



# THIEVON-WRIGHT

C O N S U L T I N G   G R O U P

## TWCG Expands Its Early Phase & IP Specialized Capabilities

### MEET US AT THESE UPCOMING CONFERENCES

Alzheimer's Association  
International Congress  
(AAIC)  
July 18th - 23rd

ISCTM  
August 27th-29th

ECNP  
August 29th - September 1st

CNS Summit  
October 8th - 11th

Since its inception 17 years ago, Thievon-Wright Consulting Group and our network of clinical research sites have experienced tremendous growth and we continue to strengthen our reputation in the industry. Currently, our network has 14 members with 17 locations--10 clinical pharmacology/inpatient units with 307 total beds, 3 sleep centers and 17 outpatient clinics. We continue to be the "go-to" network for Sponsors and CROs seeking assistance with protocol development, operational feedback and budgeting advice during the planning stages of both early and late stage CNS projects. Most recently, a top 3 pharma company awarded TWCG a contract to manage the placement of all first-in-man through Proof-of-Concept studies for their entire Neuroscience portfolio.

Over the past year, our network has broadened its therapeutic range to include several new indications in addiction, pain management and neurological disorders. Additionally, several network members are in the process of designing and building new clinical research units to meet industry demands. For example, Woodland International Research Group in Little Rock is designing a new 12-bed clinical pharmacology unit to meet the increased demand for private-based, inpatient facilities devoted to the conduct of complex clinical trials in the pediatric, adolescent and elderly patient populations. Across the network,

additional clinical and operational staff, as well as recruitment specialists, have been added to enhance site performance. Special procedures, including PET, MRI, EEG/qEEG, PSG, actigraphy, CSF sampling are routinely performed at many clinics, and fMRI imaging is accessible at Pacific Research Network (PRN) in San Diego, CA, CBH Health, Rockville, MD and Alexian Brothers Neurosciences Institute, Elk Grove, IL,

Sponsors and CROs continue to trust our sites to generate consistently reliable quality data and enroll appropriate subjects into their clinical trials. Many member sites have long been recognized as experts in recruitment and retention of study subjects, and are high-enrollers in multiple clinical trials.

Furthermore, four network members--Pacific Research Network, St. Louis Clinical Trials, Clinilabs and Alexian Brothers Neurosciences Institute are participating in a large, global trial of a genetic-based biomarker to predict the risk of MCI due Alzheimer's disease and to evaluate the efficacy of an investigational drug. The study will enroll 5,800 subjects over a five year period.

For a more detailed look at our site's most notable accomplishments and capabilities, see our Network News section on pages 2 and 3.

We invite you to explore our newly updated website at [www.cnssites.com](http://www.cnssites.com). New features include a fully functional mobile website interface, an interactive network map, easy website search, and search engine optimization tools built in.

### TWCG Network Map



### New Additions to Our Organization

**Jeanine M. Estrada, MBA** - Director of Business Development  
**Daniel Gruener, MD** - Medical Director, Phase One Services & Principal Investigator,  
 St. Louis Clinical Trials  
**Stone Blacka** - Sr. Director of Corporate Development  
**Vik Singh** - Sr. Director of Business Operations  
**NeuroTrials Research** - Atlanta, GA

**Advanced Memory Research Institute of NJ, Toms River, NJ – Outpatient Facility**

Advanced Memory Research Institute of New Jersey, under the direction of Principal Investigator and President, Dr. Sanjiv Sharma, continues to consistently meet and exceed enrollment for trials in Alzheimer's disease, dementia and MCI. Dr. Sharma and his staff are currently working on two promising clinical trials in which the site has the lowest screen failure rate study wide, and 80% of screened patients have been randomized into these studies.

**Alexian Brothers Neurosciences Institute, Elk Grove Village, IL – Outpatient Facility**

Over the past year, Alexian Brothers Neurosciences Institute expanded its facility, staff, study capabilities and portfolio. Recently, the site moved to a brand new research suite with 8 exam rooms, quiet rating rooms and an infusion suite. Additional staff was added to meet increasing study demands. Imaging capabilities include a functional MRI at ABNI's sister hospital campus and a three coil PET scanner with enhanced imaging and analysis capability in the Elk Grove Village location. In addition, the site has expanded its clinical trial portfolio to include Parkinson's disease trials for motor fluctuation, tardive dyskinesia, pain trials for lumbar radiculopathy and hip OA, and recently began enrolling subjects into a trial for frontotemporal dementia.

