

CURRICULUM VITAE

Mark J. Woyshville, MD FAASM D.ABPN

*CEO and Medical Director
North Star Medical Research, LLC*

18660 Bagley Road,
Building II, Suite 205
Middleburg Heights, OH 44130

Telephone: +01 440 234 5700
Fax: +01 440 234 5710
email: mwoyshville@northstarresearch.org

PROFESSIONAL LICENSURE: State Medical Board of Ohio, Doctor of Medicine, 35.063012, exp. 10/01/2017

DEA CERTIFICATE: Practitioner, All schedules; exp. 05/31/2017
Buprenorphine Waiver (DW-100) Added 10/8/2012

BOARD CERTIFICATIONS: 11/2007 - Diplomate, Sleep Medicine, American Board of Medical Specialties
09/2005 - Diplomate, Sleep Medicine, American Board of Sleep Medicine
06/1995 - Diplomate, Psychiatry, American Board of Psychiatry and Neurology; *Recertified July, 2005*

EDUCATION

Case Western Reserve University/University Hospitals of Cleveland	Fellowship	Jul/92 - Jun/93	Mood Disorders Special Fellow
University of California, San Diego (UCSD), La Jolla, California	Residency	Jul/90 - Jun/92	Psychiatric residency
Cleveland Clinic Foundation, Cleveland, Ohio	Internship	Jul/89 - Jun/90	Internship
University of Cincinnati College of Medicine, Cincinnati, Ohio	M.D	Sep/85 - Jun/89	Medicine
University of California, San Diego, La Jolla, California	Post-Baccalaureate Studies	Jan/84 - Jun/85	Chemistry, Biology, Mathematics
Cleveland State University, Cleveland, Ohio	B.S., Physics	Sep/76 - Jun/82	Physics

PROFESSIONAL AFFILIATIONS:

NAABT	National Alliance of Advocates for Buprenorphine Treatment
IASP	International Association for the Study of Pain
AASM	American Academy of Sleep Medicine (Fellow)
SRS	Sleep Research Society
ASCP	American Society of Clinical Psychopharmacology
AAAS	American Association for the Advancement of Science

POSITIONS AND EMPLOYMENT:

Apr07- present	North Star Medical Research LLC, CEO and Medical Director, Middleburg Heights, OH
Oct07 - present	Private Practice of General Psychiatry, Middleburg Heights, OH
Aug13- present	Fortaleza, Addiction Psychiatrist, Elyria, OH

POSITIONS AND EMPLOYMENT:

- Nov14 -present Member, Disability Evaluators Panel, Ohio Bureau of Workers' Compensation
Specialist Examiner, Industrial Commission of Ohio

- Aug14 – Jul15 Solutions Behavioral Health, Inc., Psychiatrist

- Nov14- Apr15 Avenues of Counseling & Meditation, LLC, Psychiatrist

- Jul00 - Feb11 Member, Disability Evaluators Panel, Ohio Bureau of Workers' Compensation
Specialist Examiner, Industrial Commission of Ohio

- Jan00 - Feb11 Psychiatrist, Ohio Department of Rehabilitation and Corrections

- Oct11 - Oct12 Southwest General Health Center, Medical Staff, Middleburg Heights, OH

- Aug07 - Mar09 Central Ohio Mental Health, Psychiatrist, Mount Gilead, OH

- Jan06 - Apr07 Cleveland Neuro-Sleep Research Institute, Inc., Medical Director, Middleburg Heights, OH

- Jul01 - Apr07 Southwest Cleveland Sleep Center, Co-Director; Director, Neuropsychiatric Sleep Medicine Program,
Middleburg Heights, OH

- Jul04 - Jul05 Attending psychiatrist treating the seriously and persistently mentally ill in a State custody facility; and the
dually-diagnosed mentally ill in a privately-contracted State custody setting.

