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**AFFILIATIONS:**

Fiel Family and Sports Medicine, PC/CCT Research  
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Tempe, AZ 85283

**EDUCATION:**

1992-93 Sports Medicine Fellow  
Center for Sports Medicine & Orthopedics, Phoenix, AZ

1985-89 Doctor of Osteopathic Medicine  
Kirksville College of Osteopathic Medicine, Kirksville, MO

1977-84 A.S. Respiratory Therapy  
A.S. Nursing, Premedical Sciences; Sinclair Community College, Dayton, OH

**INTERNSHIPS AND RESIDENCIES:**

1990-92 Family Practice Resident  
Grandview Hospital & Medical Center, Dayton, OH

1989-90 Family Practice Intern  
Grandview Hospital & Medical Center, Dayton, OH

**LICENSURE:**

1992: Arizona License # 2665

**CERTIFICATION:**

1993-present American Osteopathic Board of Family Physicians Board Certified  
1990 American Osteopathic Academy of Sports Medicine  
1989 American Osteopathic Association

**PROFESSIONAL EXPERIENCE:**

*Principal Investigator*, 2018 – present  
CCT Research, Scottsdale, AZ

*Physician*, 2006 – present  
Fiel Family and Sports Medicine, PC, Tempe, AZ

*Principal Investigator*, 1997 – 2018  
Radiant Research, Inc./ Clinical Research Advantage, Inc., Tempe, AZ

*Physician*, 1993 – 2006  
Fiel Family and Sports Medicine, PC/Page Family Practice, PLLC, Tempe, AZ  
(Previously Tempe Primary Care Associates)

*Registered Nurse – Cardiac ICU*, 1984 – 1986  
Grandview Hospital & Medical Center, Dayton, OH

*Registered Nurse – ICU*, 1982 – 1984  
Good Samaritan Hospital, Dayton, OH

*Respiratory Therapist*, 1979 – 1982  
Good Samaritan Hospital, Dayton, OH

**INVESTIGATOR EXPERIENCE:**

Allergy • Asthma • Attention-Deficit Hyperactive Disorder • Cardiovascular • Chronic Pain  
COVID-19 (Diagnosis, Treatment & Vaccines) • Device • Hypercholesterolemia • Hypertension  
Hypertriglyceridemia • Immunogenicity • Influenza • Insomnia  
Irritable Bowel Syndrome (Diarrhea) • Men’s Health • Migraine • Osteoarthritis • Osteoporosis  
Pain • Post Herpetic Neuralgia • Respiratory • Rheumatoid Arthritis • Type 2 Diabetes  
Vaccines • Women’s Health

**ADDITIONAL INTEREST:**

Allergy • Cardiology • Chronic Heart Failure • Chronic Obstructive Pulmonary Disease  
Chronic Regional Pain Syndrome • Collection Studies • Coronary Artery Disease  
Deep Venous Thrombosis • Dermatology • Devices • Endocrinology • Gastroenterology  
Geriatrics • Gout • Hyperlipidemia • Immunology • Infectious Disease • Metabolic

**ADDITIONAL INTEREST (*continued*):**

Musculoskeletal • Nutrition • Obesity • Orthopedics • Pain  
Oncology (Diagnostic studies and cancer pain) • Pulmonology • Rheumatology • Urology

**CLINICAL TRIAL EXPERIENCE:**

***Arthritis***

A Long Term Follow-Up of Patients with Moderate to Severe, Painful Osteoarthritis of the Knee who Participated in a Randomized, Placebo-Controlled Study of XXX

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study of XXX in Moderate to Severe, Painful Osteoarthritis of the Knee

A Phase IIb, Prospective, Double-blinded, Randomized Controlled Trial of the Micronized Dehydrated Human Amnion Chorion Membrane Injection as Compared to Saline Placebo Injection in the Treatment of Osteoarthritis of the Knee

