The CRO for Phase 1 CNS Trials
Your Pathway to CNS Approval

To take any drug or device through Phase 1, you need to plan smartly and set the stage for long-term success early. CNS development comes with unique, inherent challenges that make it that much more difficult to move with speed and confidence. That is why you need a specialty provider.

As the CRO for Phase 1 CNS trials, Clinilabs' clinical research units offer the top-tier facilities, clinical services, focused expertise, and comprehensive CRO services that you need to accelerate and enhance every aspect of your CNS clinical trial.

A Phase 1 Partnership Built for Long-Term Success

Because we share your passion for accelerating new CNS therapies to market to transform patients' lives, we offer strategic support that includes:

Early Phase Development

Clinical Trial Services & Technology

Corelabs

Advisory & Regulatory

Take the first step on your pathway to CNS approval.

Contact Clinilabs

Your Premier Clinical Research Units

Purpose-built in the New York and New Jersey area, our clinical research units have hosted over 200 Phase 1 studies, including more than 15 FIH studies:

- 100 beds of Phase 1 capability
- Clinical laboratories — CLIA-waived, with pending CLIA certification
- CNS expertise with pharmacodynamic assessment capabilities
- Compliant with all federal (DEA) and state minimum storage requirements for controlled substances
- DEA approved for Schedule 1-5 compounds
- Electronic data systems, including customizable eSource and EDC
- Experienced recruitment team to ensure enrollment of full cohorts
- Expert technology integration in Phase 1 studies with experience in many dose administration forms
- Experts in SAD, MAD, FE, DDI, and assessment of kinetic-dynamic relationships

- Experts in sleep assessment, including PSG, MWT, MSLT, and sleep deprivation studies
- Fully equipped and experienced in biomarker studies, including EEG, qEEG, EMG, CSF sampling, and neuroendocrine markers
- Modern, comfortable bedrooms and recreational facilities ideal for both short and extended inpatient stays
- Pharmacies with facilities for extemporaneous drug preparation
- Rapid study startup and subject enrollment
- Secure, locked units with 24-hour video surveillance and staffed 24/7 with licensed medical professionals
- Skilled raters for psychiatric, neurological, and cognitive assessment
- Subject transportation available for all study visits

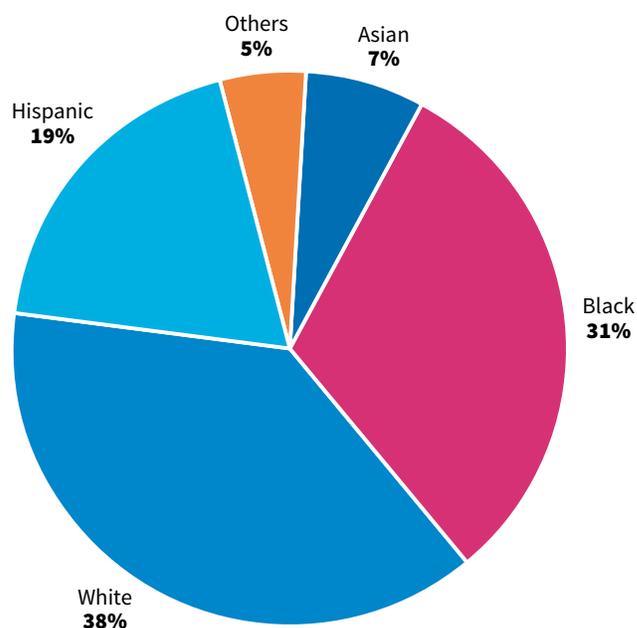**We have hosted 200+ Phase 1 studies, including 15+ FIH studies**

19.62 million individuals live in the New York metro area and speak 800+ languages.

Large, Diverse Volunteer Database

Clinilabs recruits from one of the largest and most diverse populations in the world.

Active database of 80,000 potential candidates:

- Chronic pain disorders
- Depressive disorders
- Diabetics
- Friedreich's Ataxia
- Healthy adults
- Healthy seniors
- Hypertension
- Migraine
- Parkinson's disease
- Recreational opioid users
- Sleep disorders
- Smokers and vape users
- Substance use disorders
- *And more*

Others
5%

Asian
7%

Hispanic
19%

Black
31%

White
38%

Prescreening & Authentication

Every patient enrolled at our clinical research units is prescreened and authenticated to minimize screen failures and safeguard study integrity.

Our rigorous prescreening process provides information related to:

- Age, biological sex at birth, medical history, psychiatric history, height, weight, body mass index (BMI), and medication history
- Routine tests such as urine drug screens

- Positive identification (government-issued ID and biometric)
- Confirmation that candidates are not in screening at other locations, enrolled in other studies, or in a lockout period

Your Phase 1 CNS Trial Experts

Clinilabs' clinical research units have unmatched experience in a range of specialty assessments and procedures.

Biomarker Assessments
- Cerebrospinal fluid (CSF)
- Continuous CSF (cCSF)
- Hormones
- Imaging
- Laboratory-based biomarkers

Cardiac and Pulmonary Assessments
- Holter and continuous Holter telemetry
- Pulmonary function testing
- Pulse oximetry
- QT interval assessment
- Respiratory inductance plethysmography
- Spirometry

Cognitive Assessments
- Brief cognitive assessment
- Computerized testing
- Dementia rating scales
- Executive function and attention testing
- Language functions testing
- Memory testing
- Reaction time assessment
- Sedation assessment

Metabolic Assessments
- Calorimetry
- Continuous glucose monitoring
- Doubly labeled water
- Glucose tolerance testing

Psychiatric Assessments
- Agoraphobia: AS
- Anxiety: HAM-A, GAD-7, BAI
- Cognitive impairment: ADAS-Cog, CDR
- Depression: MADRS, HDRS-17, BDI, PHQ-9
- Diagnostic instruments: MINI, SCID-5
- Disability: SDS, SF-36, GAF
- Global impression: CGI-S, CGI-I
- Modified Observer's Assessment of Alertness and Sedation: MOAA/S
- Panic: PDSS
- Psychosis: PANSS, BPRS, SAPS, SANS
- Social anxiety: LSAS, SPIN, SPS
- Structured interview: SIGH-D, SIGMA, SIGH-A
- Suicidality: C-SSRS
- Visual analog scales

Psychomotor Functioning
- Body sway
- Computerized Dynamic Posturography
- Driving simulator

Sleep and EEG Monitoring
- Actigraphy
- Electroencephalogram (EEG)
- Home sleep testing
- Hypoglossal nerve stimulation
- Insomnia models
- Maintenance of Wakefulness Test (MWT)
- Microsleep assessment
- Multiple Sleep Latency Test (MSLT)
- Polysomnography (PSG)
- Psychomotor Vigilance Test (PVT)
- Quantitative electroencephalogram (qEEG)
- Seizure monitoring
- Sleep deprivation

Other Procedures and Study Types
- Blister models
- Ethnic bridging
- Hemodialysis
- Human abuse liability
- Intra-arterial assessment
- Ketamine models
- Punch and incision biopsy
- Pupillometry
- Tissue sampling

Our vast experience is proof of our dedication to bringing new therapies to patients living with mental health, neurological, substance use, and rare CNS disorders.

200+
Phase 1 Studies

70+
Indications

80k+
Patient Database

100+
Patient Beds

75+
Specialty Procedures

When you need to get your product to the people who need it most, your pathway to CNS approval starts with Clinilabs' Phase 1 services.

Get Started