CURRICULUM VITAE

Jay Collins Rendahl

CCRC, BA

Viking Clinical Research, Ltd.

Address:	Administrative/Clinical Center Viking Clinical Research, Ltd. 29645 Rancho California Road, Suite 133 Temecula, California 92591 Office: (800) 670-4960 Fax: (800) 670-4969 Cell: (760) 689-8124 E-mail: Jay@VikingCR.com

Education:	• **Bachelor of Arts Degree, 1989** Psychology San Diego State University

Licensure / Certifications:	• Licensed Vocational Nurse, State of California, 1992 • Certified Clinical Research Coordinator, ACRP, 1998 • Member-Academy of Clinical Research Professionals since 1998
Certifications for Inter-Rater Reliability:	**MINI, SCID-I** & **SCID-II** **Schizophrenia**: BPRS, PANSS, CGI, SANS, QOL, SIMPSON-ANGUS, AIMS **Depression, Anxiety, Mania**: HAM-A, HAM-D, MADRS, Jung Mania Rating Scale, LSAS **Alzheimer's**: DAD, GDS, GBS, CATS, MMSE

Employment History:

2002 – Present:	**Co-Founder, CEO** Viking Clinical Research, Ltd. Temecula, CA
1998-2001:	**Contract Research Development** San Diego Sports Medicine & Family Health Center San Diego, CA
2000 – 2002:	**Director of Research Operations** Psychiatric Centers at San Diego San Diego, CA
1997 – 2000:	**Director of Clinical Research Services** Synergy Clinical Research Center Chula Vista, CA
1996 – 1997:	**Clinical Research Coordinator** Affiliated Research Institute San Diego, CA
1994 – 1996:	**Physician Referral Nurse** Sharp Hospital San Diego, CA
1991 – 1994:	**Clinical Assessment Counselor** Alvarado Parkway Institute, NME La Mesa, CA
1990 – 1991:	**Supervisor-Anesthesia Technicians** National Naval Medical Center Bethesda, MD
1990 – 1991:	**Clinical Assessment Counselor** Springwood Hospital, NME, Leesburg VA
1986 – 1990:	**Behavioral Health Counselor CPC** San Luis Rey Hospital Encinitas, CA
1986 – 1995:	**Hospital Corpsman ICU** Naval Hospital (USN Reserves) San Diego, CA
1984 – 1986:	**Field Medic**

		U.S. Marine Corps Camp Pendleton, CA
	1982 – 1986:	**Hospital Corpsman** U.S. Navy Active Duty Cardiopulmonary Technician Naval Hospital Philadelphia, PA
	1979 – 1982:	**Respiratory Therapist** Monadnock Community Hospital Peterborough, NH

Achievements:	• Highest enroller nationally/internationally on several protocols. The FDA subsequently audited the site for two of these protocols in 1998 and 1999, both of which resulted in no findings. • Enrolled first patient nationwide for ASTAIR study (ankle sprain). • Conducted Physical Exams to homeless veterans during Operation Stand Down three years in a row • Navy Achievement Medal • National Defense Medal • Honorable Discharge - Good Conduct Medal, U.S. Navy Certificate of Recognition given by Admiral Hagen, Surgeon General of the Navy, for managing a team of anesthesia technicians during Operation Desert Shield/Storm

Professional Memberships:	• Association of Clinical Research Professionals and Certified Research Coordinator since 1998

