



2018

ANNUAL REPORT

Baylor
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GASTROENTEROLOGY & HEPATOLOGY

Baylor College of Medicine
Houston, Texas

Gastroenterology & Hepatology

ANNUAL REPORT 2018

The Section of Gastroenterology and Hepatology had a very successful year. Section members had over \$10 million in research funding in 2018. With over 100 papers in scientific journals and over 70 presentations at the national meetings this year, the Section is a leader in research in gastrointestinal and liver diseases. The Section serves as the clinical home for the NIH funded Digestive Disease Center, one of 17 federally funded centers focusing on research in GI diseases.

Our top-notch faculty received many accolades at the local and national levels. We represent BCM in all major professional societies; our faculty holds several leadership positions within the American Gastroenterological Association, American Association for the Study of Liver Diseases, American Society of Gastroenterological Association, and the Crohn's and Colitis Foundation. The Section also serves as the home for the *Clinical Gastroenterology and Hepatology*, one of the major clinical journals in the field.

We continue to provide high quality, compassionate healthcare at Baylor St. Lukes Medical Center (BSLMC), Ben Taub General Hospital, and Michael E. DeBakey Veterans Affairs Medical Center. BSLMC nationally ranked for gastroenterology service this year. In 2018, we introduced several innovations in our practices, including cutting edge advanced endoscopic procedures, multidisciplinary treatment of complex GI disorders, and population based management programs. Our faculty continues to play an important role in advancing our understanding of digestive and liver diseases and training future clinicians and researchers.

This annual report outlines some of the achievements and recognition received during 2018.



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JULY 2017 – JUNE 2018 PUBLICATIONS

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105. Nguyen T, **Khan A**, Liu Y, **El-Serag HB, Thrift AP**. The Association Between Statin Use After Diagnosis and Mortality Risk in Patients With Esophageal Cancer: A Retrospective Cohort Study of United States Veterans. *Am J Gastroenterol*. 2018 Jun 27.
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110. **Graham DY**, Tansel A. Interchangeable use of proton pump inhibitors based on relative potency. *Clinical Gastroenterology and Hepatology*. 2018 Jun 1;16(6):800-8.
111. Yeomans ND, **Graham DY**. Editorial: gastrointestinal safety of COX-2 selective and nonselective NSAIDs-the impact of the PRECISION trial. Authors' reply. *Aliment Pharmacol Ther*. 2018 Jun;47(11):1546-1547.
112. Millien VO, Sharma A, Jain S, **Sealock RJ**. Rare Collision Tumor of the Biliary Tract. *ACG Case Rep J*. 2018 Jun 20;5:e46.
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AWARDS & HONORS

Agarwal, Arevalo Santana, Chan, Hou, Othman, Patel: Top Gastroenterologist in the City of Houston

Agarwal: Associate Program Director for Baylor St. Luke's Medical Center

Anandasabapathy: Texas Executive Women's 2017 Class of Women on the Move

Anandasabapathy: Houston Top Doctors and Texas Top Doctors

Bradford: Clinical Supervisor between the Section of Gastroenterology and Hepatology and the Department of Psychiatry

Cole: Woman of Excellence at Baylor College of Medicine

Estes: Two Prestigious American Gastroenterological Association Recognitions: William Beaumont Prize in Gastroenterology and Distinguished Mentor Award

Husain: Facilitator for the Critical Thinking and Problem Solving Course within the first year curriculum for medical students

Othman: Star Faculty Award for Excellence in Patient Care

Qureshi: Number one-selling video in the Endoscopic Learning Library of the American Society for Gastrointestinal Endoscopy- "Evaluation of the ano-rectum: physical and endoscopic examination."

Shukla: Ben Taub Internal Medicine Core Clerkship Site Director

Vierling: Elected to Fellowship in the American Gastroenterological Association

Vierling: Dr. Charles S. Lieber Lecture at DDW 2018. "Mechanisms of Autoimmune-Associated Liver Injury – How Are PBC, PSC and Autoimmune Hepatitis Alike and Different?"

