Curriculum Vitae

Terry Piedra, BS, CCRC

Professional Experience

2018-2025 Senior Director of Business Development
CenExel (Research Centers of America)
Hollywood, FL

2014-2017 Director of Business Development Vaccines
QPS MRA (Miami Research Associates)
Miami, FL

2009-2014 Project Manager, Vaccine Division
QPS MRA (Miami Research Associates)
Miami, FL

2002-2009 Senior Clinical Research Coordinator
QPS MRA (Miami Research Associates)
Miami, FL

Education and Post Graduate Training

2002-2006 Bachelor of Science, Health Services Administration (B.S.)
Barry University
Miami, FL

1996-1999 Associate in Arts
Miami Dade College
Miami, FL

Certifications

2005 ACRP Certified Clinical Research Coordinator Certification

Past Research Affiliation

CenExel Research Centers of America at Fort Lauderdale Behavioral Health Center
5757 N. Dixie Hwy
Oakland Park, FL 33334

CenExel Research Centers of America
7261 Sheridan Street, Suite 210
Hollywood, FL 33024

Clinical Research Experience

2024 **Icosavax:** A Phase 2, Randomized, Modified Double-Blind, Active Controlled Study to Characterize the Safety and Immunogenicity of XXXX in Adults 60 Years of Age and Older

2024 **Moderna:** A Phase 3, Randomized, Observer-blind, Active-controlled, Case-driven Study to Investigate the Safety, Efficacy, and Immunogenicity of XXXX Candidate Seasonal Influenza Vaccine Compared with a Licensed Inactivated Seasonal Influenza Vaccine in Adults ≥50 Years of Age

2024 **Moderna:** A Phase 2, Randomized, Observer-blind Study to Evaluate the Safety, Reactogenicity, and Immunogenicity in Relation to the Product Attributes of XXXXX (SARS-CoV-2 and Influenza) Vaccine in Adults ≥50 to <65 Years of Age

2024 **Moderna:** A Phase 3, Randomized, Observer-blinded, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXXX, A Multivalent Candidate Vaccine to Prevent Norovirus Acute Gastroenteritis in Adults ≥18 Years of Age

2024 **Pfizer:** A Study to Evaluate the Safety, Tolerability, and Immunogenicity of Modified RNA Vaccines Against Influenza in Healthy Adults

2024 **Vaxcyte:** A Phase 3, Randomized, Double-Blind, Active-Controlled Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of a 24-Valent Pneumococcal Conjugate Vaccine XXXX in Healthy Adults Aged 50 Years and Older with Immunobridging to Subjects 18–49 Years

2024 **Innorna:** A phase 1, Randomized, Multicenter, Observer-blind, Placebo- and/or Active-controlled Dose-ranging Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Herpes Zoster IN001 mRNA Vaccine (IN001) in Healthy Participants 50 Years and Older

2024 **Merck:** A Phase 1, Randomized, Double-Blind Study to Evaluate the Safety Tolerability, and Immunogenicity of XXXX Formulation XX in Healthy Adults

2024 **Merck:** A Phase 1, Randomized, Double-Blind, Comparator-Controlled, Dose-Escalation Trial to Evaluate Safety, tolerability, and Immunogenicity of XXXX in Healthy Adults

2024 **Merck:** A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Dose Escalation Trial to Evaluate Safety, Tolerability, and Immunogenicity of XXXX in Healthy Younger (18 to 49 Years Inclusive) and Healthy Older Participants (60 to 79 Years Inclusive)

2024 **Pfizer:** A Phase 1, Randomized, Observer-Blind Study to Evaluate the Safety and Tolerability of a Vaccine Candidate Against Respiratory Syncytial Virus in Healthy Individuals 18 through 49 Years of Age

2023 **GlaxoSmithKline:** A Phase 2 randomized, active-controlled, observer-blind study to assess the safety, reactogenicity, and immunogenicity of a booster dose of investigational COVID-19 XXXX vaccines in healthy adults who previously received a complete primary vaccination series with or without booster dose(s)

2023 **Icosavax**: A Phase 2a Randomized, Observer-blind, Placebo-controlled, Dosage Optimization, Multi-center Clinical Trial to Evaluate the Safety and Immunogenicity of XXXX, a Respiratory Syncytial Virus and Human Metapneumovirus Bivalent Combination Virus-like Particle Protein Subunit Vaccine, in adults 60 to 85 Years of Age

2023 **Moderna:** A Phase 2, randomized, active-controlled, observer-blind, dose-ranging study to evaluate the safety, reactogenicity and immunogenicity of XXXX vaccine candidate variations in healthy adults 18 to 49 years of age.

