

Curriculum Vitae

Amy Helen Kelley, RN, CCRC

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
Little Rock, AR 72211
(501) 553-9987 x104
(501) 553-9986 FAX

Research Affiliation

Preferred Research Partners, Inc.
11219 Financial Centre Parkway, Suite 320
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Signature: _____

A. Kelley

Date: _____

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Office

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Arkansas Center for Sleep Medicine, PLLC (Polysomnography Lab)
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Education

May 2002: Bachelor of Science in Nursing, University of Central Arkansas
Conway, AR

Work Experience

January 2009-present: Vice President, Preferred Research Partners, Inc.- Little Rock, AR
Position entails training and supervising team of research coordinators, establishing contacts with sponsors & CROs, recruiting new studies, initiating & maintaining investigator relationships, feasibility assessment, source document creation, AP & AR, regulatory, budget & contract negotiation, marketing, recruiting study participants, AE/SAE reporting, laboratory collection and processing.

May 2005-present: Research Director, Arkansas Center for Sleep Medicine, PLLC & Paul E. Wylie, MD, PA- Little Rock, AR
Responsibilities include negotiating budgets and contracts, IRB submissions, marketing, recruiting patients, recruiting new studies, ensuring all equipment functional & calibrated, creation of study ads, patient safety monitoring, profit analysis, informed consent process, oversight of research staff, establishing contacts with sponsors & CROs, patient care, CRF and source documentation completion, creation of ICFs & source documents, regulatory, filing, invoicing, scheduling, AE/SAE reporting, laboratory collection and processing.

April 2003-May 2005: Study Coordinator, Research Solutions, LLC- Little Rock, AR
Position involved conducting study visits & ensuring patient safety, AE/SAE reporting, facilitating informed consent process, collection of IRB correspondence, patient recruitment, CRF and source documentation completion, laboratory collection and processing.

June 2002- April 2003: Medicare Manager, Chenal Healthcare & Rehabilitation- Little Rock, AR
Duties included screening patients for admission to the skilled nursing facility, staffing for nurses & CNAs, supervision of nursing personnel, documentation & nursing care for Medicare & long-term care residents including formation of immediate plan of care, admission assessments, body audits, discharge planning, patient teaching, administration of medications & treatments/wound care.

Certifications/Licensures

RN license #R68675 (AR)

ACRP CCRC certification number: FDA-C-0306-214

Professional Affiliations

2019-present: Society for Clinical Research Sites

2009-present: MAGI

2009-present: Drug Information Association (DIA)

2005-present: Association of Clinical Research Professionals (ACRP)

1998-2002: National Student Nurses Association (NSNA)

1999-2001: ANSA Conventions

Presentations & Academic Research

2/2010: "Effective Subject Recruitment & Retention Strategies" presentation to all RLS sites on A0081185 for United Biosource Corporation

2007: "Recruitment & Retention Strategies for Insomnia Study" presented to all insomnia sites at coordinator meeting

2001-2002: Special study on "Treatment strategies for Alzheimer's Disease"

2000: "Effective Interventions to Decrease Caregiver Role Strain" - Poster Presentation at UCA Student Research Colloquium

Research Experience

Pharmaceutical:

- 2003: Pain due to Osteoarthritis of the Knee. Labopharm- MDT3-002/MDT3-003
- 2003: "A Double-Blind, Placebo-Controlled, Randomized, Multicenter Study to Investigate the Safety and Efficacy of 2 mg TID of Cilansetron Over 12 Weeks Followed by a 4-Week Re-randomized Treatment Period in Diarrhea-Predominant Irritable Bowel Syndrome Subjects" Solvay- S2413011

