Raj Bhandari
4108 Claire Lane
Monroe, La
71201
rbhandari@drbhandari.com
DOB: November 1, 1961

CERTIFICATION:

2021 Gastroenterology Recertification
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
July1, 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
July 1, 1988 - June 30, 1989
Medical Internship
Memorial University, St. John`s, Newfoundland, Canada
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 6th Street,
Monroe, LA 71201

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

FACILITY AFFILIATIONS:

Morehouse General Hospital
Endoscopy Center
323 W. Walnut Avenue,
Bastrop, LA 71220

Monroe Surgical Hospital
2408 Broadmoor Blvd.,
Monroe, LA 71201

St. Francis Medical Center
309 Jackson Street,
Monroe, LA 71201

Endoscopy Center of Monroe
316 S. 6th St,
Monroe, LA 71201

Richland Parish Hospital
407 Cincinnati St,
Delhi, LA 71232

West Carroll Memorial Hospital
706 Ross St,
Oak Grove, LA 71263

FACULTY APPOINTMENTS:

July 1, 2021
Associate Professor
Edward via College of Osteopathic Medicine, Monroe, La
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

2021 Teacher Physician - Edward Via College of Osteopathic Medicine

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*
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 Section is CI/HCO3-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 74th 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. Ejskjaer, 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 – 25th Conference.
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-Rangeing 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. Published 2016
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. Published 2016
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. Published 2016
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 2017
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. Published 2017
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 McKevitt, Sally Zhao, Bittoo Kanwar, John S. Sundy, Satish Keshav, and Silvio Danese. Published 2016
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. Published 2016
34. Ser-287, An Investigational Microbiome Therapeutic, Induces Remission And Endoscopic Improvement In A Placebo-Controlled, Double-Blind Randomized Trial In Patients With Active Mild-To-Moderate Ulcerative Colitis: Bharat Misra, John Curran, Hans Herfarth, Kiran Jagarlamudi, Caterina Oneto, Bal Raj Bhandari, Gregory Wiener, David Kerman, Alan Moss, Roger Pomerantz, Jeff Zhao, Patricia Bernardo, Sheri Simmons, Liyang Diao, Edward O'Brien, Matthew Henn, Michele Trucksis. This abstract is for oral presentation at DDW 2018
35. Andecaliximab (Anti-MMP9) Induction Therapy for Crohn's Disease: A Randomized, Placebo-Controlled, Phase 2 Study - Stefan Schreiber; Corey A. Siegel; Keith Friedenberg; Ursula Seidler; Bal R. Bhandari; Ziad Younes; Ke Wang; Matt McKevitt; Sally Zhao; John Sundy; Scott D. Lee; Edward V. Loftus Jr. - Poster presentation at the UEGW meeting in Barcelona
36. Andecaliximab (Anti-MMP9) Induction Therapy for Ulcerative Colitis: A Randomized, Placebo-Controlled, Phase 2 Study - William J. Sandborn; Bal R. Bhandari; Charles Randall; Ziad Younes; Tomasz Romanczyk; Hao Chai; Matt McKevitt; Sally Zhao; John Sundy; Satish Keshav; Silvio Danese - Poster presentation at the UEGW meeting in Barcelona