- Jun01 - Apr04 Forensic Psychiatrist, Ohio Department of Mental Health

- May/00 - Feb01 Psychiatrist, Family Focus Center

- Nov/98 – Jan/00 Psychiatrist, W.G. Nord Center, Loraine OH

- Mar/97 – Sept/97 Attending Psychiatrist, Veteran's Addictions Recovery Center, VAMC, Cleveland, OH
Research Psychiatrist, Veteran's Addictions Recovery Center, VAMC

- Jul/93 – Mar/97 Assistant Professor of Psychiatry, Case-Western Reserve University
Attending on the Hanna Pavilion Adult Inpatient Psychiatric Unit, Partial and Electroconvulsive Therapy
Service, Cleveland, OH

ACADEMIC RESEARCH

Peer Reviewed Research:

- Jul/94 - Jul/98 Case Western Reserve University/University Hospitals of Cleveland

Principal Investigator, "Affective Instability: Quantification, Conceptualization, and Clinical Significance."
Funding: National Alliance for Research on Schizophrenia and Depression (NARSAD) Young Investigator Award,
\$60,000.

- Mar/95 - Sep/96 Case Western Reserve University/University Hospitals of Cleveland
Mood Disorders Program

Co-Investigator in a maintenance study comparing valproate and lithium in bipolar rapid cycling.
Funding: National Institute of Mental Health; The Stanley Foundation.

Unrestricted Educational Grants:

Jul/96 - Jul/98 Case Western Reserve University/University Hospitals of Cleveland
Recipient, Wyeth-Ayerst Unrestricted Educational Grant, in support of theoretical and phenomenological work in affective disorders.

Investigator-Initiated Research:

Jul/07 - Jun/09 **North Star Medical Research, LLC:**
Principal Investigator in a double-blind, placebo-controlled randomized clinical trial (RCT) of a dopamine agonist in the management of Restless Legs Syndrome (RLS) in patients treated with serotonergically-active antidepressants.

Jan/09 **North Star Medical Research, LLC:**
Principal Investigator in an open-label study of Amitiza (lubiprostone) for the management of Psychotropic-Induced Constipation.

Industry Sponsored Research:

North Star Medical Research, LLC

A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled study evaluating the efficacy, safety and Pharmacokinetics of SAGE-547 injection in the treatment of Adult Female Subjects with Severe Postpartum Depression and Adult Female Subjects with Moderate Postpartum Depression.

Open-label safety trial of intravenous neridronic acid in subjects with complex regional pain syndrome (CRPS).

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.

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 as Measured by Quantitative Sensory Testing.

A phase III, Randomized, Double-Blind, Placebo-Controlled, Enriched-Enrollment Withdrawal, Multicenter study to evaluate the efficacy and safety of a Long-Acting Subcutaneous Injectable Depot of Buprenorphine (CAM2038) in subjects with Recent History of Moderate to Severe Chronic Low Back Pain currently treated with opioids. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of NBI-98854 in Pediatric Subjects with Tourette syndrome.

A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of NBI-98854 in Adult Subjects with Tourette Syndrome

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.

A phase III, randomized, double-blind, active-controlled, parallel group, multi-center trial assessing the efficacy and safety of a once-weekly and once-monthly, long-acting subcutaneous injectable depot of Buprenorphine (CAM2038) in treatment of adult outpatients with Opioid Use Disorder.

Interventional, randomized, double-blind, placebo controlled, active reference (fluoxetine), fixed dose study of Vortioxetine in pediatric patients aged 7 to 11 years, with Major Depressive Disorder (MDD)

Interventional, randomized, double-blind, placebo controlled, active reference (fluoxetine), fixed dose study of Vortioxetine in pediatric patients aged 12 to 17 years, with Major Depressive Disorder (MDD)

Second phase 3 randomized, 12-week, double-blind, placebo-controlled study of the safety of Plecanatide in patients with Irritable Bowel Syndrome with Constipation (IBS-C).

An open-label, long-term safety and tolerability study of Plecanatide in patients with Irritable Bowel Syndrome with Constipation (IBS-C)

A 12-week, randomized, double-blind, parallel-group, placebo-controlled, flexibility-dosed, multicenter study to evaluate the efficacy, safety and tolerability of Dasotraline in adults with moderate to severe Binge Eating Disorder.

An open-label, flexibility-dosed, 6 month extension study of Dasotraline in the treatment of adults with Binge Eating Disorder.

A phase 3 study to evaluate weight gain ALK3831 compared to Olanzapine in adults with Schizophrenia.

A retrospective chart review study in patients that have been prescribed a pharmacogenomics test to perform research on the utilization, effectiveness and outcomes related to test results.