- 2003: GSK, Epilepsy- LAM40117
- 2003: Neurocrine, Insomnia- NBI-34060-IR-0215
- 2003: Takeda, Insomnia- 01-01-TL-375-020
- 2003: AstraZeneca, Hypercholesterolemia (ARIES)- 4522US/0002
- 2003: GSK, Restless Legs Syndrome- 101468/249
- 2003: Takeda, Sleep Disorders- 01-02-TL-375-022
- 2003: Takeda, Insomnia- 01-02-TL-375-025
- 2003: Bertek, Hypertension in African Americans- NEB-202
- 2003: BMS, Type II Diabetes Mellitus- CV168-025
- 2003: Aventis, Type II Diabetes Mellitus- HOE901/4022
- 2003: Eli Lilly, Stress Urinary Incontinence- F1JUSSBCD
- 2003: Boehringer-Ingelheim, Hypertension- 502.421
- 2004: Takeda, Type II Diabetes Mellitus- 01-00-TL-OPI-506
- 2004: AstraZeneca, Hypertension- 324A
- 2004: Schering-Plough, Hypercholesterolemia- P0337-21
- 2004: Takeda, Type II Diabetes Mellitus- 01-03-TL-559-016
- 2004: CellTech, Crohn's Disease- CDP-870-031
- 2004: AstraZeneca, Cardiac Prophylaxis (JUPITER)- 4522US/0011
- 2004: ISIS, Ulcerative Colitis- 2302CS22
- 2004: Targacept, Ulcerative Colitis- TC-2403-12-CRD-00
- 2004: AstraZeneca, Type II Diabetes Mellitus (GALLANT 6)- D616C00030
- 2004: Cephalon, Excessive Sleepiness- C10953/3023/ES/MN
- 2004: BMS, Hypercholesterolemia- 800-01-01
- 2004: Sankyo, Type II Diabetes Mellitus- WEL-303
- 2004: NovoNordisk, Type II Diabetes Mellitus- NN304-1431
- 2004: Mead Johnson, Formula- 3371-2
- 2004: Roche, Osteoporosis- ML18056
- 2004: Sankyo, Type II Diabetes Mellitus- CS-011-202
- 2004: Yamanouchi, Overactive Bladder- 905-UC-007
- 2004: Takeda, Dyslipidemia- 01-04-TL-475-002
- 2004: Sankyo, Type II Diabetes Mellitus- CS-011-203
- 2004: Berlex, HRT in Essential Hypertension- 306743
- 2005: Arena, Obesity- APD356-003
- 2005: Merck, Primary Insomnia in Adults (polysomnography)- MK-0928/004
- 2005: Merck, Primary Insomnia in Elderly (polysomnography)- MK-0928/002
- 2005: Sankyo, Type II Diabetes Mellitus- 917-203
- 2005: Sankyo, Hypertension- CS8663-A-U301
- 2005: CellTech, Crohn's Disease- CDP-870-034
- 2005: Somaxon, Primary Insomnia in Elderly (polysomnography)- SP-0503
- 2006: GSK, Primary Insomnia in Adults (polysomnography)- MAD103894
- 2006: Xenoport, Restless Legs Syndrome – XP060
- 2006: Boehringer-Ingelheim, Pediatric PK Restless Legs Syndrome – 248.600
- 2006: Takeda, Sleep Maintenance Insomnia (polysomnography)– 01-05-TL-375-067
- 2006: GSK, Restless Legs Syndrome (polysomnography)– RRL103660

