

Curriculum Vitae

Maria Companioni, DNP, APRN-BC

Professional Experience

2025 - Present	Chief Executive Officer & Founder NextPhase Research Florida Hollywood, FL
2024 - Present	Clinical Director of Neuromodulation My TMS Hollywood, FL
2017 - Present	Psychiatric Nurse Practitioner My Psychiatrist Oakland Park, FL
2017 - 2025	Director of Clinical Operations/Sub-Investigator Cenexel Research Centers of America Oakland Park, FL
2015 - 2017	Assistant Director of Nursing South Florida State Hospital Pembroke Pines, FL
2014 - 2015	Performance Improvement Nurse Manager South Florida State Hospital Pembroke Pines, FL
2014 - 2014	Charge Nurse South Florida State Hospital Pembroke Pines, FL
2014 - 2014	Per Diem Registered Nurse Mercy Hospital Miami, FL
2013 - 2013	Charge Nurse New Horizons Community Mental Health Center Miami, FL
2012 - 2013	Registered Nurse Softcare Home Health Miami, FL

Education

2021 - 2023	Doctorate of Nursing Practice (DNP) Chamberlain University Chicago, IL
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2014 - 2016	Adult Nurse Practitioner (MSN) South University Savannah, GA
2013 - 2016	Bachelor of Science, Nursing (B.S.) Florida National University Miami, FL
2011 - 2012	Associates of Science in Nursing (A.S.) Florida National University Miami, FL
2005 - 2010	Associates of Medical Science Miami Dade College Miami, FL

Certifications

Advanced Practice Registered Nurse
License # APRN 9352223
State of Florida

Registered Nurse
License # RN 9352223
State of Florida

Past Research Affiliation

CenExel Research Centers of America at
Fort Lauderdale Behavioral Health Center
5757 N. Dixie Hwy
Oakland Park, FL 33334

CenExel Research Centers of America
7261 Sheridan Street, Suite 210
Hollywood, FL 33024

Professional Licensure

American Academy of Nurse Practitioners Certification Board
Certification No.: A1116003

American Nurses Credentialing Center
Psychiatric-Mental Health Nursing PMH-BC
Certification No.: 2017000776

DEA Registration
License # MC4241864
XC4241864

Society Memberships

The International Society for CNS Clinical Trials and Methodology
American Society of Clinical Psychopharmacology

Abstracts and Presentations

Evaluation of the Correlation Between the Clinical Global Impression of Improvement Scale and the Patient Global Impression of Improvement Scale in Acute Schizophrenia Companioni, M., Montero, J., and Ruiz, P. CNS Summit, (November 2024)

An Overview of the Agreement Between the Patient Global Impression of Improvement (PGI-I) and the Clinical Global Impressions – Improvement (CGI-I) Scales Companioni, M., Montero, J., Ruiz, P., Khan, A. and Nguyen, L. American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, (May 2024)

Analysis of Correlation of the Clinical and Patient Global Impression of Improvement Scales in Acute Schizophrenia Clinical Trials Companioni, M., Montero, J. and Khan, A. Abstract Submitted for Poster Proposal for the International Society of CNS Clinical Trials and Methodology (ISCTM) Annual Scientific Meeting, (February 2024)

Rater Certifications and Scales Experience

Abnormal Involuntary Movement Scale (AIMS)

Barnes Akathisia Rating Scale (BAS)

Brief Psychiatric Rating Scale (BPRS)

Calgary Depression Scale for Schizophrenia (CDSS)

Children's Depression Rating Scale (CDRS)

Clinical Global Impression Severity/Improvement (CGI-S/I)

Clinician's Interview Based Impression of Change (CIBIC)

Clinical Opiate Withdrawal Scale (COWS)

Columbia Suicide Severity Rating Scale (C-SSRS)

Extrapyramidal Symptom Rating Scale (ESRS)

Global Assessment of Functioning (GAF)

Global Assessment Scale (GAS)

Hamilton Anxiety Rating Scale (HAM-A)

Hamilton Depression Rating Scale (HAM-D)

Inventory of Depressive Symptomatology-30 (IDS-30)

Kiddie - Positive and Negative Syndrome Scale (Kiddie PANSS)

Kiddie - Schedule for Affective Disorders and Schizophrenia (K-SADS)

Mini International Neuropsychiatric Interview (MINI/MINI-Kid)

Mini-Mental State Examination (MMSE)

Modified Himmelsbach Opioid Withdrawal Scale (MHOWS)

Montgomery-Asberg Depression Rating Scale (MADRS)

Negative Symptoms Assessment-16 (NSA-16)

Personal and Social Performance Scale (PSP)

Positive and Negative Syndrome Scale (PANSS)

