

CURRICULUM VITAE
Jeffrey A. Danziger, M.D.

ADDRESS

Psychiatric Affiliates, P.A.
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Maitland, Florida 32751
Phone (407) 679-6400 Fax (407) 679-7988

CERTIFICATION

Diplomate, National Board of Medical Examiners, July 1, 1983
American Board of Psychiatry and Neurology:
Board Certified in Psychiatry, July 1988
Board Certified in Forensic Psychiatry, December 1994
Recertified April 2013 – Meeting MOC Requirements
Board Certified in Geriatric Psychiatry, October 1995
Recertified April 2015 – Meeting MOC Requirements
Board Certified in Addictions Psychiatry, April 1997
Recertified December 2017 – Meeting MOC Requirements

LICENSE

Florida Medical License ME 49703

PROFESSIONAL

Premedical: Harvard College, Cambridge, Massachusetts, B.A. Biology,
Graduated June 1978, *Magna Cum Laude with Highest Honors in Biology*

Medical: University of Miami School of Medicine, Miami, Florida,
Graduated May 1982, *Medical Honor Society – Alpha Omega Alpha*

Internship: Washington University/Barnes Hospital, St. Louis, Missouri,
Psychiatry, July 1982 through June 1983

Residency: Washington University/Barnes Hospital, St. Louis, Missouri
Psychiatry, June 1983 through June 1986

Faculty: One-year appointment as Chief Resident and Faculty Instructor
Washington University/Barnes Hospital, Department of Psychiatry,
St. Louis, Missouri, July 1986 through June 1986

PRIVATE PRACTICE

Psychiatric Affiliates, P.A., Maitland, Florida
Adult, Geriatric, and Forensic Psychiatry, December 1989 - Current

Florida Psychiatric Associates, Winter Park, Florida
Adult, Geriatric and Forensic Psychiatry, July 1987 - December 1989

POSITIONS HELD

Ali A. Kashfi, M.D., P.A.
Principal Investigator

Orlando, Florida
2013 – 2014

Florida Clinical Research Center, LLC (formerly CORE Research)
Investigator

Maitland, Florida
2008 – 2011

Functions as, or under the direction of, the Principal Investigator for assigned studies performing medical oversight for study subjects.

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<u>CORE Research INC</u> <i>Medical Director</i>	Maitland, Florida 2004 – 2007
<u>Winter Park Hospital</u> <i>Medical Director, Psychiatric Unit</i>	Winter Park, Florida 1996 – 2000
<u>University of Central Florida</u> <i>Consultant, Student Health Services</i>	Orlando, Florida 1997 – 1999
<u>John E. Polk Correctional Facility</u> <i>Contracted Psychiatrist</i>	Sanford, Florida 1997 - 1999
<u>Winter Park Hospital</u> <i>Medical Director, Medical-Psychiatric Unit</i>	Winter Park, Florida 1995 – 1999
<u>University Behavioral Center</u> <i>Medical Director, Adult Services</i>	Orlando, Florida 1993 – 1998
<u>Health Management Associates</u> <i>Corporate Medical Director of Psychiatric Services</i>	Naples, Florida 1993 – 1997
<u>West Lake Hospital</u> <i>Director, Psychiatric Intensive Evaluation Unit</i>	Longwood, Florida 1991 – 1993
<u>Winter Park Memorial Hospital</u> <i>Director, Special Medical Unit</i>	Winter Park, Florida 1990 - 1991
<u>La Amistad Foundation (Psychiatric Services)</u> <i>Medical Director</i>	Fern Park, Florida 1989 – 1991
<u>Winter Park Pavilion</u> <i>Director, Mood Disorder Unit</i>	Winter Park, Florida 1989 – 1991
<u>Florida Psychiatric Associates</u> <i>Assistant Medical Director</i>	Winter Park, Florida March 1989 – Dec 1989
<u>Florida Psychiatric Associates</u> <i>Adult, Geriatric and Forensic Psychiatry Private Practice</i>	Winter Park, Florida 1987 – 1989
<u>Washington University/Barnes Hospital, Department of Psychiatry</u> <i>Chief Resident and Instructor in Psychiatry (Faculty)</i>	St. Louis, Missouri 1986-1987

HONORS AND AWARDS

Orlando Magazine – Top Doctors 2001, 2002, 2003, 2004, 2005, 2006, 2008, 2011, and 2012
Orlando Magazine – The Best 70 Doctors in Central Florida 2000
Guide to America’s Top Physicians – 2003, 2004 & 2008
Doctors Across America – Top Doctors 2002

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Florida Monthly Magazine – Florida’s Top Doctors 2002

Selinsky Award (Outstanding Medical Student in the field of psychiatry) 1982

- Guttenberg Prize: 1978
- Outstanding Senior Research Project, Mather House, Harvard College

FORENSIC PSYCHIATRY

Testimony and written opinions given on civil and criminal matters in Federal, Circuit and County Courts: Middle District Court of the United States and the State of Florida counties of: Orange, Seminole, Osceola, Volusia, Brevard, Lake, Polk, Miami-Dade, St. Johns, Collier, Columbia & Escambia Counties, as well as Federal Court.

