

THIEVON-WRIGHT CONSULTING GROUP

12 New Providence Road
Watchung, NJ 07069

Office: 908.756.4411

Fax: 908.756.1122

www.cnssites.com

info@cnssites.com

MIDWEST CLINICAL RESEARCH CENTER



THIEVON-WRIGHT
CONSULTING GROUP®

Otto Dueno, M.D.
Bernadette D'Souza, M.D.
Isabel Arcure, D.O.
Stuart Blevins, N.P.
Gerald Cephas M.D.
Melissa Ellis, CCRC,
Site Director

Midwest Clinical Research Center

Dayton, Ohio

PSYCHIATRY

OTTO DUENO, M.D.

Otto Dueno, M.D., is the Medical Director of Midwest Clinical Research Center. He joined the center in 2011. He has served as Principal Investigator or Sub-Investigator on 82 clinical trials for Addiction, Attention Deficit Hyperactivity Disorder, Binge Eating Disorder, Bipolar Disorder, Depression, Fibromyalgia, Generalized Anxiety Disorder, Obsessive Compulsive Disorder, Post-Traumatic Stress Disorder, Schizophrenia, Smoking Cessation and Tardive Dyskinesia.

Dr. Dueno received his medical degree from Universidad Central del Caribe School of Medicine in Puerto Rico and completed his residency in Psychiatry at The Ohio State University. He is board certified by the ABPN and has been in private practice in the Dayton area since 1996.

BERNADETTE D'SOUZA, M.D.

Bernadette D'Souza, M.D., is the founder of Midwest Clinical Research Center in Dayton, Ohio. The center was established in 2002 by Dr. D'Souza for the purpose of conducting clinical research trials in psychiatric conditions. Since then, Dr. D'Souza has functioned as the Principal Investigator on more than 200 clinical studies, including research trials in Addiction, Alzheimer's Disease, Attention Deficit Hyperactivity Disorder, Binge Eating Disorder, Bipolar Disorder, Depression, Fibromyalgia and Pain, Anxiety Disorders, Insomnia, Post-Traumatic Stress Disorder, Sexual Dysfunction, Schizophrenia, Stuttering and Smoking Cessation.

Dr. D'Souza is a Certified Physician Investigator through the Association of Clinical Research Professionals. In addition, she is a staff physician at Good Samaritan Hospital in Dayton, Ohio. Dr. D'Souza is board certified in Psychiatry by the American Board of Psychiatry and Neurology, and previously served as an examiner for the Ohio Board of Psychiatry. As a researcher, Dr. D'Souza has been an investigator on clinical trials sponsored by major pharmaceutical companies as well as the National Institute of Mental Health.

STAFFING

Total Number of Staff	30
Clinical Site Manager.....	1
Unit Manager.....	1
CRCs.....	5
Raters.....	5
Sub-Investigators.....	3
Recruitment Staff.....	3
Other Staff.....	5
Unit Staff.....	12

PATIENT DATABASE

Total Number of Subjects	6,000+
Schizophrenic Subjects.....	500
Depressed Subjects.....	2,000
Anxiety Subjects.....	1,500
Alzheimer's Subjects.....	500
Bipolar Subjects.....	1,500

STUDY EXPERIENCE

Total	197
Phase I/II/III/IV.....	195
Schizophrenia (Stable).....	26
Bipolar.....	33
Depression.....	80
Anxiety Disorders.....	20
ADHD.....	9
Alzheimer's Disease.....	11
Binge Eating.....	3
Addiction.....	4
Fibromyalgia.....	6
Insomnia.....	10
PTSD.....	2
Smoking.....	3

PATIENTS ENROLLED

Schizophrenia (Stable).....	106
Schizophrenia (Acute).....	50
Addictions.....	150
Bipolar.....	453
Depression.....	1,100
Alzheimer's Disease.....	73
Fibromyalgia.....	107
ADHD.....	80
CAD.....	265
Insomnia.....	100
Pain.....	27

MIDWEST CLINICAL RESEARCH CENTER

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Midwest Clinical Research Center (MCRC) is the only site in Dayton, Ohio that is dedicated to conducting CNS clinical trials. The clinic has a strong reputation for enrolling the right subjects and providing sponsors with good, clean, quality data in a timely manner. For the vast majority of trials conducted at MCRC, the enrollment targets have been met and quite often exceeded. The staff is well trained to conduct complex studies, and all raters have consistently met the expectations set by sponsors for rater certification.

MCRC has developed internal quality monitoring for staff performance, staff training and for assessment of procedures in conducting clinical trials. MCRC uses a central IRB for regulatory submissions. MCRC has had multiple sponsor, CRO and FDA audits with no major findings.

INPATIENT AND OUTPATIENT FACILITY

MCRC is a dedicated inpatient and outpatient research facility centrally located within a large medical campus. The location affords wide visibility to potential subjects, physicians and other ancillary healthcare providers. It is also less than two miles from a hospital with full emergency medical services. The research site includes a 19-bed unit, dedicated for inpatient and clinical pharmacology research studies. The facility maintains fully equipped examination rooms, patient testing rooms with video conferencing capability and a CLIA-waived laboratory for phlebotomy and processing of samples. The research center has a -20 and -70 degree freezer for storage of samples, and a refrigerated centrifuge. Other features include high-speed internet, copier access and a temperature controlled, double locked medication room with controlled key code, video monitored access. There is also a large-source document room with controlled key code access.