PROFESSIONAL ORGANIZATIONS/ASSOCIATION OFFICES HELD

Anandasabapathy: Chair Elect, *AGA Women Committee*

El-Serag: Vice President, *American Gastroenterological Association (AGA)*

Gould Suarez: Member, *AGA Women Committee*

Gould Suarez: Member, *ACG Patient Care Committee*

Hernaes: Member, *AASLD Practice Guideline Committee*

Hou: National VA Committee Member, *IBD Technical Advisory Group*

Hou: Chair of Colon Subcommittee, *AGA GI Training Examination Committee*

Hou: Chapter Medical Advisory Committee Co-Chair, *Crohn's and Colitis Foundation of America (CCFA) South Texas Chapters*

Ketwaroo: Chair, *AGA training and Early Career Committee*

Kanwal: Chair, *AASLD Practice Metrics Committee*

Kanwal: Editor-in-Chief, *Clinical Gastroenterology and Hepatology (CGH)*

Kanwal: Member, *National VA Advanced Liver Disease Technical Advisory Board*

Natarajan: Member, *American Gastroenterological Association's (AGA) Government Affairs Committee*

Sealock: Member, *ASGE Annual Scientific Program Committee*

Shah: Member, *Crohn's & Colitis Foundation of America (CCFA) Patient Education Committee*

Shukla: Member, *Crohn's & Colitis Foundation of America (CCFA) Professional Membership Committee*

Vierling: Member Writing Group, *AASLD Practice Guidelines*

PRESS

- **Kanwal:** *Gastroenterology*. Direct-acting antivirals reduce liver cancer risk. <http://www.medicaleconomics.com/medical-economics/news/direct-acting-antivirals-reduce-liver-cancer-risk> (Jun 2017)
- **Qureshi:** World Congress of Gastroenterology at ACG 2017 meeting. “Office Management of Acute Thrombosed Hemorrhoids in a Pregnant Patient.” (Jul 2017)
- **Anandasabapathy:** *The Hindu*. “Emergency smart pods for India a possibility.” <https://www.thehindu.com/news/cities/chennai/emergency-smart-pods-for-india-a-possibility/> (Oct 2017)
- **Hou:** *GI & Hepatology News*. “One-Day Behavioral Therapy for IBD Patients.” <https://www.mdedge.com/gihepnews/clinical-edge/summary/ibd-intestinal-disorders/one-day-behavioral-therapy-ibd-patients> (Oct 2017)
- **El-Serag:** KVEO’s *RGVproud*. “October Is Liver Cancer Awareness Month.” <https://www.kveo.com/news/local-news/october-is-liver-cancer-awareness-month/> (Nov 2017)
- **Shukla:** BCM’s Momentum Series. “Healthy Habits: Planning meals, setting exercise goals key for Dr. Richa Shukla.” <https://blogs.bcm.edu/2017/11/13/healthy-habits-dr-richa-shukla/> (Nov 2017)
- **Jiao:** American Institute for Cancer’s *Cancer Research Update*. “Low-Fat Diet Effective in Reducing Pancreatic Cancer Risk Among Overweight Women.” http://www.aicr.org/cancer-research-update/2017/11_29/cru-low-fat-diet-pancreatic-cancer.html (Dec 2017)
- **Kanwal:** *MD Magazine*. “Researchers May Have Confirmed Whether HCV Treatment Poses Liver Cancer Risk .” <https://www.mdmag.com/medical-news/researchers-may-have-confirmed-whether-hcv-treatment-poses-liver-cancer-risk> (Dec 2017)
- **Mittal:** *Healio*. “10 reports from 2017 on liver cancer incidence rates, major risk factors.” <https://www.healio.com/hepatology/oncology/news/online> (Jan 2018)
- **Estes and Shroyer:** BCM’s *Cell Reports*. Researchers gain insight into how the intestine repairs itself. <https://www.bcm.edu/news/molecular-virology-and-microbiology/how-the-intestine-repairs-itself> (Jan 2018)
- **Hussain:** National VA Transplant Conference. (Feb 2018)
- **Chan:** *Clinical Gastroenterology and Hepatology*. “Physician Burnout: The Hidden Health Care Crisis.” [https://www.cghjournal.org/article/S1542-3565\(17\)30790-5/fulltext](https://www.cghjournal.org/article/S1542-3565(17)30790-5/fulltext) (Mar 2018)
- **Graham:** first annual Stefan S. Nicolau Lecture-- Carol Davila University of Medicine in Bucharest, Romania. “*Helicobacter pylori*: a bacterial cause of gastric cancer.” (Mar 2018)
- **Gould Suarez:** Colon Cancer Coalition. “Faces of Blue: Milena Gould Suarez, M.D.” <https://coloncancercoalition.org/2018/03/09/faces-of-blue-milena-gould-suarez-m-d/> (Mar 2018)

