

# Bal Raj Bhandari, MD

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## **CERTIFICATION:**

2005 Education American Board of Internal Medicine – Gastroenterology Recertification  
2003 American Board of Physician Nutrition Specialist  
1995 Board Certified, Gastroenterology  
1994 U.S. Medical Licensing Exam; Part 1, 2, and 3  
1994 Board Certified, Nutrition  
1992 Diplomat American Board of Internal Medicine  
1988 Licensing examination of Medical Colleges of Canada

## **EDUCATION:**

September 2003  
How to Coordinate Clinical Trials: The Basics  
Houston, Texas  
July 1, 1992 – June 30, 1995  
Fellowship in Gastroenterology and Nutrition  
Winthrop University Hospital - Minneola, New York  
January 1, 1992 – June 30, 1992  
Chief Medical Resident  
Our Lady of Mercy Medical Center - Bronx, New York  
January 1, 1989 – December 31, 1991  
Internal Medicine Residency  
Our Lady of Mercy Medical Center - Bronx, New York  
September 1983 – May 1987  
Graduate Medical Education  
The University of Ottawa Medical School - Ottawa, Ontario, Canada  
September 1978 – May 1983  
Undergraduate Education - BSC Chemistry (Honors)  
The University of Ottawa - Ottawa, Ontario, Canada

## **EMPLOYMENT:**

2002 – Present  
*Title: Principal Investigator*  
Delta Research Partners, LLC  
608 Grammont Street  
Monroe, LA 71201  
*Title: Principal Investigator*  
Delta Research Partners, LLC  
616 South Washington Street  
Bastrop, LA 71220

1998 – Present  
*Title: Staff Physician*  
Endoscopy Center of Monroe  
316 South 6<sup>th</sup> Street,  
Monroe, LA 71201

July 1995 – Present  
*Title: Private Practice*  
Gastroenterology and Nutritional Medical Services  
616 South Washington Street  
Bastrop, LA 71220

## **FACULTY APPOINTMENTS:**

July 1992

Preceptor – Introduction to Clinical Medicine  
SUNY Health Center at Stony Brook - Stony Brook, New York

January 1992 – July 1992

Chief Medical Resident

1989 – 1992

Assistant Clinical Instructor

## **HONORS AND AWARDS:**

September 1997

Named Spokesperson for the American Liver Foundation in Northeast Louisiana by Governor M. J. “Mike” Foster

1979, 1980, 1982, 1983

Dean’s List – University of Ottawa: Ottawa, Ontario, Canada

## **PRESENTATION:**

1992 - 1995

Staff - Lecturer-Core Lecture Series to the House  
Winthrop University Hospital  
Minneola, New York

1992

Medical Grand Rounds  
Our Lady of Mercy Medical Center  
Bronx, New York

## **AFFILIATION:**

American Board of Physician Nutrition Specialists  
American Gastroenterology Association  
American Society of Gastrointestinal Endoscopy  
American College of Physicians

## **PUBLICATIONS:**

1. C. Difficile in a Community Hospital: Badiga, M.; Bhandari, Raj; Pitchimoni, C.S.: *Gastroenterology*, 1991; 100:A405
2. Na-glucose Transport is Impaired in Villus Electrocytes of Chronically Inflamed Rabbit Ileum : C.S. Hyun; L.A. Martello; C.W.P. Chen; Raj Bhandari; S. Teichberg: *Gastroenterology*, 1994; 106:A239
3. Phorbol Ester-Induced CI Secretion in Rabbit Ileum is Associated with Translocation of PkC-isoform: Raj Bhandari, L.A. Martello, C.S. Hyun: *Gastroenterology*, 1994; 106:A222
4. Combined Treatment with Postnasal drainage: YAG Laser and Absolute Ethanol Injection compared to Nd: YAG Laser Therapy Alone in Malignant Esophageal and Rectal Obstruction: Raj Bhandari, B. Banerjee: submitted to *GI Endoscopy*
5. Current Management of Secretory Diarrhea, A Review: Raj Bhandari; R. Burakoff; accepted for Spring Issue, *The Gastroenterologist*
6. Mechanism of PDG-Induced CI Secretion in the Distal Rabbit Ileum; R. Bhandari, L. Martello, C.S. Hyun, submitted to *AJP*
7. Alteration of Enterocyte Na-glucose Co-transporter (SGLT-1) in Chronic Inflammation: C. Hyun, R. Bhandari, et al, submitted to *AJP*

