TriWest Research Associates

CURRICULUM VITAE

SIGNATURE:	MDanilychev MD	**DATE:**	09-JUL-2014
NAME: **TITLE:**	Maria V. Danilychev, M.D. Sub Investigator/Joint Assessor	**DATE UPDATED:**	July 2014

RESEARCH SITE ADDRESS & PHONE:

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EDUCATION/TRAINING:

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
San Diego Hospice, Center for Palliative Studies San Diego, CA	Research Fellowship	2005-2007	Pain and Palliative Medicine
San Diego Hospice, Center for Palliative Studies San Diego, CA	Clinical Fellowship	2004-2005	Hospice and Palliative Medicine
University of California, Los Angeles Los Angeles, CA	Fellowship	2003-2004	Geriatric Medicine
NYU Downtown Hospital New York, New York	Residency	2000-2003	Internal Medicine
Sackler School of Medicine, Tel Aviv University Tel Aviv, Israel	M.D.	1996-2000	Medicine
University of California, Irvine Irvine, CA	B.S.	1991-1996	Biological Sciences
Northwest Alabama Community College Phil Campbell, Alabama	N/A	1990-1991	Pre-Medicine

BOARD CERTIFIED:

BOARD CERTIFIED/ELIGIBLE	YEAR(s)	SPECIALTY
Medical License CA	2003	Internal Medicine
Board Certified	2005	Geriatric Medicine
Board Certified	2004	Internal Medicine
Board Certified	2003	Palliative Medicine

POSITIONS AND EMPLOYMENT:

2011-Present	Sub-Investigator, TriWest Research Associates LLC, El Cajon, CA
2011-Present	Joint Assessor, TriWest Research Associates, El Cajon, CA
2011-Present	Medicine Consultant, Light Bridge Hospice and Palliative Care, Associate Medical Director and Hospice and Palliative San Diego, CA
2007-Present	Consultant, San Diego Hospice and The Institute for Palliative Medicine, Hospice and Palliative Medicine San Diego, CA
2008-2010	Research Physician/Investigator, Profil Institute for Clinical Research, Chula Vista, CA
09/2007- 12/2007	Personal Visiting Physician, Care Level Management, South Orange County, CA
2006-2007	Investigator, San Diego Hospice and Palliative Care, Medical Director of a Long Term Care Team San Diego, CA

CLINICAL RESEARCH EXPERIENCE:

Genentech- A multicenter, open-label, single-arm study to evaluate the safety of administering XXXX at a more rapid infusion rate in patients with rheumatoid arthritis (Phase IV)

Genentech Inc: A non-interventional, multi-site retrospective chart review study in patients with Rheumatoid Arthritis

Diamyd Inc: A Phase II, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Investigate the Impact of XXXX in Subjects with Intractable Pain due to Malignancy

Abbot Laboratories: A Global Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Study Comparing the Analgesic Efficacy and Safety of XXXX to Placebo in Subjects with Osteoarthritis Pain of the Knee

Abbott: A Multicenter, Randomized, Double-blind, Placebo-and Active-Controlled Study Comparing the Analgesic Efficacy and Safety of XXXX to Placebo in Subjects with Osteoarthritis Pain of the knee

Merck Sharp & Dohme Corp.: A Phase 2a, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Worldwide, Proof-of-Concept Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of XXXX in Subjects with Active Rheumatoid Arthritis and inadequate Response or Intolerance to Anti-TNF-a Therapy

Sanofi-aventis U.S. Inc.: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate Cardiovascular Outcomes during Treatment with XXXX in Type 2 Diabetic Patients after an Acute Coronary Syndrome

Covidien: Phase 3 - An Open Label Safety Study of XXXX in Subjects With Osteoarthritis or Chronic Low Back Pain

Forest Research Institute, Inc: A Randomized, Double-Blind, Placebo-and-Active-Controlled Study to Evaluate the Safety and Efficacy of XXXX in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

Antares Pharma, Inc: A Phase 2, Multi-Center, Open-Label, Single-Dose, Single-Arm, In-Clinic Study to Evaluate the Actual Human Use of Methotrexate Subcutaneously Administered via the VIBEX™ MTX-Auto-Injector Device in Adult Patients with Rheumatoid Arthritis