37. SER-287, An Investigational Microbiome Therapeutic, Induces Remission and Endoscopic Improvement in a Placebo-Controlled, Double-Blind Randomized Trial in Patients with Mild-to-Moderate Ulcerative Colitis: B. Misra, J. Curran, H. Herfarth, K. Jagarlamudi, C. Oneto, B.R. Bhandari, G. Wiener, D. Kerman, A. Moss, R. Pomerantz, J. Zhao, P. Bernardo, S. Simmons, L. Diao, E. O'Brien, M. Henn, and M. Trucksis. Poster presentation at ECCO. 2018
38. Linaclotide in irritable bowel syndrome with constipation: A Phase 3 randomized trial in China and other regions - Yunsheng Yang, Jingyuan Fang, Xiaozhong Guo, Ning Dai, Xizhong Shen, Youlin Yang, Jing Sun, Bal Raj Bhandari, David S Reasner, Jacquelyn A Cronin, Mark G Currie, Jeffrey M Johnston, Peter Zeng, Niwat Montreewasuwat, George Zhijian Chen, Sam Lim - Journal of Gastroenterology and Hepatology published March 12, 2018
39. Efficacy of Mirikizumab on Health – Related Quality of life in Patients with Ulcerative Colitis: Sandborn B; Ferante M; Bhandari B; D'Haens; Berliba E; Feagan B; Klekotka P; Laskowski J; Durante M; Tuttle J; Naegeli A - Abstract presented at The European Gastroenterology Week April 2018
40. Efficacy and Safety of Mirikizumab in Patients with Moderate to Severe Ulcerative Colitis: Sandborn B; FeranteM; Bhandari B; D'Haens; Berliba E; Feagan B; Klekotka P; Laskowski J; Durante M; Tuttle J; Naegeli A – Oral presentation at UEGW (United European Gastroenterology Week) in Vienna October, 2018.
41. Efficacy of Mirikizumab on Health-Related Quality of Life in Patients With Ulcerative Colitis: A Randomised, Double-Blind, Controlled, Phase 2 Study - Sandborn WJ; Ferrante M; Bhandari B; D'Haens G; Berliba E; Feagan B; Klekotka P; Laskowski J; Durante M7; Tuttle J; Naegeli A - Poster presentation at UEGW (United European Gastroenterology Week), Oct 20 - 24, 2018
42. Intestinally Restricted, Orally Administered, pan-JAK Inhibitor TD-1473 Demonstrates Favorable Safety, Tolerability, Pharmacokinetics, and Signal for Clinical Activity in Subjects with Moderately-to-Severely Active Ulcerative Colitis: Julian Panes, Raj Bhandari, Jonathan Leighton, Ravi Ganeshappa, Deanna Nguyen, Brian Ferslew, Ann Olmsted, Richard A. Graham, and William Sandborn – Oral presentation at UEGW, October, 2018
43. Ptg-100, An Oral Gut-restricted Peptide A4B7 Antagonist Induces Clinical And Histologic Remission In Patients With Moderate To Severely Active Ulcerative Colitis: William J Sandborn, Brian Bressler, Scott Lee, Raj Bhandari, Bittoo Kanwar, Lucio Tozzi, Richard Shames, Geert D'Haens, Jean-Fredric Colombel, Stefan Schreiber, Silvio Danese, Rish Pai, Brian Feagan - Abstract at UEGW October 2018
