

Clinical Trial Centers AllianceSM

An alliance of quality research services

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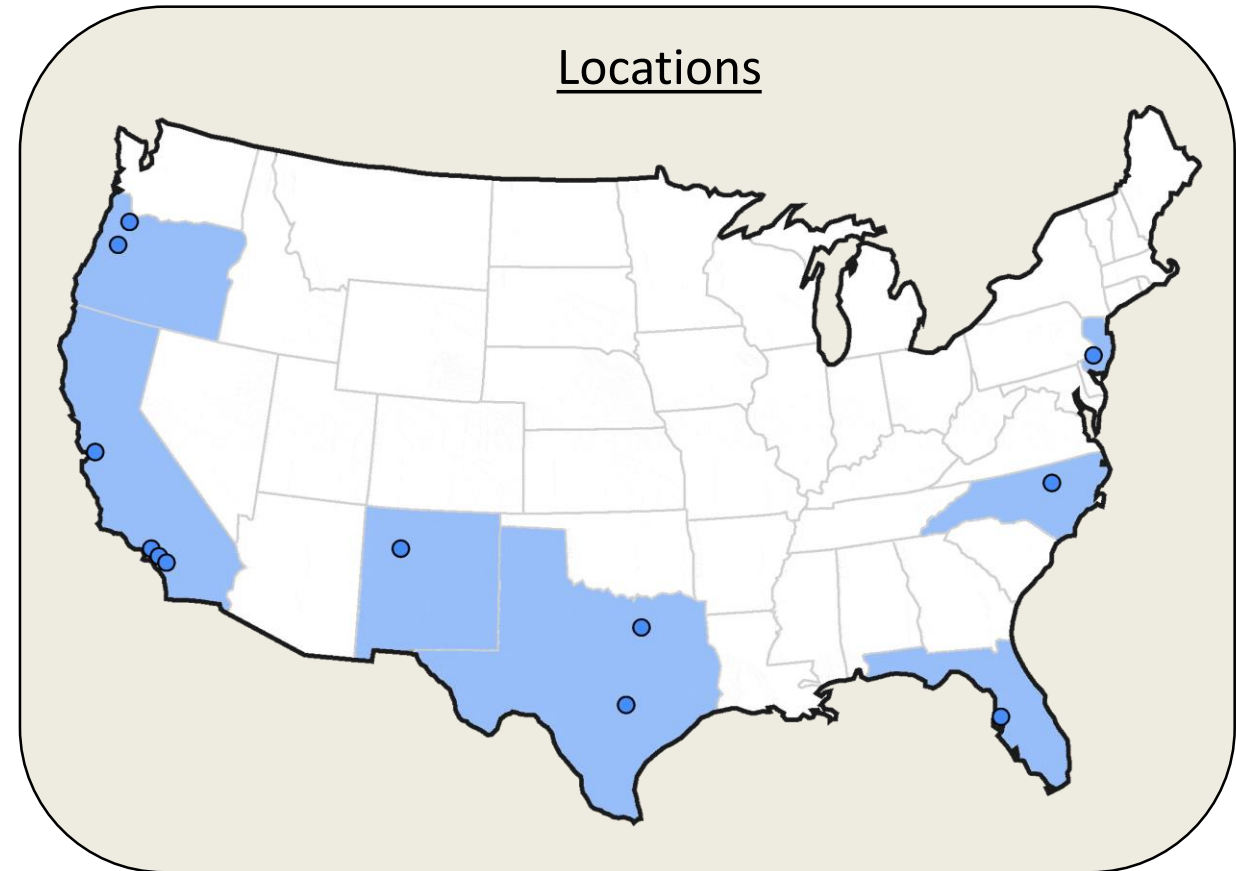
ABOUT US

Clinical Trial Centers Alliance is a unique group of independently owned and operated specialty research clinics and service providers located throughout the US.

Linked by the desire to foster mutual growth and quality in the clinical trials we conduct, Alliance members exchange best practices and expertise in various therapeutic areas, and share a business development and sponsor relations team.

We specialize in phase I-IV trial design, conduct, and management to support a full clinical program.

Alliance sites and service providers have steered and conducted more than 5,000 phase I-IV clinical trials across more than 25 therapeutic specialties since 2000.



SPONSOR RELATIONS TEAM

Dedicated to establishing and maintaining positive relationships with sponsors and CROs, our experienced sponsor relations team facilitates the site selection process (CDAs, feasibility questionnaires, CVs, site capabilities information), and leads efforts to garner new study opportunities.

With a responsive and knowledgeable team managing the study site selection process, our sites are able to focus on their studies in progress. The expert site selection coordination we offer is advantageous for not only our sites, but also sponsors and CROs.

We have worked with over 100 sponsors and CROs including biotechs, startups, and big pharma.