Clinical Research:	• **Janssen Research Foundation:** A Randomized Trial to Assess the Outcomes and Costs of Risperdal vs. Conventional Antipsychotic Therapy in Patients with Chronic Schizophrenia. 1996. • **Solvay Pharmaceuticals:** Luvox Protocol S1143101. Establishment of the Oral Fluvoxamine Dose Effective Relationship for Efficacy and Safety in Outpatients with Major Depressive Disorder. A Randomized, Double-Blind, Placebo and Sertraline Controlled, Parallel Group Multi-Center Study. 1996. • **Glaxo-Wellcome:** Protocol AK1A4003. A Multi-Center, Double-Blind, Randomized Pilot Study Comparing the Safety and Efficacy of Wellbutrin (Bupropion HCL) Sustained Release and Paroxetine in the Treatment of Elderly Outpatients with Moderate to Severe Recurrent Major Depression. 1996. • **Glaxo-Wellcome:** Protocol AK1A4002. A Multi-Center, Double-Blind, Placebo Controlled Comparison of the Effects of Sexual Functioning of Wellbutrin (Bupropion HCL) Sustained Release vs. Sertraline in Outpatients with Moderate to Severe Recurrent Major Depression. 1996. • **Glaxo-Wellcome:** Lamictal, Protocol SCAB2010. A Multi-Center, Double-Blind, Placebo Controlled, Flexible Dose Evaluation of the Safety and Efficacy of Lamictal (Lamotrigine) in the Treatment of a Major Depressive Episode in Patients Suffering from Bipolar Disorder. 1997. • **Pfizer Pharmaceuticals:** Sertraline, Protocol R-0552. An Eight Week, Multi-Center, Parallel Group, Double-Blind, Placebo Controlled Study of Sertraline in Elderly Outpatients with DSM-IV Major Depression. 1997. • **Solvay Pharmaceuticals:** Luvox, Protocol S1143102. A Multi-Center, Double-Blind, Placebo Controlled, Parallel Group Study of the Safety, Tolerability and Efficacy of Three Fixed Doses of Fluvoxamine vs. Placebo in Outpatients with Major Depressive Disorder. 1997. • **Zeneca Pharmaceuticals:** Seroquel (Quetiapine), Protocol 5077US/0004. Comparison of Safety and Tolerability of Quetiapine to Risperidone in a Broad Outpatient Population of Individuals with Schizophrenia and Other Psychotic Disorders. This protocol also compared Quality of Life between patients treated with Quetiapine and Risperidone. 1997. • **Glaxo-Wellcome:** Lamictal. A Multi-Center, Double-Blind, Double

	Dummy, Placebo and Lithium Controlled, Randomized, Flexible Dose Evaluation of the Safety and Efficacy of Lamotrigine in the Long Term Prevention of Relapses and Recurrence of Mania and/or Depression in Patients with Bipolar I Disorder. 1997. • **Takeda:** Idebenone. A Randomized, Double Blind, Placebo Controlled 12-Month Safety and Efficacy Trial of Idebenone in Patients with Probable Alzheimer's Disease. 1997. • **Eli Lilly and Co:** Olanzapine, Strategies for Switching from Conventional Anti-Psychiatric Drugs to Olanzapine. 1997. • **SmithKline:** A Randomized, Double-Blind, Placebo Controlled, Fixed Dosage Trial to Evaluate the Efficacy and Tolerability of 20 mg and 40mg/day Paroxetine in Patients with Generalized Anxiety Disorder. 1998. • **Eli Lilly and Co:** Olanzapine for the Treatment of Tardive Dyskinesia in Older Patients. 1998. • **Eli Lilly and Co:** Olanzapine Release Prevention vs. Placebo in the Treatment of Schizophrenia. 1998. • **Eli Lilly and Co:** The Comparative Efficacy of Olanzapine, Risperdal, and Haloperidol for Cognition in Schizophrenia. 1998. • **Eli Lilly and Co:** Duloxetine vs. Placebo and Paroxetine in the Acute Treatment of Major Depression. 1999. • **Eli Lilly and Co:** Long Term Open Label Treatment with R-Fluoxetine in the Treatment of Negative Symptoms in the Older Adult with Schizophrenia. 1999. • **Merck:** A Double-Blind, Placebo Controlled Study of l-759274 in the Treatment of Outpatients with Major Depression, Melancholic Features. 1999. • **Otsuka Pharmaceuticals:** A Phase II, Randomized, Double-Blind, Placebo Controlled, Fixed Dose Study of Oral OPC 14523 and Prozac in the Treatment of Outpatients with Moderate Depression. 1999. • **TAP (Takeda-Abbott) Pharmaceuticals:** TAK-637. A Comparison of TAK 637 vs. Placebo in Subjects with Major Depressive Disorder. 2000. • **Lilly/Omnicare:** Duloxetine Once Daily Dosing vs. Placebo in the Acute Treatment of Major Depression. 2000. • **Merck:** A Double-Blind, Multi-Center, Placebo Controlled Study of

L-830982 in the Treatment of Outpatients with Generalized Anxiety Disorder. 2000.

