

THIEVON-WRIGHT CONSULTING GROUP

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CLINILABS



THIEVON-WRIGHT
CONSULTING GROUP®

Maha Ahmad, M.D.
Mardik Donikyan, D.O.
Magdy Shenouda, M.D.
Sandra Comer, Ph.D.
Gary Zammit, Ph.D.

Clinilabs

New York, New York
Eatontown, New Jersey

PHASE 1

SLEEP

ASIAN BRIDGING

HUMAN ABUSE LIABILITY

DRIVING SAFETY

BIOMARKERS

Founded by President and CEO Gary Zammit, Ph.D., Clinilabs has successfully completed over 400 clinical trials involving healthy adult volunteers, patient populations and specialty populations since 2001.

INVESTIGATORS

Maha Ahmad, M.D., obtained her Bachelor of Science degree in Neuroscience from Brown University in Providence, RI. She went on to obtain Master of Medical Science and Doctor of Medicine degrees, also from Brown. Dr. Ahmad is board certified in Psychiatry and Sleep Medicine and is a Principal Investigator specializing in CNS trials, including all psychiatric and sleep indications.

Mardik Donikyan, D.O., is board certified in Emergency Medicine, and has over 18 years of experience in this specialty. He has been a Principal Investigator and Medical Monitor for the past nine years, and has extensive experience in Phase 1 clinical trials in a wide variety of therapeutic areas and specialty populations.

Magdy I. Shenouda, M.D., is board certified in Internal Medicine and is the Medical Director at Clinilabs' New Jersey CRU. Dr. Shenouda has 17 years of clinical research experience in Phase 1 and has worked in many therapeutic indications, including CNS, Hypertension, Diabetes, Cardiovascular and QTc studies, and invasive studies.

Sandra Comer, Ph.D., is a Professor of Neurobiology in the Department of Psychiatry at Columbia University and a Research Scientist VI at the New York State Psychiatric Institute. She is an expert in the treatment of human abuse liability and abuse deterrence, and is a member of the College on Problems of Drug Dependence, the longest standing group in the United States addressing problems of drug dependence and abuse. Dr. Comer has been actively involved in developing appropriate primary and secondary dependent measures to use in abuse liability trials. She has published over 115 papers, chapters, and books on issues related to drug dependence.

Gary Zammit, Ph.D., is the President and CEO of Clinilabs, Inc., the company he founded in 2001. He also is a Clinical Associate Professor at the Icahn School of Medicine at Mount Sinai in New York, NY. Dr. Zammit is widely known as a key opinion leader in the field of sleep medicine and clinical drug development. He has authored more than 135 original reports and two books, and currently serves as a principal investigator for CNS clinical trials.

STAFFING

Total Number of Staff	163
CRCs.....	7
Raters.....	6
Investigators.....	15
Recruitment Staff.....	6

SAMPLE PATIENT DATABASE

Total Number of Subjects	24,901
Normal Healthy Volunteers (18-64).....	11,897
Healthy Elderly Subjects (65+).....	1,169
Asian Subjects.....	1,285
Insomnia Subjects.....	1,401
Depression Subjects.....	2,063
Recreational Drug Users.....	1,719
Diabetic Subjects.....	238
Sleep Apnea Subjects.....	620

SPECIALTY PROCEDURES

- SAD, MAD, PK, BA, BE, drug-drug, food-drug, and kinetic-dynamic studies
- Sleep and wakefulness in an accredited sleep facility (PSG, MSLT, MWT)
- Cognitive assessment
- Metabolic assessment (calorimetry, hormone analyses)
- Reproductive safety
- EEG, EMG, evoked potentials
- Cardiorespiratory assessments
- TQT and intense ECG
- Biomarker studies, including QEEG, MRI, CSF and cCSF sampling
- Driving simulation studies

CLINILABS

THERAPEUTIC EXPERTISE

Psychiatric Disorders	Diabetes
Neurological Disorders	Infectious Diseases
Sleep Disorders	Gastrointestinal Disorders
Depression	Rare Disorders
Cardiac Conditions	Medical Devices
Cardiac Safety	Dermatology
Pulmonary Disease	Wound Healing
Pain and Anesthesia	Men's and Women's Health
Obesity	

Associate Investigator Panel: Ten associate investigators with experience in neurology, endocrinology, anesthesia/pain, abuse liability, pulmonary medicine, dermatology, cardiology, movement disorders, men's health, and women's health.

CLINILABS NEW YORK CITY

Clinilabs New York City is a 50-bed, state-of-the-art CRU located in the heart of New York City. It offers a full panel of Phase I services and experience in specialty procedures. The facility is equipped with a full range of electronic technology and medical devices. It features cognitive assessment, EEG, PSG, EMG, ECG, metabolic, and biomarker/pharmacodynamic capabilities. Clinilabs recruits its normal healthy subjects and patients from a diverse metropolitan population of over 19 million people.

CLINILABS NEW JERSEY

Clinilabs New Jersey is a 17,000 square foot, 50-bed, full-service Phase I unit featuring private and semi-private rooms, a large PK sampling facility, a pharmacy and a large infusion room. The facility is designed to accommodate the following types of studies: first in human, dose ranging- single ascending dose (SAD) and multiple ascending dose (MAD), pharmacokinetic (PK), bioequivalence (BE), bioavailability (BA), Asian bridging, and human abuse liability.