- 2007: Xenoport, Restless Legs Syndrome (PK)– XP081
- 2007: Takeda, Chronic Insomnia – 01-05-TL-375-069
- 2007: Xenoport, Restless Legs Syndrome – XP053
- 2007: Takeda, Delayed Sleep Phase Syndrome (polysomnography)– 01-04-TL-375-044
- 2007: Sanofi-Aventis, Sleep Maintenance– LTE6673 (SAMS)
- 2007: Xenoport, Restless Legs Syndrome – XP055
- 2007: Organon, Chronic Primary Insomnia (polysomnography) – 176002
- 2007: Organon, Chronic Primary Insomnia – 176004
- 2007: Pfizer, Primary Insomnia – A4251037
- 2008: Pfizer, Non-Restorative Sleep (polysomnography) – A4251033
- 2008: Lilly, Primary & Secondary Insomnia – 12K-MC-ZZAD
- 2009: Pfizer, Restless Legs Syndrome – A0081186
- 2009: Pfizer, RLS Patient Reported Outcomes – PI6034A
- 2009: Pfizer, Fibromyalgia & Sleep Maintenance Insomnia – A0081165
- 2009: Pfizer, Restless Legs Syndrome (polysomnography) – A0081185
- 2009: Romark Laboratories/SGS, Acute Uncomplicated Influenza – RM01-2027
- 2010: Pfizer, Restless Legs Syndrome – A0081184
- 2010: Sepracor, Attention Deficit Disorder & Insomnia in Children (polysomnography) – 190-246
- 2010: Sepracor, Attention Deficit Disorder & Insomnia in Children (rollover & treatment naïve) – 190-247
- 2010: Romark Laboratories/SGS, Acute Uncomplicated Influenza – RM08-3001
- 2010: Eli Lilly & Company, Sickle Cell Anemia – H7T-MC-TAEK(a)
- 2010: AstraZeneca, Major Depressive Disorder – D413C00004
- 2010: Furiex Pharmaceuticals, Diarrhea Predominant Irritable Bowel Syndrome – 27018966IBS2001
- 2011: AstraZeneca, Opioid Induced Constipation – D3820C00005 (KODIAC 5)
- 2011: AstraZeneca, Opioid Induced Constipation – D3820C00008 (KODIAC 8)
- 2011: Anchen Pharmaceuticals, Chronic Idiopathic Constipation – 71060001
- 2011: Impax Pharmaceuticals, Restless Legs Syndrome – IPX159-B11-02
- 2011: UCB, Restless Legs Syndrome in Adolescents – SP1004
- 2011: Bristol Myers Squibb, Type II Diabetes & Hypertension – MB102073
- 2011: Apotex Inc. – Chronic Idiopathic Constipation – LUBI-SGCP-05SB07-CE
- 2012: Synergy Pharmaceuticals, Chronic Idiopathic Constipation – SP304-20210
- 2012: UCB, Restless Legs Syndrome in Adolescents – SP1005
- 2012: Bristol Myers Squibb, Type II Diabetes & Hypertension – MB102077
- 2012: Forest Research Institute, Hypertension – NAC-MD-01
- 2012: Ardea BioSciences, Gout – RDEA594-301
- 2012: Orexigen, Obesity & Cardiovascular Outcomes – NB-CVOT
- 2012: Novartis, High Triglycerides – CLCQ908C2201
- 2012: Furiex Pharmaceuticals, Diarrhea Predominant Irritable Bowel Syndrome – 27018966IBS3001
- 2012: Lexicon Pharmaceuticals, Diarrhea Predominant Irritable Bowel Syndrome – LX1033-1.201