**PUBLICATIONS (Continued):**

8. Chronic Inflammation Induces Alteration in the Zonula Occludens (ZO) and Lateral Junctional Strands of Mucosal Epithelial Cells in Rabbit Ileum: C.S. Hyun, R. Bhandari, et al, submitted as abstract to *Gastroenterology*, 1995.
9. Protein Kinase-C (PKC)-Medicated Chloride Secretion is Cl/HCO<sub>3</sub>-Dependent in Rabbit Ileum: R. Bhandari, C. Hyun, submitted as an abstract to *Gastroenterology*, 1995
10. Rifaximin has a Favorable Long-Term Safety profile for maintenance of Remission from Overt Hepatic Encephalopathy: M. Sheikh, N. Bass, A. Sanyal, F. Poordad, K. Mullen, S. Sigal, T. Fredrick, R. Bhandari, R. Vemura, S. Huang, K. Merchant, A. Shaw, E. Bortey, W. Forbes, submitted as abstract to *ACG*, June 2009
11. Rifaximin has a Favorable Long-Term Safety Profile for Maintenance of Remission from Overt Hepatic Encephalopathy: M. Sheikh, N. Bass, A. Sanyal, F. Poordad, K. Mullen, S. Sigal, T. Fredrick, R. Bhandari, R. Vemura, S. Huang, K. Merchant, A. Shaw, E. Bortey, W. Forbes, submitted as abstracts for *The 74<sup>th</sup> Annual Scientific meeting of the American College of Gastroenterology: The American Journal of Gastroenterology* October 2009.
12. Safety, tolerability and preliminary activity of GS-9450, a selective caspase inhibitor, in patients with non-alcoholic steatohepatitis (NASH): P.V. Ratziu, M. Chojkier, M. Sheikh, A. Sanyal, J. Lim, H. Conjeevaram, N. Chalasani, M. Abdelmalek, Al. Bakken, C. Renou, M. Palmer, R.A. Levine, R. Bhandari, M. Cornpropst, W. Liang, B. King, E. Mondou, F.S. Rousseau, pending submission as an abstract for the *EASL 2010*.
13. **"Rifaximin Decreases Venous Ammonia Concentrations and Time-Weighted Average Ammonia Concentrations Correlate with Overt Hepatic Encephalopathy (HE) as Assessed by Conn Score in a 6-Month Study"** has been accepted for **POSTER PRESENTATION** at the International Liver Congress™ 2010 by EASL, taking place in Vienna, Austria, April 14-18, 2010.
14. Category 2b. Cirrhosis and its Complications: b. Clinical Aspects: Poster Board Number 195 Rifaximin decreases venous ammonia concentration and time-weighted average ammonia concentrations correlate with overt Hepatic Encephalopathy (HE) as assessed by CONN Score in a 6-month study.
15. A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of GS-9450 in Patients With Nonalcoholic Steatohepatitis: V. Ratziu, M. Sheikh, A. Sanyal, J. Lim, H. Conjeevaram, N. Chalasani, M. Abdelmalek, A. Bakken, C. Renou, M. Palmer, R. Levine, B. Bhandari, M. Cornpropst, W. Liang, B. King, E. Mondou, F. Rousseau, J. McHutchison, M. Chojkier, submitted as a manuscript to the journal *Hepatology*.
16. Safety Profile of Endoscopist-Directed Sedation with Propofol in a Community Setting: H. Gavini, S. Musuku, S. Bhandari, R. Bhandari, *Gastroenterology*, University of AZ, Tucson, AZ; *Gastroenterology and Nutritional Medical Services*, Monroe, LA; *Maricopa Medical Center*, Phoenix, AZ. Submitted as an abstract to *The American Journal of Gastroenterology*, Volume 107, Supplement 1, October 2012.
17. Phase 2b, randomized, double-blind 12-week studies of TZP-102, a Ghrelin Receptor Agonist for Diabetic Gastroparesis: R.W. McCallum, A. Lembo, T. Esfandyari, B. R. Bhandari, N. Ejksjaer, C. Cosentino, N. Helton, E. Mondou, J. Quinn, F. Rousseau & For the TZP-102 Phase 2b Study Group. Submitted to *Neurogastroenterology & Motility Journal*, DOI: 10.1111 / Article ID: NMO12184
18. Nitroglycerin 0.4% ointment vs placebo in the treatment of pain resulting from chronic anal fissure: a randomized, double-blind, placebocontrolled study: Scott M Berry, Charles F Barish, Raj Bhandari, Gemma Clark, Gregory V Collins, Julian Howell, John E Pappas, Dennis S Riff, Michael Safdi and Ann Yellowlees. Submitted to *BMC Gastroenterology* 2013, 13:106
19. ABT-450/r-Ombitasvir and Dasabuvir with or without Ribavirin for HCV: Peter Ferenci, M.D., David Bernstein, M.D., Jacob Lalezari, M.D., Daniel Cohen, M.D., Yan Luo, M.D., Ph.D., Curtis Cooper, M.D., Edward Tam, M.D., Rui T. Marinho, M.D., Ph.D., Naoky Tsai, M.D., Anders Nyberg, M.D., Terry D. Box, M.D., Ziad Younes, M.D., Pedram Enayati, M.D., Sinikka Green, M.D., Yaacov Baruch, M.D., Bal Raj Bhandari, M.D., Florin Alexandru Caruntu, M.D., Ph.D., Thomas Sepe, M.D., Vladimir Chulanov, M.D., Ph.D., Ewa Janczewska, M.D., Ph.D., Giuliano Rizzardini, M.D., Judit Gervain, M.D., Ph.D., Ramon Planas, M.D., Christophe Moreno, M.D., Ph.D., Tarek Hassanein, M.D., Wangang Xie, Ph.D., Martin King, Ph.D., Thomas Podsadecki, M.D., and K. Rajender Reddy, M.D. Submitted Article to *the New England Journal of Medicine* 2014; 370:1983-92. DOI:10.1056/NEJMoa1402338
20. High SVR Rates with ABT-493 + ABT-530 in Non-Cirrhotic Patients with HCV Genotypes 1, 2, 3 Infections. Authors: F. Poordad, P. Kwo, T. Hassanein, A. Asatryan, S. Wang, D. Wyles, M. Sulkowski, H. E. Vargas, P. Ruane, F. Felizarta, H. Aguilar, J. Lalezari, J. S. Overcash, M. Bennett, B. T. Malakkal, A. Sidique, Bal Raj Bhandari, T. I. Ng, R. Lie, 4 Chih-Wei Lin, S. Lovell, F. J. Mensa, J. Kort. APASL (2016) Asian Pacific Association for the Study of the Liver – 25<sup>th</sup> Conference.