44. Efficacy and Safety of Anti-interleukin-23 Therapy with Mirikizumab (LY3074828) in Patients with Ulcerative Colitis including Japanese Patients in A Phase 2 Study: Satoshi Motoya, William J. Sandborn, Marc Ferrante, Bal R. Bhandari, Geert R. D'Haens, Elina Berliba, Brian G. Feagan, Ko Nakajo, Yoichi Satoi, Janelle Laskowski, Stuart Friedrich, Michael Durante, Jay Tuttle, Mamoru Watanabe, Toshifumi Hibi - Poster presentation at 9th annual Japan Society For Inflammatory Bowel Disease
45. The gut-selective, orally administered, pan-jak inhibitor TD-1473 demonstrates favourable safety, tolerability, pharmacokinetic, and signal for clinical activity in subjects with moderately-to-severely active ulcerative colitis: William J. Sandborn, Raj Bhandari, Jonathan Leighton, Ravi Ganeshappa, Deanna Nguyen, Brian Ferslew, Ann Olmsted, Richard Graham, Julian Panes - Poster presentation at the Crohns and Colitis Congress, 2019
46. The Gut-Selective, Orally Administered, Pan-JAK Inhibitor TD-1473 Demonstrates Favorable Safety, Tolerability, Pharmacokinetics, and Signal for Clinical Activity in Subjects with Moderately-to-Severely Active Ulcerative Colitis: William Sandborn, MD; Raj Bhandari, MD; Jonathan A. Leighton, MD; Ravi Ganeshappa, MD; Deanna D. Nguyen, MD; Brian C. Ferslew, PharmD, PhD; Ann Olmsted, PhD; Richard A. Graham, PhD; and Julian Panes, MD6
47. Maintenance Treatment with Mirikizumab, a p19-directed IL-23 Antibody: 52-Week Results in Patients with Moderately-to-Severely Active Ulcerative Colitis: Geert R. D'Haens; William J. Sandborn; Marc Ferrante; Bal R. Bhandari; Elina Berliba; Toshifumi Hibi; Jay L. Tuttle; James B. Canavan; Stuart Friedrich; Michael Durante; Vipin Arora; Brian G. Feagan – Poster Presentation for ECCO 2019
48. Clinical utility and application of noninvasive tests of fibrosis in the selection of patients with advanced fibrosis due to NASH in the Phase 2 ATLAS trial: Rohit Loomba, Naim Alkhouri, Simone Strasser, Vincent Wai-Sun Wong, Raul Aguilar Schall, Bryan J. McColgan, G. Mani Subramanian, C. Stephen Djedjos, Robert P. Myers, Zachary Goodman, Aasim Sheikh, Guy Neff, Bal Bhandari, Nadege Gunn, Kris Kowdley - Poster presentation for EASL 2019
49. Efficacy And Improved Health-related Quality Of Life After 52-weeks Of Mirikizumab Treatment In Patients With Ulcerative Colitis: An Update From A Randomised, Double-blind, Controlled, Phase 2 Study - Ferrante M., Sandborn W., Bandhari B.R., D'haens G., Feagan B., Durante M., Arora V., Tuttle J., Naegeli A. – Poster Presentation ECCO 2019 & Abstract for UEGW 2019
50. Currently Available Noninvasive Tests Accurately Stage Severity Of Fibrosis In Patients With NASH: S.A. Harrison, E.J. Lawitz, V. Wong, Q Anstee, Z. Goodman, M. Trauner, M. Romero-Gomez, R. Bhandari, M. Abdelmalek, A. Sanyal, K. Patel, V. Leroy, C. Bureau, M.Sasso, C. Fournier, L Sandrin, L. Han, G. Li, K. Kersey, M. Camargo, C.S. Djedjos, R.P. Myers, Zobair M Younossi

