Curriculum Vitae

Judith Montero, PsyD

Professional Experience

2025 – Present	Chief Clinical Officer NextPhase Research Florida Hollywood, Florida
2020 - 2025	Director of Clinical Assessments CenExel CenExel Centers of Excellence (18 Sites) Sunrise, Florida
2018 - 2020	Lead Clinical Scientist Clinical Surveillance & Training Syneos Health Sunrise, Florida
2014 - 2018	Lead Assessment Scientist Syneos Health Sunrise, Florida
2010 - 2014	Senior Assessment Specialist inVentiv Health Sunrise, Florida
2003 - 2010	Investigator/Sub-Investigator/Rater Segal Institute for Clinical Research Miami, Florida
2002 - 2003	Neuropsychology Fellowship Centers for Neurology, Injury and Headache Treatment Centers Ft. Lauderdale, Florida
2001 - 2002	Mental Health Counselor and Cognitive Therapist Health South - The Bridge Ft. Lauderdale, Florida
2000 - 2001	Clinical Neuropsychology Doctoral Internship North Broward Medical Center Pompano Beach, Florida
1999 - 2000	Doctorate Practicum II Mount Sinai Medical Center, Psychiatric Department Pompano Beach, Florida
1999 - 1999	Psychometrician

	Christian del Rio Miami, Florida
1999 - 2000	Psychometrician Jay Weinstein Coral Gables, Florida
1998 - 1999	Doctorate Practicum I Goodman Center at Carlos Albizu University Miami, Florida
1996 - 1997	Master's Degree Practicum A Woman's Place Miami, Florida
1996 - 1998	Mental Health Counselor BeWell Community Mental Health Miami, Florida

Education

2002	Doctor of Psychology Albizu University Miami, Florida
1997	Master's in Counseling Psychology Albizu University Miami, Florida
1995	Bachelor's in Psychology Florida International University Miami, Florida

Professional Memberships

2002 – Present	American Psychological Association

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

Publications

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, Boston, MA 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, Miami Beach, FL 2024

An Empirical View of Our US Primary Endpoint Evaluators' Work Stress and Task Burnout. Cohen, E.A., Montero, J., Grindell, V.M., Wyka, K., Hassman, H.A., Walling, D.P., Blanchard, C.L., Opler, M.G., Mischoulon, D., Ereshefsky, L. International Society of CNS Clinical Trials and Methodology (ISCTM) Annual Scientific Meeting, Washington, DC 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. International Society of CNS Clinical Trials and Methodology (ISCTM) Annual Scientific Meeting, Washington, DC 2024

Global Raters' Work Stress and Task Burnout: An Empirical Exploration of Our Primary Endpoint Evaluators. Cohen, E.A., Montero, J., Grindell, V.M., Wyka, K., Hassman, H.A., Walling, D.P., Blanchard, C.L., Opler, M.G., Mischoulon, D., Ereshefsky, L. CNS Summit, Boston, MA 2023

Romero HR, Zhao S, Perez M, Bougard C, Montero J, Smith R, Welsh-Bohmer KA, Plassman B, Hayden K. Cognitive and functional predictors of incident Alzheimer's disease: data from the National Alzheimer's Coordinating Center (NACC). Poster session presented at: Alzheimer's Association International Conference (AAIC); 2017 Jul 18; London, England.

Cantillon, M., Montero, J., Novak, B, Wilson, G., Smith, R. Methodology of Data Quality Review in Istradefylline Phase 3 Parkinson's Disease Trial. Presented at the 1st Congress of the European Academy of Neurology; Berlin, Germany 2015

Cantillon, M., Montero, J., Novak, B, Wilson, G., Smith, R. Outcome Quality in iSTEP Istradefylline Parkinson's Disease Trial. Presented at the 19th International Congress of Parkinson's Disease and Movement Disorders; San Diego CA 2014

Rater Certifications and Scales Experience

Alzheimer's Disease Cooperative Study–Activities of Daily Living (ADCS-ADL)

Alzheimer's Disease Assessment Scale–Cognitive Subscale (ADAS-Cog)

Abnormal Involuntary Movement Scale (AIMS)

Brief Assessment of Cognitve Functioning (BACS)

Barnes Akathisia Rating Scale (BAS)

Beck Depression Inventory (BDI)

Brief Psychiatric Rating Scale (BPRS)

California Verbal Learning Test (CVLT)

Calgary Depression Scale for Schizophrenia (CDSS)

Clinical Dementia Rating (CDR)

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)

Cognitive Assessment Interview (CAI)

Columbia Suicide Severity Rating Scale (C-SSRS)

Extrapyramidal Symptom Rating Scale (ESRS)

Epworth Sleepiness Scale (ESS)

Global Assessment of Functioning (GAF)

Global Assessment Scale (GAS)

Hamilton Anxiety Rating Scale (HAM-A)

Hamilton Depression Rating Scale (HAM-D)

Hoehn and Yahr Scale (H&Y)

Inventory of Depressive Symptomatology-30 (IDS-30)

Kiddie - Positive and Negative Syndrome Scale (Kiddie PANSS)

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

MATRIC Consensus Cognitive Battery (MCCB)

Minnesota Multiphasic Personality Inventory (MMPI-2)

