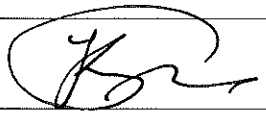
TriWest Research Associates

CURRICULUM VITAE

Signature		**DATE**	02/08/2023
NAME: **TITLE:**	Martin L. Kabongo, MD Principal Investigator/ Sub-Investigator	**DATE UPDATED:**	FEB 2023

RESEARCH SITE NAME/ ADDRESS:

TriWest Research Associates 5030 Camino De La Siesta, Suite 405 San Diego, CA 92108	Office: 619-334-4735 Fax: 619-334-4769 Email: drkabongo@triwestresearch.com

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Collaborative Institutional Training Initiative (CITI)	Certificate	2020	Good Clinical Practices
Universidad Autonoma de Cd. Juarez, School of Medicine, Ciudad Juarez, Chi., Mexico	Medical Doctor	1983-1986	General Medicine
St. Thomas Institute/ University of Cincinnati, OH	PhD	1978-1982	Microbiology and Derma-pathology
St. Thomas Institute/ University of Cincinnati, OH	MS	1978-1982	Microbiology and Exp. Medicine
Eastern Mennonite University, Harrisonburg, VA	BS	1976-1977	Biology
King College Bristole, TN	MS	1971-1978	Biology

LICENSURE:

Medical Board of California	Internal Medicine

POSITIONS AND EMPLOYMENT:

2023-Present	Investigator, TriWest Research Associates, San Diego, CA
2022- Present	Investigator, Advanced Clinical Research Center, San Diego, CA
2021-Present	Investigator, ACRC Studies, San Diego, CA
2013-2020	Investigator, Precision Research Institute, San Diego, CA
2007-2012	Investigator, Accelovance, San Diego, CA
2003-Present	Family Practice, University of California San Diego Healthcare, San Diego, CA
2003-Present	Associate Clinical Professor, University of California School of Medicine, San Diego, CA
1996-2003	Family Practice, Sharp Grossmont Hospital, La Mesa, CA
1996-2003	Family Practice, Sharp Memorial Hospital, San Diego CA
1996-2003	Family Practice, Sharp Chula Vista Medical Center, Chula Vista, CA
1994-1995	Bon Secours Eastpointe Physicians, Eastpointe, MI Staff Physicians Bon Secours Hospital, Gross Pointe, MI, Attending Physician St. John Hospital, Detroit, MI, Attending Physician Holy Cross Hospital, Detroit, MI, Attending Physician Detroit Medical Center, Detroit, MI, Attending Physician Seaway Hospital, Trenton, MI, Emergency Physician
1981-1982	PJ Hoxworth Blood Center, Cincinnati, OH, Technologist II
1980-1981	Clermont Mercy Hospital, Batavia, OH, Supervisor clinical lab
1979	University of Paris VI, Paris France, Research Associate
1978-1979	University of Cincinnati Medical Center, Cincinnati, OH, Staff Technician
1979-1981	National Health Lab, Cincinnati, OH, Assistant Supervisor

PUBLICATIONS:

Immunogenicity and safety of an investigational hepatitis B vaccine with a Toll-like receptor 9 agonist adjuvant (HBsAg-1018) compared to a licensed hepatitis B vaccine in healthy adults 40-70 years of age. Vaccine. 2013 Nov 04; 31(46):5300-5. Heyward WL, Kyle M, Blumenau J, Davis M, Reisinger K, **Kabongo ML**, Bennett S, Janssen RS, Namini H, Martin JT. PMID: 23727002.

Oral administration of an adenovirus vector encoding both an avian influenza A hemagglutinin and a TLR3 ligand induces antigen specific granzyme B and IFN-γ T cell responses in humans. Vaccine. 2013 Mar 25; 31(13):1752-8. Peters W, Brandl JR, Lindbloom JD, Martinez CJ, Scallan CD, Trager GR, Tingley DW, **Kabongo ML**, Tucker SN. PMID: 23357198.

A single dose of unadjuvanted novel 2009 H1N1 vaccine is immunogenic and well tolerated in young and elderly adults. J Infect Dis. 2010 Nov 01; 202(9):1327-37. Talaat KR, Greenberg ME, Lai MH, Hartel GF, Wichems CH, Rockman S, Jeanfreau RJ, Ghosh MR, **Kabongo ML**, Gittleson C, Karron RA. PMID: 20874515.

