safety and Efficacy of BI 655130 Induction Therapy in patients with moderate-to-severely active ulcerative colitis who have failed previous biologics therapy. **Boehringer-Ingelheim**, 2019- present.

Principal Investigator, **Protocol ABI-M201-101:** A Randomized, Double-blind, Placebo-Controlled, Multi-Center Phase 1b Study to Evaluate the Safety, Efficacy and Microbiological Response of Orally Administered ABI-M201 in Subjects with Mildly to Moderately Active Ulcerative Colitis with Ongoing Mesalamine Treatment. **Assembly Biosciences**. 2019 – Present.

**ADDITIONAL TRAINING:**

CITI Course: Basic, Human Subjects Protection Biomedical Focus, 7/11/2009.

GCP Training - Investigational Staff (Pfizer version 2.0), 1/20/2014.