51. Proof of concept for the monitoring of activity and sleep using wearable devices in a clinical trial for patients with advanced fibrosis due to nonalcoholic steatohepatitis (NASH): Rohit Loomba, Bal Raj Bhandari, Peter J. Ruane, Bryan J. McColgan, Raul Aguilar Schall, Catherine Jia, Robert P. Myers, C. Stephen Djedjos, Aasim Sheikh, Anita Kohli, Simone Strasser, Vincent Wong, Kris Kowdley, Naim Alkouri
52. Efficacy and Improved Health-related Quality of Life After 52 Weeks of Mirikizumab Treatment in Patients With Ulcerative Colitis: An Update From a Randomized, Double-blind, Controlled, Phase 2 Study: Marc Ferrante, William J. Sandborn, Bal R. Bhandari, Geert D'Haens, Brian Feagan, Michael Durante, Vipin Arora, Jay Tuttle, April N. Naegeli - Poster presentation at UEGW 2019
53. Alcohol use is underreported in clinical trials of NASH: Baseline alcohol biomarkers from a phase 2 clinical trial: Naim Alkhouri, Simone Strasser, Vincent Wai-Sun Wong, Raul Aguilar Schall, Jay Chuang, Ryan Huss, Bryan J. McColgan, C. Stephen Djedjos, Robert P. Myers, Zachary Goodman, Aasim Sheikh, Guy Neff, Bal Bhandari, Nadege Gunn, Kris Kowdley, Stephen Caldwell, Rohit Loomba - Poster presentation at AASLD 2019
54. Gut-Selective JAK Inhibitor TD-1473 Demonstrates Favorable Safety, Tolerability, Pharmacokinetics, and Clinical Activity Signal in Moderately to Severely Active Ulcerative Colitis: Katsuyoshi Matsuoka, MD, PhD; Julian Panes, MD; RajBhandari, MD; Jonathan A. Leighton, MD; Ravi Ganeshappa, MD; Deanna D. Nguyen, MD; Richard A. Graham, PhD; Brihad Abhyankar, MS, FRCS; William Sandborn, MD; - Oral presentation at Japanese Digestive Disease Week, November 2019.
55. Efficacy and Safety of Mirikizumab in a Randomized Phase 2 Study of Patients With Ulcerative Colitis: William J. Sandborn, Marc Ferrante, Bal R. Bhandari, Elina Berliba, Brian G. Feagan, Toshifumi Hibi, Jay L. Tuttle, Paul Klekotka, Stuart Friedrich, Michael Durante, MaryAnn Morgan-Cox, Janelle Laskowski, Jochen Schmitz, Geert R. D'Haens - Published in the AGA Gastroenterology Journal, August 2019
56. Early and Sustained Improvement in Stool Frequency and Rectal Bleeding Following 52 Weeks of Mirikizumab Treatment: Geert D'Haens, Toshifumi Hibi, Marc Ferrante, Bal Bhandari, Elina Berliba, Jay Tuttle, Trevor Lissoos, Nathan Morris, April N. Naegeli, Brian Feagan - Poster presention at the European Crohn's and Colitis Organization (ECCO), in Vienna, February 12-15, 2020
57. A randomized, double-blind study to evaluate the safety and tolerability of KB174, a novel synthetic glycan, in patients with well-compensated cirrhosis: Bal Raj Bhandari MD, Jeff Cehelsky, Yan Zheng, Mark Wingertzahn, Norma Alonzo Palma, Brian Meehan, Robert S Mittleman - Poster presentation EASL, 2020
58. Safety and efficacy of combination therapies including cilofexor/firsocostat in patients with bridging fibrosis and cirrhosis due to NASH: Rohit Loomba, Mazen Noureddin, Kris V. Kowdley, Anita Kohli, Aasim Sheikh, Guy Neff, Bal Raj Bhandari, Nadege Gunn, Stephen H. Caldwell, Zachary Goodman, Dora Ding, Catherine Jia, Ryan Huss, Chuhan Chung, G. Mani Subramanian, Robert P. Myers, Keyur Patel, Brian Borg, Reem Ghalib, Heidi Kabler, John Poulos, Ziad Younes, Magdy Elkhashab, Tarek Hassanein, Rajalakshmi Iyer, Peter J. Ruane, Mitchell L. Shiffman, Simone Strasser, Vincent Wai-Sun Wong, Naim Alkhouri - Presented at EASL, London, UK, April 15-19, 2020
59. Development of gut-selective pan-Janus kinase inhibitor TD-1473 for ulcerative colitis: A translational medicine program: William J Sandborn, Deanna D Nguyen, David T Beattie, Patrick Brassil, Whitney Krey, Jacky Woo, Eva Situ, Reuben Sana, Erik Sandvik, M Teresa Pulido-Rios, Raj Bhandari, Jonathan A Leighton, Ravi Ganeshappa, David L Boyle, Brihad Abhyankar, Melanie A Kleinschek, Richard A Graham, Julian Panes - Journal of Crohn's and Colitis, March 11, 2020
60. Cilofexor and Firsocostat in combination lead to greater reductions in serum bile acids which are associated with treatment response in patients with advanced fibrosis due to NASH: Raj Bhandari, et al - Poster presentation at the Liver Meeting Digital Experience 2020.
61. Combination treatment with Cilofexor and Firsocostat normalizes cell death marker cytokeratin 18 (CK18) in patients with advanced fibrosis due to NASH: Raj Bhandari, et al - Liver Meeting Digital Experience 2020.
62. Fibrosis regression and improvement in disease activity are associated with improvements in patient-reported outcomes in advanced fibrosis due to nonalcoholic steatohepatitis (NASH): Raj Bhandari, et al - Poster presentation at the Liver Meeting Digital Experience 2020.
63. Safety, Pharmacokinetic, Biomarker, Histologic, and Rectal Bleeding Activity Following Treatment with the Gut-Targeted,PHD-Inhibitor and HIF-1α Stabilizer GB004 in a Phase 1b Trial in Mild-to-Moderate Ulcerative Colitis: William Sandborn, Brian Feagan, Silvio Danese, Alina Jucov, B.R. Bhandari, Kartik Raghupathi, Allan Olson, Courtney Van Biene, Gregory J. Opiteck, Julia Ford, Richard Aranda, Barrett G. Levesque - Poster presentation at United European Gastroenterology Week (UEGW) 2020
64. A Safety and Efficacy Comparison of a New Sulfate-Based Tablet Bowel Preparation Versus a PEG and Ascorbate Comparator in Adult Subjects Undergoing Colonoscopy: Jack A. Di Palma, MD, MACG, Raj Bhandari, MD, Mark vB. Cleveland, PhD, Daniel S. Mishkin, MD, Jessica Tesoriero, BS, Sue Hall, PhD and John McGowan, MPH - The American Journal of Gastroenterology, October 2020