- 2012: Tioga Pharmaceuticals, Diarrhea Predominant Irritable Bowel Syndrome – ASMP3001
- 2012: Shionogi, Inc., Opioid Induced Constipation – 1107V9221
- 2012: Tsumura Pharmaceuticals, Crohn's Disease – TU100P2T2
- 2012: Coronado Biosciences, Crohn's Disease – CNDO-201-003
- 2012: Shire, GERD – SPD557-206
- 2012: UCB, Healthy Adult, Phase I – SP1031
- 2012: UCB, Restless Legs Syndrome – RL0003
- 2012: GSK, Restless Legs Syndrome – RXP114025
- 2013: Ardea BioSciences, Gout – RDEA594-306
- 2013: Dr. Reddy's Laboratories, Chronic Idiopathic Constipation – DRL-USG01-L/2012
- 2013: Purdue Pharma L.P., Chronic Low Back Pain & Opioid-Induced Constipation – ONU3705
- 2013: Cubist Pharmaceuticals, Inc., Opioid-induced Constipation – 5945-SOIC-12-05
- 2013: Cubist Pharmaceuticals, Inc., Opioid-induced Constipation – 5945-OIC-12-04
- 2013: Ferring International Pharmascience Center US, Inc., Chronic Idiopathic Constipation – 000080
- 2013: Ferring International Pharmascience Center US, Inc., Chronic Idiopathic Constipation – 000081
- 2013: Synergy Pharmaceuticals, Inc., Chronic Idiopathic Constipation (OLE CIC) – SP304203-01
- 2013: Shionogi, Inc., Opioid Induced Constipation – 1315V9232
- 2013: Menarini, Diarrhea-Predominant Irritable Bowel Syndrome – NAK-07 (IRIS-4)
- 2013: Synergy Pharmaceuticals, Inc., Chronic Idiopathic Constipation (CIC3) – SP304203-00
- 2014: Evoke, Diabetic Gastroparesis – METO-IN-003
- 2014: Evoke, Diabetic Gastroparesis – METO-IN-004
- 2014: Eisai, Long-Term incidence of MACE events & conversion to Type II Diabetes Mellitus in Obese & Overweight Subjects with Cardiovascular Disease or Multiple CV Risk Factors – APD356-G000-401
- 2014: Takeda Development Center Americas, Inc., Gout – FEB-XR_301
- 2014: Salix, Crohn's Disease – RECD3125
- 2014: Xenon, RLS Genetic Biomarker – XEN-RLS
- 2014: Targacept, Diabetic Gastroparesis – TC6499-12-CLP-005
- 2014: Alkermes, Schizophrenia & Schizoaffective Disorder – ALK9072-003
- 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: Alkermes, Schizophrenia & Schizoaffective Disorder – ALK9072-003EXT2

- 2015: Boehringer Ingelheim, Schizophrenia – 1289.6
- 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: Edgemont Pharmaceuticals, Generalized Anxiety Disorder – EDG004-003
- 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
- 2015: Ardelyx – IBS-C – TEN-01-301
- 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
- 2016: Applied Proteomics – Colorectal Cancer Screening – API-CP001
- 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: Janssen – Major Depressive Disorder – CNTO136MDD2001
- 2017: Allergan – Pediatric Major Depressive Disorder – LVM-MD-11
- 2017: Allergan – Diabetic Gastroparesis – RLM-MD-04
- 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 – 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
- 2020: Takeda – Idiopathic Hypersomnia – Phase 1 – TAK-925-2002
- 2020: Neurogastrx – Diabetic or Idiopathic Gastroparesis – NG101-201
- 2020: Allergan – Major Depressive Disorder – 2006-308-008
- 2020: Otsuka – Pediatric Attention Deficit Hyperactivity Disorder – 405-201-00010
- 2020: Apnimed – Obstructive Sleep Apnea – APN-006

- 2020: Janssen – Treatment-resistant Depression – 54135419TRD4005
- 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: BlackThorn – MDD with Anhedonia &/or GAD – K2-MDD-201
- 2021: Relmada – Major Depressive Disorder – REL-1017-302
- 2021: Relmada – Major Depressive Disorder – REL-1017-310

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. –

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

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

2021: Janssen – Treatment Resistant Depression Market Research – 54135419DEP4008

2021: Idorsia – Daridorexant Primary Market Research - Insomnia

Device:

05/2005: Respiroics Inc. – Efficacy of an Auto-Adjusting Bi-Level PAP Device for the Treatment of OSA. (MR-0409-AABL-XXXX)

11/2005: Respiroics Inc. – Evaluation of the M-Series REMStar Auto C-Flex Device for the Treatment of OSA. (MR-0519-AUTO-MS-G/W)

05/2006: Respiroics Inc. – Evaluation of the BIPAP Auto M-Series with Bi-flex Device for the Treatment of OSA (MR-0615-BASV-MS)

07/2006: Respiroics Inc. – The Impact of BIPAP Auto SV on OSA and Complex Sleep Apnea (MR-0634-FASV-MS)