- **Organon Pharmaceuticals:** Remeron Soltab vs. Prozac or Placebo in the Treatment of Major Depression. 2000.

- **Pfizer Pharmaceuticals:** A Randomized, Double-Blind, Alprazolam and Placebo Controlled Study in the Safety and Efficacy of CP-615, 003 in Outpatients with Generalized Anxiety Disorder. 2000.

- **Bristol-Myers Squibb:** OCTAVE, Omapatrilat Cardiovascular Treatment Assessment Versus Enalapril. 2000.

●**SmithKline:** A Double-Blind, Placebo-Controlled, Fixed Dose, Study of Paroxetine CR (12.5mg and 25mg/day) Continuous Treatment for PMDD Patients. Protocols 29060/689 and 711. 2000.

- **Janssen:** The Efficacy and Safety of Flexible Dose Ranges of Risperidone vs. Placebo in the Treatment of Manic Episodes Associated with Bipolar I Disorder. Protocol RIS-USA-239. 2000.

- **Eli Lilly and Co:** Olanzapine vs. Risperidone in the Treatment of Bipolar I Disorder, Manic or Mixed. Protocol F1D-US-HGJT. 2000.

- **Bristol-Myers Squibb:** A Multi-Center, Randomized, Double-Blind, Placebo Controlled Study of Flexible Doses of Aripiprazole in the Treatment of Hospitalized Patients with Acute Mania. CN138-009. 2001.

- **Bristol-Myers Squibb:** A Multi-Center, Open-Label, Long-Term Study of the Safety, Tolerability, and Efficacy of Aripiprazole in the Maintenance Treatment of Patients with Bipolar Disorder. CN138-037. 2001.

- **Janssen:** The Efficacy and Safety of Flexible Dose Ranges of Risperidone vs. Placebo or Divalproex Sodium in the Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder. 2001.

- **Janssen:** A Nine-Week, Open-Label, Multi-Center, Safety Trial of Flexible Dose Ranges of Risperidone in the Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder. IND # 31,931. 2001.

- **Fujisawa/Quintiles:** FK960. Efficacy and Safety in Mild to Moderate Alzheimer's Disease Patients. 2001.

- **Wyeth-Ayerst:** A Double Blind, Placebo-Controlled, Parallel-Group, Flexible Dose Study of Venlafaxine XR Capsules in Adult Patients

with Panic Disorder. 2001.

- **Wyeth-Ayerst:** A Double Blind, Placebo-Controlled, Parallel-Group, Flexible Dose Study of Venlafaxine XR Capsules in Child and Adolescent Patients with Panic Disorder. 2001.

- **Shire:** An Open Label, Multi-Center Study to Assess Tolerability, Effectiveness and Quality of Life Associated with the Use of Adderall XR in Children with ADHD in a Community Practice Setting. 2001.

- **Eli-Lilly and Co:** Type 2 Diabetes Mellitus and Dyslipidemia. 2001.

- **Merck:** A Double-Blind, Multi-Center, Placebo and Active Controlled Acute and Extension Study of Two Doses of MK-0869 in the Treatment of Outpatients with Major Depressive Disorder. 2002.

- **GlaxoSmithKline:** A Randomized, Double Blind, Parallel Group, Placebo and Active Controlled, Study Evaluating the Safety and Efficacy of Valazedone in Outpatients with Major Depressive Disorder. 2002.

- **Merck:** A Double Blind, Multi-Center, Double-Dummy, Active Comparison Study of One of Three Doses of MK-0869 in the Treatment of Patients with Major Depressive Disorder. 2002.