65. A Phase 1b study of GB004, a gut-targeted HIF-1α stabilizer in mild-moderate UC. Preliminary evidence of biologic and clinical activity: William Sandborn, Brian G. Feagan, Silvio Danese, Alina Jucov, B.R. Bhandari, Kartik Raghupathi, Allan Olson, Courtney Van Biene, Gregory J. Opiteck, Julia Ford, Richard Aranda, Barrett G. Levesque - Abstract presentation at DDW 2021
66. Fenofibrate is safe and mitigates increases in serum triglycerides in NASH patients treated with the combination of the ACC inhibitor firsocostat and the FXR agonist cilofexor: Eric J. Lawitz, Bal R. Bhandari, Peter J. Ruane, Anita Kohli, Eliza Harting, Catherine Jia, Jay Chuang, Ryan S. Huss, 5 Chuhan Chung, Robert P. Myers, Rohit Loomba - Abstract presentation EASL 2021
67. Combination Therapies Including Cilofexor and Firsocostat for Bridging Fibrosis and Cirrhosis Attributable to NASH: Rohit Loomba Mazen Noureddin Kris V. Kowdley, Anita Kohli, Aasim Sheikh, Guy Neff, Bal Raj Bhandari, Nadege Gunn, Stephen H. Caldwell, Zachary Goodman, Ilan Wapinski, Murray Resnick, Andrew H. Beck, Dora Ding, Catherine Jia, Jen-Chieh Chuang, Ryan S. Huss, Chuhan Chung, G. Mani Subramanian, Robert P. Myers, Keyur Patel, Brian B. Borg, Reem Ghalib, Heidi Kabler, John Poulos, Ziad Younes, Magdy Elkhashab, Tarek Hassanein, Rajalakshmi Iyer, Peter Ruane, Mitchell L. Shiffman, Simone Strasser, Vincent Wai-Sun Wong, Naim Alkhouri – Article published in Hepatology 2021
68. Combination Treatment With Cilofexor and Firsocostat Leads to Improvements in the FibroScan-AST Score in Patients With Advanced Fibrosis Due to NASH: Rohit Loomba, Mazen Noureddin, Kris V. Kowdley, Anita Kohli, Aasim Sheikh, Guy Neff, Bal Raj Bhandari, Nadege Gunn, Stephen H. Caldwell, Zachary Goodman, Ling Han, Catherine Jia, Jen-Chieh Chuang, Ryan S. Huss, Chuhan Chung, Robert P. Myers, Keyur Patel, Brian B. Borg, Reem Ghalib, John Poulos, Ziad Younes, Magdy Elkhashab, Tarek Hassanein, Rajalakshmi Iyer, Peter Ruane, Mitchell L. Shiffman, Simone Strasser, Vincent Wai-Sun Wong, Naim Alkhouri - Poster presentation EASL 2021
69. PTG-100, an Oral α4β7 Antagonist Peptide: Preclinical Development and Phase 1 and 2a Studies in Ulcerative Colitis: William J. Sandborn, Larry C. Mattheakis, Nishit B. Modi, David Pugatch, Brian Bressler, Scott Lee, Raj Bhandari, Bittoo Kanwar, Richard Shames, Geert D'Haens, Stefan Schreiber - AGA Journal Publication, August 29, 2021
70. GB004, an oral HIF-1α stabiliser, for treatment of ulcerative colitis: Silvio Danese, Barrett G. Levesque, Brian Feagan, Alina Jucov, B.R. Bhandari, Rish Pai, Kristen Taylor Meadows, Brian Kirby, Jean-Marie Bruey, Kartik Raghupathi, Allan Olson, Robin Osterhout, Courtney Van Biene, Julia Ford, Richard Aranda, William J. Sandborn – Phase 1b Study
71. BLI4900, A new flavor enhanced bowel preparation provides a superior patient experience compared to oral sulfate solution: Bal Raj Bhandari, Michael J. Goldstein, Joh D. McGowan, Mark D. Cleveland, Jack A. DePalma - Digestive Disease Week, 2022
72. BLI4900, A safety and efficacy comparison of new bowel preparation to oral sulfate solution: Bal Raj Bhandari, Michael J. Goldstein, Joh D. McGowan, Mark D. Cleveland, Jack A. DePalma - Digestive Disease Week, 2022
73. Favorable safety profile of TERN-201, a highly selective inhibitor of vascular adhesion protein-1, in the nonalcoholic steatohepatitis phase 1b AVIATION study: Mazen Noureddin, Eric Lawitz, Naim Alkhouri, Robert A. Jenders, Douglas Denham, Raj Bhandari, Christopher Jones, Cara Nelson, Tonya Marmon, Swapna Shenvi, Hiba Graha, Daria B. Crittenden, Erin Quirk, Diana Chung - Poster Presentation
74. The MRI and AST Score Is Correlated With Noninvasive and Histologic Markers of Fibrosis in Patients With Advanced Fibrosis Due to NASH: Mazen Noureddin, Kris V. Kowdley, Anita Kohli, Aasim Sheikh, Guy Neff, Bal Raj Bhandari, Nadege Gunn, Stephen H. Caldwell, Zachary Goodman, Dora Ding, Lily Ma, Jen-Chieh Chuang, Ryan S. Huss, Chuhan Chung, Robert P. Myers, Keyur Patel, Brian B. Borg, Reem Ghalib, John Poulos, Ziad Younes, Magdy Elkhashab, Tarek Hassanein, Rajalakshmi Iyer, Peter Ruane, Mitchell L. Shiffman, Simone Strasser, Vincent Wai-Sun Wong, Rohit Loomba, Naim Alkhouri - EASL 2022 Poster Presentation
75. Favorable Safety Profile Of TERN-201, A Highly Selective Inhibitor Of Vascular Adhesion Protein-1, In The Nonalcoholic Steatohepatitis Phase 1b Aviation Study: M. Noureddin, E. Lawitz, N. Alkhouri, R.A. Jenders, D. Denham, R. Bhandari, C. Jones, C. Nelson, T. Marmon, S. Shenvi, H. Graham, D.B. Crittenden, E. Quirk, D. Chung - Poster Presentation for ILC 2022
76. Fenofibrate Mitigates Hypertriglyceridemia in Nonalcoholic Steatohepatitis Patients Treated With Cilofexor/Firsocostat: Eric J. Lawitz, Bal Raj Bhandari, Peter J. Ruane, Anita Kohli, Eliza Harting, Robert P. Myers, Rohit Loomba - Clinical Gastroenterology and Hepatology: Volume 21/ Issue 1. January 2023