2023 **Moderna:** A Phase 3, randomized, observer-blind, active-control study to evaluate the safety, reactogenicity, and immunogenicity of XXXX (SARS-CoV-2 and influenza) vaccine in healthy participants.

2023 **Moderna:** A Phase 3 Study to Evaluate the Immunogenicity and Safety of XXXX, an XXXX Vaccine Targeting Respiratory Syncytial Virus, in High-risk Adults

2023 **Moderna:** A randomized, observer-blind, active-controlled Phase 3 study to investigate the safety, immunogenicity, and relative vaccine efficacy of XXXX administered as a booster dose compared with XXXX in participants aged 12 years and older for the prevention of COVID-19

2023 **Novavax:** A Phase 3 Study to Evaluate the Immunogenicity and Safety of Novavax COVID-19 Vaccine(s) as Second or Subsequent Boosters After XXXX Vaccines in Individuals 18 to 49 Years of Age

2023 **Pfizer:** A Phase 3, Randomized, Observer-Blinded Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Combined Modified XXXX Vaccine Candidate Against COVID-19 And Influenza in Healthy Individuals

2023 **Immorna Biotherapeutics, Inc.:** A Phase 1 Randomized, Double-Blinded, Active-Controlled, 2-Dose Study to Assess the Safety and Immunogenicity of a Herpes Zoster (HZ) Vaccine, XXXX, in Healthy Subjects 50 to 69 Years of Age.

2023 **Merck:** A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Dose Escalation Trail to Evaluate Safety, Tolerability, and Immunogenicity of XXXX in Healthy Younger (Ages>18-49 Years) and Healthy Older Participants (Ages >60-79 Years)

2023 **Moderna:** A Phase 1, randomized, placebo-controlled, observer-blind, dose-ranging study to evaluate the safety, reactogenicity, and immunogenicity of XXXX and XXXX, multivalent candidate vaccines to prevent Norovirus acute gastroenteritis in healthy adults 18 to 49 years of age and 60 to 80 years of age.

2023 **Moderna:** Phase 1/2, randomized, observer-blind, parallel, dose-ranging study to evaluate the safety, reactogenicity, and immunogenicity of XXXX pandemic influenza candidate vaccines in healthy adults ≥18 years of age.

2023 **Moderna:** A Phase 1/2, Randomized, Observer-blind, Active-Control Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-based Influenza and SARS-CoV-2 Multi-component Vaccines in Healthy Adults

2023 **Moderna:** A Phase 1/2, randomized, open-label study to evaluate the safety, reactogenicity, and immunogenicity of XXXX, XXXX and XXXX candidate seasonal influenza vaccines in healthy adults 50 to 75 years of age.

2023 **Pfizer:** A Phase 1, Randomized, Double-Blind, Study of the Safety and immunogenicity of a Multivalent Pneumococcal Conjugate Vaccine with an Adjuvant Administered in Adults 50 through 64 Years of Age

2023 **Pfizer:** A Phase 1, Randomized, Double-Blind Study of the Safety and Immunogenicity of a Multivalent XXXX Vaccine with a novel Adjuvant administered in adults 50 Through 64 Years of Age

2023 **Public Health Vaccines Inc.:** A Phase 1b Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Safety and Immunogenicity of a Prime-Boost Regimen of Three Dose Levels of XXXX, a Nipah Virus Vaccine Candidate (XXXXX) in Healthy Adults

2023 **Public Health Vaccines Inc.:** A Phase 1 Randomized, Single-Blind, Placebo Controlled, Ascending Dose Study to Evaluate the Safety and Immunogenicity of XXXX [Angola] (XXXX) in Healthy Adults a Marburg vaccine.

