CURRICULUM VITAE

1/25/12

ROBERT ENOCH LITMAN, M.D.

Date and Place of Birth:	June 6, 1956 – Elizabeth, New Jersey
Citizenship:	United States of America
Marital Status:	Married, 1986 – 3 children
Home:	6903 Hillmead Drive, Bethesda, MD 20817

CURRENT POSITION: Medical Director, Principal, CBH Health, LLC, 1996 – Present

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CBH Health, LLC
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TRAINING AND EMPLOYMENT

1996 – Present	**Medical Director, Principal** CBH Health, LLC. – Rockville, MD
1987 – Present	**Private Practice, Psychiatry and Psychopharmacology** Rockville, MD
1995 – 1996	**Director of Research** Psychiatric Institute of Washington – Washington, D.C.
1988 – 1995	**Senior Staff Fellow, Clinical Neuroscience Branch** National Institute of Mental Health, NIH – Bethesda, MD
1987 – 1988	**Medical Staff Fellow, Clinical Neuroscience Branch** National Institute of Mental Health, NIH – Bethesda, MD
1987	**Associate Medical Director** Human Resource Institute – Brookline, MA
1984 – 1987	**Clinical Assistant in Psychiatry, Department of Psychiatry** Massachusetts General Hospital – Boston, MA
1984 – 1986	**Director, Adult Inpatient Unit** Erich Lindemann Mental Health Center – Boston, MA
1983 – 1984	**Chief Resident, Adult Inpatient Unit** Erich Lindemann Mental Health Center – Boston, MA
1981 – 1984	**Resident in Psychiatry, Massachusetts General Hospital Clinical Fellow** in Psychiatry, Harvard Medical School (including Inpatient, Outpatient, Consultation-Liaison, and Community Psychiatry Training)
1980 – 1981	**Intern, Internal Medicine** Albany Medical Center Hospital – Albany, NY

PART-TIME EMPLOYMENT

1996	Consultant in Psychiatry for Quality Dialysis Center Rockville, MD
1982 – 1987	Consultant in Psychopharmacology for Medication Clinic Cape Ann Area Office – Beverly, MA
1982 – 1987	Consultant in Emergency Psychiatry Ipswich Crisis Center, Ipswich
1982 – 1983	Consultant in Inpatient Psychiatry, Haverhill-Newburyport Unit Danvers State Hospital – Danvers, MA

LICENSURE AND BOARD CERTIFICATION

1996	Diplomate, Added Qualifications in Geriatric Psychiatry The American Board of Psychiatry and Neurology
1986	Diplomate, The American Board of Psychiatry and Neurology
1981	Diplomate, National Board of Medical Examiners
1995	D.C. License Registration No. 18828
1987	Maryland License Registration No. D0035818
1981	Massachusetts License Registration No. 490851987

EDUCATION

1980	M.D.	Albany Medical College of Union University (1976-1980)
1976	B.S.	Rennselaer Polytechnic Institute (1974-1976) accepted, Six-Year Biomedical Accelerated Program (B.S.-M.D.) Dean's List (1974-1975) Magna Cum Laude (1980)

ACADEMIC APPOINTMENTS

1997 – Present	Clinical Associate Professor in Psychiatry Georgetown University Medical School
1984 – 1987	Instructor in Psychiatry Harvard Medical School

MEMBERSHIPS

American Psychiatric Association
Society for Biological Psychiatry
American Society for Clinical Pharmacology and Therapeutics

SPECIAL RECOGNITION AND APPOINTMENTS

1984 – 1987	Co-investigator, Pain Program Project Massachusetts General Hospital – Boston, MA
1983 – 1984	Consultant in Chronic Pain with Psychiatric Consultation Liaison Service Massachusetts General Hospital – Boston, MA
1977	C.V. Mosby Book Award for Outstanding Research Albany Medical College Research Symposium

CLINICAL TRIALS EXPERIENCE
PHASE II - IV

1998

An Open-Label Extension Study of Depakote in the Treatment of Signs and Symptoms of Mania in Elderly Patients with Dementia.

The Comparative Efficacy of Olanzapine, Risperidone and Haloperidol for Cognition in Schizophrenia.