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 Rebetron Compliance Assessment Program Survey (the "ReCAP Survey") being conducted by Ingenix harmaceutical 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 HCI in patients suffering from functional dyspepsia.
4. A multicenter, open-label study to evaluate the long-term safety and efficacy of ITOPRIDE HCI 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 pefingterferon 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-bind 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. HalfLytely® 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-blinde, 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 **Dete**ction of Colorectal Advanced Adenomatous **P**olyps and **C**ancer: 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 t 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 Evaluated 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 Ia 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

2017 Clinical Trials:

1. A Phase 2, Multicenter, Randomized, Parellel-arm, Placebo-Controlled Study of LY3074828 in Subjects with moderate to severely

active Crohn's Disease.
2. A Long-Term extension study to evaluate the safety of Filigotinib in subject with Ulcerative Colitis.
3. A Long-term extension study to evaluate the safety of Filgotinib in subjects with Crohn's Disease.
4. A Polite evaluation of BLI4700 bowel preparation administered with adult subjects.
5. A Phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Selonsertib in subjects with nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis.
6. A Phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Selonsertib in subjects with compensated cirrhosis due to Nonalcoholic Steatohepatitis (NASH).
7. A Phase 2, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy and Safety of Filgotinib in the Treatment of Perianal Fistulizing Crohn's Disease.
8. A follow-up study to assess resistance and durability of response to AbbVie Direct-Acting Agent (DAA) Therapy (ABT-493 and/or ABT-530.
9. Protocol for Qualitative Concept Elicitation 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) and Cognitive Interviews to Evaluate Newly Developed Measures for Adult patients Diagnosed with Exocrine pancreatic Insufficiency (EPI).
10. A 2-part, randomized, double blind and open label, placebo and active-comparator controlled trial to evaluate the safety, pharmacokinetics, and pharmacodynamics for TAK-906 in subjects with diabetes mellitus and gastroparesis or with idiopathic gastroparesis.
11. A 12 Week, randomized, double blind, placebo-controlled, phase 3 study to evaluate the safety and efficacy of Relamorelin in participants with diabetic gastroparesis.
12. A Phase 2b randomized, double-blind, placebo-controlled, parallel adaptive 2-stage, multi-center study to evaluate the safety and efficacy of Oral PTG-100 Induction in subjects with moderate to severe active Ulcerative Colitis.
13. A Phase 2b randomized, double-blind, placebo-controlled, parallel adaptive 2-stage, multi-center study to evaluate the safety and efficacy of Oral PTG-100 Induction in subjects with moderate to severe active Ulcerative Colitis.
14. A randomized, Investigator-and Colonoscopist-blinded, phase 2 study of efficacy and Safety of ECP (polyethylene glycol 3350 [PEG3350]) colon prep kit compared with MoviPrep split dose for colonoscopy preparation.
15. A randomized, double-blind, placebo-controlled Phase 2 study to evaluate the Testicular safety of Filgotinib in adult males with moderately to severely active ulcerative colitis.
16. A multicenter, randomized, double-blind, placebo-controlled trial of Emricasan, an oral Caspase Inhibitor, in subjects with Decompensated Non-Alcoholic Steatohepatitis (NASH) Cirrhosis.
17. A Phase 3, double-blind, randomized, placebo-controlled, multicenter study to evaluate the efficacy and safety of obeticholic acid in subjects with compensated cirrhosis due to nonalcoholic stentohepatitis.
18. Investigation of efficacy and safety of three dose levels of subcutaneous semaglutide once daily versus placebo in subjects with non-alcoholic steatohepatitis. A 72-week randomized, double-blind, placebo-controlled, six-armed parallel group, multi-centre, multinational trial