2023 **Sanofi:** A Phase I/II study to investigate the safety and immunogenicity of Quadrivalent Influenza mRNA Vaccines XXXX, XXXX, and XXXX in healthy participants aged 18 years and above.

2023 **Vaxcyte:** A Phase 1/2, Randomized, Observer-Blind, Dose-Finding, Active-Controlled, Parallel-Group, 2-Stage Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of a 31-Valent Pneumococcal Conjugate Vaccine (XXXX) in Healthy Adults Aged 50 Years and Older

2022 **Merck:** An Open-Label, Single-Dose Clinical Study to Evaluate the Pharmacokinetics of XXXX in Participants with Moderate Hepatic Impairment.

2022 Phase 3, randomized, 28-day, double-blind, placebo-controlled, multicenter study to assess the safety and efficacy of XXXX in subjects with acute exacerbation of schizophrenia trial, followed by a 52-week open-label extension.

2022 Double-blind, placebo-controlled, randomized withdrawal study to evaluate XXXX physical dependence in adult subjects with schizophrenia.

2022 **Prothena:** A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Study to Evaluate Safety, Tolerability, Immunogenicity, and Pharmacokinetics of PRX012 in Healthy Volunteers and Patients with Alzheimer's Disease.

2022 **Novavax:** A Randomized, Observer-Blinded, Phase 3 Study to Compare the Safety, and Immunogenicity of 3 Lots of XXXX in Adults; IND.

2022 **Pfizer:** A Phase 3, Randomized, Observer-Blinded Study to Evaluate the Relative Safety, Tolerability, Efficacy, and Immunogenicity of a modified XXXX vaccine against influenza compared to a licensed Inactivated Influenza Vaccine in Healthy Adults >65 Years of Age study.

2022 **Neurogastrx:** A Phase 3 Randomized, Double-blind, Active-controlled, Parallel-Goup Study of the safety and efficacy of XXXX administered Orally to Participants with Erosive Esophagitis.

2022 **Alnylam:** A Randomized, Double-blind, Placebo-Controlled, Dose-Ranging Multicenter Study to Evaluate the Efficacy and Safety of XXXX in Patients with Mild-to-Moderate Hypertension.

2022 **Moderna:** Exploratory study to assess the use of wearable digital sensors after mRNA vaccination in healthy adults.

2022 **Moderna:** Study to Evaluate the Safety, Reactogenicity and Immunogenicity of Modified XXXX Vaccines Using a Systems Biology Approach in Healthy Adults.

2022 **Sanofi:** A Phase I, parallel, randomized, active-controlled, multi-center, dose-escalation study with early safety data reviews to assess safety and immunogenicity of a monovalent XXXX vaccine encoding influenza hemagglutinin in adults 18 years of age and older.

2022 **Vaxcyte:** A Phase 2, Randomized, Observer-Blind, Dose-Finding, Controlled Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of a 24-Valent Pneumococcal Conjugate Vaccine XXXX in Healthy Adults 65 Years and Older.

2022 **Moderna:** Phase 1/2, randomized, stratified, observer-blind study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1073 (SARS-CoV-2 and influenza vaccine) compared to co-administered XXXXXX (influenza) and mRNA-1273 (SARS-CoV-2) vaccines and to mRNA-1010 vaccine and XXXXX vaccine alone in healthy adults 18-75 years of age.

2022 **Otonomy:** A Randomized, Double-Blind, Placebo-Controlled Phase 1 Safety Study of a Single-Dose of XXXX Given as a Single Unilateral or Bilateral Intratympanic Injection in Subjects with Subjective Tinnitus.

2022 **Lundbeck:** Interventional, randomized, double-blind, placebo-controlled, single-ascending-dose study investigating the safety, tolerability, and pharmacokinetic properties of Lu XXXX in healthy subjects and patients with Alzheimer's disease.

2022 **Pfizer:** A Phase 1, Open-Label, Randomized, Single Dose, 2-Way Crossover Study Assessing Pharmacokinetic Comparability of two XXXX Presentation, On-Body Injector and Prefilled Syringe, In Healthy Participants.