A Phase III, Randomized, Double-blind, Multi-Dose, Placebo-Controlled Study to Evaluate the Long-Term Safety and Efficacy of XXX in Patients with Pain Due to Osteoarthritis of the Knee or Hip

A Phase II, Multicenter, Randomized, Double-blinded (Within Dose), Placebo-Controlled, Parallel-Group, Dose-Range-Finding Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of XXX vs Placebo in Subjects with Mild to Moderate Osteoarthritis of the Knee

A Phase III, Multi-Center, Randomized, Double-blind, Placebo Controlled Clinical Use Study to Evaluate the Safety and Tolerability of XXX Administered Intravenously to Subjects with Active Rheumatoid Arthritis (RA) With or Without Medical Co-Morbidities Receiving Disease Modifying Anti Rheumatic Drugs (DMARDs) and/or Biologics Approved for RA

A Phase III, Multi-Center, Randomized, Double-blind, Placebo Controlled Clinical Use Study to Evaluate the Safety and Tolerability of XXX Administered Intravenously to Subjects with Active Rheumatoid Arthritis (RA) With or Without Medical Co-Morbidities Receiving Disease Modifying Anti Rheumatic Drugs (DMARDs) and/or Biologics Approved for RA

A Phase III, Multi-Center, Randomized, Double-blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of XXX in Combination with XXX vs. XXX Alone in Subjects with Active Rheumatoid Arthritis and Inadequate Response to Methotrexate XXX

A Long-Term Safety Study of XXX in Comparison to Oral XXX for the Treatment of Osteoarthritis of the Knee

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Randomized, Double-blind, Parallel-Group Study Of Cardiovascular Safety In Osteoarthritis or Rheumatoid Arthritis Patients With or at High Risk for Cardiovascular Disease Comparing XXX with XXX and XXX

A Phase III, Randomized, Double-blind, Multi-dose, Placebo-controlled Study to Evaluate the Long-term Safety and the Efficacy of XXX in Patients with Pain due to Osteoarthritis of the Knee or Hip

A Phase II, Multicenter, Randomized, Double-blind (within dose), Placebo-controlled, Parallel-group, Dose-range-finding Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of XXX Spray vs. Placebo in Subjects with Mild to Moderate Osteoarthritis of the Knee

***Asthma***

A Phase III, Multicenter, Randomized, Parallel-group, Placebo-controlled, 4-week Clinical Endpoint Bioequivalence Study Comparing XXX Inhalation Powder With XXX in Asthma Patients

***COVID-19 (Diagnosis, Treatment, and Vaccines)***

A Phase II/III, Randomized, Observer-Blind, Placebo-Controlled, Study to Assess the Safety, Efficacy, and Immunogenicity of a XXX COVID-19 Vaccine in Adults 18 Years of Age or Older and Children and Adolescents 5-17 Years of Age

A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study and Sub-study in Adults to Determine the Safety, Efficacy, and Immunogenicity of XXX, a XXX Vaccine, for the Prevention of COVID-19

A Phase II, Multicenter Adaptive Randomized Double-Blind Placebo Controlled Platform Trial of the Efficacy and Safety of XXX in COVID-19 Adults not Requiring Hospitalization at Time of Diagnosis

A Multicenter Study Conducted to Evaluate the Performance and Usability of the XXX COVID-19 Antigen Home Test

A Phase II, Randomized, Double-blind, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of Mono and Combination Therapy with Monoclonal Antibodies in Participants with Mild to Moderate COVID-19 Illness

A Randomized, Placebo-Controlled, Phase II Study to Evaluate the Efficacy and Safety of XXX in Participants with Early Mild to Moderate COVID-19 Illness

**CLINICAL TRIAL EXPERIENCE (*continued*):**

***Device***

Observational Study of Sub-populations from "A Longitudinal Study of XXX in an Average Risk Population Assessing a Three Year Test Interval" - Post-Approval Study

Blood and Stool Sample Collection in Subjects Participating in Colorectal Cancer Screening

Observational Study of Sub-populations from "A Longitudinal Study of XXX in an Average Risk Population Assessing a Three Year Test Interval" – Post-Approval Study