A Multicenter, Open-Label, Long-Term Follow-up, Safety Study of XXX in Schizophrenic and Schizoaffective Patients Who Participated in the Study XXX.

A Multicenter, Placebo-and-Active-Control, Double-Blind Randomized Study of the Efficacy, Safety and Pharmacokinetics of XXX (10 and 20 mg/day) in Schizophrenic and Schizoaffective Patients.

A Prospective, Randomized, Double-Blind, Multicenter Study of XXX to Evaluate the Safety of Two Titration Schedules and to Compare the Safety and Efficacy of B.I.D. and Q.D. Regimens to Haloperidol in Patients with Schizophrenia.

Aripiprazole: A Long-Term Open-Label Study in Stable Schizophrenia Patients.

Aripiprazole: Maintenance Treatment of Schizophrenia.

XXX Versus Placebo and Fluoxetine in a Controlled, Randomized, Double-Blind, Multicenter Study of Treatment in Major Depressive Disorders.

A Multicenter, Placebo-Controlled Study of Venlafaxine in Treatment Resistant Depression.

1999

Double-Blind, Randomized, Parallel Group Comparison Study of the Safety of XXX vs XXX in Hypertensive Patients with Peripheral Osteoarthritis Taking Antihypertensive Medication (SUCCESS VI).

The Safety and Efficacy of Risperdal (Risperidone) vs. Placebo vs. Haloperidol as Add-on Therapy to Mood Stabilizers in the Treatment of the Manic Phase of Bipolar Disorder.

A Double-Blind, Randomized, Multicenter, Parallel Group Design Study to Evaluate the Efficacy and Safety of Two Dose Ranges of XXX in Comparison with Placebo and Haloperidol in the Treatment of Schizophrenia.

A Prospective, Randomized, Double-Blind, Placebo-and Active-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Three Fixed Doses of XXX (4, 8, and 12 mg/day) Given BID for 42 Days to Schizophrenic Patients with Acute or Subacute Exacerbation, Followed by a Double-Blind, Active-Controlled, Flexible-Dose, 6-Month, Long-Term Phase with XXX (4, 8, 12, or 16 mg/day) Given QD.

A Prospective, Randomized, Double-Blind, Placebo-and-Risperidone-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Two Nonoverlapping Dose Ranges of XXX (Low vs. High) Given B.I.D. for 42 Days to Schizophrenic Patients With Acute or Subacute Exacerbation, Followed by a Risperidone-Controlled, Long-term Treatment Phase with XXX given Q.D.

An Assessment of the Efficacy and Safety of a Sublingual Dose of XXX in Subjects with Schizophrenia (in an Acutely Exacerbated State) Compared to Risperidone and Placebo in Randomized Double-Blind, Fixed Dose 6-Week Trial

An Assessment of the Long Term Efficacy and Safety of XXX, Risperidone and Placebo in Subjects with Schizophrenia.

2000

Safety and Efficacy of Depakote as Combination Therapy in the Treatment of Psychosis Associated with Schizophrenia.

Prospective Nested Case-Controlled Study of Potential Risk Factors For Angioedema in Subjects Exposed To XXX or XXX.

A Multicenter, Randomized, Double-Blind, Safety and Tolerability Study of Flexible Doses of XXX and Olanzapine in the Treatment of Patients with Acute Schizophrenia.

A Multicenter, Randomized, Double-Blind, Parallel Group Trial Comparing the Safety and Efficacy of XXX to Pioglitazone as First Line Therapy in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control with Diet and Exercise.

Clinical Protocol for a Double-Blind, Randomized, Parallel Group Comparison Study of the Safety of XXX Vs XXX in Treated Hypertensive Patients with Osteoarthritis, (SUCCESS VII).

A Randomized, Double-Blind, Placebo- and Risperidone-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Two Nonoverlapping Dose Ranges of XXX Given BID for 42 Days to Schizophrenic Patients Followed by a Long-Term Treatment Phase with XXX Given QD.

A Double-Blind, Three-Armed, Fixed-Dose, Placebo Controlled Dose-Finding study with Sublingual XXX in Subjects with Acute Phase Schizophrenia.