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

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

10/2007: Respiroics Inc. – The Impact of BiPAP AutoSV™ on Central Disregulated Breathing & Chronic Pain Patients (MR-0728-ASV3-MS)

10/2007: Restore Medical, Inc. – A Randomized, Placebo-Controlled Study of the Pillar Palatal Implant System with CPAP (protocol 845)

01/2008: Respiroics Inc. – Stardust Screening Study (MR-0735-SDSS-MS)

02/2008: Respiroics Inc. – Evaluation of a Positive Air Pressure Delivery Systems on Adherence & Outcomes (System One versus Better Together MR-0733-SYS1-SS)

08/2008: Respiroics Inc. – Evaluation of Software Enhancements to the Respiroics BiPAP AutoSV device (MR-0731-ASV3-MS)

04/2009: Respiroics Inc. – User Preference & Validation Evaluation of the New BiPAP autoSV3 device (ST-0906-ASV3VAL-MS)

07/2009: Respiroics Inc. – Evaluation of the Q-Series Auto Device for the Treatment of OSA (ST-0925-AQVM-MS-G/W)

2/2010: Philips-Respiroics Inc. – Engineering Evaluation of the Next Generation of autoSV Devices (ST-0937-ASV4ENG-MS)

6/2010: Philips Respiroics – Evaluation of the Philips Respiroics BiPAP autoSV devices in subjects with Sleep Disorders (ST-1007-ASV4-MS)

12/2010: Philips Respiroics – Philips Respiroics BiPAP autoSV4 User Preference Trial (ST-1030-ASV4PREF-SS)

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

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

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

7/2012: Philips Respiroics – User Preference/Validation Evaluation of the New Phillips Respiroics 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)

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)

Training Documentation:

May 2020	American Heart Association BLS for Healthcare Providers (CPR & AED) Program
May 2020	IATA Training – Mayo Clinic
April 2020	Janssen – Handling Controlled Substances in Clinical Trials – 2020 Update version 1.0
March 2020	Pro-ficiency – Otsuka’s Good Clinical Practice Training, ICH E6 (R2)
February 2020	Virtual Trial Capable – VirTrial
February 2020	Medidata RAVE e-Consent
January 2020	Otsuka Syneos Safety Vigilance Training – Safety Notification Training v1.0
December 2019	iMedidata RAVE RTSM
December 2019	iMedidata RAVE eCOA
November 2019	Trialbee training in online recruitment & the Trialbee Candidate Manager

October 2019	Spaulding ECG training
October 2019	Covance Central Laboratory Service (CCLS) Procedures training
October 2019	Otsuka's Global Pharmacovigilance Safety Training
September 2019	C-SSRS Refresher training V.1.2 – Blue Cloud
September 2019	Premier DataLabs v5.6 Bridge Site Users
August 2019	Janssen/DrugDev ICH GCP Interventional Version 2.0
August 2019	Janssen/DrugDev Investigator Safety Training Interventional Version 4.0
August 2019	Janssen/DrugDev Handling Controlled Substances in Clinical Trials Version 1.0
June 2019	Allergan – Overall Lessons Learned_Best Practices_Preventing Deviations_17MAY2019 – Version 1.0
May 2019	Allergan – DDO Quality Practices – Version 1.0
April 2019	CTNI Certification – Biohaven – OCD Treatment Response Questionnaire (TRQ-OCD)
April 2019	CNTI Certification – Axsome – Structured Clinical Interview for DSM-5 (SCID-5)
April 2019	CTNI Certification – Axsome – Antidepressant Treatment Response Questionnaire (ATRQ)
April 2019	CTNI Certification – Biohaven – Brown Assessment of Beliefs Scale (BABS)
April 2019	DataLabs EDC Bridge for Site Users v5.4
March 2019	Medidata Rave EDC
March 2019	rED Cap Training – BioStat International, Inc.
March 2019	CTS Database training
February 2019	CTNI Certification – Axsome – Hamilton Rating Scale for Anxiety (HAM-A)

