Cognitive Research Corporation

A full-service contract research organization (CRO) with a proven track record in assessing the safety and efficacy of products across a wide range of indications

Presented by Bobbie Theodore, M.S. – bobbie@alliancesites.com
About Us

- Founded in 2006
- Specialized in central nervous system and early phase product development
- Executive and clinical staff have decades of experience
- Relationships with experienced research facilities around the country
- Provides services that are comprehensive, flexible, quality-driven, and cost-effective, acting as a seamless extension of your organization
- Developed proprietary technologies, including the CRC Driving Simulator, applicable in a broad range of studies
CRC has worked with over 60 sponsors, and participated in hundreds of trials, completing more than 100 reports to NDA, 25 INDs, and 17 programs that led to FDA approval.

**CRC’s experience includes:**

- Single-site and multi-site programs with 850+ subjects
- Cohorts and competitive enrollments
- Adolescent, adult, and geriatric subjects
- Digital applications
- Nutraceuticals
- Oral, pulmonary, nasal, topical and transdermal, injectable, and implant drug delivery methods

Study Experience

![Pie chart showing distribution of study experience by category: Neurology, Psychiatry, Healthy, Driving, Pain, Other, Orphan.]
Study Experience

Phase I Experience

• 100+ Phase I trials in patient populations
• 50+ SAD and MAD trials in healthy volunteers
• 50+ trials with pharmacodynamic assessments
Seasoned Team of Professionals
You will always get the “A Team,” from bid to final. Founders are core contributors on project deliverables.

Recognized Scientific and Operational Expertise in Clinical Trials
With specialists in data management, cognition, and protocol development.

Ability To Meet and Beat Timelines
Proactive management of vendors, and extensive experience with protocols and investigator sites.

Relationships with High Quality Sites, and Thought Leaders in Complex Phase I Trial Designs and CNS Specialties
CRC has a network of 100+ clinical research site affiliations including movement and memory disorder clinics, imaging centers, sleep labs, a dedicated specialty clinical pharmacology unit, and a licensed, accredited psychiatric hospital.

Wide Menu of Adaptable Services
From program development to final analysis, to seamlessly fit in to your work processes.
# Therapeutic Areas

<table>
<thead>
<tr>
<th>Psychiatry</th>
<th>Neurology</th>
<th>Healthy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Addiction (cocaine, nicotine, opiates, hydrocodone)</td>
<td>• Alzheimer’s Disease</td>
<td>• Adaptive and umbrella designs</td>
</tr>
<tr>
<td>• ADHD</td>
<td>• ALS</td>
<td>• Crossover, pilot, pivotal designs</td>
</tr>
<tr>
<td>• Anxiety</td>
<td>• Cognitive Dysfunction, MCI</td>
<td>• SAD / MAD</td>
</tr>
<tr>
<td>• Bipolar Disorders</td>
<td>• Epilepsy</td>
<td>• Bioequivalence and bioavailability</td>
</tr>
<tr>
<td>• Depression</td>
<td>• Huntington’s Disease</td>
<td>• Fed, fasted</td>
</tr>
<tr>
<td>• Obsessive Compulsive Disorder</td>
<td>• Multiple Sclerosis</td>
<td>• Healthy overweight and obese</td>
</tr>
<tr>
<td>• Panic Disorder</td>
<td>• Movement Disorders</td>
<td>• Smokers, non-smokers</td>
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<tr>
<td>• Schizophrenia</td>
<td>• Parkinson’s Disease</td>
<td>• PK, PD</td>
</tr>
<tr>
<td></td>
<td>• Stroke</td>
<td>• EEG, qEEG</td>
</tr>
<tr>
<td></td>
<td>• Tourette’s Syndrome</td>
<td>• QT, QTc</td>
</tr>
</tbody>
</table>

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**Healthy Designs**
- Adaptive and umbrella designs
- Crossover, pilot, pivotal designs
- SAD / MAD
- Bioequivalence and bioavailability
- Fed, fasted
- Healthy overweight and obese
- Smokers, non-smokers
- PK, PD
- EEG, qEEG
- QT, QTc
## Therapeutic Areas

### General Medical
- Asthma and COPD
- Cardiovascular
- Dermatology
- Diabetes
- Hematology
- Immunology
- Infectious Diseases (+HIV)
- Obesity
- Osteoporosis
- Hepatic & Renal Impairment
- Urology

### Sleep
- Chronic Insomnia
- Excessive Daytime Sleepiness
- Narcolepsy
- Obstructive Sleep Apnea
- Restless Legs Syndrome (RLS)
- Sleep Maintenance

### Pain/Other
- Headache, Migraine
- Neuropathic Pain
- Osteoarthritis
- Pre/Post Surgical Pain
- Driving Impairment
- Nutraceutical
Menu of Services

Trial Design and Protocol Development
- Assist clients with trial designs
- All aspects of protocol development including protocol authoring and writing
- In-house expertise, and contracted expert panels

Clinical Trial Management
- Comprehensive project management
- Investigator selection and training
- Investigator contract negotiation and grant management
- Investigator meeting planning and coordination
- Clinical trial monitoring
- Coordination of Central Lab, imaging (MRI/PET/fMRI), and other specialized biomarkers (EEG/ERPs/ECG/PSG)