A prospective evaluation of treatment satisfaction with Buprenorphine/Naloxone Buccal Film (BBN) in opioid dependent subjects.

A phase III, double-blind, randomized, multicenter, placebo-controlled study to evaluate the efficacy and safety of TNX-102 SL tablets taken daily at bedtime in patients with fibromyalgia.

A 6- week, randomized, double-blind, multicenter, placebo-controlled, parallel group efficacy and safety study of Dasotraline versus placebo in subjects 6 to 12 years of age with Attention Deficit Hyperactivity Disorder (ADHD).

An open-label, flexibly-dosed, 26 week extension safety study of Dasotraline in children and adolescents with Attention Deficit Hyperactivity Disorder (ADHD)

A randomized, double-blind trial investigating the efficacy and safety of investigational medicinal product (IMP) in subjects with complex regional pain syndrome type I (CRPS-I)

Retrospective Registry exposure for: Various Disease States

A phase 3 Efficacy & Safety study of ALKS5461 for the adjunctive treatment of Major Depressive Disorder.

A phase 3 multicenter study of the long-term safety and tolerability of ALKS5461 for the adjunctive treatment of Major Depressive Disorder in adults who have an inadequate response to antidepressant therapy.

A national, randomized 12-week, double-blind, placebo-controlled study to assess the safety and efficacy of Plecanatide (3.0 and 6.0 mg) in patients with Chronic Idiopathic Constipation.

A multicenter, randomized, double-blind, placebo controlled, Fluoxetine-referenced, parallel group study to evaluate the efficacy, safety and tolerability of Desvenlafaxine Succinate Sustained Release (DVS SR) in the treatment of children and adolescents outpatients with Major Depressive Disorder.

A six month, open label, multi-center, flexible dose extension study to the B2061014 study to evaluate the safety, tolerability and efficacy of Desvenlafaxine Succinate Sustained Release (DVS SR) tablets in the treatment of children and adolescent outpatients with Major Depressive Disorder.

A randomized double-blind, placebo and active-controlled study of DS-5565-A-310 in subjects with pain associated with Fibromyalgia.

An open-label extension study of DS-5565-A-312 for 52 weeks in pain associated with Fibromyalgia.

A phase II, multicenter, randomized, double-blind, parallel-group, placebo-controlled study to evaluate efficacy and safety of XXX in combination with selective serotonin reuptake inhibitors in patients with Obsessive Compulsive Disorder.

A phase 2b, double-blind, randomized, multicenter, placebo-controlled study to evaluate the efficacy and safety of XXX tablets taken at bedtime in patients with Fibromyalgia.

A 12-month, multicenter, open-label extension (F203) study to evaluate the long term safety of TNX-102 SL tablets taken daily at bedtime in patients with fibromyalgia.

A randomized, placebo-controlled study to investigate the efficacy and safety of Circadian to alleviate sleep disturbances in children with Neurodevelopmental Disabilities.

A multicenter, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of fixed-dose once-daily oral Aripiprazole in children and adolescents with Tourette's Disorder.

An open-label, multicenter study evaluating the safety and tolerability of once-daily oral Aripiprazole in children and adolescents with Tourette's Disorder.

A phase 3, multicenter, randomized, double-blind, parallel-group, placebo-controlled, dose-optimization study to evaluate the efficacy, safety, and tolerability of study drug in adults aged 18-55 years with moderate to severe Binge Eating Disorder (BED).

A phase 3, multicenter, open label, 12 month extension safety and tolerability study of XXX in the treatment of adults with Binge Eating Disorder.

A phase 2, randomized, double-blind, placebo-controlled, dose titration study to assess the safety and tolerability and efficacy of study drug for the treatment of Tardive Dyskinesia.

A randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy, safety and tolerability of study drug in the treatment of patients with diarrhea-predominant Irritable Bowel Syndrome (IBS-D).

A randomized, double-blind, placebo-controlled, fixed-dose, parallel-group study to compare the efficacy, tolerability, and safety of 3 doses of gabapentin enacarbil (GSK 1838262) with placebo in the treatment of subjects with moderate-to-severe primary Restless Legs Syndrome (RLS).

