

## CURRICULUM VITAE

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#### **EDUCATION:**

1964 Doctor of Medicine, Neuroanatomy  
Universität Bern School of Medicine, Bern, Switzerland

#### **RESIDENCY AND FELLOWSHIP:**

1964 – 1965 Research Fellow in Endocrinology  
Universität Bern School of Medicine, Bern, Switzerland

1971 – 1974 Residency in Psychiatry  
Sheppard-Pratt Hospital, Towson, Maryland

#### **CERTIFICATION:**

American Board of Psychiatry & Neurology,

Certified in Psychiatry, June, 1976

#### **LICENSURE:**

Florida Medical License: June 1979, No. ME 034600

Drug Enforcement Agency License: Number available on request

#### **PROFESSIONAL EXPERIENCE:**

*Investigator*, December 2006 – Present  
Florida Clinical Research Center, LLC, Maitland, FL

*Staff Psychiatrist*, 2003 – 2006  
Orlando VA Medical Center, Orlando, FL

**PROFESSIONAL EXPERIENCE (continued):**

*Medical Director, Behavioral Health Services*, 1996 – 2003  
Orlando Regional Health Care System, Orlando, FL

*Chief of Psychiatry*, 1992 – 1996  
South Seminole Hospital, Longwood, FL

*Medical Director*, 1991 – 1992  
HCA West Lake Hospital, Longwood, FL

*Medical Director*, 1990 – 1991  
Winter Park Pavilion, Winter Park, FL

*Medical Director, Special Medical Unit*, 1989 – 1990  
Winter Park Memorial Hospital, Winter Park, FL

*Clinical Director, Adult Unit*, 1987 – 1989  
HCA West Lake Hospital, Longwood, FL

*Medical Director*, 1986 – 1987  
HSA Lynn Haven Hospital, Winter Park, FL

**INVESTIGATOR EXPERIENCE:**

Attention Deficit Hyperactivity Disorder (ADHD) • Alzheimer's Disease • Anxiety  
Bipolar Disorder • Cognition • Depression • Fibromyalgia • Insomnia • Migraine  
Obsessive Compulsive Disorder (OCD) • Panic • Schizophrenia  
Sexual Dysfunction • Sleep Disorders • Social Phobia • Substance Abuse and Addictions

**ADDITIONAL TREATMENT EXPERIENCE:**

Hypertension • Obesity • Pain • Pediatric Disorders • Smoking Cessation

**CLINICAL TRIAL EXPERIENCE:**

*Alzheimer's Disease*

A Phase II Multi-center, Randomized, Double-Blind, Two-Stage Clinical Trial to Evaluate the Efficacy and Safety of XXX in Patients with Alcohol Dependence

A Randomized Controlled Trial to Assess the Efficacy of a Medical Food in Patients with Mild to Moderate Alzheimer's Disease using Alzheimer's Disease Medication

**CLINICAL TRIAL EXPERIENCE (continued):**

A Phase IIb Nicotinic Agonist Alzheimer's Disease trial, Dose Ranging, Randomized, Double-Blind, Parallel-Group, Placebo-Controller, Multi-center Study of XXX Used as Add-On to XXX Treatment in Patients with Mild to Moderate Symptoms of Alzheimer's Disease

***ADHD***

A Double-Blind, Randomized, Placebo-Controlled, Multi-center, Fixed Dose Titration Study to Assess Efficacy, Safety, and Tolerability of XXX in Adults with Attention Deficit/Hyperactivity Disease (ADHD)

A Phase II, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX as Adjunctive Therapy in the Treatment of Adult Attention-deficit/Hyperactivity

A Placebo-controlled, Double-blind, Parallel-group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with XXX

A Randomized, Double-Blind, Placebo-Controlled, Phase 2 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 at Doses of XXX Per Day 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)

**CLINICAL TRIAL EXPERIENCE (continued):**

***Anxiety***

A Multi-center, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase II Study of Two Oral Dose Groups of XXX, with a XXX Arm, in Subjects with Generalized Anxiety Disorder (GAD)

Efficacy and Safety of Three Doses of XXX in Acute Treatment of Adults with Generalized Anxiety Disorder

A Phase III, Randomized Double-Blind, Parallel-Group 10-week Placebo-Controlled Fixed Dose Study of XXX and XXX Evaluating the Efficacy and Safety of XXX for the Treatment of GAD

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

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

***Bipolar Disorder***

A Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of XXX Treatment (150 and 200 mg/day) as Adjunctive Therapy in Adults with Major Depression Associated with Bipolar I Disorder

A 24-Week, Flexible-Dose, Open-Label Extension Study of XXX for the Treatment of Bipolar I Depression

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

A Controlled Trial of Safety and Efficacy of XXX vs. Placebo in Patients with Bipolar Depression

A Controlled Trial of XXX vs. Placebo in Patients with Bipolar Disorder in Manic or Mixed States

**CLINICAL TRIAL EXPERIENCE (continued):**

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, Parallel-Group, Double-Blind, Phase IV Comparison of the Efficacy and Safety of XXX (oral tablets daily in divided doses) 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.