2018 Clinical Trials:

1. A 46 Week, double-blind, placebo-controlled, phase 3 study with a 6-week randomized-withdrawal period to evaluate the safety and efficacy of Relamorelin in patients with diabetic gastroparesis.
2. A safety and efficacy comparison of BLI4700 bowel preparation versus and FDS-approved comparator in adult subjects prior to colonoscopy.
3. Phase 1: An open-label study evaluating the pharmacokinetics and pharmacodynamics of once daily or twice daily dosing of PTG-100 in subjects with Ulcerative Colitis.
4. Comparison of immune and inflammatory biomarkers collected by endoscopic aspirate versus recoverable sampling system (RSS) in subjects with Celiac Disease.
5. A Phase 2, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of selonsertib, GS-0976, GS-9674 and combinations in subjects with ridging (F3) Fibrosis or compensated cirrhosis (F4) due to nonalcoholic steatohepatitis (NASH)
6. A Phase 3, Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Efficacy and Safety of Mirikizumab in Patients with Moderately to Severely Active Ulcerative Colitis.
7. A Phase 3, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Induction Study of Mirikizumab in Conventional-Failed and Biologic-Failed Patients with Moderately to Severely Active Ulcerative Colitis.
8. A Phase 3b, Randomized, Double-blind, Placebo-controlled, Parallel-group Trial of linaclotide 290 ug Administered Orally for 12 weeks followed by a 4-week randomized withdrawal period in patients with Irritable Bowel Syndrome with Constipation.
9. Specimen Collection Study for Cancer.
10. ECO-RESET: A Phase 2B, Randomized, Double-blind, Placebo-Controlled, Multiple Dose, Multicenter Study to Assess Efficacy and Safety of SER-287 in Adults with Active Mild-to-Moderate Ulcerative Colitis.
11. A Phase 2b/3 multi-Center, randomized, double-blind, multi-dose, placebo-controlled, parallel-group set of studies to evaluate the efficacy and safety of Induction and Maintenance Therapy with TD-1473 in subjects with Moderately-to-Severely Active Ulcerative Colitis.
12. A 3-Year, multi-center, Long Term Safety (LTS) Study to evaluate the safety and tolerability of TD-1473 in Subjects with Ulcerative Colitis.
13. Open Label Extension Study of Relamorelin for the Treatment of Diabetic Gastroparesis.
14. AURORA: A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of

Cenicriviroc for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis

2019 Clinical Trials:

1. A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Arm, Placebo-Controlled Maintenance Study of Mirikizumab in Patients with Moderately to Severely Active Ulcerative Colitis.
2. An Evaluation of Multi-target Stool DNA (mt-sDNA) Test, Cologuard, for CRC Screening in Individuals aged 45-49 and at Average Risk for Development of Colorectal Cancer: Act Now.
3. Blood Collection Sub-Study of Exact Sciences Protocol 2018-10: An Evaluation of Multi-target Stool DNA (mt-sDNA) Test, Cologuard, for
   CRC Screening in Individuals aged 45-49 and at Average Risk for Development of Colorectal Cancer: Act Now.
4. Clinical Trial Protocol PR-100-101: A Study to Determine the Frequency of TNFSF15-Associated Variants in Subjects with Diagnosis of
   Crohn's Disease.
5. Blood and Stool Sample Collection in Subjects with a Diagnosis of Colorectal Cancer or Colorectal Lesion: Act Fast.
6. A randomized, double-blind, controlled clinical food study to evaluate the effect of KB174 compared to an easily digestible polysaccharide on
   function and structure of the gut microbiome in subjects with well-compensated cirrhosis.
7. Blood and Stool Sample Collection in Subjects participating in colorectal cancer screening.
8. A phase 1b, randomized, double-blind, placebo-controlled, multi-center study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of GB004.
9. The Laboratory for Advanced Medicine IvyGene TM Dx Liver Cancer Test Prospective Clinical Trial.
10. A 12-week, Single-blind, placebo-controlled randomized study to evaluate the safety, tolerability, and physiological regulation of an amino acid food product, AA1665, in subjects with mild and moderate hepatic insufficiency.
11. A Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Safety, Efficacy, Pharmacokinetics, and dose response of Oral
    CIN-102 in Adults with Diabetic Gastroparesis.
12. A Randomized, Placebo-Controlled, Double-Blind, Multicenter study to evaluate efficacy and safety or Oral BT-11 in Mild to Moderate Ulcerative Colitis.
13. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled, Treat-through study to evaluate the efficacy and
    safety of Mirikizumab in patients with moderately to severely active Crohn’s disease.
14. Specimen Collection Study for Colorectal Cancer and Advanced Adenomas
15. Clinical validation of an optimized Multi-Target Stool DNA (mt-sDNA 2.0) test, for Colorectal Cancer Screening "Blue-C".
16. Evaluation of the ctDNA LUNAR Test in an Average patient Screening Episode (ECLIPSE)
17. Blood Collection Sub-Study of Exact Sciences Protocol 2019-01: “Clinical validation of an optimized Multi-Target Stool DNA (mt-sDNA 2.0) test, for Colorectal Cancer Screening Blue-C”.