**CBH Health, Rockville, MD – 40-Bed Clinical Pharmacology Unit/Outpatient Facility  
Baltimore, MD – 16-Bed Clinical Research Unit/Outpatient Facility**

This has been an exciting year for CBH Health. In the past year, the ClinTrials program of CBH Health enrolled 130 patients in psychiatric and neurological studies across their two sites. The low discontinuation rate of 8.4% for these studies can be attributed to the site's intensive pre-screening process, consistent/intensive contact with patients, experienced recruitment staff, transportation team, and case management and outreach services. Additionally, CBH Health has enhanced its early phase drug development capabilities through several studies involving fMRI, electrophysiologic markers, neurocognitive measures, pharmacologic challenge paradigms, and PET imaging with an emphasis on radionuclide-labeled ligands. CBH Health is one of the only facilities in the country where these unique brain target engagement/evaluation studies can be done at one site.

**Clinilabs, New York City, NY – 50-Bed Clinical Pharmacology Unit/Outpatient Facility  
Eatontown, NJ – 50-Bed Clinical Pharmacology Unit/Outpatient Facility**

Clinilabs offers 100 Phase 1 Beds for Industry-Sponsored Trials. Clinilabs, a leading provider of Phase 1 trials, now offers sponsors a fully integrated suite of services that enables sponsors to conduct their Phase 1 studies using a single vendor. Protocol development, medical writing, study execution, data management, biostatistics, monitoring, and regulatory services are all provided under the umbrella of this organization. Among the company's latest advances are the development of subject authentication tools (to prevent dual enrollment), integration of Medidata RAVE data systems, and the ongoing implementation of electronic data capture systems. Recent additions to the investigator staff provide sponsors access to 13 principal investigators with Phase 1 and therapeutic area expertise, now including human abuse liability experts.

**The Cognitive and Research Center of NJ, Springfield, NJ – Outpatient Facility**

CRCNJ continues to expand its resources and capabilities. In recent months, the site added a satellite location and a neurologist to assist with patient assessments, expanded its office space to include additional offices/storage, and added two MD investigators. CRCNJ has been successful with its clinical trials over the past year—in one study the site was considered a "model" site for adherence to NJ State statues regarding surrogate consent. Recently, the site was the highest enroller for a mild-moderate AD study, and is continuing to enroll subjects into two additional mild-moderate AD studies after meeting the contracted number of patients for both trials. A Community Outreach Specialist serves as a liaison between CRCNJ and the community, and schedules events such as free memory screens and lunch-and-learns.

**Midwest Clinical Research Center, Dayton, OH – 15-Bed Clinical Research Unit/Outpatient Facility**

Since opening its 15-bed inpatient unit in 2011, MCRC has conducted inpatient trials in schizophrenia, depression, bipolar and opioid addiction. MCRC is now positioned to expand into select phase 1, PK and bioequivalence studies and has several early phase trials in its pipeline. Dr. Otto Dueno is taking a more prominent role as PI on multiple studies and is the lead investigator on addiction trials. Clinical Site Manager, Adam Sarvis brings a wealth of knowledge with more than eight years of clinical research experience. Another addition, Stuart Blevins, NP is experienced in critical care and mental health, and will serve as a sub-investigator. Recruitment remains a priority and the site continues to build its patient database through the development of collaborative relationships with physicians, and maintaining its current relationships with local acute care hospitals.

**Neurology Diagnostics, Dayton, OH – Outpatient Facility**

Neurology Diagnostics is being recognized for its enrollment capabilities for a recently completed Multiple Sclerosis trial. Under the direction of Principal Investigator, Dr. Joel Vandersluis, Neurology Diagnostics was the second-highest enrolling site out of 150 US sites. Additionally, Neurology Diagnostics has formalized an affiliation agreement with Flexman Clinic and Dr. Jerry Flexman, who is a neuropsychologist with over 30 years of clinical and study experience.

**NeuroTrials Research, Atlanta, GA – 15-Bed Clinical Research Unit/Outpatient Facility**

During 2015, NeuroTrials Research has either met or exceeded enrollment goals in more than 15 clinical trials. Among them, the site participated in a trial designed to encourage safer driving through the use of a state-of-the-art, on-site driving simulator. This trial attracted over 40 health volunteers, and tested patients' reaction times and driving aptitudes during monotonous drives on curvy roads following the administration of sleep medications. The facility's updated website allows for better accessibility for staff and patients alike. NeuroTrials Research is proud to announce it is the only site in Georgia, and one of 50 sites in the US to participate in the NOBLE Study—a phase 2, randomized, double-blind, placebo-controlled study on the potential of T-817MA on patients with mild to moderate Alzheimer's Disease, expected to enroll 450 people aged 55 through 85.

**Pacific Clinical Research Medical Group, Upland, CA – Outpatient Facility**

Pacific Clinical Research Medical Group is proud to announce Lori Moore, RN has rejoined its staff as a clinical study coordinator. Lori has worked in clinical research for more than 20 years, and was trained and mentored by the site's founder, Dan Zimbroff, MD. Additionally, the site has expanded its study capabilities in select pain management trials and is focused on building its elderly database through community outreach and local advertisements. Recently, Dr. Arias and her staff were recognized for their recruitment of quality and reliable study subjects into a treatment resistant depression trial. Meanwhile, Dr. Paul Miller was invited to participate in the Site Advocacy Group developed by the Society of Clinical Research Sites to engage in high-level discussions with member sponsors and CROs.

