

Brain Monitoring for Clinical Trials

REAL-TIME EEG COLLECTION, MONITORING, MANAGEMENT & ANALYSIS WITH A GLOBAL REACH

Electroencephalography (EEG) is an ideal biomarker for successful drug development, particularly in the evaluation of seizure liability and monitoring changes in sleep. Sponsors with CNS pipeline drugs are adopting EEG and QEEG for a wide range of functions: to track natural history, safety, pharmacodynamic assessments, and biomarker development.

CortiCare® provides EEG clinical research services worldwide. CortiCare is a 21 CFR Part 11 compliant provider of clinical out-patient and in-patient EEG services. We serve hospital neuro-ICUs, Neonatal ICUs and Epilepsy Monitoring Units daily, compliant to all HIPAA standards.

CortiCare works directly with sponsors or CROs and operates its EEG monitoring and EEG interpretation services under GCP standards as required for in-patient operations. CortiCare is fully compliant with ICH, GLP and GCP as it pertains to EEG and EEG interpretation. Our broad expertise translates to a single source for EEG study design, site selection, standardized data acquisition, management and interpretation in clinical trials for CNS pipeline drugs.

Data can be stored and managed on our AWS CortiCare Cloud™, with secure, HIPAA/HITECH compliant access.



BRAIN MONITORING SERVICES MADE EASY - ANYWHERE, ANYTIME

CortiCare Capabilities

EEG EQUIPMENT, STAFFING & SUPPORT

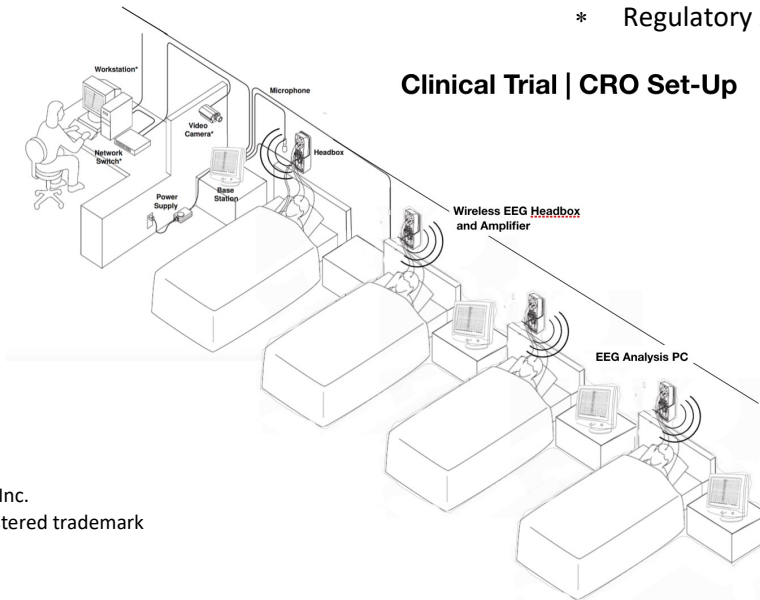
- State-of-the-art EEG systems for routine, ambulatory or multi-day recordings with digital audio/video
- Experienced staffing available for full clinical trial multi-center oversight and data acquisition and analysis
- 24/7 on-call global support for EEG monitoring and reading for dynamic, evolving clinical trials

DATA MANAGEMENT & PROCESSING

- EEG and video data uploaded to the secure CortiCare Cloud AWS EC2 server, certified compliant with SOC2, HIPAA, ISO27001, and many other standards
- EEG data can be processed for quantitative EEG analysis, sleep staging, and seizure detection
- EEG interpretation from fellowship trained epileptologists or neurophysiologists

CONSULTING & STUDY DESIGN

- Trial design and coordination with a team comprised of a Scientific Liaison, Clinical Trial Project Manager, Lead Data Manager, Informatics Project Liaison, and a Regulatory expert
- Coordination activities include:
 - * Protocol design
 - * Statistician support
 - * Pharmacometrics and biomarker development
 - * Custom database configuration
 - * Regulatory support



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