Evaluation of the Clinical Specificity of the Active Anthrax XXX Lateral Flow Immunoassay (LFI)

***Diabetes***

A Phase IIIb, Randomized, Active Comparator, Open-label, Multicenter Study to Compare the Efficacy, Safety, and Tolerability of XXX to XXX and to XXX as Add-On Therapy to XXX in Patients with Type 2 Diabetes

Efficacy and Safety of XXX Once-Weekly versus Placebo as Add-On to XXX in Subjects with Type 2 Diabetes Mellitus

A Real-World, Point-of-Care, Randomized, Parallel Group, Open, 6-Month Clinical Study to Evaluate the Effect of a Digital Disease Management Tool in Patients with Type 2 Diabetes Mellitus

Efficacy in Controlling Glycaemia with XXX as Add-On to XXX vs. XXX as Add-On to XXX After Up to 104 Weeks of Treatment in Subjects with Type 2 Diabetes Inadequately Controlled with XXX Monotherapy and Treated in a Primary Care Setting

A Long Term, Randomized, Double-blind, Placebo-Controlled Study to Determine the Effect of XXX, When Added to Standard Blood Glucose Lowering Therapies, on Major Cardiovascular Events in Patients with Type 2 Diabetes Mellitus

A 52-Week International, Multicenter, Randomized, Double-blind, Active-Controlled, Parallel Group, Phase IIIb Trial with a Blinded 104-Week Long-Term Extension Period to Evaluate the Efficacy and Safety of XXX Co-Administered with XXX in Combination with XXX Compared to XXX in Combination with XXX in Adult Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on XXX Therapy Alone

A Randomized, 30-Week, Active-Controlled, Open-label, 2-Treatment Arm, Parallel-Group, Multicenter Study Comparing the Efficacy and Safety of the XXX Fixed Ratio Combination to XXX with or without XXX in Patients with Type 2 Diabetes Mellitus (T2DM)

**CLINICAL TRIAL EXPERIENCE (continued):**

A Randomized, 30-Week, Active-Controlled, Open-label, 3-Treatment Arm, Parallel-Group, Multicenter Study Comparing the Efficacy and Safety of the XXX Fixed Ratio Combination to XXX Alone and to XXX Alone on Top of XXX in Patients with Type 2 Diabetes Mellitus (T2DM)

A Multicenter, Randomized, Double-blind, Placebo-Controlled, Parallel Group, Phase III Trial to Evaluate the Safety and Efficacy of Once Weekly XXX Therapy Added to Titrated Basal XXX Compared to Placebo Added to Titrated Basal XXX in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Basal XXX with or Without XXX

A 28-Week, Multicenter, Randomized, Double-blind, Active-Controlled, Phase III Study With a 24-Week Extension Phase to Evaluate the Efficacy and Safety of Simultaneous Administration of XXX Once Weekly 2 mg and XXX Once Daily 10 mg Compared to XXX Once Weekly 2 mg Alone and XXX Once Daily 10 mg Alone in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin

A Comparison of XXX vs XXX as Basal XXX Treatment in Insulin Naïve Patients with Type 2 Diabetes Mellitus Not Adequately Controlled With 2 or More Oral Antihyperglycemic Medications: An Open-label, Randomized Study

A Comparison of XXX vs XXX as Basal XXX Treatment in Combination with Oral Anti-Hyperglycemia Medications in Insulin-Naïve Patients with Type 2 Diabetes Mellitus: A Double-blind, Randomized Study – The IMAGINE 2 Study

A 24-Week, Open-label, Randomized, 2-Arm Parallel-Group, Multinational, Multi-Center Clinical Trial to Compare the Efficacy and Safety of XXX Injected Prior to the Main Meal of the Day vs XXX Injected Prior to Breakfast in Type 2 Diabetic Patients Not Adequately Controlled on XXX