2022 **Vaxcyte:** A Phase 1/2a Randomized, Observer-Blind, Dose-Finding, Controlled, Parallel-Group, Two-Stage Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of a 24-Valent Pneumococcal Conjugate Vaccine in Healthy Adults Aged 18 to 64 Years.

2022 **Apnimed:** Phase 2 Randomized Double-Blind Placebo-Controlled Parallel-Arm Dose Finding Study to Compare Fixed Dose Combinations of XXXX and XXXX to XXXX alone or Placebo in Obstructive Sleep Apnea.

2022 **Moderna:** A Phase 1, Randomized, Observer-Blind, Placebo-Controlled, Dose-Ranging Study of an Epstein-Barr Virus (EBV) Candidate Vaccine, mRNA-XXXX, in 18- to 30-year-old Healthy Adults.

2021 Randomized, double-blind (patient, investigator), placebo-controlled, dose-escalation study on safety, tolerability, pharmacokinetic and preliminary efficacy of XXXX as adjunctive therapy in patients with major depressive disorder after single oral dosing.

2021 Randomized, double-blind, placebo-controlled, parallel-group study of XXXX for the prevention of relapses in patients with schizophrenia.

2021 Double-blind, placebo-controlled, randomized dose-ranging trial to investigate efficacy and safety of intravenous XXXX infusion in addition to comprehensive standard of care on the rapid reduction of symptoms of Major Depressive Disorder in subjects who have suicidal ideation with intent.

2021 Two-part Phase 2 study to assess the efficacy, safety, and tolerability of XXXX administered to adults with major depressive disorder at imminent risk of suicide.

2021 Randomized, single-blind, two-period crossover to investigate the effect of XXXX on the Pharmacokinetics of Metformin in subjects with schizophrenia.

2021 Phase 3, randomized, observer-blind study to evaluate the lot consistency, safety, tolerability, and immunogenicity of the vaccine XXXX against COVID-19 in healthy adults 18 through 55 years of age.

2021 **Otonomy:** A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of OTOXXXX Given as a single Intratympanic Injection in Subjects with Unilateral Subject Tinnitus.

2021 **Otonomy:** A Randomized, Double-Blind, Placebo-Controlled Phase 1/2 Study of OTOXXXX Given as a Single Intratympanic Injection in Subjects with Speech-In-Noise Hearing Impairment.

2021 **Janssen:** A Double-Blind, Placebo-Controlled, Randomized, Multipart, Single and Multiple Ascending Dose Study to Investigate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Subcutaneously Administered JNJ-XXXX.

2021 **Pfizer:** A Phase 1, Open-Label, Fixed-Sequence, 2-Perios Study to Estimate the Effect of Multiple Dose Abrocitinib on The Pharmacokinetics of Single Doses of Caffeine, Efavirenz, And Omeprazole in Healthy Participants.

2021 **Pfizer:** A Phase 1, Open-Label, 3-Treatment, 6-Sequence, 3 Period Crossover Study to Estimate the Effect of PF-07321332/XXXXXXXXX and XXXXXXXXX on the Pharmacokinetics of Dabigatran in Healthy Participants.

2021 **Moderna:** A Phase 2, randomized, stratified, observer-blind study to evaluate the immunogenicity and XXXX, XXXX, and XXXX vaccines for SARS-CoV-2.

2021 **Moderna:** A Phase 2/3 Study to Evaluate the Immunogenicity and Safety of mRNA Vaccine Boosters for SARSCoV2 Variants.

2021 **Sanofi:** Immunogenicity and Safety of SARS-CoV-2 Recombinant Protein Vaccines with AS03 Adjuvant in Adults 18 Years of Age and Older as a Primary Series and Immunogenicity and Safety of a Booster Dose of SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (two Monovalent and one Bivalent).

2021 **Sanofi:** Safety and Immunogenicity of a First In-Human Influenza XXXX Vaccine in Healthy Adults Aged 18 to 49 Years.

2021 **GSK:** A Phase III, randomized, open label, controlled, multi-center study to evaluate the immune response and safety of both herpes zoster subunit vaccine in healthy adults aged 50 years and older AND the influenza virus vaccine in healthy adults aged 18 years and older when administered sequentially or co-administered with XXXX booster vaccination.

