Curriculum Vitae

Paul Edward Wylie, M.D.

Research Affiliation
Elligo Health Research, Inc., 2022- Present
11612 Bee Cave Road, Bldg. 1, Suites 100 & 150, Austin, TX 78738

Research Affiliation
Arkansas Center for Sleep Medicine, PLLC
11219 Financial Centre Parkway, Suite 101
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Date: 08-23-2022

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PERSONAL

Date of Birth: March 25, 1962
St. Louis, Missouri
Citizen: United States

Office: Paul E. Wylie, M.D., P.A.
11219 Financial Center Parkway
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The Arkansas Center for Sleep Medicine (ARCSM) is a private independently owned and operated sleep-testing facility that is not affiliated with or located within a hospital. The 3-bed sleep lab is research dedicated for the conduct of clinical trials.

Education

1980-84: University of Oklahoma Norman, Oklahoma Bachelor of Science - Microbiology 1984-88: University of Oklahoma Health Sciences Center Oklahoma City, Oklahoma-
Doctor of Medicine
1988-92: University of Arkansas for Medical Sciences, Little Rock, Arkansas-
Psychiatry Internship and Residency
1993-95: Training in Sleep Medicine under supervision of Robert Galbraith, M.D., ABSM and Virgil Wooten, M.D., ABSM

Medical Licensure

10-23-89 Arkansas N-7808

Current Employment

10/1997 – Present: Arkansas Center for Sleep Medicine, PLLC – Little Rock, AR – President, Medical Director, owner & Clinical Investigator for polysomnography lab

January 2009 – Present: Preferred Research Partners, Inc.- Little Rock, AR – President, Medical Director, Clinical Investigator & co-owner

11/2014 – Present: Paul E. Wylie, MD, PA – Little Rock – President, Physician & owner of Child & Adolescent Psychiatric Private Practice

8/2016 – Present: Baptist Health – Little Rock, AR – Staff Psychiatrist

Professional Memberships

1984-88: Oklahoma State Medical Association
1988-PR: Pulaski County Medical Society, Arkansas State Medical Association, American Medical Association
1993-PR: American Academy of Sleep Medicine
1997-PR: National Sleep Foundation, American Sleep Apnea Association, Restless Leg Syndrome Foundation, Narcolepsy Network
2004-PR: Association of Clinical Research Professionals Sleep Research Society

Honors and Awards

1992: Sandoz Award in Recognition of Superior Academic Achievement and Contribution to Healthcare
1992: UpJohn Achievement Award for Excellence in Clinical Care and Teaching Abilities
6/94: Certified - American Board of Psychiatry and Neurology
4/95: Certified - American Board of Sleep Medicine
2010: Elected Fellow American Academy of Sleep Medicine

Staff Positions

4/16-PR: Active Medical Staff – Baptist Health – Little Rock, AR
8/92-17: Active Medical Staff - St. Vincent Infirmary - Little Rock, AR
10/97-PR: Paul E. Wylie, MD, PA – Little Rock, AR – President, Physician & owner of Psychiatry Private Practice
10/97-16: Arkansas Center for Sleep Medicine, PLLC – Little Rock, AR – President, Physician & owner Of Sleep Medicine Private Practice
4/93-97: Medical Director - St. Vincent Infirmary Sleep Disorders Center
6/97-03: Active Medical Staff - Arkansas Heart Hospital Little Rock, Arkansas
4/94-03: Consultant Staff - Baptist Health Sleep Center Little Rock, Arkansas

Publications

2003: "An Evaluation of a New Automatically Adjusting Continuous Positive Airway Pressure (CPAP) Device"

2004: "An Evaluation of a New Bi-level Mode for the Treatment of Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS)"

6/2006 Poster Presentation & article for APSS: "A Multi-center, Randomized, Controlled Trial of the First Automatically Titrating Bi-Level Positive Airway Pressure Device during Polysomnography"

2007: World Sleep Congress – "AFlex vs. CFlex: A Randomized, Blinded, Cross-Over Comparison Study".

2007: APSS – "Evaluation of the BiPAP Auto M-Series with Biflex Device for the Treatment of OSA".

2009: "The Treatment of Complex Central Sleep Apnea (CompCSA) Including Cheyne-Stokes Breathing (CSB), with Respironics' BiPAP autoSV Advanced Therapy System".

2009: "Randomized Placebo-Controlled Study of the Pillar Palatal Implant System with CPAP: Clinical Report for Clinical Protocol 845". Published in Journal of Clinical Sleep Medicine.