Data Management
- Case report form design and printing
- Comprehensive database design and validation
- Query generation and resolution
- Coding
- SAE reconciliation
Menu of Services

**Biostatistics**
- Randomizations
- Statistical analysis plans
- Efficacy and safety analyses
- Meta analyses

**Medical Writing**
- Clinical study reports
- IND and NDA development
- Investigator’s brochures
- Full ICH reports
- Manuscripts and abstracts

**Regulatory Affairs**
- IND submissions
- IRB submissions
- Regulatory document management

Cognitive Research Corporation
Menu of Services

Quality Assurance
- Quality assurance audits
- Clinical file audits
- Investigator site audits

Behavioral Pharmacology
- Dose-response studies in cognition, sleep, psychomotor performance, etc.
- Driving performance studies
- AAMI proof-of-concept studies
- Tyramine challenge studies
- Trier Social-Anxiety Test paradigm studies

Media Services
- Internationally renowned speakers
- Continuing education programs
- Invited addresses
- Television, radio, and print exposure

Cognitive Research Corporation
Driving Simulation Solutions

CRC is the exclusive provider of the state-of-the-art PC-based driving simulator, the CRCDS MiniSim.

The CRCDS MiniSim is used to evaluate the effects of age, trauma, neurologic disease, alcohol, fatigue, and a wide variety of drugs on driving performance in both normal healthy and patient populations.

CRC has deep expertise in the current FDA guidance related to evaluating driving performance.
Leadership

- More than 75 CNS publications
- Delivered hundreds of invited lectures worldwide
- Served as Principal Investigator for 20 CNS-based studies
- Fellow of National Academy of Neuropsychology, and Associate Professor of Neurology at Georgetown University
- Consultant to dozens of pharmaceutical companies, FAA, DOD, NASA, etc.
- Board certified clinical neuropsychologist
- Provided testimony at multiple FDA hearings
- Developer of CogScreen Computerized Test Battery
- Internationally recognized expert in driving simulation
Leadership

Thomas Hochadel, PharmD
Chief Operating Officer

- 27 years of clinical trial management experience
- Specialized in CNS research, including the areas of Alzheimer’s disease, ADHD, bipolar, cognition, depression, driving simulation, mania, Parkinson’s disease, schizophrenia, and sleep disorders
- Worked on 22 INDs (2 as ‘responsible signature’)
- Participated in 12 NDAs
- Managed over 300 CNS based clinical trials
- Unique expertise in Tyramine Challenge Pressor Tests and other Phase I pharmacodynamic studies
Alliance Collaboration

In response to sponsors’ requests for full-service proposals under one contract, CRC has established relationships with leading research sites including Collaborative Neuroscience Network (CNS Network) and Hassman Research Institute (HRI), members of Clinical Trial Centers Alliance with dedicated inpatient units. The relationship is by no means exclusive, as CRC continues to work with many other research sites.

CRC partners with CNS Network and HRI to conduct early phase targeted healthy subject and complex patient trials as an integrated team when advantageous to sponsors. The partnership allows for full-service proposals, competitive pricing, one-stop contracting, and objective quality monitoring.

CNS Network is a clinical research group operating three outpatient clinics located in the Los Angeles/Orange County area. Additionally, the Long Beach facility offers a dedicated 60-bed Clinical Pharmacology Unit and a 30-bed Joint Commission-accredited inpatient Psychiatric Health Facility.

HRI is a clinical research site located on a large campus in Berlin, NJ, twenty minutes from Philadelphia. HRI’s 30-bed Early Phase Unit includes a secure inpatient unit with patient population segregation wards offering accommodations needed to support multiple patient populations.
Recent Collaborations

- A Phase I, double blind, randomized, multiple ascending dose safety, tolerability and pharmacokinetics study in patients with schizophrenia on a stable anti-psychotic regimen (includes qEEG) – Met enrollment goal of 40 in 4 months

- Phase I, randomized, double-blind, placebo-controlled, sequential dose escalation cohort study to evaluate the safety, tolerability, and pharmacokinetics of XXXX in psychiatrically stable schizophrenia subjects – Met enrollment goal of 40 in 5 months

- A Phase I, prospective, randomized, double-blind, placebo-controlled, sequential-cohort, escalating, single-dose study designed to determine the maximum tolerated oral dose of XXXX in healthy, male volunteers – Met enrollment goal of 60 in in 8 months

- A Phase I uncontrolled, sequential cohort study in healthy subjects to assess the safety and tolerability of multiple-dose administration of XXXX, assess the pharmacokinetics (PK) of XXXX following multiple-dose administration, and assess the effect of dose titration schedules on the tolerability of XXXX in healthy male subjects – Met enrollment goal of 18 in 1 month

- A Phase II, randomized, double-blind, placebo-controlled trial evaluating the efficacy, safety, and pharmacokinetic behavior of orally administered XXX in subjects with drug-Induced tardive dyskinesia – Competitive enrollment, enrolled 18 in 3 months

- A randomized, open-label, parallel design, multiple-dose, comparative bioequivalence study of XXX versus XXX in schizophrenia patients already stabilized on XXX – Competitive enrollment, enrolled 68 in four months across two CNS Network sites
Contact

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