- **Hernaes:** VA Liver Cancer Team Educational Seminar Series. “Curative and Palliative Therapies for HCC.” (Apr 2018)
- **Estes:** Baylor’s From The Labs. “Type of injury matters, when healing the small intestine.” <https://blogs.bcm.edu/2018/03/20/type-of-injury-matters-when-healing-the-small-intestine/> (Mar 2018)
- **Qureshi:** BCM DocTalk. “Colorectal Cancer Awareness Month.” (Mar 2018)
- **Graham:** Fifth Annual Ertan Lectureship at UT McGovern Medical School. “Helicobacter Pylori as a Bacterial Cause of Gastric Cancer.” (Apr 2018)
- **Hou:** *Time*. “You Asked: What Is Inflammation, And Why Should I Care About It?” <http://time.com/5235368/what-is-inflammation/> (Apr 2018)
- **Graham:** Gastrointestinal Endoscopy and Video GIE. “Meet the Master.” https://youtu.be/_VoRLbLt6PU (May 2018)
- **Bradford:** *The Wall Street Journal*. “A Surprise Medical Solution: Hypnosis.” <https://www.wsj.com/articles/a-surprise-medical-solution-hypnosis-1525698883> (May 2018)
- **Gould Suarez:** *CBS Houston*. “Colorectal Cancer Awareness.” <https://houston.cbslocal.com/2017/05/07/colorectal-cancer-awareness-5-7-17/> (May 2018)

GRANTS

Anandasabapathy

- MPI: High Resolution Microendoscopy for the Management of Esophageal Neoplasia. National Cancer Institute (NCI); R01-CA181275. 9/1/2017-8/31/2018
- A Low-Cost Tethered Capsule Endoscope for Esophageal Cancer Screening. National Institutes of Health (NIH); R21-EB023431. 1/1/2017-12/31/2018
- NCE 3 – EZPOD: Enhanced Zero-Impact, Emergency Smart Pod. Paul G. Allen Family Foundation; 11965. 5/2/2018-10/31/2018
- High Resolution Microendoscopy for the Management of Esophageal Neoplasia. National Institutes of Health (NIH)/ National Cancer Institute (NCI); RO1 CA181275. 7/1/2014-8/31/2019
- A Low-Cost Tethered Capsule Endoscope for Esophageal Cancer Screening. National Institutes of Health (NIH)/ National Cancer Institute (NCI); R21CA212691. 9/1/2016-8/31/2018
- Automated, Augmented Reality High Resolution Microendoscopy for the Management of Esophageal Neoplasia. National Institutes of Health (NIH)/ National Cancer Institute (NCI); R01CA181275. 9/1/2016-8/31/2018
- ezPod: Enhanced Zero-Impact, Emergency Smart Pod. The Paul G. Allen Family Foundation; Science & Technology – Ebola Program. 9/01/2015-10/31/2018
- Optical Systems for In Vivo Molecular Cancer Imaging. National Institutes of Health (NIH)/ National Cancer Institute (NCI); R01 CA103830. 9/3/2013-8/31/2018

Balakrishnan

- GS1944: 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). Gilead Sciences, Inc. 2019
- INT 747-304: 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 Steatohepatitis. Intercept Pharmaceuticals. 2019

