

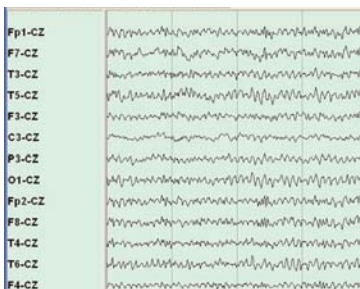
Centralized EEG

b i o m e d i c a l s y s t e m s

EEGs In Clinical Trials

The increase in the number of drugs targeted for diseases that affect the Central Nervous System has also increased the need for Electroencephalography (EEGs) in clinical research. While EEGs have been commonly used to determine the efficacy of epilepsy drugs, new studies have indicated the effectiveness of this non-invasive imaging modality to determine treatment options for anti-depressants. The recent BRITE (Biomarkers for Rapid Identification of Treatment Efficacy in Major Depression) study, which assessed the treatment of major depression in adults, monitored brain activity once a patient began treatment of a new anti-depressant drug. Utilizing an EEG recording of the brain activity on drug, the study concluded that it was possible to reduce the time required to determine the effectiveness of that drug from a norm of several weeks to as little as seven days.

Biomedical Systems' Imaging Services has been a pioneer among the Imaging Core Labs in offering new modalities for clinical trials and is the first to provide Centralized EEG Services. With a team in place that has an expertise in the EEG process and equipment, we work with Sponsors around the globe to develop protocols that reduce timelines and provide quality clinical trial data.



Biomedical Systems' EEG software allows Sponsor sites to view the digital waveforms in different montages.

Biomedical Systems' EEG Advantage

Biomedical Systems provides Sponsors with the all the expertise, equipment and accessories to conduct your next EEG study including:

- Standardized EEG equipment (or the flexibility of using site owned equipment if feasible)
- Site Qualification
- Dedicated Project Manager
- Training on equipment and protocol specifications
- Standardized manuals, electrodes and accessories
- Board certified neurologist as overreaders
- EEG protocol consulting

Our EEG services are supported by our teams in data management, quality management and our 24/7 technical support IT division.

Global Capabilities

- Offices in North American, Europe and Japan
- Participation in trials in over 75 countries
- Multilingual staff fluent in 20 languages to facilitate communication with sites
- Phase I and Phase IV studies, + Post-Marketing Safety Studies
- Project Manager and Backup Manager assigned to every study
- Web-based Sponsor access to data and reports

EEG

Biomedical Systems' Electronic Case Report Form

Client 'Traci' - CRFormView

Blinded Read Med Test

Electronic Case Report Form

Reader: Traci Masking Code: 0001 Birth Year: 1980

biomedical systems

Site assessment of patient behavior during EEG: Normal

Grading of EEGs (Final grade is the highest number): E1

* Key
E0: Normal
E1: <3 focal abnormalities (epileptiform) or non-epileptiform
E2: 3-10 focal discharges, 1-10 multifocal or generalized discharges
E3: Sharp/slow complex, runs of epileptiform abnormalities (>=1 second), more than 10 epileptiform discharges.
E4: Seizure
N/A: EEG is not gradable

Other EEG abnormalities (Check all that apply):
 Slow activity, inconsistent with state of arousal
 Fast activity, inconsistent with state of arousal
 Excessive asymmetry
 Unexpectedly high voltage
 Unexpectedly low voltage
 Unexpected wave forms, specify: _____

Epileptiform activity (Check all that apply):
 Sharp waves If checked, enter number seen: _____ Multifocal?
 Spikes If checked, enter number seen: _____ Multifocal?
 Spike-slow wave complex If checked, enter number seen: 2 Multifocal?
 Runs of spike-slow wave complexes If checked, enter number seen: _____ Multifocal? Also, length of longest run: number of SW complexes _____ and/or seconds _____

Was the EEG performed according to Protocol requirements?
 Yes No If no, did it change the assessment made? Yes No

Please state what was missing from the EEG: _____

Assessment:
Normal EEG with bifrontal muscle tension artifact noted

Final: 02 Jun 08 09:54:21 T. Cardenas

Submit >>

Biomedical Systems uses an electronic Case Report Form (eCRF) for all of our EEG studies. This form can be customized to meet Sponsor's protocol needs. The physician completes this form concurrently while viewing the EEG data provided from the site.

For more information or to schedule a presentation, please contact a Biomedical Systems' Representative at 800-877-6334 in North America or 32-2-661-20-70 in Europe. Or access our website at www.biomedsys.com.



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