Schedule for Affective Disorders and Schizophrenia - Change (SADS-C)

Simpson-Angus Scale (SAS)

Structured Clinical Interview for DSM-IV Axis I Disorder (SCID)

Young Mania Rating Scale (YMRS)

Clinical Research Experience

2023 Teva Branded Pharmaceuticals: A Multi-center, Open-label, Randomized, Parallel-group Trial to Characterize the Pharmacokinetics of Three XXXX Formulations with Different Release Rates Following Single Administration in Participants with Schizophrenia or Schizoaffective Disorder

2023 Jazz Pharmaceuticals: A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Investigate the Efficacy and Safety of XXXX in Adults with Irritability Associated with Autism Spectrum Disorder (MEADOW)

2023 Otsuka: A Phase 1, Multi-center, Randomized, Double-blind, Placebo-controlled Trial to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Following Intermittent Oral Doses of XXXX in Subjects With Treatment-resistant Depression

2023 LB Pharmaceuticals: A Randomized, Double-blinded, Placebo-controlled, Multicenter Study to Evaluate the Antipsychotic Efficacy and Safety of XXXX in the Treatment of Adult Patients with Acute Schizophrenia.

2023 Merck: A Single Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of the Long-Acting Injectable (LAI) of XXXX in Participants with Schizophrenia

2023 Merck: A Phase 2B Randomized, Double-Blind, Placebo- and Active-Controlled Trial of the Efficacy and Safety of XXXX in Participants Experiencing an Acute Episode of Schizophrenia

2023 Indivior: A single-dose study to evaluate the relative bioavailability, safety, and tolerability of XXXX at alternative injection locations in adults

2023 Karuna: A phase 1B, open-label multicenter study to evaluate the effect of XXXX on 24-hour ambulatory blood pressure in adult subjects with schizophrenia

2022 Neurocrine Biosciences, Inc.: A phase 2, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, tolerability, and pharmacokinetics of XXXX in adults with schizophrenia who warrant inpatient hospitalization

2022 Novartis: A randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy, safety, tolerability, and pharmacokinetics of single subcutaneous XXXX injection in addition to standard of care in participants with treatment-resistant depression

2022 Sunovion: A double-blind, placebo-controlled, randomized withdrawal study to evaluate XXXX physical dependence in adult subjects with schizophrenia

2022 Sunovion: A randomized, open-label, single dose, cross-over study of gastric emptying rate: XXXX vs prior antipsychotic standard of care in subjects with schizophrenia

2022 Teva: A multinational, multicenter, randomized, double-blind, parallel-group, placebo-controlled study with an open-label, long-term safety phase to evaluate the efficacy, safety, and tolerability of olanzapine for extended-release injectable suspension XXXX for subcutaneous use as treatment of adult patients with schizophrenia

2022 Karuna: Phase 3, An open-label study to assess the long-term safety, tolerability, and efficacy of XXXX in De Novo subjects with DSM-5 Schizophrenia

2022 Cerevel: A 52-week, Phase 2, open-label trial to evaluate the long-term safety and tolerability of XXXX in adult participants with schizophrenia

2022 Cerevel: A Phase 2, randomized, double-blind, placebo-controlled trial to evaluate the efficacy, safety, and tolerability of two fixed doses (10 mg and 30 mg qd) of XXXX in participants with schizophrenia experiencing an acute exacerbation of psychosis

2021 Reviva: Phase 3, randomized, 28 days, double-blind, placebo-controlled, multicenter study to assess the safety and efficacy of XXXX in subjects with acute exacerbation of schizophrenia, followed by a 52-week open-label extension

2021 Intra-Cellular: A Phase II, multicenter, randomized, double-blind, parallel group, placebo-controlled trial of the efficacy and the safety of XXXX vs. placebo in patients with an acute exacerbation of schizophrenia or schizoaffective disorder

2021 Boehringer Ingelheim: Randomized, double-blind (patient, investigator), placebo-controlled, dose-escalation study on safety, tolerability, pharmacokinetic and preliminary efficacy of XXXX as adjunctive therapy in patients with major depressive disorder after single oral dosing
2021 Seelos: A 2-part phase 2 study to assess the efficacy, safety, and tolerability of XXXX administered to adults with major depressive disorder at imminent risk of suicide

2021 Sunovion: A randomized, single-blind, two-period crossover to investigate the effect of sep-363856 on the pharmacokinetics of XXXX in subjects with schizophrenia

2021 Novartis: A double-blind, placebo-controlled, randomized dose-ranging trial to investigate efficacy and safety of intravenous XXXX in addition to comprehensive standard of care on the rapid reduction of symptoms of major depressive disorder in subjects who have suicidal ideation with intent