El-Serag

- The Texas Hepatocellular Carcinoma Consortium (THCCC). Cancer Prevention & Research Institute of Texas (CPRIT). RP150587. 6/1/2018-5/31/2019
- Effect of Aspirin on Biomarkers of Barrett's Esophagus after Successful Eradication of Barrett's Esophagus with Radiofrequency Ablation. National Cancer Institute (NCI); HHSN-26120120003414929. 6/15/2016-6/14/2019
- Center of Gastrointestinal Infection and Injury. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); P30-DK056338. 3/1/2018-2/28/2019
- Research Training in Gastroenterology. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); T32-DK083266. 2/1/2018-1/31/2019
- Extrahepatic manifestations of hepatitis C. Merck, Sharp & Dhome, Corp. 09/01/2016-12/31/2018

Finnell

- Folate Pathway Neural Tube Defects. March of Dimes; 6-FY16-169. 6/1/2018-5/31/2019
- Intervention Strategies for Non-Folate Responsive Neural Tube Defects. National Institute of Child Health and Human Development (NICHD); R01-HD083809. 2/1/2019-8/1/31/2019

- Folic Acid, Parental Mutation Rates and the Risk for Neural Tube Defects. National Institute of Child Health and Human Development (NICHD); R01-HD081216. 7/1/2018-6/30/2019

Hou

- Patient-Centered Comparative Effectiveness of Colorectal Cancer Surveillance in IBD. AHCPR-Agency for Healthcare Research and Quality (AHRQ); K08-HS024122. 8/1/2018-7/31/2019
- Advanced IBD Fellowship; Balor College of Medicine. Pfizer, Inc; Pfizer Fellowship. 7/1/2018-6/30/2019
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of ABT-494 For Induction and Maintenance Therapy in subjects with Moderately to Severely Active Ulcerative Colitis. Abbvie Inc. 2019
- A Multi Center Open-Label Extension Study to Assess the Safety and Tolerability of LYC-30937-EC in Subjects with Active Ulcerative Colitis. Lycera Corp. 2019

Kanwal

- A Personalized Surveillance program for Hepatocellular Carcinoma. American Cancer Society; RSG-17-022-01-CPPB. 7/1/2018-6/30/2019
- Cirrhosis Quality Collaborative. American Association for the Study of Liver Disease. 9/1/2018-8/31/2021
- Patient Centered Care for Individuals with Advanced Liver Disease. HSR&D IIR 16-075; I01 HX-002204-01. 4/01/18-3/31/21
- Effectiveness of Zepatier™ (elbasvir (EBR)/grazoprevir (GZR)) co-administered with Ribavirin (RBV) treatment for 16 weeks duration in chronic hepatitis C virus (HCV) genotype 1a (GT1a)-infected patients with selected baseline NS5A resistance associated substitutions: A retrospective observational analysis of the US Veterans Health Administration (VHA) National Data. Merck, Sharp & Dhome, Corp. 01/01/2018-08/31/2018
- Real-world effectiveness and impact of elbasvir/grazoprevir on outcomes among HCV-infected patients. Merck, Sharp & Dhome, Corp. 09/01/2016-12/31/2018

Kaur

- A Phase 2B, Randomized, Double-Blind, Placebo-controlled, Parallel-Group, Multicenter Protocol to Evaluate the Safety and Efficacy of JNJ-64304500 in Subjects with Moderately to Severely Active Crohn's Disease. Janssen Research & Development, LLC. 2019
- A Phase 4 Open-Label Study to Evaluate Vendolizumab IV Dose Optimization on Treatment Outcomes in Nonresponses with Moderately to Severely Active Ulcerative Colitis (Enterpret). Takeda Global Research & Development Center, Inc. 2019

Lo

- Transcription Factors in Intestinal Differentiation and Cancer. National Cancer Institute (NCI); F99-CA212443. 9/21/2016-8/31/2018

Mittal

- Prevent HCC – By Screening, Vaccination and Treatment of Viral Hepatitis. Cancer Prevention & Research Institute of Texas (CPRIT); PP160089. 8/31/2017-8/30/2018