Jeanette Caruso

Medical Division Director

Bobbie Theodore

Executive Director

Annie Speno

Operations Director

ADVANTAGES & EXPERTISE

- Single POC for site and vendor services, protocol and budget consulting
- Internationally-known KOLs in early phase and complex trial design, cognition, driving simulation, neuroscience, regulatory and pricing strategies
- History of successful recruitment and retention
- Sponsor relations team dedicated to rapid response and meeting sponsor/CRO needs
- Dedicated regulatory, and budget and contract staff for quick turnaround
- Central IRB of sponsor's choice
- Streamlined solution to meet CRO + site deliverables under one contract (when advantageous for sponsors)

THERAPEUTIC AREAS

Central Nervous System

Psychiatry

- ADHD
- Anxiety
- Autism
- Bipolar
- Depression
- Schizophrenia

Neurology

- Alzheimer's
- Cognition
- Multiple Sclerosis
- Parkinson's
- Post-stroke, movement disorders

Addictions

- Abuse liability (HAL)
- Alcohol dependence
- Binge eating
- Drug
- Opioid
- Smoking cessation

Sleep

- Insomnia
- Maintenance
- Narcolepsy
- Restless legs syndrome (RLS)
- Shift worker
- Sleep apnea

Pain

- Acute and chronic
- Dental pain
- Fibromyalgia
- Migraine
- Neuropathic pain
- Osteoarthritis
- Post-surgical pain

THERAPEUTIC AREAS

General Medical

Cardiovascular

Dermatology

Endocrinology

Gastrointestinal

Hypercholesterolemia

Immunology

Infectious diseases

Metabolic disorders

NASH/NAFLD

Obesity

Ophthalmology

Renal/hepatic impairment

Respiratory

Urology

Vaccines

Women's health

Special Patient Populations

Asian bridging

Healthy and healthy elderly

Rare/orphan diseases

CLINICAL RESEARCH SITES



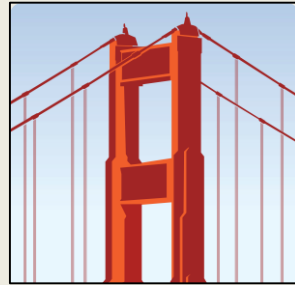
[Collaborative Neuroscience Network](#)

Torrance, Garden Grove, CA

[Collaborative Neuroscience Network](#)

[Phase I Unit](#)

Long Beach, CA



[Pacific Research Partners](#)

Oakland, CA



[Hassman Research Institute](#)

Berlin, NJ



ALBUQUERQUE
NEUROSCIENCE

[Albuquerque Neuroscience, Inc.](#)

Albuquerque, NM



[FutureSearch Trials of Neurology and](#)

[Sleep Medicine](#)

Austin, TX

[FutureSearch Trials of Dallas](#)

Dallas, TX



OCCi

[Oregon Center for Clinical](#)

[Investigations, Inc.](#)

Portland & Salem, OR

RECRUITMENT



- Full-time dedicated recruitment and outreach specialists on staff
- Large, diverse patient databases
- Affiliated private and group practices (psychiatry, neurology, family practice, sleep, endocrinology, ophthalmology, dermatology, gastroenterology, cardiology, urology, pain)
- Established relationships with physician networks for patient referrals
- Relationships w/ residential facilities, board & cares, senior and Japanese communities
- Participation in community events and support groups
- History of successful advertising
- Ability to pre-qualify patients via IRB-approved pre-screen consent form

RETENTION



- Modern inpatient facilities, some with private and semi-private rooms for caregivers
- Site-provided patient transportation
- Full-time dedicated staff reminder and follow-up phone calls, and regular communication with patient, family and caregiver
- Thorough pre-screening
- Treating physicians allow for ease in transition and follow-up

SAMPLE METRICS

Study Title	No. of Patients Contracted/Screened/Enrolled
Phase I, Escalating, Single-dose, Healthy, Male Subjects	Contracted for 5 cohorts of 12 (60) Screened 110, Enrolled 60 plus back up subjects in 5 months, single site
Phase I, Single Dose, Healthy Subjects and Subjects with Impaired Renal Function	Contracted for 16 Screened 21, Enrolled 16 in 5 months, single site
Phase I, Single Dose, Healthy Subjects and Subjects with Impaired Hepatic Function	Contracted for 24 Screened 39, Enrolled 24 in 3 months, single site
Phase I, Single and Multiple Dose, Healthy Adult Japanese Subjects - Part I and II	Contracted for 2 cohorts of 8 (16) Screened 36, Enrolled 16 in under 2 months over the holidays, single site
Phase I, Single and Multiple Ascending Dose, Intravenous Infusions, Mild to Moderate Alzheimer's Disease	Study design 5 cohorts; 1 pt/cohort from each site Screened 35, Enrolled 20 (2 cohorts of 10 each) in 12 months, multi-site (TOP ENROLLER)
Phase I, Major Depressive Disorder - (<i>Extensive PKs & multiple ECGs</i>)	Contracted for 38 Screened 38, Enrolled 22 in 6 weeks, across 2 Alliance sites (TOP ENROLLER)
Phase I, Single Oral Dose AND Ascending Multiple Oral Dose, Schizophrenia	Contracted for 7 cohorts of 15 (105) Screened 128, Enrolled 93 plus back up subjects in 3 months, single site (RESCUE SITE)
Phase I, Multiple Ascending Dose, Schizophrenia	Contracted for 36 Screened 57, Enrolled 39 in 2 months, single site
Phase IIa, Multiple Oral Doses, in Healthy Elderly Subjects (<i>incl. 3 Lumbar Punctures</i>)	Contracted for 30 Screened 37, Enrolled 15 in 1 month, single site