Phase 1 clinical trials of the safety and immunogenicity of adjuvanted plasmid DNA vaccines encoding influenza A virus H5 hemagglutinin. Vaccine. 2010 Mar 16; 28(13):2565-72. Smith LR, Wloch MK, Ye M, Reyes LR, Boutsaboualoy S, Dunne CE, Chaplin JA, Rusalov D, Rolland AP, Fisher CL, Al-Ibrahim MS, **Kabongo ML**, Steigbigel R, Belshe RB, Kitt ER, Chu AH, Moss RB. PMID: 20117262.

RESEARCH EXPERIENCE:

Principal Investigator

Novum: Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutic Equivalence xxxxxxx in the Treatment of Dyspareunia in Women with Vulvar and Vaginal Atrophy.

Shanton: A Phase 2B, Multicenter, Randomized, Double-blind,Placebo-controlled, Dose-finding Study with an Open-label Extension to Evaluate the Efficacy and Safety XXXXXX in Combination with Standard of Care in Adult Subjects with Gout, with or without Tophi.

AbbVie Inc: To evaluate the Safety and Efficacy of xxxx in Combination with Combined Oral Contraceptives in Premenopausal Women with Endometriosis and Associated Moderate to Severe Pain.

Bellus:Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm Efficacy and Safety Study with Open-label xxxxxx in Adult Participants with Refractory Chronic Cough, Including Unexplained Chronic Cough.

Astellas: A Phase 3, Randomized, Placebo-controlled, 12-week Double-blind Study, followed by a Non-Controlled Extension Treatment Period, to Assess the Efficacy and Safety of XXXXXXXXX in Women Suffering from Moderate to Severe Vasomotor Symptoms (Hot Flashes) Associated with Menopause

Astellas: A Randomized, Placebo-Controlled, Double-Blind Phase 3 Clinical Study to Investigate the Long-Term Safety of XXXXXXXXX in Women Suffering From Vasomotor Symptoms (Hot Flashes) Associated with Menopause

Mitsubishi: A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of XXXXXX in Women with Endometriosis Experiencing Endometrial Related Pain

ObsEva: A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Contolled, Clinical Study to Assess the Efficacy and Safety of XXXXXXXXX in Subjects with Moderate to Severe Endometriosis-Associated Pain.

Abbvie: A Phase 3 Study to Evaluate the Safety and Efficacy of XXXXXX in Combination with Estradiol/Norethindrone Acetate in Subjects with Moderate to Severe Endometriosis-Associated Pain

Abbvie: A Phase 3b Study to Evaluate the Long-Term Safety and Efficacy of XXXXXXX in Combination with Estradiol/Norethindrone Acetate for the Management of Heavy Menstrual Bleeding Associated with Uterine Fibroids in Premenopausal Women

Myovant: An International Phase 3 Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety to Evaluate XXXXXXX Co-Administered with and without Low-Dose Estradios and Norethindrone Acetate in Women with Heavy Menstrual Bleeding Associated with Uterine Fibroids

Myovant: An International Phase 3 Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study to Evaluate XXXXXXXX Administered with and without Low-Dose Estradiol and Norethindrone Acetate in Women with Endometriosis-Associated Pain

Ogeda: A Randomized, Placebo-Controlled, Double-Blind, Dose-Ranging, Phase 2b Study to Investigate the Efficacy of XXXXXXX in Postmenopausal Women Suffering From Vasomotor Symptoms (Hot Flashes)

Cempra: A Randomized, Double-blind, Multi-center Study to Evaluate the Safety and Efficacy of Oral XXXXXX Compared to Oral Linezolid in the Treatment of Acute Bacterial Skin and Skin Structure Infections

Starpharma: A phase 3, double-blind, multicenter, randomized, placebo-controlled study to determine the efficacy and safety of SPL7013 Gel (VivaGel®) to prevent the recurrence of bacterial vaginosis

Paratek: A Phase 3 Randomized, Double-Blind, Multi-Center Study to Compare the Safety and Efficacy of Oral XXXXXXXXX to Oral XXXXXXXX for Treating Adult Subjects with Acute Bacterial Skin and Skin Structure Infection (ABSSSI)