A Placebo-Controlled Study of XXX in Elderly Patients with Generalized Anxiety Disorder.

XXX, Placebo, and Paroxetine Comparison in Patients with Major Depressive Disorder.

XXX: Double-Blind, Randomized, Placebo and Olanzapine Controlled, Dose-Finding Study in the Treatment of Psychotic Disorders.

2001

The Safety and Efficacy of XXX Modified Release (MR) Formulation in Subjects with Mild to Moderate Hypertension.

A Multicenter, Randomized, Double-Blind, Safety and Tolerability Study of Flexible Doses of Aripiprazole and Olanzapine in the Treatment of Patients with Acute Schizophrenia.

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Flexible Dose Study of Aripiprazole in the Treatment of Institutionalized Patients with Psychosis Associated with Dementia of The Alzheimer's Type.

A Multicenter, Randomized, Double-Blind, Study of Flexible Doses of Aripiprazole Versus Perphenazine in the Treatment of Patients with Treatment-Resistant Schizophrenia.

A Comparison of Fasting Triglyceride Levels in Cohorts with Schizophrenia and Related Disorders Treated Chronically with Olanzapine, Risperidone, and Typical Antipsychotics.

Olanzapine Versus Ziprasidone in the Treatment of Schizophrenia

Efficacy and Safety of a Flexible Dose of Risperidone Versus Placebo in the Treatment of Psychosis of Alzheimer's Disease.

The Efficacy and Safety of Single Dosage Ranges of Risperidone Vs. Placebo in the Treatment of Manic Episodes Associated with Bipolar I Disorder.

A 9-Week, Open-Label, Multicenter, Safety Trial of Flexible Dose Ranges of Risperidone in the Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder.

Comparison of Glucoregulatory Function in Schizophrenia Patients Before and After Switching from Olanzapine Treatment to Risperidone Treatment.

An Assessment of the Efficacy and Safety of a Sublingual Dose of XXX in Subjects with Schizophrenia (in an Acutely Exacerbated State) Compared to Risperidone and Placebo in Randomized Double-Blind, Fixed Dose 6-Week Trial

A Parallel Group, Multicenter Flexible Dose Study with a Double-Blind, Randomized, Placebo-Controlled Phase and an Open-Label Phase to Evaluate the Efficacy and Safety of Viagra (Sildenafil Citrate) in Males with Serotonergic Antidepressant Associated Erectile Dysfunction.

SAGE: A Prospective, Randomized, Double-Blind, Multicenter Study Comparing the Effects of Aggressive Lipid Lowering with Moderate Lipid Lowering on the Reduction of the Total Duration of Myocardial Ischemia in the Elderly as Measured by Holter Monitoring by Comparing the Maximal Doses of Two Statins: Study Assessing Goals in the Elderly.

A 6-Week, Double-Blind, Randomized, Multicenter, Fixed-Dose, Placebo-Controlled Study of XXX Dosed Twice a Day in Patients With Generalized Anxiety Disorder.

A Phase II Randomized, Multicenter, Placebo-and-Active-Controlled Study of Oral XXX in Subjects with Major Depressive Disorder. A Long-Term Extension Study to Evaluate the Safety of Oral XXX in Subjects with Major Depressive Disorder.

2002

Comparative Randomized Study of Safety and Immunogenicity of a Non-Adjuvanted Respiratory Syncytial Virus (RSV) Vaccine Versus an RSV Vaccine Adjuvanted with Aluminum Phosphate When Administered Concomitantly With a Licensed Influenza Vaccine in High-Risk Adults > 65 Years of Age.

A Three-Month, Multicenter, Double-Masked, Study of the Safety and Efficacy of Travoprost 0.004% / Timolol 0.5% Ophthalmic Solution Compared to Travatan and Timolol 0.5% Dosed Concomitantly in Subjects with Open-Angle Glaucoma or Ocular Hypertension.

A Prospective, Multicenter, Open-Label Study of Aripiprazole in the Management of Patients with Schizophrenia or Schizoaffective Disorder in General Psychiatric Practices.