INVESTIGATOR EXPERIENCE

Attention-Deficit/Hyperactivity Disorder

A Randomized, Double-blind, Placebo-controlled, Phase II Dose-Ranging Study of the Safety and Efficacy of XXX in Adults with ADHD

An Open Label, Dose Titration, Long Term Safety Study to Evaluate XXX in Adults with ADHD

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Forced Dose Titration, Safety and Efficacy Study of XXX in Adults with Attention-Deficit Hyperactive Disorder

A Long Term Open Label and Single Arm Study of XXX in Children ages 6-12 with ADHD

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Safety and Efficacy Study of XXX with an Open-Label Extension in Adolescents with Attention-Deficit Hyperactivity Disorder (ADHD)

A Phase III, Multi-center, 12-Month, Open-Label Safety Study of XXX in Adults with Attention-Deficit Hyperactivity Disorder

A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Safety and Efficacy Study of XXX in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)

A Phase II, Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-Ranging Study of the Safety and Efficacy of XXX in Adults with Attention Deficit-Hyperactivity Disorder

The Long-Term Safety and Tolerability of XXX in Adults with Attention Deficit-Hyperactivity Disorder: An Open-Label Extension Study

A Double-blind, Randomized, Multi-center, Flexible Dose Study Evaluating the Efficacy and Safety of XXX in Children Aged 6-12 with Symptoms of Oppositionality and a Diagnosis of Attention Deficit- Hyperactivity Disorder

A Prospective, Open-Label, Multi-center, Dose-Optimization Study Evaluating the Efficacy, Safety and Tolerability of XXX in Children aged 6-12 Diagnosed with ADHD

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Anxiety

An Eight-Week, Multi-center, Randomized, Double-blind, Placebo-controlled Study, With XXX as an Active Control, To Evaluate the Efficacy, Safety and Tolerability of a XXX in Patients with GAD

A Multicenter Randomized, Double-blind, Parallel Group, Placebo-controlled, Active Controlled Study of the Efficacy And Safety of Sustained Release XXX Compared With Placebo in the Treatment of Generalized Anxiety Disorder

A Comparison of XXX, XXX Extended Release, and Placebo in the Treatment of Generalized Anxiety Disorder

The Efficacy of XXX as Adjunctive Therapy in Subjects with Insomnia Related to Generalized Anxiety Disorder

An Eight Week, Double-blind, Placebo-controlled, Multi-center Study with XXX as Positive Control, Evaluating the Efficacy, Safety, Tolerability of a Fixed Dose of XXX in outpatients with Generalized Anxiety Disorder (GAD)

A Multi-center Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-Controlled Study of the Efficacy and Safety of Sustained Release XXX Compared with Placebo in the Treatment of Generalized Anxiety Disorder

A Multi-center, Randomized, Double-blind, Parallel-group, Placebo-controlled Study of the Efficacy and Safety of XXX Extended-Release Compared with Placebo as an Adjunct to Treatment in Patients with Generalized Anxiety Disorder who Demonstrate Partial or No Response to a Selective Serotonin Reuptake Inhibitor or Serotonin-Norepinephrine Reuptake Inhibitor Alone or in Combination with a Benzodiazepine

Bipolar Disorder

A Randomized, Double-blind, Placebo-controlled, Proof-of-Concept, Phase II Study to Evaluate the Efficacy and Safety of once a day. TAK-375 SL 0,1 mg, 0.4 mg, and 0.8 mg as an Adjunctive Therapy to Treatment-as-Usual in the Maintenance Treatment of Bipolar I Disorder in Adult Patient

A Randomized, Double-blind, Placebo-controlled, Proof-of-Concept, Phase II Study to Evaluate the Efficacy and Safety of Once a Day, TAK-375 (Ramelteon) Tablet for Sublingual Administration (TAK-375SL Tablet) 0.1 mg, 0.4 mg, and 0.8 mg in the Treatment of Acute Depressive Episodes Associated with Bipolar I Disorder in Adult Patients who are on Lithium and/or Valproate