[Click here](#) to download a PDF with more enrollment metrics from studies our sites have conducted.

SITE STAFF HIGHLIGHTS

- Investigators and KOLs boarded in psychiatry, neurology, sleep medicine, internal medicine, addictions, and more.
- Protocol consultants to sponsors and CROs, and experts in psychiatry, cognition, neurology, addictions, and phase I study designs
- Full-time certified, psychometric clinical raters (doctorate and M.A.-level with up to 20+ years rating experience)
- Multiple full-time study coordinators including CCRCs, RNs, and LVNs
- Dedicated recruitment and outreach specialists with established referral networks in their communities
- Regulatory, QA, training, and IT personnel

SPECIALIZED PROCEDURES & EXPERIENCE

- State-of-the-art Clinical Pharmacology Units (CPU)
- CNS Biomarkers:
 - EEG and qEEG with evoked potentials
 - [Imaging](#), 1.5 and 3T MRI, PET and fMRI
 - Lumbar puncture and CSF collection
 - Ocular Assessments
 - Psychomotor Testing
- [Human Abuse Liability](#) and Hepatic & Renal Impairment Units
- 24 hour monitoring – cardiac and PSG (polysomnography)
- Serial PK and ECG
- Compounding drug
- Infusion, injection, oral, sublingual, device, implant, and transdermal patch delivery systems
- Software / Neurogaming Product Validation
- [Driving simulation](#)



EARLY PHASE RESEARCH KOLs

The Alliance Early Phase division (AEP) was recently created to combine KOL expertise in conducting complex Phase 0-2a trials across a range of healthy normal volunteers (HNV) and patient populations.

Led by Drs. Larry Ereshefsky, David Walling, and Howard Hassman, with support from Bobbie Theodore and the Alliance team, AEP PIs have conducted 500+ early phase trials in HNV subjects and CNS, medical, and Asian bridging populations, including FIH SAD/MAD, DDI, BA/BE, 505b2, and proof-of-concept (POC) designs. We provide single site and two site solutions for efficient study conduct and assuring a harmonized approach to the clinical and scientific aspects of the trial.

We have expertise in designing and conducting studies incorporating experimental medicine strategies, as well as translational drug development tools supporting neurocircuitry/biomarker based (RDoC) strategies, i.e., continuous CSF sampling, QEEG, ERP, PSG, sMRI, fMRI, PET, and cognitive and behavioral paradigms.

Our KOLs have consulted on program design, PK/PD modeling, clinical drug development plans informed by animal behavioral markers, safety signals, protocol feasibility, and vendor selection.



Larry Ereshefsky, PharmD

CSO, Early Phase Development

Collaborative Neuroscience
Network and Hassman Research
Institute

David Walling, PhD

CEO/Principal Investigator

Collaborative Neuroscience
Network

Howard Hassman, DO

CSO/Principal Investigator

Hassman Research Institute

CLINICAL RESEARCH SERVICES

We have added complementary services to our Alliance to provide full solutions to run clinical programs:

*Cognitive
Research
Corporation*

[Cognitive Research Corporation](#)

Driving study solutions and more

NEURO:COG
Reliable Responsive

[NeuroCog Trials, Inc.](#)

Clinical outcomes and neurocognitive measurement, and support for trial design, implementation, and evaluation

NCTLinguistics
Translations with a PhD™

[NCT Linguistics](#)

Language solutions for clinical trials conducted worldwide

CURRICULA VITAE

Collaborative Neuroscience Network, LLC.

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- [Armen K. Goenjian, M.D.](#)
- [Lara Shirikjian, D.O.](#)
- [Omid Omidvar, M.D.](#)
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Hassman Research Institute, LLC.

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- [Michael Hassman, D.O.](#)
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Alliance Early Phase CSO

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- [Glenn Michael Dempsey, M.D.](#)
- [Paula Lane, M.D.](#)

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- [Richard Keefe, Ph.D.](#)

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