February 2019	CTNI Certification – Axsome – Brief Psychiatric Rating Scale (BPRS)
February 2019	CTNI Certification – Axsome – Hamilton Depression Scale (HAMD-17)
February 2019	CTNI Certification – Axsome – Clinical Global Impression (CGI-S/CGI-I)
February 2019	DataLabs Premier Study Coordinator v5.6
February 2019	Medidata Rave 360 Reports
January 2019	DataLabs EDC: Data Entry v5.6
October 2018	ICON/Firecrest ICH GCP (R2) Investigator Site Training – V2.0
October 2018	Health Decisions – LiveTrial Site training
October 2018	Rave EDC Essentials – All Roles
October 2018	Janssen/DrugDev/TransCelerate – ICH GCP Training V2.0
September 2018	SecureConsent Site Staff Training
September 2018	Oracle IRT 5.5 Sites training
September 2018	Oracle InForm 5.5 for Site Users training
September 2018	Oracle InForm 6.1 for Site Users training
July 2018	Medpace – ClinTrak EDC – Clinical Research Coordinator Training
July 2018	AbbVie – GCP: New Investigator & Trial Site Responsibilities Based on the ICH E6 (R2) Addendum training
July 2018	AbbVie/TransCelerate – Good Clinical Practice for Investigators & Trial Sites based on ICH E6 (R2) (online) Version 1
June 2018	Appendix M of the NIH Guidelines Reporting Requirement & Best Practices
June 2018	Allergan – Safety Reporting Clinical_NOV2016 – Version 3.0
June 2018	Allergan – IWRS Standard Training Version 1.0
June 2018	Allergan – CTMS Site Training Version 2
June 2018	Allergan – InForm EDC Fundamentals for Study Coordinators, V6.0

June 2018	Pro-ficiency, LLC (ProCT) – Otsuka Good Clinical Practice Training (ICH Guidelines for GCP E6 R2)
May 2018	American Heart Association BLS for Healthcare Providers (CPR & AED) Program
May 2018	IATA Training – Mayo Clinic
May 2018	University of Miami Health System – Human Subjects Research – Biomedical Refresher 1
May 2018	CITI Training – Group 1: Principal Investigators, Co-Investigators & Research Staff – Refresher Course
May 2018	Otsuka’s Good Clinical Practice Training, ICH E6 (R2)
April 2018	MedAvante Virgil training
April 2018	ProPhase ADHD-RS-IV certification
April 2018	ProPhase CGI-I/CGI-S certification
April 2018	ProPhase ADHS-RS-IV Preschool Version certification
April 2018	ProPhase Peabody Picture Vocabulary Test – Fourth Edition certification
April 2018	Clinical Ink SureSource, Insight, Capture & Coordinator Module training
March 2018	ProPhase Best Practices & PROs training
March 2018	ProPhase Movement Disorders (BARS, AIMS, SAS) certification
March 2018	ProPhase Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID) certification
March 2018	ProPhase Emory Treatment Resistance Interview for PTSD (E-TRIP) certification
December 2017	Bracket/Janssen – CDR System Qualification
November 2017	Bracket/Janssen – CGI-S/I Qualification; ISI Qualification; MMSE Qualification & PWC Qualification
November 2017	Janssen/DrugDev – Investigator Safety Training (IST) V4.0