A phase 2, randomized, double-blind, placebo-controlled, multicenter study to assess the safety and tolerability of SPD503 in subjects aged 6-17 years with Generalized Anxiety Disorder (GAD), Separation Anxiety Disorder (SAD), or Social Phobia (SOP).

Pipamperone/Citalopram (PNB01) versus Citalopram (cit) and versus Pipamperone in moderate to severe Major Depressive Disorder (MDD): a randomized, double-blind phase iii clinical trial of 10 weeks.

A multicenter, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of flexible-dose once-weekly oral Aripiprazole in children and adolescents with Tourette's Disorder.

An open-label, multicenter study evaluating the safety and tolerability of once weekly oral aripiprazole in children and adolescents with Tourette's Disorder.

Antidepressant-induced sleepiness, cognitive symptoms and/or fatigue during SSRI treatment of Major Depressive Disorder (MDD).

A phase 3, multicenter, randomized, double-blind, parallel-group, placebo-controlled, flexible dose titration, efficacy and safety study of SPD489 in combination with an antidepressant in the treatment of adults with Major Depressive Disorder (MDD) with inadequate response to prospective treatment with an antidepressant.

A phase 3, open-label, multicenter, 12-month extension safety and tolerability study of SPD489 in combination with an antidepressant in the treatment of adults with Major Depressive Disorder (MDD) with residual symptoms or inadequate response following treatment with an antidepressant.

A double-blind, Paroxetine- and placebo-controlled study of 50 mg/day and 100 mg/day of eb-1010 among outpatients with Major Depressive Disorder (MDD) who have responded inadequately to prior selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs) (triple reuptake inhibitor anti-depressant effects – TRIADE study).

A randomized, double-blind, placebo-controlled, parallel-group, assessment of the efficacy, safety and tolerability of XX modified release tablets, 125 mg twice per day in subject with treatment resistant Depression.

Effect of Duloxetine 30/60 mg once daily versus placebo in adolescents with juvenile Primary Fibromyalgia Syndrome.

A multicenter, randomized, double-blind, placebo-controlled withdrawal study to evaluate the safety, tolerability, and efficacy of Milnacipran in pediatric patients with Primary Fibromyalgia.

A multicenter, open-label, 52-week extension study to evaluate the safety and efficacy of Milnacipran in pediatric patients with Primary Fibromyalgia.

A randomized, placebo-controlled, double-blind study of ly2216684 fixed-dose 12 mg and 18 mg once daily as adjunctive treatment for patients with Major Depressive Disorder (MDD) who are partial responders to selective serotonin reuptake inhibitor (SNRI) treatment.

A multicenter, randomized, placebo-controlled, double-blind study of the efficacy and safety of Lubiprostone in subjects with Opioid-Induced Bowel Dysfunction.

A multicenter, randomized, double-blind, parallel group, placebo-controlled, phase 3, efficacy and safety study of TC-5214 (S-Mecamylamine) in flexible doses as an adjunct to an antidepressant in patients with Major Depressive Disorder (MDD) with an inadequate response to antidepressant therapy (FLEX).

A multicenter, randomized, double-blind, parallel group, placebo-controlled, phase 3, long-term safety and tolerability study of TC-5214 (S-Mecamylamine) as an adjunct to an antidepressant in patients with Major Depressive Disorder who exhibit an inadequate response to antidepressant therapy (LTS).

A 52-week, multi-center, open-label study of the safety and tolerability of Agomelatine sublingual tablets in patients with Major Depressive Disorder (MDD).

A long-term, open-label, safety of XX in children (6 to 11 years) and adolescents (12 to 17 years) with Attention Deficit/Hyperactivity Disorder-Associated Insomnia.

A phase 3, randomized, double-blind, parallel-group, placebo-controlled, fixed-dose study comparing the efficacy and safety of 2 doses (10 and 20 mg) of LuAA21004 in acute treatment of adults with Major Depressive Disorder (MDD).

A phase 3, long-term, open-label, flexible dose, extension study evaluating the safety and tolerability of LuAA21004 (15 and 20 mg) in subjects with Major Depressive Disorder (MDD).

A fifteen-month, prospective, randomized, active-controlled, open-label, flexible-dose study of Paliperidone Palmitate compared with oral antipsychotic treatment in delaying time to treatment failure in adults with Schizophrenia who have been recently released from jail.