A 24-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Donepezil Hydrochloride (XXX) in Patients with Severe Alzheimer's Disease Followed by a 12 Week Open-Label Extension Period.

A Multicenter, Double-Blind, Double-Dummy, Placebo-Controlled, Randomized, Parallel Group Evaluation of the Efficacy and Safety of a Fixed-Dose of XXX (XXX), Versus Placebo Versus Risperidone in Subjects with Schizophrenia.

Efficacy and Safety of a Flexible Dose of Risperidone Versus Placebo in the Treatment of Psychosis of Alzheimer's Disease.

Open-Label Trial Exploring a Switching Regimen from Oral Neuroleptics, other than Risperidone, to Risperidone Depot Microspheres.

An Open-Label Follow-On Study of the Long-Term Safety of Aripiprazole Administered Orally in Patients with Psychosis.

XXX 60 mg (or 30 mg) Once Daily in the Treatment of Generalized Anxiety Disorder. An Open Multicenter Safety Study of 5 Months, Including a 1-Month Drug-free Follow-up Period. Follow-up to Studies XXX and XXX.

A Randomized, Double-Blind, Placebo-Controlled, Risperidone, Dose Finding Study of XXX in Treatment of Schizophrenia.

A 6-Week, Double-Blind, Randomized, Fixed-Dose, Parallel-Group Study of the Efficacy and Safety of Three Dose Levels of XXX Compared to Placebo and Haloperidol in Patients with Schizophrenia who are Experiencing an Acute Exacerbation of Symptoms.

2003

A 21-Day, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Efficacy and Safety of Depakote ER in the Treatment of the Manic Phase of Bipolar Disorder.

A Randomized, Double-Blind Study of the Safety and Efficacy of Depakote ER Plus an Atypical Antipsychotic vs. an Atypical Antipsychotic Alone in the Treatment of Schizophrenia.

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial to Evaluate the Safety and Efficacy of XXX as Monotherapy in Subjects with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control.

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of XXX in Combination with Glyburide Therapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control on Sulfonylurea Therapy Alone.

Comparison of Glucoregulatory Function in Schizophrenia Patients Before and After Switching from Olanzapine Treatment to Aripiprazole - An Open-Label, Non-Randomized, Prospective Study.

A Multicenter, Double-Blind, Double-Dummy, Placebo-Controlled, Randomized, Parallel Group Evaluation of the Efficacy and Safety of a Fixed-Dose of XXX (XXX), Versus Placebo Versus Risperidone in Subjects with Schizophrenia.

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of 50 and 100 mg-eq of Paliperidone Palmitate in Subjects with Schizophrenia.

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of 50 and 100 mg-eq of Paliperidone Palmitate in Subjects with Schizophrenia.

Open -Label Study to Evaluate the Safety and Pharmacokinetics of Single- and Multiple-Dose Extended-Release OROS Paliperidone in Pediatric Subjects (≥10 to ≤17 years of Age) with Schizophrenia, Schizoaffective Disorder, or Schizophreniform Disorder.

A Comparison of the Analgesic Efficacy and Safety of XXX Once a Day Tablets and Ultram Immediate Release for the Treatment of Pain Due to Osteoarthritis of the Knee.

The Effect of Ortho Tri-Cyclen on Bone Mineral Density in Pediatric Subjects with Anorexia Nervosa.

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose Study to Assess the Safety and Efficacy of XXX in the Treatment of Moderate to Severe Binge-Eating Disorder Associated with Obesity.

Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance (CHARISMA).

2004

A 6-week, Multicenter, Double-Blind, Double-Dummy, Randomized Comparison of the Efficacy and Safety of Sustained-Release Formulation Quetiapine Fumarate (SEROQUEL™) and Placebo in the Treatment of Acutely Ill Patients with Schizophrenia.

An International Prospective Observational Registry in Subjects at Risk of Atherothrombotic Events.

A Double-Blind Randomized Study Comparing Intramuscular Olanzapine Depot with Placebo in the Treatment of Patients with Schizophrenia.

An Open-Label Study of Intramuscular XXX Depot with Placebo in the Treatment of Patients with Schizophrenia.

A Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX as Adjunctive Treatment to Atypical Antipsychotics in Schizophrenia Patients with Persistent Residual Symptoms.

A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 2 Fixed Dosages of Extended Release OROS Paliperidone (6 and 12 mg/day) and Olanzapine (10 mg/day), With Open-Label Extension, in the Treatment of Subjects With Schizophrenia.

A Randomized, Double-Blind, Placebo- and Active Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Dosages of Extended Release OROS Paliperidone (3, 9, and 15 mg/day) and Olanzapine (10 mg/day), With Open-Label Extension, in the Treatment of Subjects with Schizophrenia.

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq, 50 mg eq, and 100 mg eq) of Paliperidone Palmitate in Subjects with Schizophrenia.

A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study of XXX in the Treatment of Bipolar I Disorder, Most Recent Episode Depressed.

Research on the Effectiveness of Risperidone in Bipolar Disorder in Adolescents and Children (REACH): A Double-Blind, Randomized, Placebo-Controlled Study of the Efficacy and Safety of Risperidone for the Treatment of Acute Mania in Bipolar I Disorder.

A Randomized, Double-Blind, Placebo-Controlled Clinical Study of the Efficacy and Safety of Risperidone for the Treatment of Schizophrenia in Adolescents.

The Efficacy and Safety of Risperidone in the Treatment of Adolescents with Schizophrenia: A Follow up Trial of XXX and XXX.

A Four-Week Double Blind Multi-Center Study Comparing the Efficacy and Safety of Ziprasidone to Aripiprazole in Subjects with Schizophrenia or Schizoaffective Disorder Needing Inpatient Care.

A Double-Blind, Eight-Week, Placebo- and Risperidone-Controlled, Dose Finding Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in the Treatment of Patients with Schizophrenia or Schizoaffective Disorder.

A Randomized, Double-Blind, Placebo-Controlled and Olanzapine-Referenced, Parallel-Group Efficacy and Safety Study of Two Fixed Doses of Bifeprunox in the Treatment of Schizophrenia.

A Randomized, Double-Blind, Olanzapine-Referenced, Parallel-Group Safety and Efficacy Study of Flexible Doses of Bifeprunox in the Long-term Treatment of Schizophrenia.

A Pharmacoeconomic Study Carried Out in Connection with the XXX and XXX Clinical Trials.

A Double-Blind, Fixed Dose Comparison of XXX and Placebo in the Treatment of Schizophrenia.

An Open Label, Multicenter 12-Month Study of Long-Term Safety and Tolerability of XXX in Patients with Schizophrenia.

2005

Exploratory Study of Exposure to Quetiapine and its Metabolite N-desalkyl quetiapine in Individuals Prescribed Seroquel and/or Subjects Enrolled in AstraZeneca Study XXX or XXX.

A Multicenter, Open Label Acceptability Study of Aripiprazole Oral Solution in the Treatment of Outpatients with Chronic Schizophrenia.

A Double-Blind Randomized Study Comparing Intramuscular Olanzapine Depot with Placebo in the Treatment of Patients with Schizophrenia.

Population Pharmacokinetic Study in Adolescent Patients with Schizophrenia or Bipolar I Disorder Treated with Olanzapine.

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (50 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects with Schizophrenia.

A Multicenter, Randomized, Double-Blind, Fixed-Dose, 6-Week Trial of the Efficacy and Safety of XXX Compared with Placebo Using Olanzapine Positive Control in Subjects with Acute Exacerbation of Schizophrenia.

A Multicenter, Double-Blind, Flexible-Dose, Long-Term Extension Trial of the Safety and Maintenance of Effect of XXX Using Olanzapine Positive Control in Subjects Who Complete Protocols XXX / XXX.

A Phase III, Randomized, Placebo-Controlled, Double-Blind Trial Evaluating the Safety and Efficacy of Sublingual XXX vs. Olanzapine and Placebo in In-Patients with an Acute Manic Episode.

A Double-Blind, 9 week Extension Study Evaluating the Safety and Maintenance of Effect of XXX vs. Olanzapine in the Treatment of Subjects with Acute Mania.