**PUBLICATIONS (Continued):**

21. SURVEYOR-II: High SVR4 Rates achieved with the Next Generation NS3/4A Protease Inhibitor ABT-493 and NS5A Inhibitor ABT-530 in Non-Cirrhotic Treatment-Naïve and Treatment-Experienced Patients with HCV Genotype 3 Infection – Presented as an oral presentation at AASLD 2015.
22. SURVEYOR-II: High SVR4 Rates achieved with the Next Generation NS3/4A Protease Inhibitor ABT-493 and NS5A Inhibitor ABT-530 in Non-Cirrhotic Treatment-Naïve and Treatment-Experienced Patients with HCV Genotype 2 Infection – D. Wyles, M. Sulkowski, S. Wang, M. Bennett, H. E. Vargas, J. S. Overcash, B. Maliakkal, A. Siddique, Bal Raj Bhandari, F. Poordad, S. S. Lovell, Chih-Wei Lin, T. I. Ng, F. J. Mensa, J. Kort. Poster Presentation: HEP DART 2015 – Frontiers in Drug Development for Viral Hepatitis.
23. A Safety, Efficacy, and Tolerance Study of Oral Sulfate Solution in Adolescents Undergoing Colonoscopy – M. Cleveland, PhD, Raj Bhandari, MD, Susan Baker, MD, John McGowen, Annual Scientific Meeting of the American College of Gastroenterology: Volume 110 Supplement 1, Oct2015, Abstract 1481.
24. Clinical Response to Anti-MMP9 Antibody (GS-5745) is Accompanied by Histologic Improvement in Ulcerative Colitis – W. J. Sandborn, Bal Raj Bhandari, R. Fogel, J. Onken, E. Yen, E. Huntzicker, Y. Xin, D. French, J. Silverman, B. Kanwar, M. Subramanian, J. G. McHutchison, S. Lee, L. M. Shackelton, L. Sititt, Rish K. Pai, B. G. Levesque, G. D’Haens, B. G. Feagan – DDW 2015.
25. High SVR Rates with ABT-493 + ABT-530 in Non-Cirrhotic Patients with HCV Genotypes 1, 2, 3 Infection – F. Poordad, P. Y. Kwo, T. Hassanein, A. Asatryan, S. Wang, D. Wyles, M. S. Sulkowski, H. E. Vargas, P. Ruane, F. Felizarta, H. Aguilar, J. Lalezari, J. S. Overcash, M. Bennett, Sandra Lovell, F. J. Mensa, J. Kort – Asian Pacific Association for the study of the liver (APASL). 2016; Tokyo DV#044583.
26. Randomized clinical trial : A Phase I, Dose-Ranging Study of the Anti-MMP9 monoclonal antibody GS-5745 for Ulcerative Colitis – Sandborn, W.; Bhandari, B.Raj; Fogel, Ronald; Onken, Jane; Yen, Elizabeth; Zhao, Xi; Jiang, Zhaoshi; Ge, Dongliang; Xin, Yan; Ye, Zhishen; French, Dorothy; Silverman, Jeffrey; Kanwar, Bittoo; Subramanian, G. Mani; McHutchison, John; Lee, Scott; Shackleton, Lisa; Pai, Rish; Levesque, Barrett; Feagan, Brian.
27. Randomized clinical trial: A Phase I, Dose-Ranging Study of the Anti-Matrix Metalloproteinase-9 Monoclonal Antibody GS-5745 versus placebo for Ulcerative Colitis – Bal Raj Bhandari, W.J. Sandborn, D. French, J.A. Silverman, B. Kanwar, G.M. Subramanian, J.G. McHutchison, S. D. Lee, L.M. Shackelton, R. K. Pai, B. G. Levesque & B. G. Feagan.