- **Johnson & Johnson, and Janssen:** The Efficacy and Safety of Flexible Dosage Ranges in Risperidone vs. Placebo in the Treatment of Manic Episodes Associated with Bipolar l Disorder. 2002.

- **Novartis:** A Multi-National Study of Diabetes Prevention and Cardiovascular Outcomes. 2002.

- **Pharmacia:** Valdecoxib vs. Rofecoxib in Relieving Osteoarthritis of the Knee. 2002.

- **Sanofi/PPD Development:** A Randomized Trial of Intra-Articular Injection of Hyalgan into the Glenohumeral Articular Space for the Treatment of Chronic Shoulder Pain. 2002.

- **McNeil:** A Randomized, Double-Blind, Parallel-Group Study Comparing the Safety and Efficacy of Acetaminophen Extended Release (xxx mg/day) and Ibuprofen (xxx mg/day) in the Treatment of Ankle Sprains. 2003-2004.

- **GlaxoSmithKline:** A Multicenter, Double-Blind, Placebo-Controlled Comparison of the Efficacy and Safety of Flexible Dose Extended-Release Bupropion Hydrochloride (HCl) xxx-xxx mg/day and Placebo Administered for Eight Weeks for the Treatment of Adult Outpatients with Major Depressive Disorder Including Symptoms of Decreased

	Energy, Pleasure, and Interest. 2003-2004. • **GlaxoSmithKline:** A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of Dutasteride xxx mg Administered Orally Once Daily for Four Years to Reduce the Risk of Biopsy-Detectable Prostate Cancer. 2003-2004. • **GlaxoSmithKline:** A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase IIb Study to Evaluate the Efficacy and Safety of Multiple xxx Dosage Regimens for the Treatment of Opioid-Induced Bowel Dysfunction in Subjects with Chronic Pain of Non-Malignant Origin. 2003-2004. • **Kos Pharmaceuticals:** The Dose Response of Niacin ER/Lovastatin on Peak Walking Time (PWT) in Patients with Intermittent Claudication – a Matrix Design. 2003-2004. • **Merck:** A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Effects of Rofecoxib in Decreasing the Risk of Prostate Cancer. 2003-2005. • **Novartis:** A Randomized, Double-Blind, Multicenter, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Valsartan (xxx mg) and Hydrochlorothiazide (xxx and xxx mg) Combined and Alone, Valsartan xxx mg and Valsartan xxx mg / Hydrochlorothiazide xxx mg in Hypertensive Patients. 2003-2004. • **Novartis:** Post-text Supplement #1: Pharmacogenetic Sub-Study for the Study Listed Above. 2003-2004. • **Novartis:** Post-text Supplement #2: A 54-Week Open-Label Extension to a Randomized, Double-Blind, Multicenter, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Valsartan (xxx mg) and Hydrochlorothiazide (xxx and xxx mg) Combined and Alone, Valsartan xxx mg and Valsartan xxx mg / Hydrochlorothiazide xxx mg in Hypertensive Patients. 2004. • **Bristol-Myers Squibb:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial to Evaluate the Safety and Efficacy of BMS-xxx as Monotherapy in Subjects with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control. 2003-2004. • **GlaxoSmithKline:** A Twelve-week, Multi-center, Randomized, Double-blind, Double-dummy, Parallel-group, Active controlled, Escalating Dose Study to Compare the Effects on Sexual Functioning of Buproprion Hydrochloride Extended-release (WELLBUTRIN™XL, xxx-xxxmg/day) and Extended-release Venlafaxine (EFFEXOR XR, xx-xxxmg/day) in Subjects with Major Depressive Disorder. 2004-2005.

- **GlaxoSmithKline:** A Multi-Centre, Randomised, Double-Blind, Parallel-Group, Placebo-Controlled, Flexible Dose Study to Evaluate the Efficacy, Safety and Tolerability of Extended-release Bupropion Hydrochloride (xxxmg-xxxmg once daily) in Elderly Subjects with Major Depressive Disorder. 2004-2005.