6-Month, Multicenter, Randomized, Open-label, Parallel-Group Study Comparing the Efficacy and Safety of a New Formulation of XXX and XXX in Insulin-Naïve Patients with Type 2 Diabetes Mellitus Not Adequately Controlled with Non-Insulin Antihyperglycemic Drugs with a 6-Month Safety Extension Period

A Multicenter, Randomized, Double-blind, Active-Controlled, Phase III Study to Evaluate the Efficacy and Safety of XXX Compared to XXX When Used in Combination with XXX in Subjects with Type 2 Diabetes

A Randomized, Double-blind, Placebo-Controlled, Phase III Study to Evaluate the Efficacy and Safety of Daily Oral XXX Compared with Placebo in Subjects with Type 2 Diabetes

A Phase II, Randomized, Double-blind, Placebo-controlled, Multi-Center, Parallel Group Study Evaluating the Efficacy, Safety and Pharmacokinetics of XXX Administered for 12 Weeks in Untreated or Metformin-treated Type 2 Diabetic Patients (BALANCE).

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Randomized Double-blind, Active-controlled Parallel Group Efficacy and Safety Study of XXX (5.0 mg, administered orally once daily) Compared to XXX (1 to 4 mg once daily) Over Two Years, in Type 2 Diabetic Patients with Insufficient Glycemic Control Despite Metformin Therapy

A Randomized, Double-blind, Placebo-controlled Parallel Group Efficacy and Safety Trial of XXX (10 and 25 mg administered orally once daily) Over 24 weeks in Patients with Type 2 Diabetes Mellitus with Insufficient Glycemic Control Despite a Background Therapy of XXX Alone or in Combination with Metformin

A Phase III Randomized, Double-blind, Placebo-controlled, Parallel Group, Efficacy and Safety Study of XXX (10 mg, 25 mg) Administered Orally, Once Daily over 24 weeks in Patients with Type 2 Diabetes Mellitus with Insufficient Glycemic Control Despite Treatment with Metformin Alone or Metformin in Combination with a XXX

A Multicenter, Randomized, Double-blind, Placebo-Controlled, Parallel Group, Phase III Trial to Evaluate the Safety and Efficacy of XXX as Monotherapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control with Diet and Exercise

A Phase III Double-blind, Extension, Placebo-controlled Parallel Group Safety and Efficacy Trial of XXX (10 and 25mg once daily) and XXX (100mg once daily) Given for Minimum 76 weeks (incl. 24 weeks of preceding trial) as Monotherapy or with Different Background Therapies in Patients with Type 2 Diabetes Mellitus Previously Completing Trial XXX, XXX, or XXX

Safety of Once Weekly XXX in Patients with Type 2 Diabetes Mellitus Treated with XXX Alone or XXX in Combination with Metformin

A Comparison of XXX versus XXX as Basal Insulin Treatment in Combination with Oral Anti-Hyperglycemia Medications in Insulin-Naïve Patients with Type 2 Diabetes Mellitus: A Double-Blind, Randomized Study

A Comparison of XXX versus XXX as Basal Insulin Treatment in Insulin-Naïve Patients with Type 2 Diabetes Mellitus not Adequately Controlled with 2 or more Oral Antihyperglycemic Medications: An Open-label, Randomized Study

A Long Term, Randomized, Double-blind, Placebo-controlled Study to Determine the Effect of XXX, When Added to Standard Blood Glucose Lowering Therapies, on Major Cardiovascular Events in Patients with Type 2 Diabetes Mellitus

A Phase IIIb, Randomized, Active Comparator, Open-label, Multicenter Study to Compare the Efficacy, Safety, and Tolerability of XXX to XXX and to XXX as Add-on Therapy to Metformin in Patients with Type 2 Diabetes

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Phase III Randomized, Active-Comparator XXX Controlled Clinical Trial to Study the Efficacy and Safety of XXX (A Fixed-Dose Combination Tablet of XXX and XXX) in Patients with Type 2 Diabetes Mellitus