Symbio: A Randomized, Double-Blinded, Vehicle-Controlled, Parallel-Group, Multicenter Study to Compare Perrigo UK Finco's Estradiol Vaginal Cream 0.01% to XXXXXXXX (Estradiol) Vaginal Cream, USP, 0.01% (Warner Chilcott (US), LLC) and Both Active Treaments to a Vehicle Control in the Treatment of Vulvar and Vaginal Atrophy

Shionogi: A Phase 3, Multicenter, Randomized, Double-blind Study of a Single Dose of XXXXXXXX Compared with Placebo or XXXXXXXX 75 mg Twice Daily for 5 Days in Patients with Influenza at High Risk of Influenza Complications

Sub-Investigator

Intercept: A Phase 3, Double-Blind, Randomized, Long-Term, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of XXXXXXXXXX Acid in Subjects with Nonalcoholic Steatohepatitis

Actavis: An Open-label, Long-term Study to Assess the Immunogenicity of XXXX Administered Orally to Adult Patients with Irritable Bowel Syndrome with Constipation or Chronic Idiopathic Constipation

Astra Zeneca: A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel group, Phase 3 Trial to Evaluate the Safety and Efficacy of Once Weekly XXXX Therapy Added to Titrated XXXX Compared to Placebo Added to Titrated XXXX in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on XXXX with or without Metformin

Astra Zeneca: A 28-week, Multicenter, Randomized, Double-Blind, Active-Controlled,Phase 3 Study with a 24-week Extension Phase to Evaluate the Efficacy and Safety of Simultaneous Administration of XXXX Once Weekly 2 mg and XXXX Once Daily 10 mg Compared to XXXX Once Weekly 2 mg Alone and XXXX Once Daily 10 mg Alone in Patients with Type 2 Diabetes who have Inadequate Glycemic Control on Metformin.

Starpharma: A phase 3, double-blind, multicentre, randomized, placebo-controlled study to determine the efficacy and safety of XXXX to prevent the recurrence of bacterial vaginosis

Cempra: A Randomized, Double-blind, Multi-center Study to Evaluate the Safety and Efficacy of XXXX Compared to Oral XXXX in the Treatment of Acute Bacterial Skin and Skin Structure Infections A Phase 3 Study

Genentech: AN OPEN-LABEL EXTENSION AND SAFETY MONITORING STUDY OF MODERATE TO SEVERE ULCERATIVE COLITIS PATIENTS PREVIOUSLY ENROLLED IN ETROLIZUMAB PHASE III STUDIES

Genentech: PHASE III, RANDOMIZED, DOUBLE-BLIND, DOUBLE-DUMMY, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY (INDUCTION OF REMISSION) AND SAFETY OF XXXX COMPARED WITH XXXX AND PLACEBO IN PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS WHO ARE NAIVE TO TNF INHIBITORS

Melinta - A Phase 3, multicenter, randomized, double-blind, active controlled study to evaluate the efficacy and safety of IV and oral XXXX compared with XXXX + XXXX in patients with acute bacterial skin and skin structure infections

Merck- A Phase II, Randomized, Open-Label Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of XXXX and XXXX with Either XXXX or XXXX in Subjects with Chronic HCV GT1 and GT2 Infection

Merck: A Long-term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Resistance Patterns of Subjects with Chronic Hepatitis C Who Have Been Previously Treated with XXXX in a Prior Clinical Trial

Paion: A Phase III Study Evaluating the Efficacy and Safety of XXXX Compared to Placebo and Midazolam in Patients Undergoing Colonoscopy.

BI: A phase II, multicenter, randomized, double-blind, multiple dose, placebo-controlled, parallel-group study to evaluate the efficacy, pharmacokinetics, and safety of XXXX, an IL-23 p19 antagonist monoclonal antibody, in patients with moderately to severely active Crohn's disease, who are naïve to, or were previously treated with anti-TNF therapy

gICare: A Randomized, Double-Blind, Placebo-Controlled Phase IIa Proof-Of-Concept Study of XXXX in the Management of Visceral Pain in Subjects Undergoing Sedation-Free Full Colonoscopy

SK life science: A Double-Blind, Randomized, Placebo-Controlled, 12-Week, Dose-Range-Finding Trial of 5 and 20mg Capsules of XXXX Administered Once Daily at Doses of 5, 10, or 30mg to Subjects with Chronic Idiopathic Constipation

