

CURRICULUM VITAE

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AFFILIATIONS:

Lakeside Behavioral Healthcare
Orlando, FL

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Bradenton, FL

EDUCATION:

Doctor of Philosophy, Ph.D. in Child Health Psychology
University of Sheffield, Sheffield, UK 2004

Bachelor of Science
University of Warwick, Warwick, UK 2000

CERTIFICATION:

Certified Clinical Research Professional (CCRP) 2007

PROFESSIONAL EXPERIENCE:

Investigator 2007-Present
Florida Clinical Research Center, LLC, Maitland and Leesburg, FL

Lead Clinical Research Associate/Coordinator 2006- 2007
St Jude Children's Research Hospital, Memphis, TN

Curriculum Vitae, Joanne L. Northcutt, Ph.D.

PROFESSIONAL EXPERIENCE (continued):

Clinical Research Associate/Coordinator 2004- 2006
St Jude Children's Research Hospital, Memphis, TN

Clinical Research Coordinator 2000- 2004
University of Sheffield, Sheffield, UK

Clinical Research Assistant 1999- 2000
University of Warwick, Warwick, UK

INVESTIGATOR EXPERIENCE:

Attention Deficit Hyperactivity Disorder (ADHD- Adult & Child) • Alzheimer's Disease
Anxiety Disorders • Bipolar Disorder • Cognitive Impairment • Depression • Insomnia
Migraine • Psychotic Disorders

ADDITIONAL TREATMENT EXPERIENCE:

• Child ODD (Oppositional Defiant Disorder) & CD (Conduct Disorder)

CLINICAL TRIAL EXPERIENCE:

ADHD

A 40-week, Double blind, Placebo controlled, Multi-center, Randomized Withdrawal Study to Evaluate the Long Term Efficacy of XXX Extended Release in Children and Adolescents with ADHD

A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of XXX Extended-Release Tablets as Adjunctive Therapy in Children with Impulsive Aggression Comorbid with Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of XXX Extended-Release Tablets as Adjunctive Therapy in Children with Impulsive Aggression Comorbid with Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase III, parallel, randomized, double-blind, multi-center, placebo-controlled, forced dose study to evaluate the safety and efficacy of XXX extended release capsules in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric and adolescent patients aged 6 up to 18 years

CLINICAL TRIAL EXPERIENCE (continued):

A Phase III, Randomised, Double-blind, Multicentre, Parallel-group, Placebo- and Active-reference, Dose-optimisation Efficacy and Safety Study of Extended-release XXX in Children and Adolescents aged 6-17 years with Attention-Deficit/Hyperactivity Disorder

A Phase IV, Randomized, Double-Blind, Multicenter, Placebo-Controlled, Parallel-Group Study Evaluating the Safety and Efficacy of XXX on Executive Function (Self-Regulation) Behaviors in Adults with Attention-Deficit/Hyperactivity Disorder (ADHD) Reporting Clinically Significant Impairment of Real-World Executive Function Behavior

A Phase III, Double-blind, Placebo-Controlled, Multi-centre, Randomized-Withdrawal, Long-Term Maintenance of Efficacy and Safety Study of Extended-release XXX in Children and Adolescents Aged 6-17 With Attention-deficit/Hyperactivity Disorder

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

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

A Phase III, Double-blind, Randomized, Multi-center, Placebo controlled, Dose Optimization Study Evaluating the Tolerability and Efficacy of AM and PM Once Daily Dosing with Extended-release XXX in Children Aged 6-12 with a Diagnosis of Attention-Deficit/Hyperactivity Disorder

A Phase III Evaluation of the Efficacy and Safety of XXX as Add-On to Psychostimulant Medication versus Psychostimulant Medication Alone in the Treatment of Children and Adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multi-Center, Dose Optimization Study Evaluating the Efficacy and Safety of XXX in Combination with Psychostimulants in Children and Adolescents Aged 6-17 Years with a Diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD)