Efficacy and Safety of XXX Once-weekly versus Placebo as Add-on to XXX in Subjects with Type 2 Diabetes Mellitus

A 24-week, Open-label, Randomized, 2-arm Parallel Group, Multinational, Multi-center Clinical Trial to Compare the Efficacy and Safety of XXX Injected Prior to the main meal of the day versus XXX Injected Prior to Breakfast in Type 2 Diabetic Patients not Adequately Controlled on Metformin

6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of XXX and XXX in Insulin-Naïve Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Non-Insulin Antihyperglycemic Drugs with a 6-month Safety Extension Period

A Randomized, 30 week, Active-controlled, Open-label, 3-treatment Arm, Parallel Group Multicenter Study Comparing the Efficacy and Safety of XXX/XXX Fixed Ratio Combination to XXX Alone and to XXX Alone on top of Metformin in Patients with Type 2 Diabetes Mellitus

A Randomized, 30-week, Active-controlled, Open-label, 2-treatment Arm, Parallel-group, Multicenter Study Comparing the Efficacy and Safety of the XXX Fixed Ratio Combination to XXX with or without Metformin in Patients with Type 2 Diabetes Mellitus

A Randomized, Open-label, Active-controlled, 2-arm Parallel-group, Multicenter 24-week Study Assessing the Efficacy and Safety of XXX vs. XXX on top of Metformin in Patients with Type II Diabetes not Adequately Controlled with Metformin

A Multicenter, Randomized, Double-blind, Active-Controlled Study to Evaluate the Durability of the Efficacy and Safety of XXX Compared to XXX When Used in Combination with Metformin in Subjects with Type 2 Diabetes

A Multicenter, Randomized, Double-blind, Placebo-Controlled Study to Determine the Efficacy and Safety of XXX Plus Metformin, XXX Alone, or Metformin Alone in Subjects with Type 2 Diabetes

A Multicenter, Randomized, Double-blind, Active-Controlled, Phase III Study to Evaluate the Efficacy and Safety of XXX 25 mg and 50 mg Compared to XXX When Used in Combination with Metformin in Subjects with Type 2 Diabetes

A Multicenter, Randomized, Double-blind, Placebo-Controlled, Phase III Study to Evaluate Cardiovascular Outcomes of XXX, 50 mg in Addition to Standard of Care in Subjects with Type 2 Diabetes and with Cardiovascular Disease or Multiple Risk Factors for Cardiovascular Events



**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Randomized, Double-blind, Placebo-controlled, Dose-ranging Study of the Safety and Efficacy of XXX in Subjects with Type 2 Diabetes Mellitus on Stable Metformin Monotherapy

A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel group, Phase III Trial to Evaluate the Safety and Efficacy of Once Weekly XXX Therapy Added to Titrated XXX Compared to Placebo Added to Titrated in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on XXX with or without Metformin

A Real-world, Point-of-care, Randomized, Parallel Group, Open, 6-month Clinical Study to Evaluate the Effect of a Digital Disease Management Tool in Patients with Type 2 Diabetes Mellitus

***Hypertension***

Blood Pressure Control in All Subgroups with Hypertension A Prospective, Open-label, Titration Study to Evaluate the Efficacy and Safety of XXX in Multiple Subgroups of Hypertensive Subjects Who Are Non-Responders to Anti-Hypertensive Monotherapy

A Randomized, Double-blind, Active-Comparator, 8-Week Forced-Titration Study of the Efficacy and Safety of XXX vs. XXX in Hypertensive Subjects

A Multicenter, Randomized, Double-blind, Placebo-Controlled, 8-Week Study to Evaluate the Safety and Efficacy of XXX and XXX Given as a Fixed-Dose Combination in Patients with Stage 1 or 2 Essential Hypertension

A Multicenter, Open-label, Single-Arm, Free Tablet Combination, Long-Term Study to Evaluate the Safety of XXX in Combination with XXX in Patients with Stage 1 or Stage 2 Essential Hypertension

Safety Follow Up Study of Cardiovascular Events in Subjects Who Participated in Selected XXX/XXX Studies