Mini International Neuropsychiatric Interview (MINI/MINI-Kid)

Mini-Mental State Examination (MMSE)

Montreal Cognitive Assessment (MoCA)

Modified Himmelsbach Opioid Withdrawal Scale (MHOWS)

Montgomery-Asberg Depression Rating Scale (MADRS)

Movement Disorder Society–Unified Parkinson’s Disease Rating Scale (MDS-UPDRS)

Negative Symptoms Assessment-16 (NSA-16)

Neuropsychiatric Inventory (NPI)

Peabody Picture Vocabulary Test (PPVT)

Personal and Social Performance Scale (PSP)

Positive and Negative Syndrome Scale (PANSS)

Rey Complex Figure Test

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

Simpson-Angus Scale (SAS)

Stroop Color Word Test

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

Sheehan Disability Scale (SDS)

Timed Up and Go Test (TUG)

Visual Analog Scale (VAS)

Wechsler Adult Intelligence Scale (WAIS)

Wechsler Intelligence Scale for Children (WISC)

Wechsler Memory Scale (WMS)

Wide Range Achievement Test (WRAT)

Wisconsin Card Sorting Test

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 access 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 Ingleheim: 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

2010: Placebo- and active-controlled trial of XXXX in opioid dependence.

2010: Long-term study of XXXX vs. standard of care in schizophrenia.

2010: Comparator study of XXXX in schizophrenia patients.

2010: Study of XXXX in schizophrenia patients with predominant negative symptoms on stable atypical antipsychotics.

2010: Phase II study on XXXX doses vs. placebo in schizophrenia patients.

2010: 12-week, placebo-controlled study of XXXX in sub-optimally controlled schizophrenia symptoms.

2010: Study of XXXX in treatment-resistant major depression.

2010: XXXX vs. placebo in patients with depression and painful physical symptoms.

2010: XXXX vs. placebo in children/adolescents with major depressive disorder.

2010: Worldwide, open-label trial to examine long-term safety of XXXX in pediatric migraine patients.

2010: Placebo-controlled trial evaluating XXXX in pediatric and adolescent migraine (ages 6–17).

2010: Short-term randomized withdrawal study of XXXX in DSM-IV-TR schizophrenia.

2010: 24-week, placebo-controlled study of XXXX for persistent negative symptoms of schizophrenia.

2010: Phase IV, international, longitudinal study on individuals with ADHD.

2010: Study of XXXX in children/adolescents with ADHD (6 to 18 years).

2010: Effect of anti-amyloid beta monoclonal antibody XXXX on Alzheimer's progression.

2010: Evaluation of XXXX in agitation/psychosis in Alzheimer's patients.

2010: Bayesian adaptive design study of XXXX in mild-to-moderate Alzheimer's on stable AChEI therapy.

2010: Flexible-dose study of XXXX in bipolar I depression.

2010: Adjunctive XXXX for major depression in bipolar I disorder.

2009: Long-term, open-label safety study of XXXX in children and adolescents with ADHD-associated insomnia.

2009: Phase IV, double-blind, placebo-controlled withdrawal study of XXXX in adults aged 18–55 with ADHD.

2009: Study of XXXX in elderly subjects with psychosis and behavioral disturbances related to Alzheimer's disease.

2009: Multi-center, placebo-controlled, double-blind, phase II study on XXXX in generalized anxiety disorder (GAD).

2009: Study assessing efficacy and safety of XXXX and XXXX combination therapy for bipolar I disorder in adolescents.

2009: Study evaluating poor metabolizer prevalence among depression patients treated with XXXX.

2009: Double-blind, placebo-controlled, fixed-dose study on XXXX in adult outpatients with major depressive disorder.

2009: Study comparing XXXX versus placebo in elderly patients with major depressive disorder.

2009: 52-week, open-label study of XXXX as maintenance treatment in schizophrenia.

2008: Phase III evaluation of the efficacy and safety of [HCI sustained-release] as add-on to psychostimulant medication vs. psychostimulant medication alone in the treatment of children and adolescents with attention deficit hyperactivity disorder (ADHD).

2008: Open-label chronic exposure evaluation of the safety of XXXX [HCI sustained-release] in the treatment of children and adolescents with attention deficit hyperactivity disorder (ADHD).

2008: Controlled trial on safety and efficacy of XXXX versus placebo in patients with bipolar depression.

2008: Controlled trial on XXXX versus placebo in patients with bipolar disorder in manic or mixed states.

2008: 52-week, open-label extension trial evaluating XXXX in chronic primary insomnia who completed clinical trial XXXX.

2008: 24-week, double-blind, placebo-controlled, parallel-group, fixed-dosage study of XXXX as adjunctive therapy in schizophrenia-related cognitive impairment.

2008: Multi-center, double-blind, randomized, placebo-controlled study of long-term efficacy, safety, and tolerability of an intramuscular depot formulation of XXXX in patients with schizophrenia.

2008: Randomized, active-comparator controlled, long-term study of XXXX in schizophrenia/schizoaffective disorder.

2008: Double-blind, randomized, placebo-controlled, multi-center study on the efficacy, safety, and tolerability of XXXX in adults with ADHD.

By signing this form, I certify that the information provided is true, complete, and accurately reflects my current qualifications.

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Signature *Date of Signature*