- **Pfizer Inc:** A Double Blind, Placebo Controlled, Parallel Group, Multicenter Study to Assess the Time to Onset, Safety, and Toleration of Differing Doses and Combinations of Immediate Release and Modified Release Formulations of xxx in Adult Male Subjects with Erectile Dysfunction. 2004-2005.

- **Novartis:** A 16 week, randomized, double-blind, active-controlled, parallel group study to evaluate the effect on insulin sensitivity of valsartan (xxxmg) and hydrochorothiazide (xxmg) combined and alone, in patients with metabolic syndrome. 2004-2005.

- **Novartis:** Effects of Blood Pressure Reduction on High Sensitivity C-Reactive Protein (hsCRP): A Multicenter, Randomized, Open-label, 2-Arm Parallel Group Study to Evaluate the Efficacy of Moderate Vs. Aggressive Antihypertensive Therapy with Diovan® and Diovan HCT® to Reduce Blood Pressure and Plasma hsCRP levels in Patients with Stage 2 Hypertension. 2004-2005.

- **Aventis:** A Randomized, Double-Blind, Parallel-Group, Multicenter Study to Compare Clinical Health Outcomes of XXX versus XXX in Outpatients with Community-Acquired Lower Respiratory Tract Infections. 2004-2005.

- **GlaxoSmithKline:** Two Identical Double-blind, Double-dummy, Multicenter, Comparative Phase III Studies of the Safety and Efficacy of Topical xxx, Applied Twice Daily, versus Oral Cephalexin, xxxmg in Adults, or xxxmg/kg in Children, Twice Daily, in the Treatment of Uncomplicated Secondarily Infected Traumatic Lesions. 2004-2005.

- **Watson Laboratories, Inc.:** A Multi-Center, Randomized, Double-Blind, Placebo Controlled, Parallel Comparison of the Efficacy and Safety of Fixed-Dose Extended-Release xxx/xxx in the Relief of Moderate to Moderately Severe Chronic Osteoarthritis Pain of the Hip or Knee. 2004.

- **Sankyo:** A Randomized, Double-Blind, Placebo-Controlled Factorial Study Evaluating the Efficacy and Safety of Co-Administration of xxx plus xxx Compared to Monotherapy in Patients with Mild to Severe Hypertension. 2004-2005.

- **Novartis Pharmaceuticals:** A 6-Week, Multicenter, Randomized,

	Double-Blind, Parallel Group Study to Evaluate the Combination of Valsartan/HCTZ (xx/xxmg) Compared to Valsartan Monotherapy (xxmg to xxmg) as Initial Therapy in Patients with Severe Hypertension. 2005-2006. • **Pfizer Inc:** A Randomized, Double Blind, Placebo Controlled, Four Arm Study to Evaluate the Clinical Efficacy of xxx in Men who have frequency and urgency, with or without urinary urge incontinence, with or without bladder outlet obstruction. 2005-2006. • **Pfizer Inc:** A Phase 2, 8-week, Multi-Center, Randomized Double-Blind, Placebo Controlled, Parallel Group Study Evaluating the Efficacy, Tolerability and Safety of xxx for Stress Urinary Incontinence in Women. 2006. • **Pfizer Inc:** A Phase 3, Randomized, 6-Month, Double-Blind Trial in Subjects with Bipolar I Disorder to Evaluate the Continued Safety and Maintenance of Effect of xxx plus a Mood Stabilizer (vs Placebo plus a Mood Stabilizer) Following a Minimum of 4 Months of Response to Open-Label Treatment with Both Agents. 2006. • **Sanofi Aventis:** An Eight-Week, Double-Blind, Placebo-Controlled, Multicenter Study with XXX as Positive Control, Evaluating the Efficacy, Safety, Tolerability of a Fixed Dose of XX in Outpatients with MDD. 2006. • **Novartis:** A 6-Week, Multicenter, Randomized, Double-Blind, Parallel-Group Study to Evaluate the Combination of Valsartan/HCTZ (xx/xxmg) With Forced Titration to a Maximum Dose of xx/xxmg) Compared to Valsartan Monotherapy (xxmg With Forced Titration to xxmg) as Initial Therapy in Patients with Severe Hypertension. 2006. • **Novartis:** An 8-Week, Multicenter, Randomized, Double-blind, Parallel-Group Study to Evaluate the Efficacy and Safety of the Combination of XX/XX/XX Compared to XX/XX, XX/XX, and XX/XX in Patients with Moderate to Severe Hypertension. 2006. • **Merck:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Sequential-Design Study to Evaluate the Lipid-Altering Efficacy and Tolerability of XX-XXXX in Patients with Dyslipidemia. 2006-2007. • **Merck:** A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Dose-Ranging Study of XXX in Postmenopausal Women with Overactive Bladder. 2006-2007. • **King:** A Randomized, Double-Blind, Multicenter, Parallel-Study

