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CLINILABS



THIEVON-WRIGHT
CONSULTING GROUP®

Maha Ahmad, M.D.
Sandra Connolly, M.D.
Mardik Donikyan, D.O.
Marc Epstein, D.O.
Magdy Shenouda, M.D.
Gary Zammit, Ph.D.

Clinilabs

New York, New York
Eatontown, New Jersey

PHASE 1, ASIAN BRIDGING,
HUMAN ABUSE LIABILITY,
SLEEP

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.

Sandra Connolly, M.D., is a specialist in family and emergency medicine who graduated from Robert Wood Johnson Medical School. She has over 10 years of experience in early phase clinical research. Sandra is a Certified Physician Investigator who leads Phase 1 studies with normal healthy volunteers.

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.

Marc Epstein, D.O., is a board-certified Psychiatrist who specializes in the evaluation and treatment of addictive disorders, with a primary focus on the treatment of acute withdrawal from opiates and alcohol dependence. He currently serves as a Subinvestigator, alongside our subject matter experts, for human abuse liability and abuse deterrent trials.

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.

STAFFING

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

SAMPLE PATIENT DATABASE

Total Number of Subjects	23,655
Normal Healthy Volunteers	10,652
Healthy Elderly Subjects	1,270
Asian Subjects	1,297
Insomnia Subjects	2,799
Depression Subjects	3,645
Recreational Drug Users	1,400
Diabetic Subjects	1,725
Sleep Apnea Subjects	1,125
HIV+ Subjects	1,297

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 by licensed psychologists (paper and computerized)
- Metabolic assessment (calorimetry, hormone analyses)
- Reproductive safety (sperm count, motility, morphology)
- EEG, EMG, evoked potentials
- Cardiorespiratory assessments
- TQT and intense ECG
- Biomarker studies, including QEEG, MRI, CSF and cCSF sampling

CLINILABS

THERAPEUTIC EXPERTISE

Psychiatric Disorders	Infectious Diseases
Neurological Disorders	Gastrointestinal Disorders
Sleep Disorders	Chronic Pain
Cardiac Conditions	Rare Disorders
Cardiac Safety	Medical Devices
Pulmonary Disease	Dermatology
Asthma and Allergies	Wound Healing
Obesity	Men’s and Women’s Health
Diabetes	

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.