2010: "Sham controlled trial of the effect of Pillar implant on adherence to CPAP therapy in Obstructive Sleep Apnea/Hypopnea Syndrome".

2011: "The Performance of Two Automatic Servo-ventilation Devices in the Treatment of Central Sleep Apnea". Published in Sleep; 34(12):1693-1698.

2013: "A-Flex Versus C-Flex: A Randomized, Blinded, Cross-Over Comparison Study".

2013: "Home-use Servo Ventilation Therapy in Chronic Pain Patients with Central Sleep Apnea: Initial and 3-month follow-up".

2014: "Treatment of Central Sleep Apnea in Adaptive Pressure Support Servo-ventilation; Acute and Long-term Efficacy".

Research Projects

Device:

2/2000: Respironics Inc. - Comparison of Profile Lite Gel Mask to Gold Seal Gel Mask - Patient Preference

3/2000: Respironics Inc.- Simplicity Mask and Headgear - Design Consultation and Effectiveness in Patient Care

9/2000: Respironics Inc.- Simplicity Mask - Comparison of Patient Preference for Prototypes

1/2001: Respironics Inc.- Comparison of Effectiveness in Treatment of Obstructive Sleep Apnea-BiPAP versus BiFLEX

5/2001: Respironics Inc.- Comparison of Simplicity Deluxe Mask Prototype to Simplicity Original Mask

5/2001: Respironics Inc.- Evaluation of the REMSTAR AutoPAP Performance in the Treatment of Obstructive Sleep Apnea

9/2001: Respironics Inc:- Patient In-Home Comparison / Preference Study - BiPAP versus BiFlex

9/2001: Respironics Inc. - Evaluation of a new device (Synchrony) for the treatment of Cheyne-Stokes respiration in patients with congestive heart failure.

1/2002: Respironics Inc.- Comparison of Standard CPAP versus REMStar AutoPAP device versus RESMED AutoSet-T

4/2002: Respironics Inc. – User Validation Testing of the REMstar Pro with C-Flex.

6/2002: Respironics Inc.- Validation of feasibility of Average Volume Assured Pressure Support Software when Used with BiPAP Synchrony on Patients with Respiratory Insufficiency.

10/2002: Respironics Inc. - Validation of feasibility of an Auto-Adjusting Bi-Level PAP device for the treatment of OSA.

1/2003: Respironics Inc. – Validation of software upgrades to the Therapy Algorithm of an Auto-Adjusting REMstar CPAP device.

3/2004: Respironics Inc. – Evaluation of a new device – Heart PAP – for the treatment of patients with sleep disordered breathing.

05/2005: Respironics Inc. – Efficacy of an Auto-Adjusting Bi-Level PAP Device for the Treatment of OSA.

11/2005: Respironics Inc. – Evaluation of the M-Series REMStar Auto C-Flex Device for the Treatment of OSA.

05/2006:Respironics Inc.- Evaluation of the BIPAP Auto M-Series with Bi-flex Device for the Treatment of OSA

07/2006: Respironics Inc. – The Impact of BIPAP Auto SV on OSA and Complex Sleep Apnea

12/2006: Respironics Inc.- Comparison of Auto A-Flex to Auto C-flex

01/2007: Respironics Inc.- Encore Anywhere User Preference Beta Test

01/2007: Respironics Inc. – The Impact of BIPAP Auto SV on OSA and Complex Sleep Apnea.

10/2007: Respironics Inc. – The Impact of BiPAP AutoSVTM on Central Disregulated Breathing & Chronic Pain Patients

10/2007: Restore Medical, Inc. – A Randomized, Placebo-Controlled Study of the Pillar Palatal Implant System with CPAP

01/2008: Respironics Inc. – Stardust Screening Study

02/2008: Respironics Inc. – Evaluation of a Positive Air Pressure Delivery Systems on Adherence & Outcomes (System One versus Better Together)

08/2008: Respironics Inc. – Evaluation of Software Enhancements to the Respironics BiPAP AutoSV device

04/2009: Respironics Inc. – User Preference & Validation Evaluation of the New BiPAP autoSV3 device

07/2009: Philips Respironics – Evaluation of the Q-Series Auto Device for the Treatment of OSA

10/2009: Philips Respironics – Engineering Evaluation of the Next Generation of autoSV Devices