Astra Zeneca: A randomized, double-blind, parallel group, multicenter phase IIIb study to compare ticagrelor with clopidogrel treatment on the risk of cardiovascular death, myocardial infarction and ischemic stroke in patients with established Peripheral Artery Disease

AstraZeneca: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXXX in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC)

Bayer: A prospective, randomized, open-label, parallel-group, active-controlled, multicenter study exploring the efficacy and safety of once-daily oral XXXX compared to vitamin K antagonist (VKA) for the prevention of cardiovascular events in subjects with nonvalvular atrial fibrillation scheduled for cardioversion

Eli Lilly: Psychometric Validation of Performance Based Measures for Use with Hip Fracture and Elective Hip and Knee Replacement Populations

Cubist Pharmaceuticals, Inc.: 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

Takeda: A Multicenter, randomized, active control, phase 3b study to evaluate the cardiovascular safety of XXXX and Allopurinol in subjects with Gout and cardiovascular comorbidities

Collegium: A Phase 3, Multi-Center, Randomized, Double-blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of XXXX Versus Placebo in Opioid-Experienced and Opioid-Naïve Subjects with Moderate-to-Severe Chronic Low Back Pain

Cephalon: A Randomized, Double-blind, Placebo-Controlled, Ascending-Dose Study to Evaluate the Safety and Efficacy of XXXX Administered at Single Doses of 0.5, 1, 3, 6, or 12 mg by the Transforaminal Epidural Route for the Treatment of Patients with Lumbosacral Radicular Pain Associated with Disk Herniation

Furiex: A Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of XXXX in the Treatment of Patients with Diarrhea-Predominant Irritable Bowel Syndrome

Purdue: A Multicenter, Randomized, Double-blind, Placebo-controlled Study With an Open-Label Run – in to Assess the Efficacy and Safety of XXXX Tablets to 20 to 120 mg Once daily in Subjects with Moderate to Severe Chronic Low Back Pain

Purdue Pharma L.P.: An Open-label, Multicenter Study to Assess the Long-term Safety of XXXX Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Nonmalignant and Nonneuropathic Pain

Purdue Pharma L.P.: A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of XXXX/XXXX Controlled-release Tablets (OXN) Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy

Purdue: A Randomized, Double-blind, Double-dummy, Placebo controlled, Active-Controlled, Parallel-group, Multicenter Trial of XXXX to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to XXXX) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy

Purdue: A Randomized, Double-blind, Double-dummy, Placebo controlled, Active-Controlled, Parallel-group, Multicenter Trial of XXXX to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to XXXX) in Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy

Janssen Research & Development: A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Study of XXXX (sirukumab), A Human Anti-IL-6 Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Rheumatoid Arthritis Despite Anti-TNF-a Therapy

Janssen Research & Development: A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Study of XXXX (sirukumab), a Human Anti-IL-6 Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Rheumatoid Arthritis despite DMARD Therapy

Forest: A Multicenter, Randomized, Double-blind, Placebo-controlled, 8-week Study to Evaluate the Safety and Efficacy of XXXX and XXXX given as a Fixed-Dose Combination with Stage 1 or 2 Essential Hypertension

Sanofi-aventis U.S. Inc: 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin XXXX and Lantus® in Insulin-Naïve Patients with Type 2 Diabetes Mellitus not adequately controlled with Non-Insulin Antihyperglycemic Drugs with a 6-month Safety Extension Period

Sanofi-aventis U.S. Inc: A 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin XXXX and Lantus® Injected in the Morning of Evening in Patients with Type 1 Diabetes Mellitus with a 6-month Safety Extension Period

Eli Lilly: A Phase 3b, multicenter, open-label study to evaluate the long term safety and efficacy of XXXX in patients with Rheumatoid Arthritis (FLEX M)

Eli Lilly: A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of XXXX in patients with Moderate to severe Rheumatoid Arthritis (RA) who had an inadequate response to one or more TNF-inhibitors (FLEX V)

Eli Lilly: A Phase 3b, multicenter, open-label study to evaluate the long term safety and efficacy of XXXX in patients with Rheumatoid Arthritis (RA)