A phase 3b multicenter, double-blind, randomized withdrawal efficacy and safety study of Pregabalin in the treatment of patients with inadequately treated painful Diabetic Peripheral Neuropathy (DPN).

A double-blind, efficacy and safety study of duloxetine versus placebo in the treatment of children and adolescents with Major Depressive Disorder (MDD).

A randomized, double-blind, placebo-controlled study to assess the efficacy and tolerability of Armodafinil treatment (150 mg) in improving clinical condition late in the shift and in improving functional and patient-reported outcomes in adult patients with excessive sleepiness associated with Shift Work Disorder.

A phase 2b, randomized, double-blind, two-arm, multi-center, placebo-controlled, study to assess the efficacy and safety of EN3224 (Axomadol) in subjects with moderate to severe Chronic Low Back Pain.

A prospective, randomized, active-controlled, rater-blinded study of the prevention of relapse comparing Paliperidone Palmitate with oral Risperidone in adults with recently-diagnosed Schizophrenia who are at high risk of relapse.

A phase 2, multicenter, randomized, double-blind, parallel group, placebo-controlled exploratory efficacy and safety study of SPD489 in adults 18-55 years with Major Depressive Disorder (MDD) as augmentation therapy to an antidepressant.

A 12 week, randomized, double-blind, placebo-controlled, parallel-group, fixed dosage, study to evaluate the efficacy and safety of Armodafinil as treatment for patients with excessive sleepiness associated with mild or moderate closed Traumatic Brain Injury (TBI).

A phase 2, multicenter, randomized, double-blind, placebo-controlled study of the safety and efficacy of OPC-34712 as adjunctive therapy in the treatment of patients with Major Depressive Disorder (MDD).

Continuation Study – A phase II, multicenter, open-label study to assess the safety and tolerability of oral OPC-34712 as adjunctive therapy in adult patients with Major Depressive Disorder (MDD).

A 52-week, multicenter, open-label study to evaluate the effectiveness of Aripiprazole intramuscular depot as maintenance treatment in patients with Schizophrenia “ASPIRE open-label” (Aripiprazole intramuscular depot program in Schizophrenia).”

A multi-center, randomized, placebo-controlled, double-blind, parallel group, efficacy and safety study of AZD7325 in the treatment of Generalized Anxiety Disorder (GAD).

A 3-arm, double-blind, placebo controlled clinical trial to assess the efficacy, safety and tolerability of Pagoclone for the adult treatment of adults with Stuttering.

A randomized double blind placebo controlled four week study of the efficacy and safety of four doses (0.05 mg, 0.1 mg, 0.25 mg, 0.5 mg) of Aplindore MR tablets vs. placebo in idiopathic Restless Legs Syndrome (RLS).

A phase III, double-blind, randomized, efficacy and safety study comparing the TAK-491 plus Chlorthalidone fixed dose combination vs Benicar HCT® (Olmesartan Medoxomil-Hydrochlorothiazide) in subjects with moderate to severe essential Hypertension (HPTN).

A randomized, double-blind, parallel-group, placebo controlled, duloxetine-referenced, fixed dose study comparing the efficacy and safety of LuAA21004 in acute treatment of Major Depressive Disorder (MDD) in elderly patients.

A randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of Armodafinil at a target dosage of 200 mg/day as treatment for adults with excessive sleepiness associated with Obstructive Sleep Apnea/Hypopnea Syndrome (OSA) with comorbid Major Depressive Disorder (MDD) or Dysthymic Disorder.

A randomized, double-blind, placebo-controlled subjective study to assess the efficacy of APD125 in patients with primary Insomnia characterized by difficulty maintaining sleep.

A randomized, double-blind, parallel-group, placebo-controlled, fixed dose study comparing the efficacy and safety of 2 doses of LuAA21004 in acute treatment of adults with Generalized Anxiety Disorder (GAD).

A double-blind, randomized, placebo and active-controlled, multi-center study examining the efficacy and safety of SEP-225441 in subjects with Generalized Anxiety Disorder (GAD).

A year-long, open-label, multicenter study of the safety and efficacy of vilazodone in subjects with Major Depressive Disorder (MDD).