6/2010: Philips Respironics – Evaluation of the Philips Respironics BiPAP autoSV devices in subjects with Sleep Disorders

12/2010: Philips Respironics – Philips Respironics BiPAP autoSV4 User Preference Trial

8/2011: Philips Respironics – BiPAP autoSV System One Advanced in Patients with Chronic Pain and Sleep Disordered Breathing (SDBPM-2011-01)

9/2011: Philips Respironics – Automated Graduated CPAP for Improved Adherence in Newly Diagnosed OSA Patients: Multicenter Trial (AR-1112-AGPAP-MS)

6/2012: Philips Respironics – BiPAP autoSV Advanced in Central Apnea Patients (ST-1001-ASVWO-MS)

7/2012: Philips Respironics – User Preference/Validation Evaluation of the New Phillips Respironics PAP Application (ST1203-APP-MS)

12/2012: Cereve - A Multi-center Prospective, Blinded, Randomized Crossover Study to Compare the Cereve Sleep System at Two Different Temperatures in Primary Insomnia Patients (CIP-003)

6/2013: Philips Respironics – Evaluation of the OmniLab 2.0 (ST-1311-OmniLab-MS)

6/2014: Philips Respironics – BIG4 CPAP Study (PGI-BIG4-1331-MS)

7/2014: Philips Respironics – Evaluation of Two Servo-Ventilation Devices (ST-1431-ASV Evaluation-ARK)

5/2015: Somnarus – Comparison of the Somnarus Sleep Apnea Diagnostic Technology SomnaPatch with Polysomnography (001-D)

7/2015: Philips Respironics – Servo-Ventilation In-Lab PSG Evaluation (ST-1517-ALE-MS)

7/2016: Akili Interactive Labs, Inc. - A study to assess the feasibility of and to characterize Project: EVO Monitor game-play cognitive function measurements when played daily, weekly, or multiple times per day in adults 40-55 years old (Akili-026)

9/2016: Philips Respironics - In-lab PSG Evaluation of Two Philips ASV Devices (ST-PHASV-16092-JP)

4/2017: Philips Respironics - A Double-Blind Placebo-Controlled Multi-Site Randomized Cross-Over Study of the Effectiveness and Efficacy of the PowerSleep device (AI-16128-PSPIV-LO)

Other:
2009: Development of a Sleep Measure in Restless Legs Syndrome - Pfizer

2014: Colorectal Cancer Biomarker Specimen Collection Study – Applied Proteomics – API-CP001

2014: Sequencing Study to Investigate the Underlying Genetic Cause(s) in Subjects with Restless Leg Syndrome – Xenon Pharmaceuticals, Inc.

2019: Guardant Health - Evaluation of ctDNA LUNAR-2 Assay in an Average Patient Screening Episode – 02-GI-002

Pharmaceutical:
1/2002: A Double-Blind, Randomized, Placebo Controlled, Parallel Group Study to Investigate the Tolerability of a Dose-Escalating Regimen of XXX in Patients Suffering from Restless Legs Syndrome.

2003: A Phase III, Open-Label, Fixed Dose Study to Determine the Safety of Long-Term Administration of XXX in Subjects with Chronic Insomnia.

2003: A Phase III, randomized, double blind, placebo-controlled outpatient study to assess the efficacy and safety of two dose levels of XXX in elderly patients with primary insomnia

2003: A 12-Week, Double-Blind, Placebo-Controlled, Parallel Group Study to Assess the Efficacy and Safety of XXX in Patients Suffering from Restless Leg Syndrome.

2003: A Phase III, Double-Blind, Outpatient, Extension Study to Assess the Long-Term Safety of Two Dose Levels of XXX in Elderly Patients with Primary Insomnia.

2004: A 12-month, Open-Label, Flexible-Dosage (100 to 250mg/day) Study of the Safety and Efficacy of XXX in the Treatment of Patients with Excessive Sleepiness Associated with Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, or Chronic Shift Work Sleep Disorder

2004: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXX in Elderly Primary Insomnia Patients with Sleep Maintenance Difficulties

2005: A Double-Blind, Randomized, Placebo-Controlled, Multicenter, 30-Night Polysomnographic Study of XXX in Adult Patients with Primary Insomnia.

2005: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Assess the Long Term Efficacy and Safety of XXX in Primary Elderly Insomnia Patients with Sleep Maintenance Difficulties.

2006: A 28-day, Polysomnographic and Subjective Assessment of XXX, 10 and 30 mg, for the Treatment of Primary Insomnia: A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Trial.