A Randomized, Multi-Center, Double-Blind, 3 x 3 Cross-Over Study Demonstrating Superior Efficacy of XXX versus XXX at 10, 11 and 12 Hour Time points (Post-Dose) in Children, Aged 6-12 years, with Attention-Deficit/Hyperactivity Disorder (ADHD) in a 12-Hour Laboratory Classroom Setting

CLINICAL TRIAL EXPERIENCE (continued):

A Randomized, Placebo-Controlled, Double-Blind, Fixed-Dose Study of the Efficacy and Safety of in Children and Adolescents 6 through 17 Years of Age with Attention-Deficit/Hyperactivity Disorder-Associated Insomnia & A Long Term, Open Label, Safety Study of in Children (6-11) and Adolescents (12-17) with Attention Deficit/Hyperactivity Disorder-Associated Insomnia

A Long-Term, Open-Label, Safety Study of XXX in Children (6 to 11 years) and Adolescents (12 to 17 years) with Attention Deficit/Hyperactivity Disorder-Associated Insomnia

A Randomized, Placebo-Controlled, Double-Blind, Fixed-Dose Study of the Efficacy and Safety of XXX in Children (6 to 11 years) and Adolescents (12 to 17 years) with Attention-Deficit/Hyperactivity Disorder-Associated Insomnia

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

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

Alzheimer's Disease

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

A Phase III, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate The Safety and Tolerability of XXX for up to 26 Weeks in Patients with Mild to Moderate Alzheimer's Disease

A Dose Ranging, Randomized, Double Blind, Parallel-Group, Placebo-Controlled Multi-Center Study of XXX used as Add-On to Donepezil Treatment in Patients with Mild to Moderate Symptoms of Alzheimer's Disease.

Anxiety Disorder

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Active-Referenced, Fixed-Dose Study Comparing the Efficacy and Safety of 3 Doses of XXX in Acute Treatment of Adults with Generalized Anxiety Disorder

A 52-Week Open-Label Safety Study of XXX in Subjects with Generalized Anxiety Disorder

CLINICAL TRIAL EXPERIENCE (continued):

A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase II Study of 2 Oral Groups of XXX, with a Lorazepam Arm, in Subjects with Generalized Anxiety Disorder (GAD)

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

A Phase III Randomized Double-Blind Parallel Group 10-week Placebo Controlled Fixed Dose Study of XXX and XXX evaluating the Efficacy and Safety of XXX for the Treatment of Generalized Anxiety Disorder

Bipolar Disorder

A 6-Month, Open-Label, Fixed-Dosage Extension Study of the Safety and Efficacy of XXX Treatment as Adjunctive Therapy in Adults with Major Depression Associated with Bipolar Disorder

A Randomized, 7-Week, Double-Blind, Placebo-Controlled, Quetiapine-Referenced, Parallel-Group Study to Evaluate the Safety, Efficacy, and Tolerability with Fixed Doses of XXX in Adults with Bipolar Depression

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

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

A Randomized, 6-Week, Double-Blind, Placebo-Controlled, Fixed-Flexible Dose, Parallel-Group Study of XXX in the Treatment of Bipolar I Depression

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

A Controlled Trial of XXX versus Placebo in Patients with Bipolar Depression

Cognitive Impairment

The Cognitive Effects of XXX and XXX in Older Volunteers

CLINICAL TRIAL EXPERIENCE (continued):

Learning Impairments Among Survivors of Childhood Cancer

Working Memory Performance Among Childhood Brain Tumor Survivors Treated with Conformal Radiation Therapy

Neural Systems Supporting Working Memory: A Pilot Study

A Total Therapy Study XV for Newly Diagnosed Patients with Acute Lymphoblastic Leukemia (ALL)

A Phase II Study of Image Guided Radiation Therapy for Pediatric Central Nervous System (CNS) Tumors and Quantification of Radiation-Related CNS Effects

Depression

A 52-Week, Multi-Center, Open-Label Study of the Safety and Tolerability of XXX in Patients with Major Depressive Disorder