28. A Randomized Phase 3 Trial of Sofosbuvir/Velpatasvir/Voxilaprevir for 8 Weeks Compared to Sofosbuvir/Velpatasvir for 12 Weeks in DAA-naïve Genotype 1-6 HCV-Infected Patients: The POLARIS-2 Study – Ira M. Jacobson, Tarik Asselah, Ronald Nahass, Bal R. Bhandari, Albert Tran, Robert H. Hyland, Luisa M. Stamm, Hadas Dvory-Sobol, Yanni Zhu, Diana M. Brainard, Subramanian Mani, John G. McHutchison, Stephen Shafran, Mitchell Davis, Catherine A. Stedman, Eric Lawitz, Edward J. Gane. Hepatitis: Therapeutic: New Agents (not approved, phase 2-3) Late Breaking Oral or Poster Presentation, AASLD 2016.
29. A Randomized Phase 3 Trial of Sofosbuvir/Velpatasvir/Voxilaprevir for 8 Weeks Compared to Sofosbuvir/Velpatasvir for 12 Weeks in DAA-Naïve Genotype 1–6 HCV Infected Patients: The POLARIS-2 Study - Ira M. Jacobson, Tarik Asselah, Ronald Nahass, Bal R. Bhandari, Albert Tran, Robert H. Hyland, Luisa M. Stamm, Hadas Dvory-Sobol, Yanni Zhu, Diana M. Brainard, G. Mani Subramanian, John G. McHutchison, Stephen Shafran, Mitchell Davis, Catherine A. Stedman, Eric Lawitz, Edward J. Gane
30. Symptom Severity Influences Drug Efficacy in Women with Diabetic Gastroparesis: Results of a Phase 3 Study with Metoclopramide Nasal Spray. Poster presentation at DDW
31. Efficacy of 8 Weeks of Sofosbuvir, Velpatasvir, and Voxilaprevir in Patients With Chronic HCV Infection: 2 Phase 3 Randomized Trials - Ira M. Jacobson, Eric Lawitz, Edward J. Gane, Bernard E. Willems, Peter J. Ruane, Ronald G. Nahass, Sergio M. Borgia, Stephen D. Shafran, Kimberly A. Workowski, Brian Pearlman, Robert H. Hyland, Luisa M. Stamm, Evguenia Svarovskaia, Hadas Dvory-Sobol, Yanni Zhu, G. Mani Subramanian, Diana M. Brainard, John G. McHutchison, Norbert Bräu, Thomas Berg, Kosh Agarwal, Bal Raj Bhandari, Mitchell Davis, Jordan J. Feld, Gregory J. Dore, Catherine A. M. Stedman, Alexander J. Thompson, Tarik Asselah, Stuart K. Roberts, and Graham R. Foster
32. Andecaliximab (anti-matrix metalloproteinase-9) induction therapy for ulcerative colitis: a double-blind, randomized, placebo-controlled, phase 2/3 study in patients with moderate to severe disease - William Sandborn, Bal R. Bhandari, Charles Randall, Ziad H. Younes, Tomasz Romanczyk, Yan Xin, Emily Wendt, Hao Chai, Matt McKeivitt, Sally Zhao, Bittoo Kanwar, John S. Sundry, Satish Keshav, and Silvio Danese
33. Remimazolam for colonoscopy in high risk (ASA III/IV) patients: a randomized placebo (double blind) and midazolam (open label) controlled trial - Douglas K. Rex, MD, MACG, Bal Raj Bhandari, MD, Jonathan Schroeder, MD