2006: A Long-Term Study of XXX versus Placebo Treatment Assessing Maintenance of Efficacy & Safety in Patients with Restless Legs Syndrome.

2006: A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter Proof-of-Concept Study to Evaluate the Safety and Efficacy of XXX Taken in Combination with XXX for the Treatment of Subjects with Chronic Insomnia

2006: A 12-Week, Multi-Center, Double-Blind, Placebo-Controlled, Parallel Group, Flexible Dose Polysomnography Study of XXX Controlled Release for Restless Legs Syndrome (RLS) in RLS Patients with Sleep Disturbance and Periodic Limb Movements (PLM) During Sleep.

2006: An Open-Label Clinical Study to Investigate Pharmacokinetics (PK) of Different Doses (0.125 mt, 0.25 mg, 0.5 mg) of XXX Administered Once Daily in Pediatric Patients who are Individually Optimized to Stable XXX Doses for the Treatment of Idiopathic Restless Legs Syndrome (RLS).

2007: A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy, Safety, and Pharmacokinetics of XXX in Patients with Restless Legs Syndrome.

2007: A Randomized, Double Blind, Placebo-Controlled, Parallel Group Study to Demonstrate the Subjective Treatment Effects of XXX on Sleep Using a Post Sleep Questionnaire- Interactive Voice Response System (PSQ-IVRS) in an "At-Home Setting" in and Adult Population with Chronic Insomnia.

2007: An Open-Label, 52-week Extension Study Assessing XXX Safety and Efficacy in Patient with Restless Legs Syndrome.

2007: A Randomized, Double-Blind, Placebo-Controlled, Parallel, Proof of Concept Study to Evaluate the Effectiveness of XXX to Advance the Timing of Sleep in Individuals with Delayed Sleep Phase Syndrome (DSPS).

2007: Efficacy and Safety of 2 mg/day of XXX on Sleep Maintenance Insomnia with a Sub-Study of the Effect of XXX on Stable Type II Diabetes Mellitus: a One Year, Mult-Center, Randomized, Double-Blind, Placebo-Controlled Study.

2007: A Six-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Efficacy and Safety, Sleep Lab Trial with XXX in Patients with Chronic Primary Insomnia.

2007: A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of XXX in Patients with Restless Legs Syndrome.

2007: Fifty-Two Weeks, Open Label Extension Trial to Evaluate Safety and Efficacy of XXX in Outpatients with Chronic Primary Insomnia who Completed the Clinical Trial Protocol 176001 or 176002.

2007: A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter Outpatient Trial of XXX in Adults with Primary Insomnia.

2008: XXX Dose-Ranging Trial: A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter Outpatient Trial of XXX in Adults with Nonrestorative Sleep.

2008: A Phase 2, Randomized, Double-Blind, Placebo-and Active-Comparator-Controlled Study of the Safety and Efficacy of XXX in Outpatients with Insomnia.

2009: Randomized, Double-Blind, 12-Month Study of XXX in Subjects With Restless Legs Syndrome.

2009: A Randomized, Double-Blind, Placebo-Controlled, 3-Way Crossover, Multicenter Polysomnography Study of Pregabalin and Pramipexole in Adults with Restless Legs Syndrome.

2009: Effects of Pregabalin on Sleep Maintenance in Subjects with Fibromyalgia Syndrome and Sleep Maintenance Disturbance: A Randomized, Placebo-Controlled, 2-Way Crossover, Polysomnography Study

2010: A Randomized, Placebo-Controlled, Double-Blind, Fixed-Dose Study of the Efficacy and Safety of Eszopiclone in Children (6 to 11 years) and Adolescents (12 to 17 years) with Attention-Deficit/Hyperactivity Disorder-Associated Insomnia.

2010: A Long-Term, Open-Label, Safety Study of Eszopiclone in Children (6 to 11 years) and Adolescents (12 to 17 years) with Attention-Deficit/Hyperactivity Disorder-Associated Insomnia.