A multicenter, double-blind, randomized, placebo-controlled study examining the safety, efficacy, and tolerability of SEP-225289 in subjects with Major Depressive Disorder (MDD) (including atypical and melancholic features).

A multicenter, multiple dose, double-blind, randomized, placebo-controlled, parallel group study of the safety and efficacy of AGN 203818 in female patients with Fibromyalgia Syndrome.

Cleveland Neuro-Sleep Research Institute, Inc.

A phase 3 pivotal, multi-center, double-blind, randomized, placebo-controlled mono-therapy study of Milnacipran for treatment of Fibromyalgia.

A long-term study of XP13512 vs. placebo treatment assessing maintenance of efficacy and safety in patients with Restless Legs Syndrome (RLS).

A 6-month, phase 3, randomized, double-blind, parallel-group, controlled, multi-center study to evaluate the incidence of Gastric Ulcers following administration of either PN 200 or Naproxen in subjects who are at risk for developing NSAID-associated ulcers.

A multi-centre, double-blind, randomised-withdrawal, parallel-group, placebo-controlled phase III study of the efficacy and safety of Quetiapine Fumarate Sustained Release (Seroquel SR™) as monotherapy in the maintenance treatment of patients with Major Depressive Disorder (MDD) following an open-label stabilisation period (AMETHYST study).

A multi-center, double-blind, randomized-withdrawal, parallel-group, placebo-controlled phase III study of the efficacy and safety of Quetiapine Fumarate Sustained Release (Seroquel SR™) as monotherapy in the maintenance treatment of patients with Generalized Anxiety Disorder (GAD) following an open-label stabilization period (PLATNIUM study).

A comparison of Zolpidem Tartrate Extended-Release (XR) 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 comparison of Zolpidem Tartrate Extended-Release (XR) vs. placebo in the treatment of Insomnia associated with Generalized Anxiety Disorder (GAD) when used concomitantly with Escitalopram.

A 28 day, polysomnographic and subjective assessment of GW679769, 10 and 30 mg, for the treatment of primary Insomnia: A randomized, double-blind, parallel-group, placebo-controlled trial.

A 52-Week, open-label study to assess the long-term safety of Ropinirole Extended release (XR) in patients with Restless Legs Syndrome (RLS).

A randomized, double-blind, placebo-controlled, safety and efficacy study of Xyrem® (sodium oxybate) in subjects with Fibromyalgia.

A long-term, open-label safety and efficacy study of Xyrem® (sodium oxybate) in subjects with Fibromyalgia.

Southwest Cleveland Sleep Center

A phase 2, double-blind, randomized, placebo-controlled, parallel-group, multicenter, proof-of-concept study to evaluate the safety and efficacy of Rozerem™ taken in combination with Gabapentin for the treatment of subjects with Chronic Insomnia.

A randomized, double-blind, placebo-controlled, 3-way cross-over study to evaluate effects of APD125 in patients with Insomnia.

A phase III, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to assess the long term efficacy and safety of Doxepin HCl in primary elderly Insomnia patients with sleep maintenance difficulties.

Efficacy and safety of Eplivanserin 5 mg/day on sleep maintenance Insomnia: a 12-week multicenter, randomized, double-blind, placebo-controlled study followed by an open treatment phase extension with Eplivanserin for 40 weeks period.

The efficacy of Eszopiclone 3 mg as adjunctive therapy in subjects with Insomnia related to Generalized Anxiety Disorder (GAD).

A double-blind, randomized, placebo-controlled, multicenter, 30-night polysomnographic study of MK-0928 in adult patients with Insomnia.

A double-blind, randomized, placebo-controlled, multicenter, 30-night polysomnographic study of MK-0928 in elderly patients with Insomnia.

A 12 week, double-blind, placebo controlled, parallel group study to assess the efficacy and safety of Ropinirole XR (extended release) in patients with Restless Legs Syndrome (RLS).

Randomized, double-blind, positive-controlled, multicenter study comparing the efficacy of Carvedilol Phosphate modified release formulation (Coreg™ MR) and Metoprolol Succinate extended release (Toprol-XL®) on the reduction of microalbuminuria in patients with Hypertension and Microalbuminuria.

