Q-METRX
ASSOCIATED PUBLICATIONS

A Phase 1B, randomized, double blind, placebo controlled, multiple-dose escalation study of NSI-189 phosphate, a neurogenic compound, in depressed patients.

TAK-063 Increases Gamma Synchrony in Subjects With Schizophrenia (Poster)
A Phase 1B, randomized, double blind, placebo controlled, multiple-dose escalation study of NSI-189 phosphate, a neurogenic compound, in depressed patients.

Molecular Psychiatry vol21, pages1372–1380 (2016)

Use of translational pharmacodynamic biomarkers in early phase clinical studies for schizophrenia.

Biomark Med. 2014;8(1):2949

Examination of Org 26576, an AMPA receptor positive allosteric modulator, in patients diagnosed with major depressive disorder: an exploratory, randomized, double-blind, placebo-controlled trial.

J Psychopharmacol. 2012 Dec;26(12):152539

Validation of an automated wireless system to monitor sleep in healthy adults.

J Sleep Res. 2012 Apr;21(2):22130

Probe evoked potentials: theory, method and applications.

Int J Neurosci. 1984 Oct;24(2)

Bispectral analysis of the EEG: a brief tutorial,

J Neurotherapy 2002;6:77-81.

PROFESSIONAL COLLABORATORS

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SLEEP

SLEEP PROCEDURES: Q-METRX CAPABILITIES

Utilized to assess the effects of drugs which can alter arousal and sleep.

Allows investigators to determine the efficacy of drugs or cutting-edge devices and their impact on sleep and wakefulness throughout the night and day using the following procedures:

Overnight Attended Sleep Study (polysomnography - PSG)

Pre and post-dose assessments summarizing sleep stages, percent of delta and REM, latencies to each stage, RDI, AHI and more.

Multiple Sleep Latency Testing (MSLT)

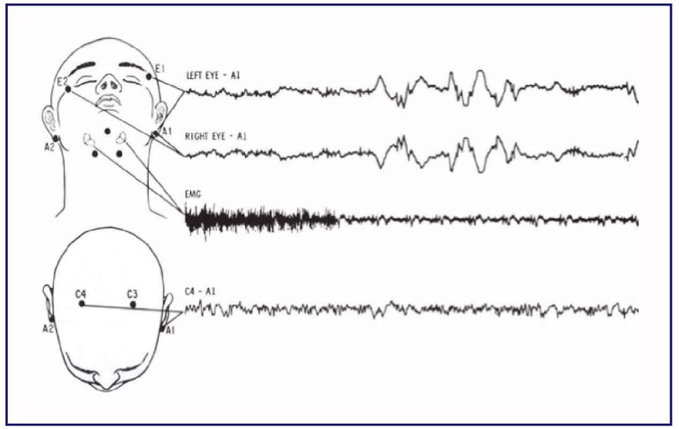
Four to five naps every 2 hours
Quantifies sleepiness across the day

Maintenance of Wakefulness Testing (MWT)

Four to five “quiet periods” throughout the day
Tests subject's ability to remain awake post-dose or post-treatment

Actigraphy

Monitors daytime activity, napping, lights out and lights on (useful for determining if subject meets inclusion/exclusion criteria)



Q-Metrx, Inc.

EEG, qEEG, ERP and Polysomnography

Electrophysiological Biomarker Development, Validation, and Application to De-Risk CNS Drug Development

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ABOUT Q-METRX

Q-Metrx was incorporated in 1999 by Dr. Jack Johnstone whose research interests included brain electrical activity, neuromodulation, clinical neuroscience, sleep disorders and cognitive development.

Q-Metrx continues to provide high quality EEG related services to researchers. Beginning with only three employees, Q-Metrx now retains a staff of administrative personnel, neuroscientists, EEG and Sleep technologists, as well as independent clinicians and consultants who regularly lend their expertise to the company.

Q-Metrx is a recognized leader in the design and execution of electrophysiological strategies designed to translate preclinical findings to clinical trials in healthy and patient populations.

CLINICAL TRIALS

Q-Metrx has performed over three dozen clinical trials across multiple modalities, including EEG,qEEG,ERPs, actigraphy,pupillometry and PSG.

