



Research Associates

CURRICULUM VITAE

SIGNATURE:		DATE:	1-22-15
NAME:	Donald C. Lipkis, M.D.	DATE	
TITLE:	Principal Investigator	UPDATED:	January 2015

RESEARCH SITE ADDRESS & PHONE:

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EDUCATION/TRAINING:

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Southern California Medical Center, Los Angeles, CA	B.S.	1966-1969	Science
University of Southern California Medical Center, Los Angeles, CA	M.D.	1969-1973	Internal Medicine
University of Southern California Medical Center, Los Angeles, CA	Internship	1973-1974	Internal Medicine
University of Southern California Medical Center, Los Angeles, CA	Residency	1974-1976	Internal Medicine
University of Southern California Medical Center, Los Angeles, CA	Fellowship	1976-1978	Gastroenterology

BOARD CERTIFIED:

BOARD CERTIFIED/ELIGIBLE	YEAR(s)	SPECIALTY
Board of Medical Examiners	1974	Medicine
American Board of Internal Medicine	1974	Internal Medicine
American Board of Internal Medicine	1979	Gastroenterology

POSITIONS AND EMPLOYMENT:

2013-Present	Principal Investigator, TriWest Research Associates LLC, El Cajon, CA
1995-Present	Institute of Healthcare Assessment, Inc., San Diego, CA
1978-Present	Donald C. Lipkis, M.D., Inc. San Diego, CA
1976-1978	Instructor in Medicine, University of Southern California, Los Angeles, CA
1978-1983	Instructor in Medicine, University of California, San Diego, CA
1983-1992	Assistant Clinical Professor of Medicine, University of California, San Diego, CA
1992-2000	Associate Clinical Professor of Medicine, University of California, San Diego, CA

CLINICAL RESEARCH EXPERIENCE:

- AstraZeneca (erosive esophagitis)
- Clinmark (H-pylori)
- Searle (arthritis)
- Park Davis (arthritis)
- Searle (arthritis)
- Tap Holdings, Inc. (erosive esophagitis)
- Glaxo Welcome (irritable bowel)
- Novartis (dyspepsia)
- National Cancer Institute (colorectal adenomas prevention)
- AstraZeneca (erosive esophagitis)

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

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)

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

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 Pharma L.P.: A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of XXXX/XXXX Controlled-release Tablets (OXN) to

Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY)) 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 Pharma L.P: A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of XXXX/XXXX Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY)) IN Opioid-experienced Subjects with Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy

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

Cubist Pharmaceuticals, Inc: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of XXXX for the Treatment of Opioid-Induced Constipation In Adults Taking Opioid Therapy For Chronic Non-Cancer Pain

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

Synergy Pharmaceuticals Inc: 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

Applied Proteomics Inc: Colorectal Cancer Biomarker Specimen Collection Study

Rhythm Pharmaceuticals: A Phase 2b, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of XXXX Administered to Patients with Vomiting Symptoms and Moderate to Severe Diabetic Gastroparesis