2021 **GSK:** First Time-in Human (FTiH), randomized, observer-blind, placebo-controlled, dose escalation study to assess safety, reactogenicity and immunogenicity of a candidate cytomegalovirus (CMV) vaccine comprising recombinant protein and adjuvant when administered intramuscularly in healthy adults.

2021 **Medicago:** A Randomized, Observer-Blind, Placebo-Controlled, Phase 2/3 Study to Assess the Safety, Efficacy, and Immunogenicity of a Recombinant Coronavirus-Like Particle COVID-19 Vaccine in Adults 18 Years of Age or Older.

2021 **Moderna:** A Phase 1/2 , Randomized, Stratified, Observer-Blind, Dose Ranging Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-XXXX Seasonal Influenza Vaccine in Healthy Adults 18 Years and Older.

2021 **Janssen:** A Randomized, Double-blind, Phase 2 Study to Evaluate the Immunogenicity, Reactogenicity and Safety of XXXX Administered as Booster Vaccination in Adults 18 Years if Age and Older Who Have Previously Received Primary Vaccination with XXXX or XXXX.

2021 **Janssen:** A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Evaluate the Immunogenicity and Safety of XXXX.preF-based Vaccine and High-dose Seasonal Influenza Vaccine, With and Without Coadministration, in Adults Aged 65 Years and Older.

2021 **Pfizer:** A phase 3, randomized, double-blind trial to describe the safety and immunogenicity of 20-valent pneumococcal conjugate vaccine when co-administered with a booster dose of XXXX in adults 65 years of age and older.

2021 Pfizer: A Phase 3 Master Protocol to Evaluate Additional Dose(S) of XXXX in Healthy Adults Previously Vaccinated with XXXX.

2021 **Eisai:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 2-Period, Crossover Study to Evaluate the Respiratory Safety of XXXX in Adult and Elderly Subjects with Moderate to Severe Obstructive Sleep Apnea and Adult and Elderly Subjects With Moderate to Severe Chronic Obstructive Pulmonary Disease.

2021 **Pfizer:** A Phase 1, Randomized, Open-Label, Cross-Over, Single-Dose Study to Evaluate the Bioequivalence of Candidate Capsule Formulations of XXXXXXX to Tables and Estimate the Effect of High-Fat Meal on Bioavailability in Healthy Participants.

2021 **Merck:** A Clinical Trial to Study the Effect of a Single Dose of XXXXX (XX) on the Pharmacokinetics of Methadone.

2021 **Pfizer:** A Phase 3, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Lyophilized formulation of the vaccine candidate XXXX against COVID-19 in Healthy Adults 18 Through 55 Years of Age.

2021 **Pfizer:** A Phase 3, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, And Immunogenicity of Multiple Production Lots and Dose Levels of the Vaccine Candidate XXXX Against COVID-19 In Healthy Participants 12 Through 50 Years of Age.

2021 **Intra-Cellular:** An Open-label Multiple Dose Study to Determine the Pharmacokinetics, Safety, and Tolerability of XXXXX in Patients, Ages 13 to 17 Years, Diagnosed with Schizophrenia or schizoaffective disorder.

2021 **Kymera:** A Phase 1 randomized, placebo-controlled, single and multiple ascending dose trial to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of orally administered KTXXXXX in healthy adult volunteers and patients with atopic dermatitis (AD) or hidradenitis suppurativa (HS).

2020 Phase 3, randomized, double-blind, parallel-group, placebo-controlled, multicenter study to evaluate the efficacy and safety of XXXX in acutely psychotic hospitalized adults with DSM-5 schizophrenia.

2020 Open-label extension study to assess the long-term safety, tolerability and efficacy of XXXX in subjects with DSM-5 schizophrenia.

2020 Phase 2B placebo/active-controlled XXXX in schizophrenia.

2020 A multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of iloperidone for 4 weeks in the treatment of patients with acute manic episodes associated with Bipolar I Disorder.

2020 Phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of sars-cov-2 XXXX vaccine candidates against covid-19 in healthy individuals.