2010: A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Nitazoxanide in Adults with Acute Uncomplicated Influenza. (Sub-Investigator)

2010: 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. (Sub-Investigator)

2010: A Double-Blind, Randomized, Multicenter Study of Prasugrel Compared to Placebo in Adult Patients with Sickle Cell Disease. (Sub-Investigator)

2010: A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Peramivir in Subjects with Uncomplicated Influenza. The RELIEF Study. (Sub-Investigator)

2011: A Randomized, Double-Blind, Placebo-Controlled Study of Nitazoxanide in Adults and Adolescents with Acute Uncomplicated Influenza. (Sub-investigator)

2011: A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase III, Efficacy & Safety Study of 3 Fixed Dose Groups of TC-5214 (S-mecamylamine) as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder Who Exhibit an Inadequate Response to Antidepressant Therapy.

2011: A Multicenter, Open Label, 2-Group, Dose Escalation Study of Monotherapy Administration of Rotigotine in Pediatric Subjects with Idiopathic Restless Legs Syndrome. Phase IIA

2011: An Open Label, Long-Term Follow-Up Study to Determine the Safety, Tolerability, & Efficacy of Rotigotine Transdermal System as Monotherapy in Pediatric Subjects with Restless Legs Syndrome. Phase IIA

2011: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with inadequately controlled hypertension on an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) – Bristol Myers Squibb MB102073 (Sub-Investigator)

2012: A Randomized, 12-Week, Double-Blind, Placebo-Controlled, Repeat Dose, Oral, Dose-Ranging Study to Assess the Safety and Efficacy of Plecanatide in Patients with Chronic Idiopathic Constipation – Synergy Pharmaceuticals – SP304-20210

2012: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with inadequately controlled hypertension treated with an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) and an additional Antihypertensive medication - Bristol Myers Squibb MB102077 (Sub-Investigator)

2012: A Multicenter, Randomized, Double-blind, Placebo-Controlled, 8-Week Study to Evaluate the Safety and Efficacy of Nebivolol and Valsartan Given as a Fixed-Dose Combination in Patients With Stage 1 or 2 Essential Hypertension – Forest Research Institute, Hypertension – NAC-MD-01

2012: A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of Lesinurad and Allopurinol Compared to Allopurinol Alone in Subjects with Gout who have had an Inadequate Hypouricemic
Response to Standard of Care Allopurinol – Ardea Biosciences, Gout – RDEA594-301

2012: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Assessing the Occurrence of Major Adverse Cardiovascular Events (MACE) in Overweight and Obese Subjects with Cardiovascular Risk Factors Receiving Naltrexone SR/Bupropion SR – Orexigen, Obesity – NB-CVOT

2012: A multicenter, randomized, active comparator, placebo controlled, double-blind pilot study to assess the efficacy and safety of LCQ908 alone and in combination with fenofibrate or Lovaza in patient with severe hypertriglyceridemia – Novartis, High Triglycerides – CLCQ908C2201

2012: A Randomized, Double Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients with Diarrhea-Predominant Irritable Bowel Syndrome – Furiex Pharmaceuticals – 27018966IBS3001

2012: A Phase 2, Multi-Center, Randomized, Double Blind, Placebo-Controlled, Multiple-Dose Study to Determine the Safety and Efficacy of Orally Administered LX1033 in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D) – Lexicon Pharmaceuticals – LX1033-1.201

2012: A 12-Week, Randomized, Double-Blind,Placebo-Controlled Study of Asimadoline in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome – Tioga Pharmaceuticals – ASMP3001

2012: A Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study of S-297995 for the Treatment of Opioid-induced Constipation (OIC) in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy – Shionogi, Inc., OIC, Phase II – 1107V9221

2012: A Multicenter, Randomized, Double-blinded, Placebo-controlled Study of Daikenchuto (TU100) in Subjects with Moderate Crohn's Disease – Tsumura Pharmaceuticals – TU100P2T2

2012: A PHASE II STUDY TO EVALUATE THE EFFICACY AND SAFETY OF 12 WEEKS OF TREATMENT WITH ORAL CNDO 201 TRICHURIS SUIS OVA SUSPENSION (TSO) AS COMPARED TO PLACEBO, FOLLOWED BY A 12 WEEK OPEN-LABEL TREATMENT PERIOD IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE – Coronado Biosciences – CNDO-201-003

2012: A Phase 2b, Double-blind, Randomized, Placebo-controlled, Dose-finding Study to Evaluate Efficacy of a Novel Selective 5-HT4 Receptor Agonist, SSP-002358 Taken in Addition to a Proton Pump Inhibitor in Subjects with Gastroesophageal Reflux Disease with Persistent Regurgitation with or without Heartburn while on Proton Pump Inhibitor Therapy – Shire Pharmaceuticals – SPD557-206