Alzheimer's,Dementia,Essential Tremor,HNVs,MDD,Narcolepsy,Parkinson's, Schizophrenia, Seizure,& Sleep

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Q-METRX CLINICAL TRIAL SERVICE OVERVIEW

EEG, qEEG, ERP, PSG

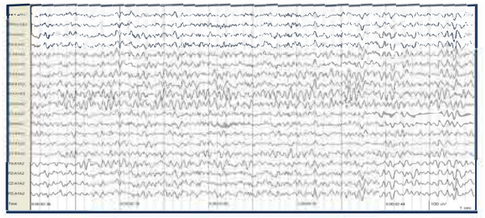
Assist in identifying translatable EEG-related pre-clinical targets within all phases of drug development or proof-of-concept studies

<u>Study Design</u>
Experimental Design Considerations
KOL Consultation

<u>Study Execution</u>
Data Acquisition (hardware, software, staffing)
Data Management
Data Processing
Statistical Analysis Plans (SAPs)

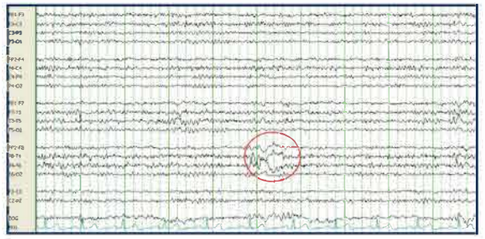
<u>Post-Acquisition Analysis and Evaluation</u>
Customized Statistical Analyses
Summary Report

EEG



Electroencephalography (EEG) is a non-invasive method of recording real-time, spontaneous electrical activity of the brain and is the cornerstone of Q-Metrx services. EEG is a valuable tool for research and clinical trials, as it offers high temporal resolution (on the order of milliseconds), is relatively mobile, and is tolerant of subject movement, which is not true of other brain imaging techniques.

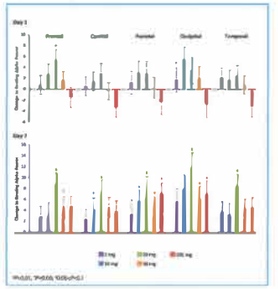
SAFETY EEG

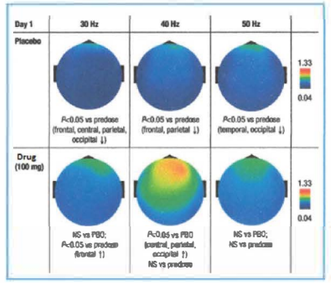


Safety EEGs are clinical EEGs that are read by a board-certified neurologist and can be used during a clinical trial to help assess safety and tolerability of a novel compound. Safety EEGs can be used as an admission tool to exclude subjects with underlying seizure potential, or they can be used during a trial to ensure that no EEG abnormalities are found after dosing.

QEEG

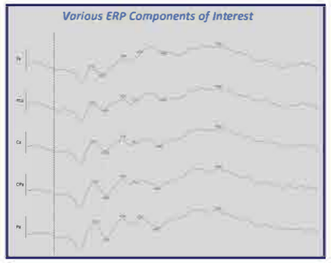
Quantitative EEG, or qEEG, involves digital EEG recording under standardized conditions, removal of extracerebral artifact, and extraction of specific properties of the signal (e.g. amplitude or coherence). Results can be shown graphically or numerically where subsequent statistical processing can be performed. Quantitative analysis techniques can be used for identification of biomarkers, documentation of penetration into the nervous system, pre vs. post drug comparisons, exposure-response analysis, time trend analyses, source localization, and evaluation of patterns of connectivity.





ERP

Event-Related Potentials, or ERPs, are elicited brain responses (measured via EEG) to a specific sensory stimulus. Common modalities involve auditory or visual stimuli to produce responses that are averaged over many trials which produce various components of interest. ERP paradigms can show pre-cognitive, automated processes as well as explicit cognitive processing even in the absence of behavioral change or subject attention to the stimulus. ERP component abnormalities in clinical research have been shown in conditions such as: Alzheimer's (and other dementia types), Schizophrenia, Parkinson's Disease, Multiple Sclerosis, and other neurological disorders.



ERP Paradigms Used in Past Clinical Trials:

- Contralateral Delay Activity
- Implicit Reward-Biasing Task
- 3-stimulus auditory oddball task
- Sensory Gating Paradigm
- Auditory Steady-State Response
- Visual Evoked Potentials