2020 Randomized, subject and investigator-blinded, placebo controlled, cross-over, multi-center Proof of Concept (PoC) study to assess the wakefulness promoting effect, safety, tolerability, and pharmacokinetics of XXXX in shift work disorder (SWD) patients.

2020 Phase 1, open-label, randomized, single ascending dose trial to determine the pharmacokinetics, safety, and tolerability of XXXX long acting injectable in adult subjects with schizophrenia.

2020 Phase 1, open label, randomized, single ascending dose trial to determine the pharmacokinetics, safety, and tolerability of XXXX long acting injectable in adult subjects with schizophrenia.

2020 **Janssen:** A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of XXXX for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older.

2020 **Novavax:** A Phase 3, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant in Adult Participants ≥ 18 Years with a Pediatric Expansion in Adolescents (12 to < 18 Years).

2020 **Sanofi:** Immunogenicity and Safety of SARS-CoV-2 Recombinant Protein Vaccine Formulations (with or without adjuvant) in Healthy Adults 18 Years of Age and Older.

2020 **Merck:** A Phase 1/Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Trial to Evaluate the Safety, Tolerability and Immunogenicity of XXXX (COVID-19 Vaccine) in Healthy Younger and Older Participants.

2020 **Pfizer:** A Phase 1/2 Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to describe the safety, Tolerability, Immunogenicity, and Potential Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Adults ('Study') to be conducted at the Institution under the Pfizer Protocol identified above ('Protocol').

2020 **Moderna:** A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-XXXX SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older.

2020 **Lundbeck:** Interventional, randomized, double-blind, sequential-group, placebo-controlled, single-ascending-dose study investigating the safety, tolerability and pharmacokinetic and pharmacodynamic properties of Lu XXXX in healthy non-Japanese and Japanese subjects and in patients with Parkinson's disease.

2020 **Seqirus:** A Phase 2, Randomized, Stratified, Observer-Blind Clinical Study to Evaluate Safety and Immunogenicity of the MXXXXX-Adjuvanted Quadrivalent Subunit Inactivated Cell-derived Influenza Vaccine (XXXX) in adults ≥50 years of age.

2020 **Imbrium:** A Phase 2, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group Study to Evaluate Safety, Tolerability, and Efficacy of XXXX in Subjects with an Alcohol Use Disorder who are Experiencing Insomnia Associated with Alcohol Cessation.

2020 **Takeda:** A Phase 1b Randomized, Double-Blind, Placebo-Controlled, Crossover Study of a Single Intravenous Infusion Dose of XXXX in Patients with Idiopathic Hypersomnia.

2020 **Sanofi:** Safety and Efficacy of 4 Investigational HSV-2 Vaccines Administered by Intramuscular Route in Adults with Recurrent Genital Herpes Caused by HSV-2.

2020 **Phathom:** A Phase 3, Randomized, Double-Blind, Two-Phase, Multicenter Study to Evaluate the Efficacy and Safety of Vonoprazan 20 mg Compared to Lansoprazole 30 mg for Healing in Patients with Erosive Esophagitis and to Evaluate the Efficacy and Safety of Vonoprazan (10 mg and 20 mg) Compared to Lansoprazole 15 mg for the Maintenance of Healing in Patients with Healed Erosive Esophagitis.

2020 **Phathom:** A Phase 3 Randomized Multicenter Study to Evaluate the Efficacy and Safety of Open-Label Dual Therapy with Oral Vonoprazan 20 mg or Double-Blind Triple Therapy with Oral Vonoprazan 20 mg Compared to Double-Blind Triple Therapy with Oral Lansoprazole 30 mg Daily in Patients with Helicobacter Pylori Infection.

2020 **Sanofi:** Safety and Immunogenicity of an Investigational Meningococcal Group B Vaccine in Healthy Adults.

2020 **Otsuka:** A Phase 1b, Multicenter, Open-label, Multiple Ascending Dose Trial to Assess the Pharmacokinetics, Safety and Tolerability of Centanafadine Extended-release Capsules after Oral Administration in Pediatric Subjects (4 to 12 years, inclusive) with Attention-deficit/Hyperactivity Disorder.