A 12 month open-label, flexible-dosage (100-250 mg/day) extension study of the safety and efficacy of CEP-10953 in the treatment of patients with excessive sleepiness associated with Narcolepsy, Obstructive Sleep Apnea (OSA)/Hypopnea Syndrome, or Chronic Shift Work Sleep Disorder.

Randomized, double-blind, placebo-controlled, parallel-group, multi-center trial comparing the effects of orally administered Xyrem® (Sodium Oxybate) with placebo for the treatment of Fibromyalgia.

A 12-week, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of CEP-10953 (150 mg/day) as treatment for adults with residual excessive sleepiness associated with Obstructive Sleep Apnea (OSA)/Hypopnea Syndrome.

Randomized, double-blind, placebo controlled, parallel-group, multi-center trial comparing the effects of orally administered Xyrem® (Sodium Oxybate) with placebo for the treatment of Narcolepsy.

Randomized, double-blind, double-dummy, placebo-controlled, parallel-group, multi-center trial comparing the effects of orally administered Xyrem® (Sodium Oxybate) with Modafinil with placebo for the treatment of daytime sleepiness in Narcolepsy.

Case Western Reserve University/University Hospitals of Cleveland Mood Disorders Program:

A study investigating the antimanic efficacy of the anticonvulsant Gabapentin (Neurontin), which is thought to act by blocking the uptake of GABA by the neuroglia and by inhibiting the synthesis of excitatory amino acids.

A study comparing the rate of onset of antidepressant action of venlafaxine (Effexor) vs. fluoxetine (Prozac) in Major Depression (MDD).

Clinical trials of Lamotrigine (Lamictal), an anticonvulsant which acts by antagonizing sodium channel mediated excitatory neurotransmitter release, in the management of Bipolar Disorder.

A double-blind, placebo-controlled study of the safety and efficacy of Paroxetine (Paxil) vs. Imipramine in Bipolar Depression.

Double-blind maintenance study comparing Valproate to Lithium and placebo in the treatment of Bipolar Disorder.

A study evaluating the efficacy of Clozapine (Clozaril) in the treatment of refractory Bipolar Mood Disorder and Schizoaffective Disorder, B0ipolar Subtype.

A study comparing Amesergide, a novel 5-HT type 2 antagonist, to placebo and Fluoxetine in the treatment of Major Depressive Disorder (MDD).

Dose-finding study researching Roxindole, a novel agent with D-2 autoreceptor and 5-HT type 1A agonist activities, and 5-HT re-uptake blockade action, in comparison with placebo in the treatment of Major Depressive Disorder (MDD).

Pre-doctoral Research:

3/89-5/89 National Institutes of Health, National Library of Medicine,
Artificial Intelligence Branch.

Designed and implemented a utility in Prolog (an artificial intelligence programming language) to facilitate the assignment of Medical Subject Headings to nodes in the National Library of Medicine Semantic Network.
Funding: National Institutes of Health

6/86-5/89 University of Cincinnati College of Medicine
Division of Geriatrics/Alzheimer's Research Center

Investigated EEG changes in Alzheimer's dementia using the fractal dimension as a quantifier. Researched the relationship between non-linear metric studies on the EEG and clinical grades of severity in the dementias.
Funding: University of Cincinnati College of Medicine

6/85-5/89 University of Cincinnati College of Medicine
Division of Pharmacology and Cell Biophysics

Researched mathematical models capable of simulating certain aspects of neuronal behavior. This work involved investigations of model nonlinear dynamical systems using analog computers.
Funding: University of Cincinnati College of Medicine

11/84-6/85 University of California, San Diego, School of Medicine.
Laboratory of Biological Dynamics and Theoretical Medicine

Expanded the capabilities of the laboratory to include analog computation for solving nonlinear differential equations by continuous time-domain integration.
Funding: University of California, San Diego, School of Medicine.

PUBLICATIONS

Peer Reviewed Publications:

Woysville MJ, Ahmed M. Insomnia: An Overview. (Review Article). Indian Journal of Sleep Medicine (IJSM) 2006; 1(3).

Woysville MJ, Lackamp JM, Eisengart JA, Gilliland JAM. On the meaning and measurement of affective instability: Clues from chaos theory. (Original Paper). Biological Psychiatry 1999; 45(3):261-269.

