Curriculum Vitae

James V. Chabala, MD
Principal Investigator/Subinvestigator

Signature: _____ Date: 6/22/16

Licensure and Specialty

Licensure: Doctor of Medicine (MD), License #G31377, California
Specialty: Family Practice, Board Certified 1982 to 2011, Board Eligible 2011 to Present

Site Affiliation

North County Clinical Research
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Oceanside, California 92056
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Hospital Affiliations

TriCity Medical Center
4002 Vista Way
Oceanside, California 92056

Professional Affiliation/Education

1976	Residency – Family Practice Naval Regional Medical Center, Camp Pendleton, California
1974	Internship Naval Regional Medical Center, Camp Pendleton, California
1973	Doctor of Medicine (MD) Loyola, Stritch School of Medicine, Maywood, Illinois
1969	Bachelor of Science University of Illinois (Chicago Circle Campus), Chicago, Illinois

Professional Experience

July 2010 to Present	Principal Investigator and Subinvestigator North County Clinical Research, Oceanside, California
2009 to Present	Independent Contractor Graybill Medical Group, Escondido, California
1997 to Present	Attending Physician Tri-City Medical Center, Oceanside, California
1992 to 2013	Doctor of Medicine (MD) QualityCare Medical Center, Oceanside, California
1982	Chief of Family Practice Department Tri-City Medical Center, Oceanside, California
1979 to 1992	Doctor of Medicine (MD)/Physician Partner/Member Cassidy Medical Group, Oceanside, California

Memberships

Member, American Academy of Family Physicians

Military Service

- 6.5 years of active duty, US Navy. Includes 1 year of medical school, 3 years of residency, 3 years of teaching family practice residency (Camp Pendleton, CA), and a 6 month recall for Operation Desert Storm.
- Established and ran Del Mar Branch, Family Practice Clinic (Camp Pendleton, CA) from 1976 to 1979.
- 15.5 years of active reserve duty. Commanding office for 3 separate marine medical detachments (tanks, infantry, and artillery).
- Rank of Senior Navy Captain, Retired

Community Activities

- Post Co-Chairman, Oceanside Community Clinic
- Member, Kiwanis Club Oceanside/Pacific since 1984
- President Elect, Kiwanis Club from 1988 to 1989 and 2012 to 2013
- Fund-Raising Chair or Co-Chair, Kiwanis Club from 1990 to present
- Scottish American Military Society
- Member, Scottish Knights Templar (Charitable Scottish Society)
- Past member, Local HICFA Committee (Governor Jerri Brown era)

Training and Certifications

2010 to Present National Institutes of Health (NIH) Training and Certification

Other Clinical Trial Experience

Asthma

A double-blind, randomized, placebo-controlled, study for the level of asthma control achieved with XXXX/XXXX XXXX combination discus dry powder compared with XXXX XXXX XXXX inhaler alone in adults and adolescents

Bronchitis

A comparative study of the efficacy and safety of XXXX extended release tables and XXX tables for the treatment of acute bronchitis

Candidiasis

A multi-center, prospective, randomized, single-blind parallel group comparison of XXXX 3 day regime with the 7 day regime, for the treatment of vulvovaginal candidiasis

Conjunctivitis

The use of a topical ophthalmic antibiotic solution for the treatment of bacterial conjunctivitis in pediatric and adult populations

Osteoarthritis

The use of a novel topical non-steroidal gel, for the treatment of knee pain in osteoarthritis

Otitis Externa

Evaluation of topical XXXX drops for the treatment of acute otitis externa

Miscellaneous

A multi-center, randomized, blinded study for the evaluation of the use of a unique testosterone topical gel formation, and a transdermal testosterone patch in males with a testosterone level at or less than 200 mg/ml