**RESEARCH TRAINING:**

*Available Upon Request*

**REFERENCES:**

*Available Upon Request*

**RESEARCH EXPERIENCE:**

***September 2003***

How to Coordinate Clinical Trials: The Basics - Houston, Texas

**Co-Investigator of three Hepatitis-C Studies:**

1. Dr. Ira Jacobson study: Comparison of PEG Interferon Alfa-2B plus Ribavirin given as a fixed dose for on a weight optimized basis for treatment of chronic hepatitis-C in previously untreated adult subjects.
2. A randomized multi-center trial comparing induction PEG-Intron-A plus Ribavirin versus PEG Intron-A plus Ribavirin in patients who have previously not responded or have relapsed following Intron-A based therapy for chronic hepatitis-C, with maintenance therapy for patients who continue to remain non-responsive. Principal investigator: Eric Lawiz, M.D., Gastroenterology Clinic, Brooke Army Medical Center.
3. Consultant for Rebetrone Compliance Assessment Program Survey (the "ReCAP Survey") being conducted by Ingenix pharmaceutical Services for Schering Corporation.

**Investigator:**

1. Limited access protocol for the use of oral cisapride in the treatment of refractory Gastroesophageal reflux disease (GERD) and other gastrointestinal motility disorders

***2004 Clinical Trials:***

1. A Phase III, randomized, open-label study to assess the safety and efficacy of AQUAVAN Injection versus Midazolam HCl for sedation in patients undergoing colonoscopy procedures.
2. A Phase 2b study of merimepodib in combination with pegylated interferon alfa-2a (Pegasys) and Ribavirin in subjects with chronic genotype I hepatitis-C non-responsive to prior therapy with pegylated interferon alfa and ribavirin.
3. A Phase 2b multicenter, randomized, double-blind, placebo-controlled, parallel group, dose-ranging study of YM443 in subjects with functional dyspepsia
4. A 12-week, randomized, double-blind, placebo-controlled study with PRN BID and fixed Dosing regimens of Alosetron in Female Subjects with severe diarrhea-predominant irritable bowel syndrome who have failed conventional therapy.

***2005 Clinical Trials:***

1. A 12-week, multicenter, double-blind, randomized efficacy and safety study of LUBIPROSTONE in subjects with constipation-predominant Irritable Bowel Syndrome.
2. A randomized, double-blind, dose-response study to assess the efficacy and safety of AQUAVAN Injection for procedural sedation in patients undergoing colonoscopy.
3. A multicenter, randomized, double-blind, placebo-controlled study of efficacy and safety of ITOPRIDE HCl in patients suffering from functional dyspepsia.
4. A multicenter, open-label study to evaluate the long-term safety and efficacy of ITOPRIDE HCl in patients suffering from functional dyspepsia.
5. A multicenter, randomized, blinded, placebo controlled, cross-over study to investigate the safety and tolerability of intravenous VIT-45 in patients with Iron Deficiency Anemia.
6. A Phase II randomized, double-blind, placebo controlled, parallel group, multicenter study to evaluate the efficacy and safety of a four-week treatment with ATI-7505 for the healing of acute erosive esophagitis.
7. A Phase II randomized, double-blind, placebo controlled, parallel group, multicenter study to evaluate the efficacy and safety of a four-week treatment with ATI-7505 for the relief of heartburn symptoms in patients with symptomatic Gastroesophageal Reflux Disease (GERD)-Amendment 1.

***2006 Clinical Trials:***

1. Comparison of weight-based doses of Taribavirin combined with peginterferon Alfa-2b verses Ribavirin combined with pefinterferon Alfa-2b in therapy-naïve patients with Chronic Hepatitis C Virus Genotype 1 Infection.
2. Non-responsive to prior therapy and Pegylated Interferon Alfa and Ribavirin.

3. The safety and efficacy of hematinic agent in the treatment of postpartum patients.

### **2007 Clinical Trials:**

1. Procurement of blood samples for use in the development of a gastrointestinal disease test panel.
2. A safety and efficacy evaluation of BLI-008 Oral Sulfate Solution vs. MoviePrep® as bowel cleansing preparations in adult subjects.
3. Clinical efficacy and safety of MAX-002 vs. Canasa® in the treatment of mild to moderate ulcerative proctitis: a multicenter, open-label, randomized, parallel group, non-inferiority study.
4. A phase II, randomized, adaptive design, multicenter, parallel group, placebo-controlled, 58 day, dose-ranging study of ATI-7505 in patients with Postprandial Distress Syndrome.
5. A randomized, multi-center, double-blind, placebo-controlled, dose-range-finding, parallel group, Phase 2 trial of Oral Linaclotide Acetate Administered to patients with Chronic Constipation.
6. A randomized, multi-center, double-blind, placebo-controlled, dose-range-finding, parallel-group, Phase 2 trial of Oral Linaclotide Acetate Administered to patients with Irritable Bowel Syndrome with Constipation.
7. A Phase 2, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of three different doses (275, 550, 1100mg) of Rifaximin associated irritable bowel syndrome.
8. A randomized, double-blind, placebo-controlled multicenter Phase II/III study to evaluate the efficacy and safety of Tegaserod and placebo given orally for 12 weeks for the treatment of Opioid-Induced Constipation in patients with Chronic Non-Cancer Pain.
9. A 52-week extension to study CHTF919N2201 to evaluate the safety and efficacy of tegaserod (6mg BID and 12mg BID OD) given orally for the treatment of Opioid-Induced Constipation in patients with Chronic Non-Chronic Pain.
10. A randomized, double-blind, placebo-controlled, multicenter evaluation of the efficacy and safety of tegaserod 6mg BID administered orally for 12 weeks, to patients with Chronic Constipation, aged 65 or older.
11. A randomized, double-blind phase 3 study of the efficacy and safety of HZT-501 in subject requiring NSAID treatment.
12. A double-blind follow-on safety study of HZT-501 in subjects who have completed participation in Horizon Protocol HZ-CZ-301 or Horizon Protocol HZ-CA-303.
13. A randomized, double-blind, placebo-controlled, multi-national study to determine the effect of Cellegesic Nitroglycerin Ointment 0.4% on the pain associated with a chronic anal fissure.
14. A multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy, safety and tolerability of Rifaximin 550 mg BID for 6 months in preventing Hepatic Encephalopathy.
15. A multi-center, open-label trial to evaluate the long-term safety and tolerability of Rifaximin 550 mg BID in subjects with a history of Hepatic Encephalopathy.
16. A multi-center, Investigator-blinded, randomized, 12-month, parallel-group, non-inferiority study to compare the efficacy of 1.6 to 2.4g Asacol® therapy QD divided dose BID in the Maintenance of Remission of Ulcerative Colitis.
17. 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 (400mg Mesalamine tablet), followed by a 9 month treatment-free observation period.