Opekun

- QA Purity, Activity and Ancillary Testing of Commercially Available Gras-Listed Enzymes (Does Not Include Human or Animal Studies). Association in Transformational Oncology Management (ATOM); Testing Agreement. 3/1/2016-3/11/2019

Othman

- Population Screening for Familial Chylomicronemia Syndrome (“FCS”). Akcea Therapeutics, Inc. 3/13/2018-3/12/2019
- Phase IIA Trial Evaluating the Safety of Intratumoral Injection of Nanopac in Subjects with Locally Advanced Pancreatic Adenocarcinoma. US Biotest, Inc. 2019.
- A Trial Evaluating Escalating Doses and the Safety of Intracystic Injection of Nanopac in Subjects with Mucinous Cystic Pancreatic Neoplasms. US Biotest, Inc. 2019.

Shroyer

- MPI-Investigation of Regional Identity in Human Intestinal Stem Cells—Subcontract. National Institutes of Health (NIH); U01-DK103117. 9/1/2017-8/31/2018
- Nutrigenomics of Intestinal Vitamin D Action. National Institutes of Health (NIH); R01-DK112365. 4/1/2018-3/31/2019

Thrift

- Prevent HCC – By Screening Vaccination and Treatment of Viral Hepatitis. Cancer Prevention & Research Institute of Texas (CPRIT); PP160089. 8/31/2017-8/30/2018

Vierling

- A Phase 2b, Dose-Ranging, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating The Safety And Efficacy Of GS-6624, A Monoclonal Antibody Against Lysyl Oxidase Like 2 (LOXL2) In Subjects With Primary Sclerosing Cholangitis (PSC). Gilead GS-US-321-0102. 3/2013 –12/2016
- A Follow-Up Study To Assess Resistance And Durability Of Response To Abbvie Direct-Acting Antiviral Agent (DAA) Therapy In Subjects Who Participated In Phase 2 Or 3 Clinical Studies For The Treatment Of Chronic Hepatitis C Virus (HCV) Infection. Abbvie M13-102. 7/2013 –12/2016
- Clinical Utility Of Cepheid Xpert® HCV VL Assay. CEPHEID 167A US-IVD. 5/2015 – 12/2016
- A Phase II, Randomized, Open-Label Clinical Trial To Study The Efficacy And Safety Of The Combination Regimen Of MK-5172 And MK-3682 With Either MK-8742 Or MK-8408 In Subjects With Chronic HCV GT1 And GT2 Infection. Merck 3682-011. 8/2015 – 01/2017
- 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 Subjects with Chronic Genotype 3 HCV Infection and Cirrhosis. Gilead Polaris 3 GS-US-367-1173, 2/2016 – 11/2016
- A Phase 3, Double Blind, Placebo Controlled Trial And Long Term Safety Extension Of Obeticholic Acid In Patients With Primary Biliary Cirrhosis. Intercept 747-301. 1/2012 – OPEN
- A Long-Term Follow-Up Study Of Subjects Who Participated In A Clinical Trial In Which BMS-650032 And/Or BMS-790052 Was Administered For The Treatment Of Chronic Hepatitis C. BMS AI444-046. 2/2012 – OPEN
- A Long-Term Follow-Up Study To Evaluate The Durability Of Virologic Response And/Or Viral Resistance Patterns Of Subjects With Chronic Hepatitis C Who Have Been Previously Treated With MK-5172 In A Prior Clinical Trial. Merck MK5172-017. 1/2013 – OPEN
- A Phase 2b, Dose-Ranging, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating The Safety And Efficacy Of GS-6624, A Monoclonal Antibody Against Lysyl Oxidase-Like 2 (LOXL2), In Subjects With Advanced Liver Fibrosis But Not Cirrhosis Secondary To Non-Alcoholic Steatohepatitis (NASH). Gilead GS-US-321-0105. 3/2013 – 2/2017
- A Phase 2b, Dose-Ranging, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating The Safety And Efficacy Of GS-6624, A Monoclonal Antibody Against Lysyl Oxidase-Like 2 (LOXL2), In