A Double-Blind, 40-Week Continuation Study Evaluating the Safety of XXX and Olanzapine in the Treatment of Subjects with Acute Mania.

A Phase III, Randomized, Placebo-Controlled, Double-Blind Trial Evaluating the Safety and Efficacy of XXX in Subjects Continuing Lithium or Valproic Acid/Divalproex Sodium for the Treatment of an Acute Manic or Mixed Episode.

A Phase III, Placebo-Controlled, Double-Blinded Continuation Trial Evaluating the Safety and Efficacy of XXX in Subjects Completing Trial XXX and Continuing Lithium or Valproic Acid/Divalproex Sodium for the Treatment of an Acute Manic or Mixed Episode.

A Double-Blind, Placebo-Controlled, Dose Ranging, Parallel-Group Study of XXX in Adults with Cognitive Impairment Associated with Schizophrenia.

2006

Olanzapine Versus Aripiprazole in the Treatment of Acutely Ill Patients with Schizophrenia.

A Randomized , Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response, Multicenter Study to Evaluate the Efficacy and Safety of Three Fixed Doses of Extended-Release Paliperidone (3, 6, and 12 mg/day) in the Treatment of Subjects with Acute Manic and Mixed Episodes Associated with Bipolar I Disorder.

A Randomized Double-Blind, Placebo- and Ziprasidone- Controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of a 24 mg/day Dose XXX Given B.I.D. for 28 Days to Schizophrenic Patients in Acute Exacerbation Followed by a Long-Term Treatment Phase.

A Six-Week Multicenter, Randomized, Olanzapine Referenced, Double-Blind, Parallel-Group Study to Assess the Efficacy and Safety of XXX Versus Placebo in Adult Patients With Acute Exacerbations of Schizophrenia Requiring Hospitalization.

2007

A Six-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center, Phase II Study To Assess The Safety And Efficacy Of XXX In Acutely Exacerbated Subjects With Schizophrenia.

A Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Phase III Study of the Efficacy and Safety of Quetiapine Fumarate (Seroquel) Sustained-Release as Monotherapy in Adult Patients with Acute Bipolar Mania.

A Phase IIa, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Two-Way, Crossover Study to Assess the Antidepressant Effect and Onset of Effect of XXX in Treatment-Resistant Major Depressive Disorder Patients.

A Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in the Acute Exacerbation of Schizophrenia.

A Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in Patients with Acute Mania Associated with Bipolar I Disorder.

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Flexibly-Dosed Extended-Release XXX as Adjunctive Therapy to Mood Stabilizers in the Treatment of Acute Manic and Mixed Episodes Associated with Bipolar I Disorder.

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Two Fixed Doses of Extended Release XXX (1.5 and 6 mg/day) in the Treatment of Subjects with Schizophrenia.

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq., 100 mg eq., and 150 mg eq.) of XXX in Subjects with Schizophrenia.

A Phase 3 Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of Three Doses of XXX in Acutely Psychotic Patients with Schizophrenia.

A Randomized, Double-Blind, Placebo-Controlled, Risperidone-Referenced, Parallel-Group, Adaptive-Design Study of the Efficacy, Safety, and Tolerability of XXX in Subjects with Acute Exacerbations of Schizophrenia.

2008

A Phase IIa, Double-Blind, Double-Dummy, Placebo-Controlled, Randomized, Parallel-Group Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of XXX in Adult Schizophrenia Patients.

Evaluation of the Safety and Efficacy of XXX in the Acute Exacerbation of Schizophrenia.

2009

A Phase IIa, Double-Blind, Double-Dummy, Placebo-Controlled, Active-Controlled, Randomized, Parallel-Group Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of XXX in Adult Schizophrenia Patients.

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Trial of XXX (XXX) in Patients with Mild to Moderate Alzheimer's Disease Who Are Apolipoprotein Eε4 Non-Carriers.

A Long-Term, Open-Label Extension Study of the Safety and Tolerability of XXX in Patients with Schizophrenia

Multiple Dose, Open-Label, Multi-Center Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of XXX as Adjunctive Therapy in Pediatric Subjects with Refractory Partial Epilepsy.