### **2008 Clinical Trials:**

1. A multi-center, randomized, controlled study to investigate the safety dose of intravenous Ferric Carboxymaltose (FCM) vs. Standard Medical Care in treating Iron Deficiency Anemia in subjects who are not Dialysis dependant.
2. A multi-center, randomized, controlled study to investigate the safety and tolerability of Intravenous Ferric Carboxymaltose (FCM) vs. Standard Medical Care in treating Iron Deficiency Anemia.
3. A Phase 2 multi-center, 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.
4. A Phase 3 multi-center, 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.
5. A Safety and efficacy evaluation of BLI850 vs. HalfLytyly® and Bisacodyl Bowel prep kit as Bowel Cleansing preparation in adult subjects.
6. A phase IIIb, multinational, randomized, double-blind, placebo-controlled trial to assess the efficiency 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.
7. 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 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 study C87085.
8. A randomized, double-blind, placebo-controlled study of AGI-003 (Averapamil) in the treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D).
9. An open-label, roll-over safety study of AGI-003 (Averapamil) in the treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D)
10. A phase 3, randomized, double-blind, placebo-controlled, multi-center study to assess the efficacy and safety of Rifaximin 550mg TID in the treatment of subjects with Non-Constipation Irritable Bowel Syndrome.
11. A multi-center, randomized, placebo-controlled, double-blinded study of the efficacy and safety of Lubiprostone in patients with Opioid-induced bowel dysfunction.

12. Validation of patient-reported outcome measures for the assessment of GERD symptoms and their subsequent impact on patients with a partial response to PPI treatment in a two part multi-center phase IIA study including a four week randomized double-blind, placebo-controlled parallel- group treatment period with AZD3355, 65 mg BID as add-on treatment of PPI.
13. A phase 3, randomized, double blinded, placebo-controlled, parallel-group Trial of Linaclotide administered orally for 12 weeks followed by a 4-week randomized withdrawal period in patients with Chronic Constipation.
14. An Open-label, long term safety study of oral Linaclotide administered to patients with Chronic Constipation or Irritable Bowel Syndrome with Constipation.

### **2009 Clinical Trials:**

1. A phase 3, randomized, double-blind, placebo-controlled, parallel-group trial of Linaclotide administered orally for 26 weeks in patients with Irritable Bowel Syndrome with Constipation.
2. A phase 2, multi-center, randomized, double-blind, placebo-controlled, dose-ranging trial to evaluate the efficacy safety and tolerability of AST-120 (Spherical Carbon Absorbent) for 8 weeks in the treatment of mild hepatic encephalopathy.
3. A Dose-Response Efficacy and safety Study of Arbaclofen Placarbil (XP19986) as Adjunctive Therapy in Subjects with Gastroesophageal Reflux Disease (GERD) who are Incomplete Responders to a Proton Pump Inhibitor (PPI).
4. A Phase IIb, Double-blind, Randomized, Placebo-controlled, Multi-centre, Dose-finding Efficacy and Safety Study of a Range of Doses of A3309 in Patients with Chronic Idiopathic Constipation.
5. A Multi-center, Randomized, Active Controlled Study to Investigate the Efficacy and Safety of Intravenous Ferric Carboxymaltose (FCM) in Patients with Iron Deficiency Anemia (IDA).
6. Collection of Blood Samples for the Discovery of Biomarkers Associated With Irritable Bowel Syndrome.
7. A Double-Blind, Double-Dummy, Randomized, Active-Comparator, Arthritis Non-Inferiority Study of LT-NS001 versus Naprosyn for Twelve Weeks in Osteoarthritis Patients to Compare Endoscopic Gastric Ulcer Rates.
8. A Phase 2, Randomized, Double-Blind, parallel-Group, Placebo-Controlled Study to Investigate the Safety, Tolerability, Pharmacokinetics and Activity of GS-9450 in Adults with Non-Alcoholic Steatohepatitis (NASH).

### **2010 Clinical Trials:**

1. A Multicenter, Randomized, Double-blind, Placebo-controlled, parallel group, dose-ranging clinical study to evaluate the efficacy and safety of metoclopramide nasal spray solution in Diabetic subjects with Gastroparesis
2. 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.
3. A Randomized, Double-blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GSK1605786A in the Treatment of Subjects with Moderately-to-Severely Active Crohn's Disease.
4. A Randomized, Double Blind, Placebo-Controlled Study to Investigate the Efficacy and safety of GSK1605786A in The Maintenance of Subjects with Crohn's Disease.
5. An Open-Label Extension Study to Assess the Safety of GSK16057A in Subjects with Crohn's disease.
6. Linaclotide Long Term safety Study Follow-up participant Interviews.