A Safety and Tolerability Study of XXX in Participants with Essential Hypertension Efficacy and Safety of XXX in Participants with Essential Hypertension

***Hypercholesterolemia***

A Randomized, Double-blind, Active-Controlled, Multicenter Study of Patients with Primary Hypercholesterolemia and High Cardiovascular Risk Who are not Adequately Controlled with XXX 10 mg: A Comparison of the Efficacy and Safety of Switching to Coadministration XXX and XXX Versus Doubling the Dose of XXX or Switching to XXX

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Phase III Multicenter, Double-blind, Crossover Design Study to Evaluate Lipid-Altering Efficacy and Safety of 1 g/10 mg Extended-Release XXX/XXX/XXX Combination Tablets in Patients with Primary Hypercholesterolemia or Mixed Dyslipidemia

A Double-blind, Randomized, 12-month, Parallel group, fixed dose Placebo-controlled Study of the Efficacy and Safety of XXX 25mg/day and 50 mg/day in Patients with primary hypercholesterolemia

A 12-week Open-label, Randomized, Parallel-group, Multicentre, Phase IIIb Study to Compare the Efficacy and Safety of XXX 10 mg and 20 mg in Combination with XXX 10 mg and XXX 40 mg and 80 mg in Combination with XXX 10 mg (fixed dose combination) in Patients with Hypercholesterolemia and Coronary Heart Disease (CHD) or a CHD Risk Equivalent, Atherosclerosis or a 10-year CHD Risk of >20%

***Hypertriglyceridemia***

A Phase III, Double-blind, Long-Term Outcomes Study to Assess Statin Residual Risk Reduction with XX in HiGh Cardiovascular Risk Patients with Hypertriglyceridemia (XXX)

***Irritable Bowel Syndrome***

A Randomized, Double-blind, Placebo-controlled, Parallel group, Dose ranging, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in the Treatment of Patients with Irritable Bowel Syndrome with Diarrhea

***Men's Health***

A Phase IV, Testosterone Replacement Therapy for Assessment of Long-term Vascular Events and Efficacy Response in Hypogonadal Men Study

A Randomized, Double-blind, Placebo-Controlled Parallel Study with an Open-label Extension to Assess the Impact of XXX Solution on Total Testosterone, Sex Drive and Energy in Hypogonadal Men

An Open-label, 12-Month, Single-Blind Placebo-Controlled Phase III Study to Assess the Effects of XXX on Bone Mineral Density in Men with Secondary Hypogonadism

A Pivotal Phase III trial to investigate the Efficacy and Safety of an XXX Tablet XXX versus Placebo in the treatment of men with ED-a fixed dose, Double-blind, Randomized multi-center Trial-POTENT 2

An Open-label, 12-Month, Single-Blind Placebo-Controlled Phase III Study to Assess the Effects of XXX Treatment on Bone Mineral Density in Men with Secondary Hypogonadism

**CLINICAL TRIAL EXPERIENCE (*continued*):**

A Randomized, Placebo-controlled, Double-blind, Parallel Design, Phase III Study to Assess the Safety and Efficacy of XXX Tablets in Male Subjects with Erectile Dysfunction

An Open-label Phase III Study to Evaluate the Long-Term Safety and Efficacy of XXX Tablets in Male Subjects with Erectile Dysfunction

***Migraine***

A Study of Two Doses of XXX Compared to Placebo in the Acute Treatment of Migraine: A Randomized, Double-blind, Placebo-Controlled Parallel Group Study (XXX)

An Open-label Long Term Safety Study of XXX in the Acute Treatment of Migraine

Assessment of the Effect of XXX and XXX Combination Tablet, XXX Tablet, and XXX Tablet Treatment on Blood Pressure when Administered Intermittently for Six Months for the Acute Treatment of Migraine Attacks, with or without Aura in Adults

XXX versus XXX-containing Combination Medications for the Acute Treatment of Migraine in Adults