Evaluating the Efficacy and Safety of a Combination of XX Plus XXX Versus the Component Monotherapies in Subjects with Essential Hypertension (Stage 1 or 2). 2006-2007.

- **Takeda:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of the Combination of XXX and XX in Subjects with Type 2 Diabetes. 2006-2007.

- **Novartis:** A 12-Week, Open-Label, Non-Randomized, Multicenter Study to Evaluate the Patient's Perception of Outcome After Treatment With XXX in Overactive Bladder Patients Dissatisfied With Previous Anticholinergic Therapy. 2006-2007.

- **Novartis:** An 8-Week, Randomized, Fixed-Dose, Placebo-Controlled, Parallel-Group, Multi-Center Study of the Efficacy, Safety and Tolerability of XXX and XX mg in the Treatment of Major Depressive Disorder (MDD). 2006-2007.

- **Novartis:** A 16-week Double-Blind, Randomized, Multicenter, Forced-Titration Study to Evaluate the Antihypertensive Efficacy of XX/XXX Therapy Compared to XXX Based Therapy in Obese, Hypertensive Patients. 2006-2007.

- **GlaxoSmithKline:** A 12 Week Flexible Dose Study of XXX, Placebo and Active Control in the Treatment of Social Anxiety Disorder (SocAD). 2006-2007.

- **Sanofi-Aventis:** 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. 2007.

- **Pfizer:** A sixteen week, multi-center, open label study evaluating the safety, efficacy and tolerability of switching from quetiapine to ziprasidone in subjects diagnosed with schizophrenia or schizoaffective disorder. 2008

- **Pfizer:** A Phase III, Randomized, Double-Blind-Parallel Group, 10 Week Placebo Controlled Fixed Dose Study of XXXX and Paroxetine Evaluating the Efficacy and Safety of XXXX for the Treatment of Generalized Anxiety Disorder. 2008-2009

- **Novartis:** Randomized, Double Blind, Controlled, Parallel Group, 12-Week Treatment Study to Compare the Efficacy and Safety of the Combination of XXX Once Daily With Open Label Tiotropium Once Daily Versus Open Label Tiotropium Once Daily in Patient's With

Moderate to Severe Chronic Obstructive Pulmonary Disease.

- **Novartis:** A 24-Week, Prospective, Randomized, Parallel Group, double-Blind Multi-Center Study Comparing the Effects of XXX Patch 15cm2 Vs. XXX Patch 5cm2 on Activities of Daily Living and Cognition in Patients with Severe Dementia of the Alzheimer's Type

- **Novartis:** An 8-Week Randomized Double Blind, Parallel Group Multicenter Active Controlled Dose Escalation Study to Evaluate the Efficacy and Safety of XXX HCTS Compared to XXXX in Patients with Stage 2 Systolic Hypertension and Diabetes Mellitus

- **Novartis:** An 8-Week Randomized Double Blind Parallel Multi-Center Forced Titration Study to Evaluate the Safety and Efficacy of XXX plus HCTZ Versus XXX Monotherapy in Metabolic Syndrome Patients with Stage 2 Hypertension

- **Forest:** Metabolic Effects of XXX Compared to XXXXER in Hypertensive Patients with Impaired Glucose Tolerance or Impaired Fasting Glucose