Gordon RT, Cantor RJ, **Woysville MJ**. A new chaos-based approach to data conceptualization. (Article) In: Dagi CH, Akay M, Chen CL, Fernandez BR, Ghosh J, eds. Intelligent Engineering Systems Through Artificial Neural Networks, Vol 6, ASME press, New York, 1996.

Calabrese JR, Kimmel SE, **Woysville MJ**, et al. Clozapine in treatment refractory mania. (Article). American Journal of Psychiatry 1996;153:759-764.

Calabrese JR, Fatemi SH, Kujawa M, **Woysville MJ**. Predictors of differential response to mood stabilizers. (Article). Journal of Clinical Psychopharmacology 1996. 16[2 suppl 1]:24S-31S.

Calabrese JR, **Woysville MJ**. Lithium therapy: Limitations and alternatives in the treatment of bipolar disorders. (Article). Annals of Clinical Psychiatry 1995;7(2):103-112.

Calabrese JR, **Woysville MJ**. A medication algorithm for treatment of rapid cycling? (Article). Journal of Clinical Psychiatry 1995;5[suppl 3]:11-18.

Kimmel SE, Calabrese JR, **Woysville MJ**, Meltzer HY. Clozapine in treatment refractory mood disorders. (Article). Journal of Clinical Psychiatry 1994; 55(supplement B):91-93.

Woysville MJ, Calabrese JR. Quantification of occipital EEG changes in Alzheimer's disease utilizing a new metric: The fractal dimension. (Article). Biological Psychiatry 1994; 35(6):381-387.

Calabrese JR, **Woysville MJ**, Kimmel SE, and Rapport DJ. Mixed states and bipolar rapid cycling and their treatment with valproate. (Article). Psychiatric Annals 1993; 23(2):70-78.

Calabrese JR, **Woysville MJ**, Kimmel SE, and Rapport DJ. Predictors of valproate response in bipolar rapid cycling. (Brief Report). Journal of Clinical Psychopharmacology 1993; 13(4):280-283.

Calabrese JR, Rapport DJ, Kimmel SE, Reece B, and **Woysville MJ**. Rapid cycling bipolar disorder and its treatment with valproate. (Article). Canadian Journal of Psychiatry. 1993; 38:45-51.

Abstracts:

Calabrese JR, **Woysville MJ**, Bowden C, et al: Spectrum of efficacy of lamotrigine in treatment-refractory manic depression. Presented at the Second International Conference on Affective Disorders. Jerusalem, Israel. September 4-8, 1995

Letters:

Calabrese JR, Fatemi SH, **Woysville MJ**: Antidepressant effects of lamotrigine in rapid cycling bipolar disorder. Am J Psychiatry 1996;153(9):1236.

Book Chapters:

Calabrese JR, Bowden CL, McElroy S, Cookson J, Andersen J, Rhodes L, **Woysville MJ**, Keck P, Kundu S, Paterson G, Ascher J, Bolden-Watson, C. Efficacy of lamotrigine in bipolar disorders: Preliminary data on the affective disorders. In: Manji H, Bowden C, Belmaker R, eds. Mechanisms Of Antibipolar Disorder Treatments: Focus On Lithium, Valproate, And Carbamazepine. Washington DC: American Psychiatric Press; 1997.

Calabrese JR, Fatemi SH, **Woysville MJ**. Diagnosis and treatment of rapid cycling bipolar disorder. In: Dunner DL, ed. Current Psychiatric Therapy II. W.B. Saunders Co. 1997.

Calabrese JR, Bowden C, **Woysville MJ**. Lithium and anticonvulsants in bipolar disorder. In: Bloom FE, Kupfer DJ, eds. Psychopharmacology: The Fourth Generation of Progress. Raven Press, Inc. NY, NY. 1995

Calabrese JR, **Woysville MJ**, Rapport DJ. Clinical efficacy of valproate. In: Joffe RT, Calabrese JR, eds. Anticonvulsants in Mood Disorders. Marcel Dekker, Inc. NY, NY. 1994.

CME Publications:

Calabrese JR, **Woysville MJ**. Diagnosis and treatment of rapid-cycling bipolar disorder. (Lesson). Directions in Psychiatry 1994; 14(16).