***Pain***

A Phase II, Dose Ranging Study of XXX in Acute Muscle Spasm of the Back

A Randomized, Double-blind, Multi-Dose, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of XXX in Patients with Moderate to Severe Chronic Low Back Pain

A Multicenter, Randomized, Double-blind, Parallel-Group, Comparative Study of XXX vs. XXX for the Prevention of Post-Hepatic Neuralgia and Treatment of Acute Herpes Zoster-Associated Pain

A Randomized, Multicenter, Double-blind, Placebo-controlled, Two-week Study to Assess the Efficacy and Safety of XXX in Subjects with Acute Shoulder Pain

A Study to Evaluate the Effectiveness and Safety of XXX Extended Release (ER) in Patients with Moderate to Severe Chronic Low Back Pain

An Open-label Extension Study with Flexible Dosing of Extended-release (ER) XXX to Treat Patients with Moderate to Severe Chronic Pain

A 12-Week, Randomized, Double-blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of XXX Patch in Patients with Chronic Low Back Pain

**CLINICAL TRIAL EXPERIENCE (*continued*):**

Study to Evaluate Two Formulations of XXX in Subjects with Musculoskeletal Spasm of the Lower Back

A Randomized, Double-blind, Multi-Dose, Active- and Placebo Controlled, Multi-Center, Parallel Group Study of the Analgesic Effects of XXX in Adult Patients with Chronic Low Back Pain

An Open-label, Multicenter, Long Term Study of the Safety of XXX in Patients with Chronic Low Back Pain

A Phase III, international, multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study in order to Evaluate the Safety and Efficacy of oral XXX for the treatment of opioid induced constipation in Subjects with chronic, non-malignant pain

A Randomized, Double-blind, Multi-dose, Placebo-controlled Phase III Study to Evaluate the Efficacy and Safety of XXX in Patients with Moderate to Severed Chronic Low Back Pain

***Vaccines***

A Phase III, Randomized, Active-controlled, Observer-blinded Trial to Assess the Safety, Tolerability, and Immunogenicity of XXX in Healthy Participants  $\geq 10$  TO  $< 26$  Years of Age

A Phase III, Controlled, Multicenter Study to Evaluate Antibody Persistence at 1, 3, 5, and 9 Years Following Administration of a Single Dose of XXX Vaccine to Healthy Subjects, 19 Years of Age and Older in the Study XXX and to Evaluate the Immunogenicity and Safety of XXX as a Second Dose of XXX, When Administered at Year 9

A Phase III, Randomized, Placebo-Controlled, Observer-Blinded, Trial to Assess the Safety, Tolerability, and Immunogenicity of Bivalent XXX Vaccine when Administered as a 3-Dose Regimen in Healthy Young Adults Aged 18 to  $< 26$  Years

An Open, Phase III, Non-Randomized, Multi-Center Study to Assess the Immunogenicity and Safety of a Booster Dose of XXX Combined Reduced Antigen Content Diphtheria-Tetanus Toxoids and Acellular Pertussis Vaccine XXX, When Administered in Young Adults, 10 Years After Previous Booster Vaccination in Study XXX

A Randomized, Observer-blind, Active-controlled Phase III Study to Demonstrate the Superior Efficacy of XXX Adjuvanted Influenza Candidate Vaccine XXX, Administered Intramuscularly in Elderly Aged 65 years or above, as Compared to XXX

A Controlled, Multicenter Study to Evaluate antibody persistence at 1, 3, 5, and 10 years following administration of a single dose of Tdap vaccine in healthy Subjects 19 years and older

**CLINICAL TRIAL EXPERIENCE (*continued*):**

An Open, Phase III, non-Randomized, Multi-center Study to Assess the Immunogenicity and Safety of a Booster Dose of XXX Combined Reduced Antigen Content Diphtheria-tetanus Toxoids and Acellular Pertussis Vaccine XXX, when Administered in Young Adults, 10 years after Previous Booster Vaccination in Study XXX