Eli Lilly: A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Subcutaneous XXXX in Patients with Systemic Lupus Erythematosus (SLE) (Illuminate-2)

Eli Lilly: A Phase 3b, multicenter, open-label study to evaluate the long term safety and efficacy of subcutaneous XXXX in patients with Systemic Lupus Erythematous (SLE) (ILLUMINATE-X)

AstraZeneca: An Open-Label 52-week Study to Assess the Long-Term Safety of XXXX in Opioid Induced Constipation (OIC) in Patients with Non-Cancer-Related Pain

Novo Nordisk Inc.: A Randomized, double-blind, placebo-controlled, multiple dose, phase 2b, 24 week trial followed by an open label extension of XXXX, an anti-IL-20 biologic, in patients with active rheumatoid arthritis who are inadequate responders to anti-TNf-a biologics

Novo Nordisk Inc.: A Randomized, double-blind, placebo-controlled, multiple dose, phase 2b, 24 week trial followed by an open label extension of XXXX, an anti-IL-20 biologic, in patients with active rheumatoid arthritis who are inadequate responders to Methotrexate

Human Genome Sciences: A Randomized, Double-Blind, Placebo-Controlled 52-Week Study to Assess Adverse Events of Special Interest in Adults with Active, Autoantibody-Positive Systemic Lupus Erythematous Receiving Belimumab

Boehringer Ingelgeim: A randomized, double-blind, parallel arm, multiple dose, active comparator trial, efficacy, Pharmacokinetics, and safety of XXXX versus rituximab in patients with moderately to severely active rheumatoid arthritis

UCB: A Multicenter, Single-Blind, Randomized Parallel-Group Study to Assess the Short-and-Long-Term Efficacy of XXXX plus Methotrexate Compared with Adalmumab plus Methotrexate in Subjects with Moderate to Severe Rheumatoid Arthritis Responding Inadequately to Methotrexate

QMED: A Multicenter, Randomized, Double Blind, Saline Controlled Study of a Single Injection of XXXX versus a Single Injection of Phosphate Buffered Saline (PBS) to Treat Pain Associated with Osteoarthritis of the Knee

Takeda: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate Cardiovascular Outcomes of XXXX, 50 mg in Addition to Standard of Car in Subjects with Type 2 Diabetes and with Cardiovascular Disease or Multiple Risk Factors for Cardiovascular Events

Mannkind Corporation: 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 a 12-month Treatment Period with a 2-month Follow-up

Novartis: A Randomized, Double-Blind, Placebo-and active-controlled Study of XXXX to Demonstrate the Efficacy at 24 Weeks and to assess the safety, tolerability and long term efficacy up to 1 year in patients with active rheumatoid arthritis who have an inadequate response to anti-TNFa agents

Takeda: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Daily Oral XXXX 25 mg and 50 mg Compared to Placebo When Used in Combination with Sitagliptin in Subjects with Type 2 Diabetes

Theravance: A Phase 2 Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study of XXXX in Subjects with Fibromyalgia (FM)

Astra Zeneca: Prospective observational study, estimate the rate of inadequate response to laxatives (LIR) in a cohort of patients with OIC

Sativex: A double blind, randomized, placebo-controlled, parallel group study of XXXX oromucosal spray, as adjunctive therapy in relieving uncontrolled persistent chronic pain in patients with advanced cancer, who experience inadequate analgesia during optimized chronic opioid therapy

Sativex: A multicenter, non-comparative, open-label extension study to assess the long term safety of XXXX oromucosal spray as adjunctive therapy in patients with uncontrolled persistent chronic cancer related pain

Auxillium Pharmaceuticals, Inc.: A Randomized, Double-Blind, Placebo-Controlled Study Of The Safety And Efficacy of XXXX For The Treatment Of Adhesive Capsulitis Of The Shoulder

Eli Lilly and Company: Phase 3, Psychometric Validation of Performance Based Measures for Use with Hip Fracture and Elective Hip and Knee Replacement Populations