October 2017	C-SSRS Refresher training v1.3 – 2 nd Refresher training – Blue Cloud
October 2017	INC GCP ICH E6, Rev 2 Changes for Site Personnel Working on Clinical Research Studies
September 2017	CAIRN Diagnostics: C-Spirulina GEBT Training
September 2017	DataLabs v5.4 EDC training
September 2017	ProPhase Best Practices Including Overview of Caregiver Scales
July 2017	Columbia- Suicide Severity Rating Scale Training/Certification
June 2017	National Institutes of Health web-based training on “Protecting Human Research Participants”
May 2017	ICON Firecrest ICH GCP (R2) training: Common Rule update
March 2017	DataTrak Training
October 2016	Bracket: CGI-S & M.I.N.I. certification
August 2016	Janssen eCRF-Trial Specific Training for Site Personnel & Investigator; Patient Reported Outcomes Site Training; HRUQ; Cogstate LTM/SM Training
July 2016	Data Labs v5.4 EDC Data Entry Training
May 2016	American Heart Association BLS for Healthcare Providers (CPR & AED) Program
May 2016	Sunovion Placebo Response Training, PRO Training (SDS, PSQI, BRIEF-A, DEQ, AIM-A, ASRS, TASS & AMSES), SMWQ & DESS Training
April 2016	IATA training
December 2015	Sunovion ICH/GCP training & CTS Database Training
November 2015	CNS Ratings LLC AIMS Certification
October 2015	Cogstate HVLTR Rater & Test Supervisor
October 2015	J&J ICH GCP Training – TransCelerate
October 2015	Janssen Investigator Safety Training version 2

September 2015	Clintara Rater Certification: IDS-C, CADSS, BPRS, PWC-20, MOAA/S, MCH-ATRQ, C-SSRS, MADRS, SIGH-A
July 2015	iMedidata Rave 5.6 EDC Essentials for Clinical Research Coordinators
April 2015	CITI Training
November 2014	SIGH-A, Covi Anxiety Scale, Raskin Depression Scale, CGI training & certification
September 2014	Medidata RAVE EDC & Balance
May 2014	American Heart Association BLS for Healthcare Providers (CPR & AED) Program
November 2013	PPD Oracle OCRDC 4.6.2 training
October 2013	TrialMaster, OmniComm Systems, Inc., eClinical Solutions for Life, EDC software eLearning Course: 4.1 Study Coordinator
October 2013	COWS (Central Opioid Withdrawal Scale) training – Shionogi, Inc.
October 2013	ERT ePRO training
October 2013	Annual Bloodborne Pathogens Training – Stericycle
July 2013	Numoda Study Coordinator Single Interface Training
July 2013	Quintiles ICH GCP training for Clinical Trial Sites
August 2012	Medidata RAVE 5.6 training: Certified Clinical Research Coordinator
August 2012	Oracle OCRDC training
May 2012	National Institutes of Health web-based training on “Protecting Human Research Participants”
May 2012	American Heart Association BLS for Healthcare Providers (CPR & AED) Program
March 2012	IATA training
November 2011	Columbia- Suicide Severity Rating Scale Training/Certification
July 2011	IATA training

December 2010	IntraLinks Clinical Reviewer v1.0 training
September 2010	InForm 4.6 Phase Forward training
July 2010	Quintiles ICH GCP training for Clinical Trial Sites
June 2010	National Institutes of Health web-based training on "Protecting Human Research Participants"
May 2010	ACRP Clinical Research Coordinator Certification Maintenance
April 2010	CPR & AED training
April 2009	IATA training
April 2008	ACRP Clinical Research Coordinator Certification Maintenance
December 2008	Pfizer OC-RDC 4.5.3 training
January 2008	Stericycle Blood Borne Pathogen training
December 2007	Pfizer Investigator Site Data Capture course
June 2007	HIPAA & Clinical Trials training
May 2007	IATA training
March 2007	Third Annual Pediatric Sleep Medicine conference: Next steps in research, patient care, policy & education (Warren Alpert Medical School of Brown University)
September 2006	IntraLinks Clinical Reviewer (v1.0) training
May 2005	CPR & AED Training
March 2005	IATA training
May 2003	GCP Manual/Code of Federal Regulations Review IATA Training CD Phlebotomy Training Informed Consent Training Vital Signs Training EKG Training Coordinator Training Video Job Shadowing Blood Borne Pathogen Training

CRF Training
SOP Manual Review and Sign-Off
Lab Processing Training
HIPAA Training