**Pacific Research Network, San Diego, CA – 7-Bed Clinical Research Unit/Outpatient Facility  
Rancho Bernardo, CA - Outpatient Facility**

Pacific Research Network has continued to expand over the past year. PRN's strong presence in the community through participation in charity walks, health fairs, social media campaigns, educational symposiums and screening days has contributed to higher enrollment in its Alzheimer's, sleep and MS trials. The site extended its office hours to include Saturday appointments and hired an additional CRC, a research assistant and a dedicated recruitment specialist to support its recruitment activities. The certified sleep lab continues to operate seven days per week. Collectively, these efforts have resulted in an increase in the volume of clinical trials contracted and the amount of subjects ultimately randomized.

**SPRI Clinical Trials, Brooklyn, NY – Outpatient Facility**

With more than 30 years of clinical trial experience, SPRI continues to broaden its range of therapeutic areas in which it successfully conducts clinical studies. In the past year, SPRI has increased its focus on pain indications, including fibromyalgia, PHN, OA, chronic low back pain and migraine, robustly enrolling in multiple trials. The site continues to expand its reach within the community by fostering several new relationships with local multispecialty clinics. Additionally, SPRI has significantly increased its database of potential candidates for cognition trials by conducting regular free memory screenings.

**St. Louis Clinical Trials, St. Louis, MO – 38-Bed Clinical Pharmacology Unit\*/Outpatient Facility (\*Ability to Flex Up To 50 Beds)**

St. Louis Clinical Trials is pleased to announce Dr. Daniel Gruener has joined Dr. Rick Mofsen to create a formidable team of investigators in the areas of psychiatry, pain management, addiction, abuse liability and hepatitis. Dr. Gruener is an expert and thought leader in pain management and addiction, has been a principal investigator on more than 250 clinical trials. In July 2014, SLCT moved into a purpose-built facility with 38 beds, an 8-bed increase from the prior location. This new space has the ability to "flex" up to 50 beds and increase its early phase capabilities. Full-time EMTs are on staff 24-hours per day to ensure safe subject monitoring. Additionally, the site continues to expand its patient database through referring physicians, social service agencies, and RCF/skilled care facilities, community outreach events, referrals from prior study participants and local advertising.

**Woodland International Research Group, Little Rock, AR—8-Bed Clinical Pharmacology Unit/32-Bed Clinical Research Unit  
Coming in Fall 2015--12 Bed Clinical Pharmacology Unit/Outpatient Facility**

Woodland International Research Group expects to complete the expansion of its new clinical pharmacology unit (CPU) by the fall of 2015. In addition to the current 8-bed CPU, this expansion includes a new 12-bed CPU which is designed to meet the increased demand for private-based inpatient and outpatient facilities that can house complex clinical trials for pediatric and adolescent patients. The new unit will come complete with state-of-the-art technology including bedside TVs, video games, and larger recreation areas for ensuring patient comfort. This new unit will also have access to a nursing station that ensures staff can constantly monitor the safety of patients. WIRG also is proud to announce a successful outcome following an FDA inspection in 2015; a volume audit of an IP schizophrenia trial including review of 78 patients enrolled.

**Woodland Research Northwest, Springdale, AR – 24-Bed Clinical Research Unit/Outpatient Facility**

Woodland Research Northwest welcomes two new members to its staff—Justin Collins, who will serve as a rater on clinical trials, and Robert Marshall, who will serve as a dedicated patient recruiter. These gentlemen have already become invaluable members of WRN's established, successful staff. Additionally, WRN has expanded into new therapeutic indications during the past year by conducting studies in opioid withdrawal and Alzheimer's disease. The site is looking forward to further expanding its capabilities with the build out of a new 50-bed clinical pharmacology unit (CPU) scheduled to open in 2016.

# OUR NETWORK

For all your clinical trial needs, please contact the Thievon-Wright Consulting Group at (908) 756-4411. We will recommend the best sites depending upon the indication and study design, and provide feasibility feedback in a timely manner with expert investigator input.

## Advanced Memory Institute of NJ

9 Mule Road, Suite E-8  
Toms River, NJ 08755  
Sanjiv Sharma, M.D.

## Alexian Brothers Neurosciences Institute

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Concetta Forchetti, M.D., Ph.D.

## CBH Health

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Robert E. Litman, M.D. | Khaled Khalafallah, M.D.

## CBH Health

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## Clinilabs NJ

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## The Cognitive and Research Center of NJ

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## Midwest Clinical Research Center

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## Neurology Diagnostics, Inc.

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Joel Vandersluis, M.D.

## NeuroTrials Research, Inc.

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## Pacific Clinical Research Medical Group

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## Pacific Research Network

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## Woodland Research Northwest

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