North County Clinical Research

Clinical Research Trials

James V. Chabala, MD

Year Started	Phase	Indication	Protocol Title
2016	Phase 4	Chronic Pain	A randomized, double-blind, placebo-controlled, clinical trial of structured opioid discontinuation versus continued opioid therapy in suboptimal and optimal responders to high-dose long-term opioid analgesic therapy for chronic pain
2014	2b	Influenza	A phase 2b, randomized, double-blind, placebo-controlled, parallel-group, multicenter study of 2 dose levels of XXXX administered as monotherapy and one dose level of XXXX administered in combination with XXXX for the treatment of acute uncomplicated seasonal influenza A in adult subjects
2014	Phase 3	Generalized Anxiety Disorder	A randomized double-blind, placebo controlled, flexible and fixed dose, parallel group study of extended-release XXXX (XXXX) for the treatment of generalized anxiety disorder (GAD)
2014	Phase 3	Neuropathic Pain	A randomized double-blind placebo controlled parallel group study of the efficacy and safety of XXXX (BID) in subjects with post-traumatic peripheral neuropathic pain
2014	Phase 3	Tardive Dyskinesia	A phase 3, randomized, double-blind, placebo-controlled, parallel, fixed-dose study to assess the efficacy, safety, and tolerability of XXXX for the treatment of tardive dyskinesia
2013	Phase 2	Cocaine Dependency	A 12-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of once-weekly intra-muscular injections of XXXX (150 mg/week or 300 mg/week) as treatment for facilitation of abstinence in cocaine-dependent subjects
2013	Phase 3	Opioid Dependence	A randomized, blinded, active-controlled non-inferiority study of the efficacy and safety of XXXX for the induction of treatment of opioid dependence
2013	Phase 3	Opioid Dependence	Phase III - A multi-center, open-label, 24-week, follow-up study to assess safety, efficacy and treatment adherence for maintenance treatment of opioid dependence with XXXX
2013	Phase 3	Opioid-Induced Constipation	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
2013	Phase 3	Opioid-Induced Constipation	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

2012	Phase 2	Bipolar I Disorder	A prospective, randomized, double-blind, placebo-controlled, phase 2 safety and efficacy study of oral XXXX as an adjunctive maintenance treatment in patients with bipolar I disorder
2012	Phase 3	Bipolar 1 Disorder with Depression	A randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy and safety of once a day, XXXX (XXXX) tablet for sublingual administration (XXXX Tablet) 0.1 mg and 0.4 mg as an adjunctive therapy in the treatment of acute depressive episodes associated with bipolar 1 disorder in adult subjects
2012	Phase 3	Bipolar 1 Disorder with Depression	A randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy and safety of once a day, XXXX 0.1 and 0.4 mg as an adjunctive therapy to treatment-as-usual in the maintenance treatment of bipolar 1 disorder in adult subjects
2012	Phase 3	Bipolar I Disorder	A 52-week, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of an intramuscular depot formulation of XXXX (XXXX) as maintenance treatment in patients with bipolar I disorder
2012	Phase 3	Bipolar I Disorder	A 52-week, multicenter, open-label study to evaluate the effectiveness of an intramuscular depot formulation of XXXX (XXXX) as maintenance treatment in patients with bipolar I disorder
2012	Phase 3	Low Back Pain/Opioid Induced Constipation	A randomized, double-blind, double-dummy, placebo-controlled, active-controlled, parallel-group, multicenter trial of XXXX/XXXX controlled-release tablets (XXXX) to assess the analgesic efficacy (compared to placebo) and the management of opioid-induced constipation (compared to XXXX controlled-release tablets (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
2012	Phase 3	Opioid-Induced Constipation	A andomized, 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)
2012	Phase 3	Schizophrenia	A randomized, multicenter, double-blind, non-inferiority study of XXXX XXXX 3 month and 1 month formulations for the treatment of subjects with schizophrenia
2012	Phase 4	Smoking Cessation Cardiac Assessments	A phase 4, non-treatment follow-up for cardiac assessments following use of smoking cessation treatments in subjects with and without a history of psychiatric disorders
2011	Phase 2	Gout	A randomized, double-blind, dose-response study of the safety and efficacy of oral XXXX added to XXXX in subjects with gout who have not adequately responded to XXXX monotherapy
2011	Phase 3	Opioid Induced Bowel Dysfunction	A multicenter, randomized, placebo-controlled, double-blinded study of the efficacy and safety of XXXX in subjects with opioid-induced bowel dysfunction
2011	Phase 3	Opioid-Induced Constipation	An open-label 52-week study to assess the long-term safety of XXXX-XX in opioid-induced constipation (OIC) in patients with non-cancer-related pain

2011	Phase 3	Schizophrenia	An open-label, multicenter, rollover, long-term study of XXXX intramuscular depot in patients with schizophrenia
2011	Phase 3b	Schizophrenia	A multicenter, open-label study to assess hospitalization rates in adult subjects with schizophrenia treated prospectively for 6 months with XXXX IM Depot compared with 6-month retrospective treatment with oral antipsychotics in a naturalistic community setting in the united states
2011	Phase 4	Smoking Cessation	A phase 4, randomized , double-blind, active and placebo-controlled, multicenter study evaluating the neuropsychiatric safety and efficacy of 12 weeks XXXX XXXX 1mg BID and XXXX XXXX 150mg BID for smoking cessation in subjects with and without a history of pschiatric disorders
2009	Phase 3	Schizophenia	A 52-week, multicenter, open-label study to evaluate the effectiveness of XXXX intramuscular depot as maintenance treatment in patients with schizophrenia