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 Weeks, and 52 Weeks, Open Label Extension Study to Evaluate the Safety and Tolerability of XXX in the Treatment of Manic Episodes of Bipolar I Disorder

A 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

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

***Depression***

A Phase III, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses (10 and 20 mg) of XXX in Acute Treatment of Adults With Major Depressive Disorder

A Multi-center, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase III, Long-Term Safety and Tolerability Study of XXX as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder Who Exhibit an Inadequate response to Antidepressant Therapy

**CLINICAL TRIAL EXPERIENCE (continued):**

A Phase IIA, Double Blind, Placebo-Controlled Study of the Efficacy and Safety of XXX Augmentation of Antidepressant Therapy in Major Depression

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, XXX-Referenced, Fixed Dose Study Comparing the Efficacy and Safety of XXX in Acute Treatment of Major Depressive Disorder in Elderly Patients

Hypo-Sexual Dysfunction in Patients with Depression

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed Dose Study Evaluating the Efficacy and Safety of XXX in Subjects with Major Depressive Disorder

A Randomized Double-Blind, Parallel-Group, Placebo-Controlled, Active Referenced, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses of XXX in Acute Treatment of Adults with Major Depressive Disorder

A Multi-center, Double-Blind, Parallel-Group, Fixed Dose, Four-Arm, Placebo and XXX-Controlled Eight Week Efficacy Study of Two Oral Doses of in Adult Outpatients with MDD

An Eight-Week, Multi-center, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy, Safety and Tolerability of One Fixed Dose of XXX in Patients with Major Depressive Disorder

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

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 Multi-center, Randomized, 30- to 52 -Week, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX Once Daily 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 Once Daily

The Repetitive Transcranial Magnetic Stimulation in Major Depression. Phase III Study, South Seminole Hospital, Longwood Florida. Placebo-Controlled, with 40 Subjects (30 Active Treatment, 10 Placebo) 2000-2002

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

**CLINICAL TRIAL EXPERIENCE (continued):**

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 of a Flexible Dose of XXX SR in Adult Outpatients with MDD

An Eight-Week, Multi-center, Double-Blind, Placebo-Controlled Study of XXX in Elderly Outpatients with Major Depressive Disorder

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

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

A Double-Blind, Randomized, Multi-center, 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

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

An 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

**CLINICAL TRIAL EXPERIENCE (continued):**

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

***Migraine***

A Six Month Phase II/III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of XXX for Prevention of Menstrually Related Migraine in Female Patients with Episodic Migraine

A Phase IIa, Multi-center, Randomized, Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of XXX for Migraine Prophylaxis in Patients with Episodic Migraine

A Multi-center, Randomized, Double-Blind (With In-House Blinding), Active-Controlled, Parallel-Group Clinical Trial to Evaluate the Long Term Safety and Tolerability of Oral XXX 300 mg in Adults with Acute Migraine With or Without Aura

A Phase IIb, Randomized, Double-Blind, Active and Placebo Controlled, Parallel-Group Study to Assess the Efficacy and Safety of XXX Compared to Placebo and Sumatriptan in Adult Patients with Acute Migraine With or Without Aura

A 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

***Schizophrenia***

A Proof of Concept, Multi-center, Randomized, Double-Blind, Parallel, Placebo-Controlled Study of XXX versus Placebo in the Prevention of Weight Gain Associated with Therapy for Psychosis

The 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

The Allelic Variations in Schizophrenia

**CLINICAL TRIAL EXPERIENCE (continued):**

*Other Indications*

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 12-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study of XXX o Evaluate Responsiveness of, and Estimate the Clinically Important Difference in, a Novel Fatigue Tool in Subjects with Fibromyalgia

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multi-center Outpatient Trial of in Adults with Primary Insomnia

A Double-Blind, Randomized, Multi-center, Placebo-Controlled, Parallel-Groups, Efficacy and Safety Extension Study of XXX in the Treatment of Adult Outpatients with Primary Insomnia

A Double-Blind, Placebo-Controlled Trial of XXX in Panic Disorder, 12 Weeks, with a Continuation Phase

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

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

An Open-Label Trial of XXX in Obsessive-Compulsive Disorder

An Open-Label XXX Continuation Study

A Diagnosis of patients age 55 and older admitted to Sheppard Pratt Hospital. Retrospective Chart Review. Presented at Scientific Day at Sheppard Pratt 1973.

MMPI Profiles in Relatives of Schizophrenics

MMPI Profiles in Veterans who Died from Cirrhosis of the Liver. Tuscaloosa VAMC 1976.

XXX in the Treatment of Chronic Schizophrenia, Phase IV Study, Tuscaloosa VAMC 1977

Suicidal Ideation in Veterans Requesting Admission, Gainesville VAMC, 1977

CT Scan Measurements and Neuropsychological Test performance in Chronic Schizophrenic patients, Gainesville VAMC, presented at Florida Psychiatric Society Meeting 1981

XXX in the Treatment of Panic Disorder, Phase III, Future Health, Altamonte Springs, FL.

Curriculum Vitae, Eduard Gfeller, M.D.