A Confirmatory, Multi-center, Double-blind, Randomized, Placebo-controlled Study of the Use of XXX in the Treatment of Patients with Bipolar Depression

A Randomized, Double-blind, Placebo-controlled, Multi-center Study To Evaluate The Efficacy And Tolerability Of XXX in the Treatment of Manic Episodes Of Bipolar Disorder Over 3 Week, and 52 Week, Open Label Extension Study to Evaluate the Safety and Tolerability of XXX in the Treatment of Manic Episodes of Bipolar 1 Disorder

A Multi-center, Randomized, Parallel-group, Double-blind, Phase IV Comparison of the Efficacy and Safety of XXX to Placebo as Adjunct Therapy to Mood Stabilizers (XXX or XXX) in the Treatment of Bipolar I Disorder and Alcohol Dependence in Adult Patient Receiving Treatment for 12 Weeks

Multi-center, Randomized, Double-blind, Placebo-controlled Clinical Research Study to Evaluate the Safety and Efficacy of XXX in Patients with Acute Mania in Bipolar Disorder

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A Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose Response, Multi-center Study to Evaluate the Efficacy and Safety of Three Fixed Doses of Extended Release XXX in the Treatment Of Subjects with Acute Manic and Mixed Episodes Associated with Bipolar I Disorder

A Multi-center, Randomized, Parallel-group, Double-blind, Phase III Comparison of the Efficacy And Safety of XXX to Placebo When Used as Adjunct to Mood Stabilizers in the Maintenance Treatment of Bipolar I Disorder in Adult Patients

A Phase IIIb, Randomized, Double-blind, Parallel-group Study in Bipolar I Patients to Assess the Efficacy and Safety of XXX Administered Once-Daily vs. Twice-Daily in the Treatment of Manic Symptoms

A Phase IIIb, Open-Label Observational Safety Study of Extended-Release XXX Used in Combination with Other Psychotropic Medications for the Treatment of Bipolar I Disorder

An International, Multi-center, Double-blind, Randomized, Parallel-group, Placebo-controlled, Phase III Study of the Efficacy and Safety of XXX and XXX as Monotherapy in Adult Patients with Bipolar Depression for 8 weeks and XXX in Continuation Treatment for 26 up to 52 weeks

Efficacy of XXX in Combination with XXX or XXX in the Treatment of Manic Patients with Bipolar I Disorder Partially Nonresponsive to XXX or XXX Monotherapy

A Multicenter, Double-blind, Randomized, Parallel-group, Placebo-controlled, Phase III Study of the Efficacy and Safety of XXX Sustained Release as Monotherapy in Adult Patients with Acute Bipolar Depression

A Phase III, Randomized, 6-Month, Double-blind Trial in Subjects with Bipolar I Disorder to Evaluate the Continued Safety and Maintenance of XXX Plus a Mood Stabilizer (versus Placebo Plus a Mood Stabilizer) Following a Minimum of 2 months of Response to Open Label Treatment with Both Agents

A Multi-center, Randomized, Parallel-group, Double-blind, Phase IV Comparison of the Efficacy and Safety of XXX to Placebo as Adjunct Therapy to Mood Stabilizers in the Treatment of Bipolar I Disorder and Alcohol Dependence in Adult Patient Receiving Treatment for 12 Weeks

Controlled Trial of Safety and Efficacy of XXX Versus Placebo in Patients with Bipolar Depression

Controlled Trial of XXX versus Placebo in Patients with Bipolar Disorder in Manic or Mixed States

Depression

A Phase II, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging Efficacy and Safety Study of XXXX in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant 2012

A Phase III, Open-label, Multi-center, 12-month Extension Safety and Tolerability Study of XXXX in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Residual Symptoms or Inadequate Response Following Treatment with an Antidepressant 2012

Interventional, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study to Evaluate the Efficacy and Safety of XXXXXXXX (1 and 3 mg/day) as Adjunctive Treatment in Elderly Patients with Major Depressive Disorder with an Inadequate response to Antidepressant Treatment 2013

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A Multi-center, Double-blind, Parallel Group, Fixed Dose, 4-Arm, Placebo and XXX Controlled 8 Week Efficacy Study of 2 Oral Doses of XXX in Adult Outpatients With MDD

A Multi-center, Double-blind, Randomized, Parallel-group, Placebo-controlled and Active Controlled Phase III Study of the Efficacy and Safety of XXX Sustained Release as Monotherapy in the Treatment of Patients with Major Depressive Disorder