2010

A Phase IIa, Double-Blind, Double-Dummy, Placebo-Controlled, Active-Controlled, Randomized, Parallel-Group Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of XXX in Adult Schizophrenia Patients.

A Phase III, Double-Blind, Placebo-Controlled, Evaluation of the Safety and Efficacy of XXX in Patients with Acute Mania Associated with Bipolar I Disorder.

A Phase III, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in the Acute Exacerbation of Schizophrenia.

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Trial of XXX (XXX) in Patients with Mild to Moderate Alzheimer's Disease Who Are Apolipoprotein Eε4 Non-Carriers.

A Phase III, Long-Term Evaluation of the Safety, Tolerability, and Pharmacokinetics of XXX in Adult Schizophrenia Patients.

A Phase IIa, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of Two Different Doses XXX in Adult Schizophrenia Patients on Chronic Stable Atypical Anti-Psychotic Therapy.

A Phase IIa, Double-Blind, Placebo-Controlled, Active Controlled, Randomized, Parallel-Group Study to Assess the Safety and Efficacy of Two Fixed Doses of XXX in the Acute Exacerbation of Schizophrenia.

2011

A Phase IIa, Double-Blind, Placebo-Controlled, Active Controlled, Randomized, Parallel-Group Study to Assess the Safety and Efficacy of Two Fixed Doses of XXX in the Acute Exacerbation of Schizophrenia.

A Phase III, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXX in the Acute Exacerbation of Schizophrenia.

A Phase III, Long-Term Evaluation of the Safety, Tolerability, and Pharmacokinetics of XXX in Patients with Schizophrenia.

A Phase III, Double-Blind, Placebo-Controlled, Evaluation of the Safety and Efficacy of XXX in Patients with Acute Mania Associated with Bipolar I Disorder.

A Phase III, Long-term Open-Label Evaluation of the Safety and Tolerability of XXX in Patients with Bipolar I Disorder.

A Phase II, Randomized, Double-Blind, Parallel-Group, Explorative Study of the Safety, Tolerability, and Pharmacokinetics of Daily Dosing Compared to Weekly Dosing of XXX in Patients with Schizophrenia.

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of XXX in Subjects with Acute Exacerbation of Schizophrenia

A Phase III, Double-Blind, Placebo-Controlled, Randomized Withdrawal Study of XXX for the Maintenance Treatment of Subjects with Schizophrenia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX in the Prevention of Relapse in Patients with Schizophrenia

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Antipsychotic Efficacy of XXX in Patients with Schizophrenia

2012

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of XXX in Subjects with Acute Exacerbation of Schizophrenia

A Phase III, Double-Blind, Placebo-Controlled, Randomized Withdrawal Study of XXX for the Maintenance Treatment of Subjects with Schizophrenia

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of XXX in the Prevention of Relapse in Patients with Schizophrenia

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Antipsychotic Efficacy of XXX in Patients with Schizophrenia

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effect of Add-On XXX on Schizophrenia Negative Symptoms

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Efficacy and Safety Trial of XXX in Subjects with Mild to Moderate Alzheimer Disease Who Are Apolipoprotein E ε4 Non-Carriers

CLINICAL TRIALS EXPERIENCE
PHASE I

2000

Rising Single and Multiple Dose Tolerance Study of XXX in Patients with Schizophrenia or Schizoaffective Disorder.

2001

A Comparative Study of the Steady-State Pharmacokinetics of Risperidone and Topiramate on Monotherapy and During Combination Therapy in Subjects with Bipolar or Schizoaffective Disorders.

2002

A Double-Blind, Placebo-Controlled Trial to Estimate the Maximum Tolerated Dose (MTD) of XXX in Patients with Schizophrenia or Schizoaffective Disorder Who Are Poor Metabolizers for the CYP2D6 Enzyme.

A Randomized, Double-Blind, Multiple Dose Study of the Relative Bioavailability and Tolerability of a Slow-Release Formulation and a Medium-Release Formulation of XXX in Patients with Schizophrenia or Schizoaffective Disorder.