2020 **Sage:** A Phase 3 Multicenter, Double-Blind, Randomized, Placebo-Controlled Study Evaluating The Efficacy Of Sage-XXXX In The Treatment of Adult Subjects with Major Depressive Disorder.

2020 **Supernus:** A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Flexible-Dose Study of the Efficacy and Safety of XXXX in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD).

2020 **Supernus:** An Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of XXXX in Adults with Attention-Deficit/Hyperactivity Disorder.

2020 **Jazz:** A 12-Week, Double-blind, Placebo-controlled, Randomized, Parallel-Group, Multicenter Study of the Efficacy and safety of XXXX (XXXX) to Improve Wakefulness in Adult Patients with Excessive Daytime Sleepiness Associated with Major Depressive Disorder with a 40-Week Open-Label Safety Extension and Randomized withdrawal Period.

2019 Lot consistency trial of XXXX for anthrax prophylaxis.

2019 Major depressive disorder trial of XXXX.

2019 Acute suicidal ideation in bipolar depression study.

2019 Non-alcoholic fatty liver disease study of XXXX + XXXX.

2019 XXXX in acutely psychotic schizophrenia patients.

2019 **Merck:** A Phase 2a, Double-Blind, Placebo-Controlled Study to Evaluate Safety, Tolerability, and Pharmacokinetic Pharmacokinetics of Oral MK-XXXX Once-Monthly in Participants at Low-Risk for HIV-1 Infection.

2019 **FluGen:** Phase lb clinical study to investigate the safety and immunogenicity of the Bris l0 (A/Brisbane/10/2007) M2SR and Sing2016 (A/Singapore/INFIMH-16-0019/2016

2019 **Novavax:** A Phase 3, Randomized, Observer-Blinded, Active-Controlled Trial to Evaluate the Immunogenicity and Safety of a Recombinant Quadrivalent Nanoparticle Influenza Vaccine (Quad-NIV) with XXXX™ Adjuvant Against Fluzone® Quadrivalent in Clinically Stable Adults ≥ 65 Years of Age.

2019 **Astellas:** A Phase 1/2, Randomized, Single Ascending Dose Study in Adults (Stage 1) and Randomized, Single Ascending Dose-Finding Study (Stage 2) in Elderly Subjects with XXXXX, a Pneumococcal Vaccine.

2019 **Satsuma:** A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Single Doses of XXXX (Dihydroergotamine Nasal Powder) in the Acute Treatment of Migraine.

2019 **Emergent:** A Phase 3, Randomized, Double-blind, Parallel-group Trial to Evaluate the Lot Consistency, Immunogenicity, and Safety of XXXX for Postexposure Prophylaxis of Anthrax in Healthy Adults.

2019 **Merck:** A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of XXXX in Healthy Adults 50 Years of Age or Older.

2019 **Merck:** A Phase 1/Phase 2, Randomized, Double-blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Polyvalent Pneumococcal Conjugate Vaccine in Adults.

2019 **Pfizer:** A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of A 20-Valent Pneumococcal Conjugate Vaccine-Naïve Adults 18 Years of Age and Older.

2019 **Sanofi:** Safety and Immunogenicity of Quadrivalent Recombinant Influenza Vaccine Formulations Containing Different H3 Hemagglutinin Antigens in Healthy Adult Subjects 18 to 30 Years of Age.

2019 **Moderna:** A Phase 1, Randomized, Observer-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Cytomegalovirus Vaccines XXXXX and XXXXX When Administered to Healthy Adults.

2019 **Axsome:** MOMENTUM (Maximizing Outcomes in Treating Acute Migraine): A Randomized, Double-blind, Single-dose, Placebo-controlled Study to Assess the Efficacy and Safety of XXXXX (meloxicam and rizatriptan) for the Acute Treatment of Migraine in Adults.

2019 **Sage:** A Randomized, Double-Blind, Placebo-Controlled Study of Safety, Tolerability, and Efficacy of XXXX Compared to Placebo in Adult Subject with Comorbid Major Depression Disorder and Insomnia.

2018 **Idorsia:** Multi-center, double-blind, randomized, placebo-controlled, parallel-group, polysomnography study to assess the efficacy and safety of XXXXXX in adult and elderly subjects with insomnia.