### **2011 Clinical Trials:**

1. A Multicenter, 1-Week, Double-Blind, Randomized, Placebo-Controlled Trial Comparing the Lubiprostone 24-ug capsule formulation (Apotex, Inc) with Amitiza (lubiprostone) 24-ug capsule formulation (Sucampo Pharma Americas, Inc. and Takeda Pharmaceutical America, Inc) in Subjects with Chronic Idiopathic Constipation.
2. A Randomized, Double-Blind, Placebo-Controlled study to assess the safety and efficacy of RDX5791 for the treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C).
3. A Phase 3, 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.
4. A Phase 3b/4, Open-label, Multicenter, Prospective Study to Evaluate the Effect of Remission Status on the Ability to Maintain or Achieve Clinical and Endoscopic Remission During a 12-Month, Long-term Maintenance Phase With 2.4g/day MMX® Mesalamine/mesalazine Once Daily in Adult Subjects With Ulcerative Colitis
5. Multi-Target Colorectal Cancer Screening Test for the Detection of Colorectal Advanced Adenomatous Polyps and Cancer: DeeP-C Study
6. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Efficacy and Safety of Once-Daily Administrations of TZP 102 for the Treatment of Symptoms Associated with Diabetic Gastroparesis
7. A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of TD-1211 in Subjects with Opioid-Induced Constipation.

### **2012 Clinical Trials:**

1. Protocol BLI800-440: A Safety, Tolerance and Efficacy Evaluation of 3 Different Bowel Cleansing Treatments in Adult Subjects, Including the Elderly and Subjects with Hepatic or Renal Insufficiency
2. A Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety and Tolerability of JNJ-27018966 in the Treatment of Patients With Diarrhea-Predominant Irritable Bowel Syndrome.
3. A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of RM-131 Administered to Patients with Diabetic Gastroparesis
4. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Efficacy and Safety of TZP 102 Given Orally Three Times a Day for the Treatment of Symptoms Associated with Diabetic Gastroparesis
5. A Safety and Efficacy Evaluation of BLI801 Laxative in Constipated Adults
6. A Phase 3b, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial of Linaclotide administered orally for 12 weeks to patients with Chronic Constipation and Prominent Bloating at Baseline.
7. A Randomized, Open-Label, Multicenter Study to Evaluate the Safety and Antiviral Activity of the Combination of ABT-450 with Ritonavir (ABT-450/r), ABT-267, and ABT-333 With and Without Ribavirin in Treatment-Experienced Subjects with Genotype 1 Chronic Hepatitis C Virus (HCV) Infection (PEARL-II).
8. A Phase 3b, Randomized, Double-blind, Placebo-Controlled, Parallel-Treatment Group, Multicenter Efficacy and Safety Study of Topical Diltiazem Chloride 2% Cream in subjects with Anal Fissure.

### ***2013 Clinical Trials:***

1. 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.
2. 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.
3. Study Protocol for the Validation of Ulcerative Colitis Patient-Reported Outcomes (US-PRO) instrument in Patients with Ulcerative Colitis.
4. A Multicenter, Randomized, Open-Label, Active-Controlled, Trial to Evaluate the Safety and Efficacy of Rifaximin 550mg with and without Lactulose in Subjects with a history of recurrent overt hepatic Encephalopathy.
5. A Phase I, Double-blind, Randomized, Placebo-Controlled, Staggered, Single and Multiple Ascending Dose, Multicenter Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of GS-5745 in Subjects with Moderate to Severe Ulcerative Colitis.
6. A Phase III, Randomized, Multi-Center, Double-Blind, Placebo-Controlled Trial of HMPL-004 in Patients with Mild to Moderate Ulcerative Colitis.
7. A Randomized, Double-Blind, Controlled Study to Evaluate the Efficacy and Safety of Combination of ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 With and Without Ribavirin (RBV) in Treatment Naïve Adults with Genotype 1a Chronic Hepatitis C (HCV) Infection (PEARL-IV).
8. A Phase III Double Blind, Multi-Center Placebo Controlled Maintenance Trial of HMPL-004 in Subjects with Mild to Moderate Ulcerative Colitis with clinical Remission or Response from Induction Therapy.
9. A Randomized, Double-Blind, Placebo-Controlled, Dose-ranging, Multicenter Study to Assess the Efficacy and Safety of Rifaximin Soluble Dispersion tablets for the Prevention of Complications in Subjects with Compensated Liver Cirrhosis.
10. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 study to evaluate the efficacy and safety of CB-5945 for the treatment of Opioid-Induced Constipation in Adults taking Opioid Therapy for Chronic Non-Cancer Pain.
11. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of AZD1722 for the Treatment of Constipation-Predominant Irritable Bowel Syndrome.
12. A Phase III, 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 Severe Active Crohn's Disease.