A Multi-center, Randomized, 30- To 52 -Week, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in the Prevention Of Relapse or Recurrence of Depressive Symptoms in Outpatients with Major Depressive Disorder Who Maintained Clinical Stability After an Initial Response to Open-label Treatment With XXX

An Eight Week, Multi-center, Double-blind, Placebo-controlled Study Evaluating the Efficacy, Safety and Tolerability of One Fixed-dose of XXX in Subjects with Major Depressive Disorder

A Randomized, Double-blind, Placebo-controlled Study of XXX in the Treatment of Patients with Bipolar I Disorder with a Major Depressive Episode

An Extension to A Randomized, Double-blind, Placebo-controlled Study of XXX in the Treatment of Patients with Bipolar I Disorder with a Major Depressive Episode

A Multi-center, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of XXX as Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder

A Ten Month Open Label Evaluation of the Long Term Safety of XXX SR in Outpatients with Major Depressive Disorder

A Multi-center Randomized Double-blind Placebo-controlled Parallel-group Efficacy and Safety Study if a Flexible Dose of XXX SR in Adult Outpatients with MDD

An Eight Week, Multicenter, Double-blind, Placebo-controlled Study of XXX in Elderly Outpatients with Major Depressive Disorder

Weekly Enteric-Coated XXX vs. Daily XXX or Placebo in the Continuation Treatment of Major Depressive Disorder

XXX Alone and In Combination with XXX vs. Placebo in Major Depressive Disorder With Psychotic Features

A Double-blind, Randomized, Multicenter, Parallel Design Study to Evaluate The Efficacy and Safety of Three Dose Ranges of a Novel Agent Vs. Placebo and Active Control in Outpatients with Major Depressive Disorder

A Double-blind Study, XXX vs. Placebo, in Child and Adolescent Major Depressive Disorder

A Double-blind Study, XXX vs. Placebo and Active Control, in Major Depressive Disorder

A Multi-center, 10-Week, Randomized, Double-blind, Placebo-controlled, Flexible Dose Outpatient Study of XXX in Child/Adolescent Major Depressive Disorder

A Fixed-dose Comparison of the Safety and Efficacy of XXX, XXX and Placebo in Major Depressive Disorder

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A Placebo-controlled Evaluation of the Safety and Efficacy of XXX in the Presentation of Relapse in Major Depressive Disorder

A Double-blind, Placebo-controlled Efficacy Study of XXX vs. Active Control in Producing Remission in Outpatients with Major Depressive Disorder

Evaluation of the Safety and Efficacy of XXX in the Prevention of Recurrence in Major Depressive Disorder

A Phase IIB, Six-Week, Double-blind, Placebo-and XXX-Controlled Multi-center Study to Evaluate the Safety and Efficacy of an Oral XXX in Outpatients with Major Depressive Disorder

A Seven-Week, Double-blind Extension Of A Phase IIB Six-Week, Double-blind, Placebo- And XXX-Controlled Multi-center Study to Evaluate the Safety and Efficacy of an Oral XXX In Outpatients with Major Depressive Disorder

A Double-blind, Multi-center, Placebo-controlled, Acute and Extension Study of Two Doses of XXX in Major Depressive Disorder

A Multicenter, Double-blind, Randomized, Parallel-group, Placebo-controlled Phase III Study of the Efficacy and Safety of XXX as Mono-therapy in the Treatment of Adult Patients with Major Depressive Disorder

An Eight-Week, Multicenter, Double-blind, Placebo-controlled Study Evaluating the Efficacy, Safety and Tolerability of One Fixed 100 mg Dose of XXX in Patients with Major Depressive Disorder

An Eight-week, randomized, Double-blind, Fixed-dosage, Placebo-controlled, Parallel-group, Multi-center study of the Safety and Tolerability of XXX in the treatment of Major Depressive Disorder (MDD) followed by a 52-week open-label extension

A Multi-center, Double-blind, Parallel Group, Fixed Dose, 4-arm, Placebo and XXX-Controlled 8 Week Efficacy Study of 2 Oral Doses of XXX in adult outpatients with Major Depressive Disorder

A Multi-center, Randomized, 8-week Double-blind Acute Phase Followed by a 6-month Continuation Phase (Open-label or Double-blind) Study to Evaluate the Efficacy, Safety, and Tolerability of XXX versus XXX in Post-Menopausal Women with Major Depressive Disorder