Astra Zeneca: A Phase 2a to Evaluate the Efficacy and Safety of XXXX in Subjects with Moderate to Severe Crohn's Disease Who Have Failed or Are Intolerant to Anti-Tumor Necrosis Factory-alpha Threapy

Abbvie: A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of XXXX in Patients with Moderately to Severely Active Ulcerative Colitis (UC)

ONO Pharma: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXX In Female Subjects with Diarrhea-Predominant Irritable Bowel Syndrome (IBS)

Genentech: A Phase III, Double-Blinded, Placebo-Controlled, Multicenter Study of the Efficacy and Safety of XXXX During Induction and Maintenance in Patients with Moderate to Severe Active Ulcerative Colitis who Are Refractory to or Intolerant of TNF Inhibitors

Janssen: A Phase 2a Open-label Study to Evaluate Prediction of Response to XXXX Using a Transcriptomic Profile in Subjects with Moderately to Severely Active Ulcerative Colitis

Synergy: A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXXX(3.0 and 6.0 mg) in Patients with Chronic Idiopathic Constipation

BMS: A Phase 3 Evaluation of XXXX Plus XXXX in Treatment-naïve and Treatment experienced Chronic Hepatitis C (Genotype 1, 2, 3, 4, 5, or 6) Subjects Co infected with Human Immunodeficiency Virus (HIV)

BMS: A Phase 3 Evaluation of XXXX and XXXX in Treatment Naïve and Treatment Experienced Subjects with Genotype 3 Chronic Hepatitis C Infection

Merck: A Phase II/III Randomized Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of XXXX and XXXX in Subjects with Chronic Hepatitis C Virus Infection and Chronic Kidney Disease

Ferring: A Double-blind, Randomised, Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of XXXX 5 mg and 10 mg for 12 Weeks Followed by a 4-week Withdrawal Period

GSK: A phase III, 52 week, randomized, double-blind, 3-arm parallel group study, comparing the efficacy, safety and tolerability of the fixed dose triple combination FF/UMEC/VI with the fixed dose dual combinations of FF/VI and UMEC/VI, all administered once-daily in the morning via a dry powder inhaler in subjects with chronic obstructive pulmonary disease

Ferring: A Multicenter, Open-label, Safety and Tolerability Extension Trial of 5 mg and 10 mg XXXXDaily in the Treatment of Chronic Idiopathic Constipation

BI: Safety, antiviral effect and pharmacokinetics of XXXX in combination with XXXX and with or without XXXX for 4, 16, 24, 28 or 40 weeks in patients with chronic HCV genotype 1 infection (randomized Phase Ib/II)

BI: A phase III randomised, double-blind and placebo-controlled study of XXXX in combination with XXXXand XXXX in patients with moderate hepatic impairment (Child-Pugh B) with genotype 1b chronic hepatitis C infection

BI: A phase III randomised, partially double-blind and placebo-controlled study of XXXX in combination with XXXX and XXXX for chronic genotype 1 hepatitis C infection in an extended population of treatment naïve patients that includes those ineligible to receive XXXX

BMS: A Long-Term Follow-up Study of Subjects Who Participated in a Clinical Trial in Which XXXX and/or XXXX Was Administered for the Treatment of Chronic Hepatitis C

Salix:A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Multicenter Study To Assess the Efficacy and Safety of XXXX Soluble Solid Dispersion (SSD) Tablets for the Prevention of Complications in Subjects with Early Decompensated Liver Cirrhosis

Sanofi: A randomized, double-blind, placebo-controlled, multicenter study evaluating efficacy and safety of XXXX in patients with active moderate to severe Ulcerative Colitis (UC).