2012: A MULTICENTER, OPEN-LABEL STUDY TO DETERMINE THE EFFECTS OF LACOSAMIDE ON SLEEP IN HEALTHY SUBJECTS - UCB, Healthy Adult, Phase I – SP1031

2012: A Phase 3B, Double-Blind, Randomized, Placebo-Controlled, Study of Rotigotine and its Effect on All-day Functioning and Quality of Life in Subjects with Moderate to Severe Idiopathic Restless Legs Syndrome – UCB, Restless Legs Syndrome – RL0003

2012: A Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose, Parallel-Group Study to Compare the Efficacy, Tolerability, and Safety of 3 Doses of Gabapentin Enacarbil (GSK1838262) With Placebo

in the Treatment of Subject With Moderate-to-Severe Primary Restless Legs Syndrome (RLS) – GSK/Xenoport RXP114025, Phase IV Study

2013: A Long-Term Extension Study of Lesinurad in Combination with Allopurinol for Subjects Completing an Efficacy & Safety Study of Lesinurad & Allopurinol – Ardea Biosciences, Gout – RDEA594-306

2013: A Randomized, Double-blind, Double dummy, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Clinical Equivalence of Lubiprostone 24 mcg Capsules (Dr. Reddy's Laboratories Ltd.) With AMITIZA® (Lubiprostone) 24 mcg Capsules (Sucampo Pharmaceuticals, Inc.) in the Treatment of Chronic Idiopathic Constipation – Dr. Reddy's Laboratories, CIC – DRL-USG01-L/2012

2013: A Randomized, Double-Blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-Induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY)) in Opioid-experienced Subjects with Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy – Purdue Pharma L.P. – ONU3705

2013: A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III 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 – Cubist Pharmaceuticals, Inc. – 5945-SOIC-12-05

2013: A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate Efficacy and Safety of CB-5945 for the Treatment of Opioid-induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain – Cubist Pharmaceuticals, Inc. – 5945-OIC-12-04

2013: A Double-blind, Randomised, Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of Elobixibat 5 mg and 10 mg for 12 Weeks Followed by a 4-week Withdrawal Period – Ferring International Pharmascience Center US, Inc. – 000080

2013: A Multicenter, Open-label, Safety and Tolerability Extension Trial of 5 mg and 10 mg Elobixibat Daily in the Treatment of Chronic Idiopathic Constipation – Ferring International Pharmascience Center US, Inc – 000081

2013: An Open-Label Extension (OLE), Long-term Safety and Tolerability Study of Plecanatide in Patients with Chronic Idiopathic Constipation (CIC) – Synergy Pharmaceuticals, Inc. – SP304203-01 (CIC-OLE)

2013: A Randomized, Double-blind, Placebo-controlled, Parallel-group Study of Naldemedine in the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy – Shionogi, Inc. – 1315V9232

2013: A 52-week, double-blind, randomised, placebo-controlled, parallel-group phase III study with re-randomisation at week 25 to evaluate the efficacy and safety of oral ibodutant 10 mg once daily in female patients with irritable bowel syndrome with diarrhoea (IBS-D) – Menarini Ricerche S.p.A. – NAK-07 (IRIS-4)

2013: A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Plecanatide (3.0 and 6.0 mg) in Patients with Chronic Idiopathic Constipation – Synergy Pharmaceuticals, Inc. – SP304203-00 (CIC3)

2014: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of Metoclopramide Nasal Spray in Women with Symptoms Associated with Diabetic Gastroparesis – Evoke Pharma – METO-IN-003

2014: 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 – Evoke Pharma – METO-IN-004

2014: A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Effect of Long-term Treatment with BELVIQ (lorcaserin HCl) on the Incidence of Major Adverse Cardiovascular Events and Conversion to Type 2 Diabetes Mellitus in Obese and Overweight Subjects with Cardiovascular Disease or Multiple Cardiovascular Risk – Eisai Inc. – APD356-G000-401 (CAMELLIA)

2014: A Phase 3, Randomized, Double Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of Febuxostat 40 mg XR, 80 mg XR, 40 mg IR and 80 mg IR in Subjects With Gout – Takeda Development Center Americas, Inc. – FEB-XR_301

2014: A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Multiregional, One Year Study to Assess the Efficacy and Safety of Twice Daily Oral Rifaximin Delayed Release Tablets for Induction of Clinical Remission with Endoscopic Response at 16 Weeks followed by Clinical and Endoscopic Remission at 52 Weeks in Subjects with Active Moderate Crohn's Disease – Salix Pharmaceuticals, Inc. – RECD3125