Subjects With Compensated Cirrhosis Secondary To Non-Alcoholic Steatohepatitis (NASH). Gilead GS-US-321-0106. 3/2013 – 2/2017

- Multicenter, Randomized Phase 2B Study To Evaluate The Efficacy, Safety And Tolerability Of OCR-002 (Ornithine Phenylacetate) In Hospitalized Patients With Cirrhosis And Associated Hyperammonemia With An Episode Of Hepatic Encephalopathy (STOP-HE). Ocera Therapeutics OCR002-HE209. 10/2013 – 2/2017
- A Randomized, Global, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Once-daily Oral Avatrombopag for the Treatment of Adults with Thrombocytopenia Associated with Liver Disease Prior to an Elective Procedure. Eisai E5501-G000-310. 4/2014 – 3/2017
- An Open-Label Study to Evaluate the Safety and Efficacy of Ombitasvir/AB450/Ritonavir and Dasabuvir with or without Ribavirin (RBV) in Adults with Genotype 1 Chronic Hepatitis C Virus (HCV) Infection, with Severe Renal Impairment or End-Stage Renal Disease (RUBY-I). AbbVie M14-226. 9/2014 – 1/2017
- A Phase 3b, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Effect of Obeticholic Acid on Clinical Outcomes in Subjects with Primary Biliary Cirrhosis. Intercept 747-302. 12/2014 – OPEN
- A Phase II, Randomized, Double-blind, Placebo-controlled Study of IMM-124E for Patients with Non-alcoholic Steatohepatitis. Immuron IMM-124E-2001. 12/2014 – 6/2017
- A Randomized, Open-Label, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Co-Administration of ABT-493 and ABT-530 With and Without RBV in Subjects With Chronic Hepatitis C Virus (HCV) Genotype 2 or Genotype 3 Infection (SURVEYOR-II). AbbVie M14-868. 1/2015 – 3/2017
- Clinical Study Of The Breathid® System To Train The Algorithm For The ¹³C-Octanoate Breath Test With Or Without The ¹³C-Methacetin Breath Test (OBT And MBT Respectively) For Correlation With Histological Findings Of Non-Alcoholic Fatty Liver Disease (NAFLD). Exalenz NASH-EX-1114. 5/2015 – 8/2017
- A Phase II, Randomized, Open-Label Clinical Trial To Study The Efficacy And Safety Of The Combination Regimen Of MK-5172 And MK-3682 With Either MK-8742 Or MK-8408 In Subjects With Chronic HCV GT3 Infection. Merck 3682-012. 7/2015 – 1/2017
- A Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group, Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of GR-MD-02 for the Treatment of Liver Fibrosis and Resultant Portal Hypertension in Patients with NASH Cirrhosis. The NASH-CX Trial. GALECTIN GT-026. 9/2015 – OPEN
- A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multiple Dose Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamic Effects of BMS-986036 in Adults with Non-alcoholic Steatohepatitis. BMS MB130045. 9/2015 – 1/2018
- A Randomized, Open-Label, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Co-Administration of ABT-493 and ABT-530 With and Without RBV in Subjects With Chronic Hepatitis C Virus (HCV) Genotype 2 or Genotype 3 Infection (SURVEYOR-II). AbbVie M14-868. 1-2015 – 3/2017
- Clinical Study Of The Breathid® System To Train The Algorithm For The ¹³C-Octanoate Breath Test With Or Without The ¹³C-Methacetin Breath Test (OBT And MBT Respectively) For Correlation With Histological Findings Of Non-Alcoholic Fatty Liver Disease (NAFLD). Exalenz NASH-EX-1114. 5/2015 – 8/2017