Sanofi: A single-arm open label extension study evaluating the long term safety and tolerability of XXXX in patients with Ulcerative Colitis (UC)

Cubist: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-Term Safety and Tolerability of XXXX for the Treatment of Opioid-Induced Constipation in Adults Taking Opioid Therapy for Chronic Non Cancer Pain

Cubist: A Randomized, Double-Blind, Placebo controlled, Phase 3 Study to Evaluate the Efficacy and Safety of XXXX for the Treatmetn of Opioid-Induced Constipation in Adults Taking Opioid Theraphy for Chronic Non-Cancer Pain

Novartis: A randomized, multicenter, double-blind, placebo-controlled, parallel-group, 24-week pilot study to assess the efficacy, safety and tolerability of XXXX in patients with non-alcoholic fatty liver disease

Astra Zeneca: A Longitudinal Study of Patients with Opioid-Induced Constipation

BMS: A Phase 2 study of XXXX in combination with XXXX Alfa-2a and XXXX in Treatment Naïve Subjects with Chronic Hepatitis C Genotype 1 and 4 Infection

BMS: Open-Label, Multiple-Dose, Dose Escalation Study to Evaluate the Pharmacodynamics, Pharmacokinetics, and Safety of Co administration of XXXX, XXXX, and XXXX when administered for 24 or 12 weeks in Treatment-Naïve Subjects Infected with Hepatitis C Virus Genotype 1

BMS: A Phase 3, Randomized, Double-Blind, Controlled Study Evaluating the Efficacy and Safety of XXXX, with and without XXXX, Compared to XXXX, Each in Combination with XXXX, in the Treatment of Naïve Genotype 2 and 3 Chronic Hepatitis C Subjects

Salix: A Study to Assess Repeat Treatment Efficacy and Safety of XXXX 550 mg TID in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)
Purdue: A Randomized, Double-Blind, Double-Dummy, Placebo controlled, Active controlled parallel group, Multicenter trial of XXXX Controlled release tablets to Assess the Analgesic Efficacy and management of opioid induced constipation compared to XXXX Controlled release Tablets in Uncontrolled moderate/ severe Chronic Low back pain

Purdue: A Randomized, Double-Blind, Double-Dummy, Placebo controlled, Active controlled parallel group, Multicenter trial of XXXX Controlled release tablets to Assess the Analgesic Efficacy and management of opioid induced constipation compared to XXXX Controlled release Tablets in Controlled moderate/ severe Chronic Low back pain

Millennium: A Phase 3, Open-label Study to Determine the Long-term Safety and Efficacy of XXXX in Patients with Ulcerative Colitis and Crohn's Disease

Novartis: A Randomized, open-label trial of the safety and efficacy of XXXX in combination with XXXX and XXXXand XXXX in combination with XXXX in African-American treatment naïve subjects with Chronic Hepatitis C genotype 1

Novo Nordisk: A trial comparing cardiovascular safety of XXXX \ versus XXXX in subjects with type 2 diabetes at high risk of cardiovascular events

Mitsubishi: A Phase 2, randomized, double-blind, placebo-controlled, fixed-dose, parallel-group, multicenter, efficacy, and safety study of XXXX for treatment of uremic pruritus in subjects with end-stagerenal disease receiving hemodialysis

ManKind: A Phase 3, Multicenter, Open-label, Randomized Clinical Trial to Evaluate the Safety of XXXX Insulin Inhalation Powder in Type 1 or Type 2 Diabetic Subjects with Obstructive Pulmonary Disease (Asthma or Chronic Obstructive Pulmonary Disease) Over a12-month Treatment Period with a 2-month Follow-up

BI: A phase III, randomized, double-blind, parallel group study to evaluate the efficacy and safety of XXXX 5 mg compared to placebo, administered as oral fixed dose combination with XXXX 10 mg or 25 mg for 24 weeks, in patients with type 2

Intarcia: A Phase 3, Randomized, Active Comparator, Double-Blind, Multi-Center Study to Compare the Efficacy, Safety and Tolerability of XXXX to XXXX as Add-on Therapy to XXXX in Patients with Type 2 Diabetes

Basic Skin Cancer Triage - NIH subcontract with Brown University --a randomized trial in primary care physicians of web-based training of fficacy in changing physician behavior on how they screen for skin cancer.