Abbott: A Multicenter Study of the Prevalence of Axial Spondyloarthritis (SpA) in the United States among Subjects with Chronic Back Pain and Other SpA-Related Features

Human Genome Sciences: A Randomized, Double-Blind, Placebo-Controlled 52-Week Study to Assess Adverse Events of Special Interest in Adults with Active, Autoantibody-Positive Systemic Lupus Erythematosus Receiving Belimumab

Takeda: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Daily Oral XXXX 25 mg and 50 mg Compared to Placebo When Used in Combination with Sitagliptin in Subjects with Type 2 Diabetes

Eli Lilly: A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of XXXX in Patients with Moderately to Severely Active Rheumatoid Arthritis Who have Lad Limited or No Treatment with Disease-Modifying Antirheumatic Drugs

Amgen: A Randomized, Double-Blind, Phase 3 Study of XXXX Efficacy and Safety Compared to Adalimumab in Subjects with Moderate to Severe Rheumatoid Arthritis

Janssen: A Multicenter, Parallel-group Study of Long-term Safety and Efficacy of XXXX (sirukumab) for Rheumatoid Arthritis in Subjects Completing Treatment in Studies CNTO136ARA3002 (SIRROUND-D) and CNTO136ARA3003 (SIRROUND-T)

Santarus: A Randomized, Double-blind, Placebo-Controlled, Multiple Ascending Dose Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Escalating Doses of XXXX in Patients with Active Rheumatoid Arthritis with Inadequate Response to Disease-Modifying Anti-rheumatic Drug(s)

Regeneron: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of the Safety and Efficacy of 3-Month Subcutaneous XXXX Treatment in Patients with Sarcopenia

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

Auxilium Pharmaceuticals: A Phase 2b, Double-Blind, Placebo Controlled Study of the Safety and Efficacy of XXXXXX for the Treatment of Adhesive Capsulitis of the Shoulder

Eli Lilly and Company: Pharmacokinetic Evaluations of XXXX Following Subcutaneous Administration by Prefilled Syringe or Auto Injector in Patients with Systemic Lupus Erythematosus

Teva: A 6-Month, Open-Label, Extension Study to Evaluate the Safety of Hydrocodone Bitartrate Extended-Release Tablets (XXXX) at 15 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Patients With Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time

Teva Branded Pharmaceutical Products R&D, Inc.: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Topically Applied XXXX (4% and 8% w/w Ointment) in Patients with Primary Osteartbritis Affecting a Single Knee

Bioventus: A Multicenter, Randomized, Double-Blind, Parallel, Active Controlled Non-Inferiority Clinical Trial Comparing Three Weekly Intra-Articular Injections of XXXX versus Three Weekly Intra-Articular Injections Of XXXXFor Treatment Of Osteoarthritis Pain Of The Knee

Flexion: A Double-Blind, Randomized, Parallel Group, Dose-Ranging Study to Assess the Safety and Efficacy of XXXX for the Treatment of Pain in Patients with Osteoarthritis of the Knee

Kowa Research Institute, Inc.: A Phase III, Multicenter, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXX Compared With Placebo for the Treatment of Mild to Moderate Acute Pain Associated With Ankle Strain or Sprain

Novo Nordisk: A Randomized, double-blind, cross-over trial comparing the safety and efficacy of insulin XXX and insulin XXXX, with or without OADs in subjects with type 2 diabetes

CymaBay Therapeutics: A Randomized, Double-Blind, Active and Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXX for Preventing Flares and Reducing Serum Uric Acid in Gout Patients

Fidia Farmaceutici S.p.A.: A multic-center, parallel, double-blind, randomized, placebo-controlled study to evaluate the safety and effectiveness of XXXX, a new viscoelastic hydrogel, for the treatment of osteoarthritis of the knee

Samumed: A Phase 1, Placebo-Controlled, Double-Blind, Dose-Escalation Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXXX injected in the Target Knee Joint of Moderately to Severely Symptomatic Osteoarthritis Subjects

Novartis: A 56-week, randomized, multi-center, double-blind, placebo-controlled, phase IIa/IIb study to evaluate the safety and efficacy of i.v. bimagrumab on total lean body mass and physical performance in patients after surgical treatment of hip fracture