- A Phase II, Randomized, Open-Label Clinical Trial To Study The Efficacy And Safety Of The Combination Regimen Of MK-5172 And MK-3682 With Either MK-8742 Or MK-8408 In Subjects With Chronic HCV GT3 Infection. Merck 3682-012. 7/2015 – 1/2017
- A Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group, Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of GR-MD-02 for the Treatment of Liver Fibrosis and Resultant Portal Hypertension in Patients with NASH Cirrhosis. The NASH-CX Trial. GALECTIN GT-026. 9/2015 – OPEN
- A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multiple Dose Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamic Effects of BMS-986036 in Adults with Non-alcoholic Steatohepatitis. BMS MB130045. 9/2015 – 1/2018
- Phase 3, Double-Blind, Randomized, Long-Term, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of Obeticholic Acid in Subjects with Nonalcoholic Steatohepatitis. The REGENERATE Study: Intercept 747-303. 10/2015 – OPEN
- A Randomized, Open-Label, Active-Controlled, Multicenter Study to Compare Efficacy and Safety of ABT-493/ABT-530 to Sofosbuvir Co-Administered with Ribavirin in Adults with Chronic Hepatitis C Virus Genotype 3 Infection (ENDURANCE-3). AbbVie M13-594. 10/2015 – 7/2017
- 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. Gilead Polaris 1 GS-US-367-1171. 10/2015 – 7/2017
- 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. Polaris 2 GS-US-367-1172. 10/2015 – 2/2017
- A Phase II, Randomized, Open-Label Clinical Trial to Study The Efficacy and Safety of the Combination Regimen of MK-3682B (MK-5172 + MK-3682 + MK-8408 Fixed Dose Combination (FDC)) in Subjects with Chronic HCV GT1 or GT3 Infection who have failed a Direct Acting Antiviral Regimen. Merck 3682-021. 1/2016 – OPEN
- 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. Gilead Polaris 4 GS-US-367-1170. 3/2016 – 2/2017
- A Phase 2, Pilot Study of JKB-122 to Assess Liver Tests (ALT) in Autoimmune Hepatitis Patients who are Refractory or Intolerant to Current Therapies. Taiwan JKB-122AIH. 6/2016- OPEN
- A Phase 2, Randomized, Double Blind, Placebo Controlled, Parallel Group, Multiple Center Study to Evaluate the Safety, Tolerability, and Efficacy of NGM282 Administered for 12 Weeks in Patients with Primary Sclerosing Cholangitis (PSC). NGM 15-0106. 6/2016 – 8/2017
- A Multicenter, Randomized, Double-Blind, Placebo- Controlled Trial of Emricasan (IDN-6556), an Oral Caspase Inhibitor, in Subjects with Non-alcoholic Steatohepatitis (NASH) Fibrosis. Conatus IDN-6556-12. 03/2016 – OPEN
- A Multi-Center, Randomized, Placebo-Controlled, Double-Blind Study to Confirm Efficacy and Safety of Terlipressin in Subjects with Hepatorenal Syndrome Type 1 (The Confirm Study). Mallinckrodt Pharmaceuticals, Inc. MNK 19013058. 08/2016 – OPEN