### ***2014 Clinical Trials:***

1. Efficacy, Safety and Tolerability of Bowel Cleansing Preparation (BLI800) in Pediatric Subjects Undergoing Colonoscopy.
2. 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.
3. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of Metoclopramide Nasal Spray in Men with Symptoms Associated with Diabetic Gastroparesis.
4. Protocol for Qualitative Focus Group Study to Understand the Patient Symptom Experience, Treatment Experience, and Barriers to Pancreatic Enzyme Replacement Therapy (PERT) in Adult Patients Diagnosed with Exocrine Pancreatic Insufficiency (EPI).
5. Sample Collection Study to Evaluate DNA Markers in Subjects with Inflammatory Bowel Disease.
6. A Phase 3, Multicenter, Open-Label Study to Investigate the Efficacy and safety of Sofosbuvir/GS-5816 Fixed Dose Combination in Subjects with Chronic HCV Infection and Child-Pugh Class B Cirrhosis.
7. A Phase 3, Multicenter, Randomized, Open-Label Study to Compare the Efficacy and Safety of Sofosbuvir/GS5816 Fixed Dose Combination for 12 Weeks with Sofosbuvir and Ribavirin for 12 Weeks in Subjects with Chronic Genotype 2 HCV Infection.
8. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 2a Study of Oral IW-9179 Administered Once and Twice Daily for 4 Weeks to Patients with Diabetic Gastroparesis.



9. 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 (IBSC).
10. 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.
11. A Phase 2a Study to Evaluate the Effect of IW-3718 Administered Orally for 4 weeks in Patients with GERD Not Completely Responsive to Proton Pump Inhibitors.
12. A Randomized, 12 Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Plecanatide in Patients with Chronic Idiopathic Constipation (CIC).
13. An Open Label Extension (OLE), Long term Safety and Tolerability Study of Plecanatide in Patients with Chronic Idiopathic Constipation (CIC).

### **2015 Clinical Trials:**

1. 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.
2. A Phase III study evaluating the efficacy and safety of Remimazolam (CNS 7056) compared to placebo and midazolam in patients undergoing colonoscopy.
3. 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.
4. A safety and efficacy evaluation of BLI400 laxative in constipated adults.
5. A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Plecanatide in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)
6. A Qualitative Interviews with patients diagnosed with Crohn's Disease
7. A registry for subjects with cirrhosis who achieve a sustained virologic response following treatment with a Sofosbuvir-based regimen without Interferon for chronic hepatitis c infection.
8. A combined Phase 2/3, 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.
9. A long term follow-up registry for subjects who achieve a sustained virologic response to treatment in Gilead-sponsored trials in subjects with Chronic Hepatitis C Infection.
10. A Phase 2, multicenter, randomized, double-blind, parallel, placebo-controlled study of LY3074828 in subjects with moderate to severe ulcerative colitis.
11. A study evaluating the safety and efficacy of Remimazolam (CNS-7056) compared to placebo and Midazolam in ASA III and IV patients undergoing colonoscopy.
12. A Phase 3, Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed Dose Combination for 12 Weeks in Direct-Acting Antiviral-Experienced Subjects with Chronic HCV Infection
13. A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS 9857 Fixed-Dose Combination for 8 Weeks Compared to Sofosbuvir/Velpatasvir for 12 Weeks in Direct Acting Antiviral-Naïve Subjects with Chronic HCV Infection
14. A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS 9857 Fixed-Dose Combination for 8 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks in Subjects with Chronic Genotype 3 HCV Infection and Cirrhosis.
15. A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS 9857 Fixed-Dose Combination for 12 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks in Direct Acting Antiviral-Experienced Subjects with Chronic HCV Infection who Have Not Received an NS5A Inhibitor

### **2016 Clinical Trials:**

1. A 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
2. A Pilot Study of BLI801 Laxative in Adults Experiencing Non-Idiopathic Constipation.
3. Ardelyx TEN-01-301 - "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-01-301
4. A Phase 2b, Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-range-finding Trial of IW-3718 Administered Orally for 8 Weeks to Patients with Symptomatic Gastroesophageal Reflux Disease Not completely Responsive to Proton Pump Inhibitors.
5. A Qualitative Interviews with patients diagnosed with Ulcerative Colitis
6. A Safety and Efficacy Evaluation of BLI400 Laxative in Constipated Adults
7. A Randomized, Placebo-Controlled Trial to Evaluate the Effect of a Nutritional Intervention to Improve the Intestinal Mucosal Health Status in Subjects with Crohn's Disease (CD) Receiving Induction Anti-TNF Therapy PIONEER-CD
8. A Phase 2, Randomized, Double-Blind, Placebo-Controlled, 12-Month, Multiple-Dose Study to Evaluate the Safety, Tolerability and Efficacy of Three Dose Levels of MSDC-0602K in Patients with NASH

9. A Phase 1b Multi-Center, Randomized, Double-Blind, Multi-Dose, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacodynamics, and Plasma Exposure of TD-1473 in Subjects with Moderately-to-Severely Active Ulcerative Colitis
10. A Multiple Dose Study to Evaluate the Safety, Tolerability and Microbiome Dynamics of SER-287 in Subjects with Mild-to-Moderate Ulcerative Colitis