2021 Intra-Cellular: A randomized, double-blind, placebo-controlled, parallel-group study of XXXX for the prevention of relapse in patients with schizophrenia

2020 Karuna: A Phase 3, randomized, double-blind, parallel-group, placebo-controlled, multicenter study to evaluate the efficacy and safety of XXXX in acutely psychotic hospitalized adults with DSM-5 schizophrenia

2020 Karuna: A Phase 3, randomized, double-blind, parallel-group, placebo-controlled, multicenter study to evaluate the efficacy and safety of XXXX in acutely psychotic hospitalized adults with DSM-5 schizophrenia

2020 Roche: A Phase II, multicenter, randomized, double-blind, parallel group, placebo- controlled trial of the efficacy and the safety of XXXX vs. placebo in patients with an acute exacerbation of schizophrenia or schizoaffective disorder

2020 Otsuka: A Phase 1, open-label, randomized, single ascending dose trial to determine the pharmacokinetics, safety, and tolerability of XXXX long acting injectable in adult subjects with schizophrenia

2020 Merck: A 2-part randomized clinical study to evaluate the safety, tolerability and pharmacokinetics of alternate XXXX in young adult participants with schizophrenia and to evaluate the safety, tolerability and pharmacokinetics of XXXX in elderly participants with schizophrenia

2020 Merck: A Phase 2B randomized, double-blind, placebo- and active-controlled trial of the efficacy and safety of XXXX in participants experiencing an acute episode of schizophrenia

2020 Vanda: A multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of XXXX for 4 weeks in the treatment of patients with acute manic episodes associated with Bipolar I Disorder

2019 Sunovion: A Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed- dose, Multicenter Study to Evaluate the Efficacy and Safety of XXXX in Acutely Psychotic Subjects with Schizophrenia

2019 Otsuka: A Phase 1b, open-label, multiple-dose, randomized, parallel-arm, safety, tolerability, and pharmacokinetic trial of XXXX administered in the gluteal muscle in adult subjects with schizophrenia or Bipolar I Disorder

2019 Sunovion: An open-label extension study to assess the safety and tolerability of XXXX in subjects with schizophrenia.

2019 Sunovion: A randomized, double-blind, parallel-group, placebo-controlled, fixed-dose, multicenter study to evaluate the efficacy and safety of XXXX in acutely psychotic subjects with schizophrenia

2019 NeuroRx: Acute stabilization (XXXX vs. placebo) for treatment of acute suicidal ideation and behavior in patients with severe Bipolar Depression

2019 NeuroRx: Treatment of severe bipolar depression in patients with acute suicidal ideation and behavior: The SBD-ASIB study

2019 Allergan: An open-label study to assess the long-term safety and efficacy of XXXX in subjects with major depressive disorder

2019 Boehringer Ingleheim: A randomized, double-blind, placebo-controlled study of the safety, tolerability, pharmacokinetics, and preliminary efficacy of single doses of XXXX in healthy volunteers and subject with treatment-resistant depression.

2019 Eisai Inc: A randomized double-blind clinical trial to evaluate the effects of in participants with obstructive sleep apnea

2019 Merck: A Phase 3, multicenter, randomized, double-blind, active comparator controlled study to evaluate the safety, tolerability, and immunogenicity of XXXX in healthy adults 50 years of age or older.

2019 Astellas: A Phase 1/2, randomized, single ascending dose study in adults (Stage 1) and randomized, single ascending dose-finding study (Stage 2) in elderly subjects with XXXX, a pneumococcal vaccine

2019 Emergent: A Phase 3, randomized, double-blind, parallel-group trial to evaluate the lot consistency, immunogenicity, and safety of XXXX for postexposure prophylaxis of anthrax in healthy adults

2019 FluGen: Phase 1b clinical study to investigate the safety and immunogenicity of the Bris10 (A/Brisbane/10/2007) M2SR and Sing2016 (A/Singapore/INFIMH-16-0019/2016) XXXX monovalent influenza vaccines

2019 Pfizer: A Phase 3, randomized, double-blind trial to evaluate the safety and immunogenicity of 3 lots of 20-valent conjugate vaccine in XXXX– naïve adults 18 through 49 years of age.

2019 Pfizer: A Phase 3, randomized, double-blind trial to evaluate the safety and immunogenicity of a 20-valent conjugate vaccine in XXXX v–naïve adults 18 years of age and older.

2019 Lundbeck: Interventional, randomized, double-blind, sequential-group, placebo-controlled, single-ascending-dose study investigating the safety, tolerability and pharmacokinetic and pharmacodynamic properties of XXXX in healthy non-Japanese and Japanese subjects and in patients with Parkinson’s disease

2019 Novavax: A randomized, observer-blind, active comparator-controlled, multicenter, phase 3 study to assess the efficacy, safety and immunogenicity of a plant derived XXXX in adults 65 years of age and older.