2020 Clinical Trials:

1. A Phase 3, multicenter, open-label, long-term extension study to evaluate the long-term efficacy and safety of Mirikizumab in Patients with Crohn's Disease
2. A Phase 2, randomized, double-blind, placebo-controlled, multi-center study to evaluate GB004 in adult subjects with mild-to-moderate active ulcerative colitis
3. A Safety and Efficacy Comparison of BLI4900 Bowel Preparation versus and FDS-approved Comparator in Adult Subjects prior to Colonoscopy
4. A Randomized, Double-Blind, Parallel-Group, multicenter study to assess efficacy, safety, and tolerability of oral tropifexor (LJN452) & licogliflozin (LIK066) combination therapy and each monotherapy, compared with placebo for treatment of adult participants with nonalcoholic steatohepatitis (NASH) and liver fibrosis (ELIVATE).
5. A Safety and Efficacy Comparison of BLI490 Bowel Preparation versus an FDA-approved comparator in adult subjects prior to colonoscopy.
6. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 1a Clinical Trial to evaluate the safety, tolerability, efficacy, and pharmacokinetics of orally administered TERN-101 in adult patients with Presumed Non-Cirrhotic Nonalcoholic Steatohepatitis.
7. Open-Label Rollover Study of Cenicriviroc for the Treatment of Liver Fibrosis in adult subjects with Nonalcoholic Steatohepatitis (NASH).

2021 Clinical Trials:

1. A Multi-Center, Randomized, Double-Blind, Dose-ranging, Placebo-controlled, proof of concept, adaptive, Phase 1b clinical study to evaluate the safety, pharmacokinetics, Pharmacodynamics, and efficacy of orally administered TERN-201 in patients with presumed Non-Cirrhotic Non-Alcoholic Steatohepatitis (NASH).
2. Prevention of Colorectal Cancer through Multiomics Blood Testing.

3. Prospective Blood Sample Collection study for product development in detecting Colorectal Cancer & Advanced Adenoma.
4. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Phase 1 b Study to evaluate the safety, tolerability, and pharmacokinetics of BMS-963272 in participants with Nonalcoholic Fatty Liver Disease.
5. Clinical performance evaluation of the LIVERFAST Tests to determine fibrosis staging, inflammatory activity and steatosis grading compared with liver biopsy in patients with metabolic factors and presumed Non-Alcoholic Fatty Liver Disease (NAFLD).
6. A Randomized, Double-Blind, Placebo-Controlled, dose-ranging study to evaluate the safety, tolerability, and efficacy of AZA1125 in subjects with Non-Cirrhotic, Non-Alcoholic Steatohepatitis and Fibrosis (EMMPACT)
7. Performance of a Multi-Target Hepatocellular Carcinoma (HCC) Test in subject with increased risk.
8. Multi-Center, Double-Blind, Parallel-Group, Randomized, 48 weeks, dose-ranging, placebo-controlled phase II trial to evaluate efficacy, safety and tolerability of multiple subcutaneous (s.c.) doses of BI 456906 in patients with non-alcoholic steatohepatitis (NASH) and fibrosis.
9. A Phase 2b, Randomized, Double-Blind, Placebo-Controlled study evaluating the safety and efficacy of Efruxifermin in subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis (NASH).
10. A Randomized, Double-Blind, Placebo-Controlled, multicenter study to assess the efficacy and safety of Rifaximin Soluble Solid Dispersion (SSD) tablets for the delay of Encephalopathy Decompensation of Cirrhosis (RED-C).

RESEARCH TRAINING:

Available Upon Request

REFERENCES:

Available Upon Request