Errors in Primary Care – AHRQ sponsored study in collaboration with Cook county Hospital

Misoprostol in Induction of Labor (still pending)

Critical review of literature and systematic evaluation of available evidences for the use of misoprostol in induction is a two-phase study. The first phase consisted of evidence collection and critical appraisal of the literature. The second phase of the study was focus groups study evaluation by misoprostol primary care users in the community. Both phases have been completed. Analysis of compiled data collected and possibly three papers are currently being processed

Diabetes and Cultural Competency (on hold)
What would be the outcomes of the Diabetes managed in a culturally competent manners in Surf*Net practices? Larry Palinkas and Surf*Net Diabetes Study Group. Received Funding from UCSD Academic Senate for pilot Study.
A Phase 1, Double-Blinded Study to Evaluate the Safety, Tolerability, and Immunogenicity of Pandemic Influenza Plasmid DNA Vaccines

A Phase 1, Double-Blinded Study to Evaluate the Safety, Tolerability, and Immunogenicity of Pandemic Influenza Plasmid DNA Vaccines Administered with the (XXXX®) 2000 Needle-free System.

Audrey Project Consumer Focus Group Study.10/4 person focus groups to review a feminine care product.

A Randomized, Double-Blind, Placebo Controlled, Parallel Design, Multiple-Site Clinical Study to Evaluate the Bioequivalence of Two (XXXX) 0.1% Topical Ointment Formulations in Patients with Moderate to Severe Atopic Dermatitis.2008

A prospective, multi-center, paired data, cohort screening trial comparing (XXXX) to the fasting Plasma Glucose Testing in Subject at Risk for Diabetes.

A Randomized, Double-Blind, Multiple Site, Placebo Controlled, Parallel Design, Clinical Study to Evaluate the BioEquivalence of (XXXX) 5% (XXXX) Compared to (XXXX®) (XXXX) Cream 5 % (XXXX) in Patients with Actinic Keratosis.

A Phase II, Multicenter, Randomized, Observer-Blind, Placebo Controlled Study to Evaluate the Immunogenicity, Safety and Tolerability of (XXXX) H1N1 Influenza Vaccine in Healthy Adults Aged 18 Years and Older.

An Observer-Blinded, Randomized, Parallel-Group, Multi-Center Study Comparing the Safety and Immunogenicity of (XXXX™) to Licensed Vaccine (XXXXX®) among Healthy Subjects 40 to 70 Years of Age.

A Phase 1 Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a (XXXX) DNA Vaccine against (XXXX) H1N1 Influenza Virus in Healthy Adults

A Randomized, Controlled Clinical Trial to Evaluate Wheat Fiber and Fiber from (XXXX) Blends on Regularity in Healthy Men.

Open label trial in healthy infants and children (ages 6 months through 35 months) who are eligible to receive influenza vaccine for the first time, to obtain serum for determination if antibodies induced by a (XXXX) inactivated influenza vaccine effectively inhibit currently circulating influenza viruses.

Randomized, observer-blinded, active-controlled, multi-center, three-arm, Phase III Of 4940 subjects in two age strata (6 months to ≤ 35 months and 3 years to > 9 Years of age).

A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of (XXXXX) Extended-Release Tablets at 15 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Patients with Osteoarthritis or Low Back Pain Who Require Opiod Treatment for an Extended Period of Time.

Open label trial in healthy infants and children (ages 6 months through 35 months) who are eligible to receive influenza vaccine for the first time, to obtain serum for determination if antibodies induced by a trivalent inactivated influenza vaccine effectively inhibit currently circulating influenza viruses.

Open label trial in healthy infants and children (ages 6 months through 35 months) who are eligible to receive influenza vaccine for the first time, to obtain serum for determination if antibodies induced by a trivalent inactivated influenza vaccine effectively inhibit currently circulating influenza viruses.

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Gastrointestinal Tolerability of (XXXX) and (XXXX) Nutritional Shake in Healthy Subjects.

Phase IV, randomized, observer-blinded, active-controlled, multi-center study of the safety and immune response in adults to (XXXX) or (XXXX) (Td Adsorbed) approximately 10 years after a previous dose of (XXXX) vaccine.

A Phase 2, Multicenter, Randomized, Placebo-controlled, Double-blind, Placebo- masked, Parallel-group Pilot Trial to Compare the Efficacy, Tolerability, and Safety of (XXXX) Modified-release and Immediate-release Formulations in Subjects with Autosomal Dominant Polycystic Kidney Disease.

A Multi-center, Longitudinal, Observational Study of Patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD) to Establish the Rate, Characteristics, and Determinants of Disease Progression.

GSK-HZC(Summit): A Clinical Outcomes Study to compare the effect of Fluticasone Furoate/Vilanterol Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at increased risk for cardiovascular disease.