- **Forest:** A Multicenter Prospective Randomized Double-Blind Placebo Controlled Dose Titration Study of XXX Monotherapy in Hispanic Patients with Stage I or Stage II Hypertension

- **Cephalon:** A Double Blind, Placebo Controlled, Parallel Group, Fixed Dosage Study to Evaluate the Efficacy and Safety of Armodafinil in Adults with Major Depression Associated with Bipolar I Disorder 2010-2011

- **Novartis:** An 8-Week, Randomized, Double Blind. Placebo Controlled, Parallel Group, Multi-Center Study of the Efficacy and Safety of Agomelatine 0.5mg and 1mg Sublingual Tablets Administered Once Daily in Patients with Major Depressive Disorder (MDD) 2010-2011

- **Novartis:** A 12-week, Randomized, Multi-Center, Open Label, Iloperidone (12-24mg/day), Flexible dose study assessing the efficacy, safety and tolerability of two switch approaches in schizophrenia patients currently receiving Risperidone, Olanzapine or Aripiprazole. 2010-2011.

- **Pfizer:** A Phase IV, Multicenter, Randomized, 8-week, Double-Blind, Placebo-Controlled, Parallel-Group Study To Evaluate The Efficacy Of 2 Fixed Doses (50 AND 100 MG/DAY) Of ********** In Adult Outpatients with Major Depressive Disorder. 2011-2012

- **Otsuka:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of the Safety and Efficacy of Two Fixed Doses of ******** as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder 2011-2014

- **Otsuka:** A Long-term, Phase 3, Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of Oral ******* as Adjunctive Therapy in Adults with Major Depressive Disorder, 2011-2015

- **Forest:** A Double-blind, Placebo-Controlled Evaluation of the Safety and Efficacy of ******* in Patients With Bipolar Depression 2011-2013

- **Forest:** A Double-Blind, Placebo- and Active-Controlled, Fixed-Dose Study of ******** in Patients with Major Depressive Disorder 2011-2013

- **Eli Lilly:** A Randomized Placebo-Controlled, Double-Blind Study of ******** Flexible-Dose 12 to 18 mg Once Daily as Adjunctive Treatment for Patients with Major Depressive Disorder Who Are Partial Responders to Selective Serotonin Reuptake Inhibitor Treatment 2012-2014

- **Otsuka**: A 52-week, Multicenter, Open-label Study to Evaluate the Effectiveness of an Intramuscular Depot Formulation of xxxxxxxxxxxxx as Maintenance Treatment in Patients with Bipolar I Disorder 2013-

- **Lundbeck**: Interventional, randomised, double-blind, parallel-group, placebo-controlled, flexible-dose long-term study to evaluate the maintenance of efficacy and safety of 1 to 3 mg/day of xxxxxxxx as adjunctive treatment in patients with major depressive disorder with an inadequate response to antidepressant treatment 2014-

- **Otsuka**: A Phase 3b, Multicenter, Open-label Exploratory Trial to Evaluate the Efficacy, Safety, and Subject Satisfaction with xxxxxxxx as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder and an Inadequate Response to Previous Adjunctive Therapy 2014-2015

- **Alkermes:** A Phase 3 Efficacy and Safety Study of xxxxxxx for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-3 Study) 2014-

- **Alkermes:** A Phase 3 Multicenter Study of the Long-term Safety and Tolerability of xxxxxxx for the Adjunctive Treatment of Major Depressive Disorder in Adults who Have an Inadequate Response to Antidepressant Therapy (the FORWARD-2 Study) 2014-

	• **Edgemont:** A Randomized Double-Blind, Placebo Controlled, Flexible Dose, Parallel Group Study of Extended-Release xxxxxxxxxx for the Treatment of Generalized Anxiety Disorder (GAD) 2015- • **Avanir**: A Phase 2, randomized, double-dummy, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of XXXXXXXXXX for the treatment of symptoms of agitation in patients with Alzheimer's disease. 2013-2014 • **Avanir:** Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of XXXXXX for the treatment of agitation in patients with dementia of the Alzheimer's type 2015-