2003

A Phase I, Randomized, Parallel Group, Multicenter Study to Compare the Safety and Tolerability of Two Titration Schemes for Quetiapine Fumarate (Sustained-Release) with a Constant-Dose Scheme of Quetiapine Fumarate (Sustained Release) in Schizophrenic and Schizoaffective Patients.

2004

A Phase I, Randomized, Open-Label, 5-Treatment, 5-Period, 4-Sequence Crossover Study to Compare the Pharmacokinetics of 4 Sustained release Formulations and the Immediate release Formulation of Quetiapine Fumarate (Seroquel™) in Adults with Schizophrenia, Schizoaffective Disorder, or Bipolar Disorder.

A Study to Characterize the Steady-State Pharmacokinetics and Safety and Tolerability of Quetiapine Fumarate (Seroquel) in Adults with Selected Psychotic Disorders.

An Open Label, Ascending Single-Dose Study of the Safety, Tolerance, and Pharmacokinetics of Ziprasidone Aqueous Suspension Intramuscular Depot Formulations in Healthy Volunteers and Schizophrenic Patients.

2005

A Placebo- and Positive-Controlled, Randomized Study Evaluating QT and QTc Intervals Following Administration of Immediate-Release Paliperidone in Subjects with Schizophrenia or Schizoaffective Disorder.

Open Label, Parallel, Randomized Study to Explore the In Vitro/In Vivo Correlation of Paliperidone Palmitate Long-Acting Formulations and the Comparability of the XXX and XXX Formulations in Subjects with Schizophrenia.

Efficacy and Safety of XXX 5mg/day on Sleep Maintenance Insomnia: A 12-week Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Followed by an Open Treatment Phase Extension with XXX for 40 weeks Period.

2006

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Evaluating QT/QTc Intervals Following Administration of Extended-Release Paliperidone and Quetiapine in Subjects with Schizophrenia or Schizoaffective Disorder.

2007

A Bioequivalence Study Comparing the Steady-State Pharmacokinetics, Safety and Tolerability of Three Formulations of XXX, (Slow Release) 400 mg Tablets.

A Double-Blind, Placebo-Controlled Study Evaluating the Pharmacodynamic Effects of Two Fixed Doses of XXX (250 mg bid and 100 mg bid) on Hypothalamic-Pituitary-Adrenal Axis Function in Outpatients with Major Depressive Disorder.

2009

An Ascending Multiple-Dose Study of the Safety, Pharmacokinetics, and Pharmacodynamics of XXX administered Orally to Subjects with Schizophrenia.

2010

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Adaptive, Multiple Ascending Dose Study of the Safety, Tolerability, and Pharmacokinetics of XXX in Subjects with Mild to Moderate Alzheimer's Disease.

2011

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Adaptive, Multiple Ascending Dose Study of the Safety, Tolerability, and Pharmacokinetics of XXX in Subjects with Mild to Moderate Alzheimer's Disease.

A Multicenter, Open-label Extension, Multiple Dose, Parallel Group Study of the Safety and Tolerability of XXX in Subjects with Mild to Moderate Alzheimer's Disease.

A Parallel-Arm, Double-Blind, Placebo and Positive Controlled Multiple Oral Dose Administration Trial to Evaluate the Effects of XXX on QT/QTc in Subjects with Schizophrenia or Schizoaffective Disorder

A Phase I, Open-Label, Exploratory Study in Stabilized Schizophrenic Patients to Evaluate the Pharmacokinetics of XXX and XXX When XXX is Administered From a Polyurethane Implant

2012

A Multicenter, Open-label Extension, Multiple Dose, Parallel Group Study of the Safety and Tolerability of XXX in Subjects with Mild to Moderate Alzheimer's Disease.

A Parallel-Arm, Double-Blind, Placebo and Positive Controlled Multiple Oral Dose Administration Trial to Evaluate the Effects of XXX on QT/QTc in Subjects with Schizophrenia or Schizoaffective Disorder

A Phase I, Open-Label, Exploratory Study in Stabilized Schizophrenic Patients to Evaluate the Pharmacokinetics of XXX and XXX When XXX is Administered From a Polyurethane Implant

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