A Phase III, controlled, multicenter Study to Evaluate antibody persistence at 1, 3, 5, and 9 years following administration of a single dose of Tdap vaccine to healthy Subjects, 19 years of age and older in the Study XXX and to Evaluate the immunogenicity and Safety of XXX as a second dose of Tdap, when administered at Year 9

Safety Study of Herpes Simplex Vaccine in HSV Seronegative and Seropositive Females Between 10 and 17 Years Old

A Phase IIIb, controlled, multicenter Study to Evaluate antibody persistence at 1, 3, 5, and 10 years following administration of a single dose of Tdap vaccine to healthy Subjects, 19 years of age and older in the Study (XXX)

A Phase III Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of Zoster Vaccine Live XXX in Patients on Chronic/Maintenance Corticosteroids

A Phase II, Randomized, Active-controlled, Observer-blinded Trial to Assess the Safety, Tolerability, and Immunogenicity of XXX, Tdap Vaccine, and XXX Vaccine when Administered Concomitantly in Healthy Subjects Aged 10 to <13 years

A Phase III, Randomized, Placebo-Controlled, Observer-Blinded, Trial To Assess The Safety, Tolerability, And Immunogenicity Of XXX Vaccine When Administered As A 3-Dose Regimen In Healthy Young Adults Aged 18 to <26 Years

A Randomized, Double-blind, Placebo Controlled Study of XXX in Adults and Adolescents with Acute Uncomplicated Influenza

Phase IV Multi-Year Efficacy Study of XXX High-Dose XXX Vaccine Compared with XXX Vaccine in Adults >65 Years of Age

Efficacy Study of XXX High-Dose Vaccine Compared with XXX Vaccine in Elderly Adults Study Evaluating Persistence of Antibody Response Elicited by XXX In Healthy Adults Previously Vaccinated

***Women's Health***

A multicenter, Open-label, three-arm, active-controlled Study to Assess the Efficacy and Safety of the oral contraceptive XXX in two flexible extended regimens and a conventional regimen of XXX in 1756 healthy females for 1 year

**CLINICAL TRIAL EXPERIENCE (*continued*):**

Open-label Study of the Safety and Efficacy of a Low Dose Oral Contraceptive Containing XXX and XXX

***Other Indications***

A Longitudinal Study of XXX in an Average Risk Population Assessing a Three-Year Test Interval

A Phase III, Observer-Blinded, Randomized, Active- Controlled XXX, Multicenter Trial of the Safety and Immunogenicity of XXX in Adults 18 to 70 Years of Age

Randomized, Modified Double-blind, Active-Controlled, Multi-Center Trial in Elderly Adults

A Phase III Clinical Trial to Evaluate the Efficacy, Immunogenicity, Safety and Tolerability of XXX in Subjects 50 to 59 Years of Age

A Long Term Safety Study of XXX in Participants with Primary Insomnia (XXX) Study of Ragweed Allergy Immunotherapy Tablet in Adults with Ragweed Allergies (XXX)

A Phase IV Clinical Trial to Evaluate the Safety and Tolerability of XXX in Subjects = 60 Years of Age

Double-blind Extension of XXX Pivotal Fracture Trial (XXX in the Treatment of Postmenopausal Osteoporosis)

A Randomized, Double-blind, Placebo-Controlled, Parallel-Group, Multicenter Study of the Safety and Efficacy of XXX in an extended release bi-layer tablet for Symptomatic Therapy in Patients with Acute Upper Respiratory Tract Infections Who Seek Treatment

A Study to Evaluate Infants with Potential Exposure to XXX Before Birth

Efficacy and Safety of XXX Treatment for Sleep Maintenance Insomnia Followed by Optional Extension up to 1 Year

Consortium for the Lifespan Examination of ADHD Registry (CLEAR) Study: An International longitudinal, observational Study of Individuals with Attention-Deficit Hyperactive Disorder (ADHD)

Subjective Efficacy of XXX on Sleep in Adults with Chronic Insomnia