2019 Axsome: MOMENTUM (Maximizing Outcomes in Treating Acute Migraine) A randomized, double-blind, single-dose, placebo-controlled study to assess the efficacy and safety of XXXX for the acute treatment of migraine in adults.

2019 Axsome: A randomized, double-blind, placebo-controlled trial of XXXX in subjects with major depressive disorder

2019 Guardant Health Inc: Evaluation of the XXX Test in an Average Patient Screening Episode.

2019 Janssen: A randomized, double-blind, placebo-controlled Phase 2 study comparing the efficacy and safety of XXXX versus placebo in patients with nonalcoholic steatohepatitis

2019 Pfizer: A Phase 2A, randomized, double Blind, (sponsor open) placebo controlled, parallel group, study to access the pharmacodynamics, safety and tolerability of XXXX co-administered for 6 weeks in adults with non-alcoholic fatty liver disease

2019 Otsuka: A Phase 1b, open-label, multiple-dose, randomized, parallel-arm, safety, tolerability, and pharmacokinetic trial of XXXX administered in the gluteal muscle in adult subjects with schizophrenia or Bipolar I Disorder

2019 Otsuka: A Phase 1, open-label, randomized, single ascending dose trial to determine the pharmacokinetics, safety, and tolerability of XXXX long acting injectable in adult subjects with schizophrenia

2019 Sage: A Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, and Efficacy of XXXX Compared to Placebo in Adult Subject with Comorbid Major Depression Disorder and Insomnia

2018 Otsuka: A Multicenter, randomized, double blind trial of XXXX versus placebo for the acute treatment of maniac episodes, with or without mixed features, associated with Bipolar I Disorder

2018 Allergan: A randomized, double blind, placebo controlled, multicenter study of XXXX in the prevention of relapse in patients with major Depressive Disorder.

2018 Allergan: A double-blind, placebo-controlled, randomized withdrawal, multicenter clinical trial evaluating the efficacy, safety, and tolerability of XXXX in a dose- reduction paradigm in the prevention of relapse in Bipolar I Disorder patients whose current episode is manic or depressive, with or without mixed features

2018 Allergan: Randomized, double-blind, placebo-controlled, multicenter study of XXXX as monotherapy in patients with major depressive disorder.

2018 Navrex: A randomized, double-blind, placebo-controlled, multicenter, efficacy and safety study of XXXX for rapid treatment of symptoms of depression and suicidality in adult patients with major depressive disorder.

2018 Idorsia: Multi-center, double blind, randomized, placebo controlled, parallel group, polysomnography study to assess the efficacy and safety of XXXX in adults and elderly subjects with insomnia disorder.

2018 Sage: A Phase 3, Multicenter, double-blind, randomized, Placebo controlled study evaluating the efficacy of XXXX in the treatment of adult subjects with major depressive disorder

2018 Idorsia: Multi-center, double-blind, parallel-group, randomized, placebo-controlled, three doses, 40-week extension to studies id-078a301 and id-078a302 to assess the long-term safety and tolerability of XXXX in adult and elderly subjects with insomnia disorder.

2018 Novartis: A Randomized, subject and investigator- blinded, placebo controlled, cross- over, multi center proof of concept (PoC) study to assess the wakefulness promoting effect, safety, tolerability, and pharmacokinetics of XXXX in Shift Work Disorder (SWD) patients

2018 Pfizer: A Phase 3, placebo-controlled, randomized, observer-blinded study to evaluate the lot consistency, safety, tolerability, and immunogenicity of a XXXX vaccine in healthy adults 65 to 85 years of age.

2017 Allergan: A Randomized, Double-blind, Placebo-controlled, Multicenter Study of XXXX as Adjunctive Therapy in Major Depressive Disorder

2017 Lundbeck: A Phase 3, interventional, open-label, flexible-dose, long-term safety study of XXXX in adult patients with schizophrenia.

2017 Alkermes: A Phase 3 study to evaluate the safety, tolerability, and efficacy of XXXX for use in conjunction with buprenorphine in adults with opioid use disorder transitioning from buprenorphine maintenance prior to first dose of XXXX.

2017 Vanda: A double-blind, placebo-controlled study to investigate XXXX in healthy subjects with jet-lag type insomnia induced by an 8-hour phase advance

2017 Allergan: A randomized, double-blind, placebo-controlled, multicenter, efficacy and safety study of XXXX for rapid treatment of symptoms of depression and suicidality in adult patients with major depressive disorder

2016 Avaniv: A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of XXXX for the treatment of agitation in patients with dementia of the Alzheimer's type