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

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Relapse-Prevention Study with XXX in Patients with Major Depressive Disorder

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

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

An 8-week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Study of the Efficacy and Safety of XXX Administered Once Daily in Patients with Major Depressive Disorder (MDD)

A Randomized, Double-Blind, Parallel-Group, Study to Compare Discontinuation Symptoms in Abrupt Discontinuation Versus a 1-Week Tapering Regimen in Subjects with Major Depressive Disorder Treated for 24 Weeks with Open Label XXX

CLINICAL TRIAL EXPERIENCE (continued):

A Study to Assess the Long-Term Efficacy and Safety of XXX and XXX Combination Versus XXX Only in the Relapse Prevention of Stabilized Patients with Treatment-Resistant Depression

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

Hypo-Sexual Dysfunction in Patients with Depression

A Randomized, Double-Blind Assessment Comparing Discontinuation Symptoms in Abrupt Discontinuation vs. a One Week Tapering Regimen in MDD Patients Treated for 6 Months Open Label with 50 mg XXX Sustained Release

A Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of XXX in Subjects with Major Depressive Disorder

A Multi-center, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate Functional Outcome in Outpatients with Major Depressive Disorder Treated with XXX

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

A Controlled Trial of XXX versus Placebo in Patients with Bipolar Depression

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

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

An Eight-Week, Double-blind Study to Evaluate the Efficacy, Safety, and Tolerability of Two Fixed Doses of XXX Once Daily in Combination with XXX Once Daily Compared to XXX Placebo in Combination with XXX Once Daily in Patients with Major Depressive Disorder

An Eight-Week, Randomized, Fixed-Dose, Placebo-Controlled, Parallel-Group, Multi-Center Study of the Efficacy, Safety and Tolerability of XXX in the Treatment of Major Depressive Disorder (MDD)

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

CLINICAL TRIAL EXPERIENCE (continued):

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

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

Psychiatric Co-Morbidity in HIV-Infected Children and Adolescents

The Diagnostic Disclosure and Medical Adherence in Adolescents and Young Adults with HIV/AIDS

The Factors Related to Diagnostic Disclosure and Adherence in Perinatal HIV Infection

Insomnia

A Phase II, Randomized, Double-Blind, Placebo- and Active-Comparator-Controlled Study of the Safety and Efficacy of XXX in Outpatients with Insomnia

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

A 6-Month Double-Blind Randomized Placebo-Controlled Parallel Group Outpatient Trial Investigating the Efficacy and Safety of XXX in Adult Patients with Chronic Primary Insomnia

The Efficacy and Safety of XXX on Sleep Maintenance Insomnia with a Sub-Study of the Effect of XXX on Stable Type II Diabetes Mellitus: a 12-Week, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study

Migraine

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

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

CLINICAL TRIAL EXPERIENCE (continued):

A Multicenter, Randomized, Double-Blind (with in-house blinding), Active-Controlled, Parallel-Group Clinical Trial to Evaluate the Long Term Safety and Tolerability of XXX in Adults with Acute Migraine with or Without Aura

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

Psychotic Disorders

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

Other Indications

A Phase IV study: Safety and Efficacy of XXX in the Long-Term Maintenance Treatment of Pediatric Patients with Irritability Associated with Autistic Disorder

A 52-week, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX as Maintenance Treatment in Patients with Schizophrenia

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose Study Evaluating the Efficacy and Safety of XXX in Posttraumatic Stress Disorder (PTSD)

A Phase II, Multi-center, Randomized, Double-blind, Placebo-controlled Adaptive Study of the Safety and Efficacy of XXX in Adults with Alcohol Dependence

The Learning Impairments among Survivors of Childhood Cancer

A 12-week, Randomized, Double-Blind, Placebo-Controlled, Phase III Safety Trial of XXX in Women Taking a Selective Serotonin or Serotonin-Norepinephrine Reuptake Inhibitor with decreased Sexual desire and distress