- A Randomized, Double-Blind, Placebo Controlled, 2- Part, Adaptive Design, Multicenter 12-Week Study To Assess Safety, Tolerability And Efficacy Of LJN452 In Patients With Non-Alcoholic Steatohepatitis (NASH). Novartis CLJN425A2202. 06/2016 – OPEN
- A Multicentre Randomized, Double-Blind, Placebo- Controlled Phase III Study To Evaluate The Efficacy And Safety Of Elafibranor In Patients With Non-Alcoholic Steatohepatitis (Nash) And Fibrosis. Genfit GFT505-315-1 NASH. 09/2016 – OPEN
- 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 (SVR Registry). Gilead Sciences, Inc. GS-US-248-0122. 1/2017 – OPEN
- An 8-week, dose ranging, open label, randomized, Phase 2 study with an 18-week extension, to evaluate the safety and efficacy of MBX-8025 in subjects with Primary Biliary Cholangitis (PBC) and an inadequate response to or intolerance to ursodeoxycholic acid (UDCA). CymaBay Therapeutics, Inc. CB8025-21629. 2/2017 – OPEN
- A Phase 2 Double-Blind, Randomized, Placebo-controlled, Dose-finding Study to Evaluate the Safety, Tolerability and Efficacy of Volixibat Potassium, an Apical Sodium-Dependent Bile Acid Transporter Inhibitor (ASBTi) in Adults with Nonalcoholic Steatohepatitis (NASH). Shire SHP626-201. 3/2017 – OPEN
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Emricasan, an Oral Caspase Inhibitor, in Subjects with Non-Alcoholic Steatohepatitis (NASH) Cirrhosis and Severe Portal Hypertension. Conatus Pharmaceuticals IDN-6556-14. 4/2017 – OPEN
- 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. Gilead GS-US-337-1431 - LTFU with Cirrhosis. 4/2017 – OPEN
- Procurement of Blood Samples from Subjects with Diagnosed Nonalcoholic Steatohepatitis (NASH) or Nonalcoholic Fatty Liver Disease (NAFLD) for Use in the Development of a Liver Fibrosis Test. Prometheus 16HEP01. 5/2017 – OPEN
- A Phase 2, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Safety, Tolerability, and Efficacy of GS-9674 in Subjects with Primary Biliary Cholangitis Without Cirrhosis. Gilead Sciences, Inc. GS-US-427-4024. 5/2017 – OPEN
- A Phase 2, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Safety, Tolerability, and Efficacy of GS-9674 in Subjects with Primary Sclerosing Cholangitis Without Cirrhosis. Gilead Sciences, Inc. GS-US-428-4025. 5/2017 – OPEN
- A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Phase 2 Study to Evaluate the Efficacy and Safety of Elafibranor at Doses of 80mg and 120mg After 12 Weeks of Treatment in Patients With Primary Biliary Cholangitis and Inadequate Response to Ursodeoxycholic Acid. GenFit GFT505B-216-1. 6/2017 – OPEN
- 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. Gilead Sciences, Inc. GS-US-384-1943. 6/2017 – OPEN
- 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). Gilead Sciences, Inc. GS-US-384-1944. 6/2017 – OPEN
- A Multicenter, Randomized, Double-Blind, Placebo- Controlled Trial of Emricasan, an Oral Caspase Inhibitor, in Subjects with Decompensated Non-Alcoholic Steatohepatitis (NASH) Cirrhosis. Conatus IDN-6556-17. 6/2017 - OPEN

- A Phase 2a, randomized, double-blind, placebo-controlled, dose-ranging, parallel group study to evaluate safety, tolerability, and pharmacodynamics of PF 05221304 administered daily for 16-weeks to adult subjects with nonalcoholic fatty liver disease. Pfizer C1171002. 8/2017 - OPEN
- A Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Assess the Efficacy and Safety of Oral GKT137831 in Patients with Primary Biliary Cholangitis Receiving Ursodeoxycholic Acid and with Persistently Elevated Alkaline Phosphatase. Genkyotex GSN000300. 02/2018 – OPEN
- A Phase 2 Dose Ranging, Randomized, Double Blind, and Placebo-Controlled Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of EDP-305 in Subjects with Non-Alcoholic Steatohepatitis (NASH). Enanta EDP 305-101. 5/2018 – OPEN
- An Open Label Long-Term Study to Evaluate the Safety and Tolerability of Seladelpar in Subjects with Primary Biliary Cholangitis (PBC). CymaBay CB8025-31731. 5/2018 – OPEN
- 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 Steatohepatitis. Intercept 747-304. 5/2018 – OPEN
- A Phase 1, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate Safety, Pharmacokinetics, and Pharmacodynamics of Obeticholic Acid in Subjects with Nonalcoholic Steatohepatitis with Fibrosis. Intercept 747-117. 5/2018 – 6/2018
- A two-part randomized, double-blind, placebo-controlled multicenter dose ranging and confirmatory study to assess the safety and efficacy of VAY736 in autoimmune hepatitis patients with incomplete response to or intolerance of standard therapy (AMBER). Novartis VAY B2201. 5/2018 - OPEN
- A Phase 2 Dose Ranging, Randomized, Double Blind, Placebo-Controlled Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of EDP-305 in Subjects with Primary Biliary Cholangitis (PBC) with or without an Inadequate Response to Ursodeoxycholic Acid (UDCA). Enanta EDP 305-201. 3/2018 - OPEN