2014: A Randomized Double-Blind, Placebo Controlled, Flexible and Fixed Dose, Parallel Group Study of Extended-Release Lorazepam (EDG004) for the Treatment of Generalized Anxiety Disorder (GAD) – Edgemont Pharmaceuticals – EDG004-003

2014: A Randomized, Double-Blind, Placebo-Controlled, Crossover Study To Assess The Effects Of TC-6499 on Gastric Emptying Time In Diabetic Subjects with Gastroparesis – Targacept – TC-6499-12-CLP-005

2015: Rhythm Pharmaceuticals, Diabetic Gastroparesis – RM-131-009

2015: Jazz Pharmaceuticals, Narcolepsy & Excessive Daytime Sleepiness – 14-002

2015: Jazz Pharmaceuticals, Obstructive Sleep Apnea & Excessive Daytime Sleepiness – 14-003

2015: Jazz Pharmaceuticals, Long-term extension study for Obstructive Sleep Apnea or Narcolepsy with Excessive Daytime Sleepiness – 14-005

2015: Neurocrine Biosciences, Inc., Tardive Dyskinesia – NBI-98854-1304 (KINECT3)

2015: Theravance, Diabetic or Idiopathic Gastroparesis – 0099

2015: Synergy Pharmaceuticals, Inc., Irritable Bowel Syndrome-Constipation – SP304203-04

2015: Forest Research Institute, Inc., Irritable Bowel Syndrome-Constipation &/or Chronic Idiopathic Constipation – LIN-MD-10

2015: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3001 (TRANSFORM-1)

2015: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3003 (SUSTAIN-1)

2015: Neurocrine Biosciences, Inc., Tardive Dyskinesia – NBI-98854-1402 (KINECT4)

2015: Naurex Inc., Major Depressive Disorder – NRX1074-C-202

2015: Gilead, Ulcerative Colitis – GS-US-326-1100

2015: Sunovion Pharmaceuticals, Adult Attention Deficit Hyperactivity Disorder (ADHD) – SEP360-301

2016: Ferring International Pharmascience Center US, Inc., Ulcerative Colitis – 000174

2016: Ferring International Pharmascience Center US, Inc., Ulcerative Colitis – 000175

2016: Conatus Pharmaceuticals, Non-alcoholic Steatohepatitis (NASH) – IDN-6556-12

2016: Synergy Pharmaceuticals, Irritable Bowel Syndrome with Constipation (IBS-C) – SP304203-06

2016: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3008

2016: Eisai Pharmaceuticals, Elderly Insomnia – E2006-G000-304

2016: Luitpold Pharmaceuticals, Inc., Restless Legs Syndrome – 1VIT14037

2016: Braintree Laboratories, Chronic Constipation – BLI400-302

2016: Braintree Laboratories, Opioid Induced Constipation – BLI801-203

2017: Takeda Pharmaceuticals – Diabetic or Idiopathic Gastroparesis – TAK906-1002

2017: Conatus Pharmaceuticals – Non-Alcoholic Cirrhosis – IDN-6556-17

2017: Shire Pharmaceuticals – Preschooler ADHD – SPD489-347

2017: Shire Pharmaceuticals – Preschooler ADHD – SPD489-348

2017: Allergan – Diabetic Gastroparesis – RLM-MD-01

2017: Braintree Laboratories, Bowel Prep for Colonoscopy – BLI4700-302

2017: Tonix Pharmaceuticals, Military-Related PTSD – TNX-CY-P301

2017: Vanda Pharmaceuticals, Inc. – Diabetic or Idiopathic Gastroparesis – VP-VLY-686-2301

2017: Allergan – Diabetic Gastroparesis – RLM-MD-04

2018: Freenome Holdings, Inc., Health Decisions – Colorectal Cancer Screening, FRE-001

2018: Allergan – Diabetic Gastroparesis – RLM-MD-03

2018: Tonix Pharmaceuticals, Military-Related PTSD – TNX-CY-P303

2018: Janssen Research & Development, Insomnia – 42847922ISM2005

2018: Shire Pharmaceuticals – Preschooler ADHD PK – SHP465-112

2018: Shire Pharmaceuticals – Adolescent ADHD – SHP465-308

2018: Shire Pharmaceuticals – Adolescent ADHD – SHP465-309

2018: AbbVie – Testosterone Replacement Therapy for Hypogonadism – M16-100

2018: Otsuka Pharmaceuticals – Post Traumatic Stress Disorder – 331-201-00061

2018: Idorsia Pharmaceuticals – Insomnia – ID-078A301

2018: Idorsia Pharmaceuticals – Insomnia – ID-078A303

2018: Janssen Research & Development – Major Depressive Disorder – 67953964MDD2001