A Randomized, Double-blind, Placebo-controlled Study of the Efficacy of XXX in Patients with Major Depressive Disorder

XXX versus Placebo in Patients with Major Depressive Disorder (MDD): Assessment of Energy and Vitality in MDD

A Phase IIa, Multi-center, Randomized, Double-blind, Double-dummy, and Placebo- and Active-Controlled Study to Investigate the Safety and Efficacy of XXX Administered to Subjects with Major Depressive Disorder

A Double-blind, Randomized, Placebo-controlled Study Examining, the Safety, Efficacy, and Tolerability of XXX in Subjects with Major Depressive Disorder (including Atypical and Melancholic Features)

An Eight-Week, Double-blind study to evaluate the efficacy, Safety and Tolerability of Two Fixed Doses of XXX Once Daily in combination with XXX once daily compared to placebo in combination with XXX once daily in patients with Major Depressive Disorder

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Insomnia

A Double-blind, Randomized, Multicenter, Placebo-controlled, Parallel Groups, Efficacy and Safety Extension Study of XXX in the Treatment of Adult Outpatients with Primary Insomnia

A Comparison of XXX vs. Placebo in the Treatment of Insomnia Associated with Newly Diagnosed Major Depressive Disorder (MDD) or Untreated MDD Relapse, When Used Concomitantly with Escitalopram

A Long-Term Safety and Efficacy Study of XXX in Elderly Subjects with Primary Chronic Insomnia

Efficacy and Safety of 2 mg/day of XXX on Sleep Maintenance Insomnia with a Sub-Study of the effect of XXX on Stable Type II Diabetes Mellitus: a 12 week Multi-center, Randomized, Double-blind, Placebo-controlled Study

A 6-Month, Double-blind, Randomized, Placebo-controlled, Parallel-group Out-Patient Trial, Investigating the Efficacy and Safety of XXX in Adult Patients with Chronic Primary Insomnia

Schizophrenia

A Randomized, Double-blind, Placebo-controlled, Parallel, 26-Week, Phase 3 Study of 2 Doses of an Alpha-7, Nicotinic Acetylcholine Receptor Agonist (EVP-6124) or Placebo as an Adjunctive Pro-cognitive Treatment in Schizophrenia Subjects on Chronic Stable Atypical Antipsychotic "Therapy," Protocol No. EVP-6124-016, ("Protocol") to be Conducted at Institution and to Involve Trial Subjects ("Trial")

A Multi-center 26-Week Extension Study to Evaluate the Safety and Clinical Effects of Prolonged Exposure to 1 and 2 mg Doses of EVP-6124, an Alpha-7 Nicotinic Acetylcholine Receptor Agonist, as an Adjunctive, Pro-cognitive Treatment in Subjects with Schizophrenia on Chronic Stable Atypical Antipsychotic "Therapy," Protocol No. EVP-6124-017, ("Protocol") to be Conducted at Institution and to Involve Trial Subjects ("Trial")

Efficacy of High Dose XXX in A Controlled Fixed Dose Response Trail for Treatment of Schizophrenia and Schizoaffective Disorders

A Double-blind, Randomized, Multi-center, Parallel-group Design Study to Evaluate the Safety and Efficacy of Two Dose Ranges of a Novel Antipsychotic Agent vs. Placebo and Active Control in Schizophrenia

A Double-blind, Five-Armed, Fixed-dose, Active- And Placebo-controlled Dose Finding Study with Sublingual XXX in Subjects with Acute Phase Schizophrenia

Allelic Variations in Schizophrenia

Other Indications

Double-blind, Placebo-controlled Trial of XXX in Panic Disorder, 12-Weeks, With a Continuation Phase

A Multi-center, Randomized, Double-blind, Placebo-controlled Study to Evaluate a Novel Agent in Patients with Probable Alzheimer's Disease of Mild to Moderate Severity

A Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose Range Finding Study to Evaluate the Safety and Efficacy of Four Doses of XXX in Patients with Social Phobia

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A 12-Week, Randomized, Double-blind, Placebo-controlled, Flexible Dose Study of XXX in Social Anxiety Disorder

A Double-blind, Randomized, Parallel-group, Active- and Placebo-controlled Study to Evaluate the Safety and Efficacy of XXX in Social Phobia

Open-Label Trial of XXX in Obsessive-Compulsive Disorder

Open-Label XXX Continuation Study

Multi-center, Parallel-group, Double-blind, Placebo-controlled, Dose Ranging Study of the Efficacy and Tolerability of XXX in the Prophylaxis of Migraine Headache and Open Label Extension

References available upon request