2018: Neos Therapeutics – Attention Deficit Disorder in Children 4-6 y/o – NT0202.1009

2018: Neos Therapeutics – Attention Deficit Disorder in Children 4-6 y/o – NT0202.1010

2018: Tonix Pharmaceuticals - Military-Related PTSD – TNX-CY-P306

2018: Allergan – Diabetic Gastroparesis – 3071-305-020

2018: Ironwood Pharmaceuticals – GERD – C3718-302

2019: Tonix Pharmaceuticals - PTSD – TNX-CY-P302

2019: Apnimed – Obstructive Sleep Apnea – APN-002

2019: Aptinyx – Post-Traumatic Stress Disorder – NYX-783-2004

2019: Axsome Pharmaceuticals – Treatment-Resistant Depression – AXS05-301

2019: Biohaven Pharmaceuticals – Obsessive Compulsive Disorder – BHV4157-202

2019: Otsuka Pharmaceuticals – Post Traumatic Stress Disorder – 331-201-00071

2019: Takeda – Obstructive Sleep Apnea & Excessive Daytime Sleepiness – Phase 1 – TAK-925-2001

2019: LG Chem – Gout with Hyperuricemia – LG-GDCL002
2019: Applied Therapeutics - Diabetic Cardiomyopathy / Stage B Heart Failure at High Risk of Progression to Overt Heart Failure (Stage C Heart Failure) – AT-001-2001

2019: Adare Pharmaceuticals – Eosinophilic Erosive Esophagitis – SP-1011-003

2019: Allergan - Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis – 3152-301-002

2019: Allergan – Constipation in Children 6-17 y/o – LIN-MD-64

2019: Allergan – Pediatric Participants with Functional Constipation (FC) or Irritable Bowel Syndrome with Constipation (IBS-C) – LIN-MD-66

2019: Allergan - Pediatric Participants (Age 2 to 5 Years) with Functional Constipation – LIN-MD-67

2019: Braintree Laboratories - Bowel Prep for Colonoscopy – BLI4900-302

2019: Phathom Pharmaceuticals – Erosive Esophagitis – EE-301

2019: Phathom Pharmaceuticals – H. Pylori – HP-301

2019: Vanda Pharmaceuticals – Diabetic or Idiopathic Gastroparesis – VP-VLY-686-3301

2019: Vibrant Ltd – Chronic Idiopathic Constipation – V270

2019: OrphoMed – Diarrhea-predominant Irritable Bowel Syndrome (IBS-D) – OM-201

2020: Takeda – Idiopathic Hypersomnia – Phase 1 – TAK-925-2002

2020: Otsuka Pharmaceuticals – ADHD in Children – Phase 1 – 405-201-00010

2020: Neurogastrx – Diabetic or Idiopathic Gastroparesis – NG101-201

2020: Guardant Health – Colorectal Cancer Screening – 02-GI-002 ECLIPSE

2020: Janssen – Treatment-resistant Depression – 54135419TRD4005

2020: Allergan – Major Depressive Disorder - 2006-308-008

2020: Janssen – Major Depression & Insomnia – 42847922MDD3002

2020: Novavax – COVID-19 Vaccine – 2019nCoV-301

2020: Supernus – ADHD in Preschoolers – 812P401

2021: Otsuka Pharmaceuticals – ADHD in Children – 405-201-00046

2021: Apnimed – Obstructive Sleep Apnea – APC-003

2021: Apnimed – Obstructive Sleep Apnea – APC-003-OLE

2021: Moderna – CMV Vaccine – mRNA-1647-P301

2021: Acerus Pharmaceuticals – Ambulatory BP monitoring in Hypogonadism – NAT-2020-01

2021: Purdue Pharma LP – ADHD in Preschoolers & Children – ADA4004

2021: Apnimed – Obstruction Sleep Apnea – APC-005

2021: Relmada – Major Depressive Disorder – REL-1017-302

2021: Relmada – Major Depressive Disorder – REL-1017-310