UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **November 2, 2009**

CNS RESPONSE, INC.

(Exact name of Company as specified in its charter)

Delaware	**0-26285**	**87-0419387**
(State or other jurisdiction of incorporation)	(Commission File No.)	(I.R.S. Employer Identification No.)

2755 Bristol Street, Suite 285
Costa Mesa, CA 92626
(Address of principal executive offices)

(714) 545-3288
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On November 3, 2009, CNS Response, Inc. (the "Company") issued a press release reporting the results of a study presented by Charles DeBattista, D.M.H, M.D., at the U.S. Psychiatric and Mental Health Congress. A copy of the press release is included as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference. A copy of the poster presented by Dr. DeBattista on November 2, 2009 at the U.S. Psychiatric and Mental Health Congress is included as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

The Company will be holding a conference call to discuss the top-line results of its recently completed study. CNS stockholders are encouraged to participate in the conference call, which will be held today at 8:00 a.m. PST. Please call Suzanne Schnitzer at 949.553.9748 to register for the call. You will be given the toll-free dial-in number and access code to the conference call, along with the login instructions to join the simultaneous web conference. A copy of the materials to be presented by the Company over the web are included as Exhibit 99.3 to this Form 8-K and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are filed herewith:

99.1	Press Release Issued November 3, 2009.
99.2	Copy of poster presented at U.S. Psychiatric and Mental Health Congress.
99.3	Copy of web presentation materials.

SIGNATURES

Pursuant to the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CNS Response, Inc.

By: /s/ George Carpenter
George Carpenter
Chief Executive Officer

November 3, 2009

Exhibit Index

99.1	Press Release Issued November 3, 2009.
99.2	Copy of poster presented at U.S. Psychiatric and Mental Health Congress.
99.3	Copy of web presentation materials.

news

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Breakthrough Results in Depression Care Announced by CNS Response at the U.S. Psychiatric and Mental Health Congress

Patients Using rEEG® -Guided Treatment Had Considerably Better Outcomes
with Statistical Significance "Exceeding Expectations"

Costa Mesa, CA – November 3, 2009 – **CNS Response, Inc.** (OTCBB: CNSO) reported the results of a landmark study presented by Charles DeBattista, D.M.H, M.D., at the U.S. Psychiatric and Mental Health Congress. The poster presentation, titled *Referenced-EEG® (rEEG) Efficacy Compared to STAR*D For Patients With Depression Treatment Failure: First Look At Final Results*, highlighted a dramatic improvement in personalized medicine technology for use in treatment of patients with depression. In this study, rEEG proved effective at predicting medication response for treatment-resistant patients approximately 65 percent of the time.

The study included 114 patients in 12 medical centers, including Harvard, Stanford, Cornell, UCI and Rush. The 12-week study found that rEEG significantly outperformed the modified STAR*D treatment algorithm. The difference, or separation, between rEEG and the control group was 50 and 100 percent for the study's two primary endpoints. Typically, separation between a new treatment and a control group is about 10 percent in antidepressant studies.

"These outcomes are consistent with previous rEEG studies, which included three prospective, controlled trials and eight case series, but the robustness and statistical significance of these results exceeded our expectations," said CNS president and chief medical officer Daniel Hoffman, M.D.

"Psychiatry has lacked useful laboratory tests to select medications for treatment-resistant depressed patients. While needing further study, this trial is one of the larger ones to demonstrate that there may be a role for technology that assists physicians in selecting better treatment options for their patients," said Dr. Charles DeBattista, an award-winning doctor at Stanford University Medical Center, who helped lead the study on rEEG.

Depression costs U.S. employers $83 billion annually, with treatment-resistant depression accounting for over half of that cost. On average, these patients cost $8,500 more per year than patients with ordinary depression. rEEG is the first objective, physiology-based, personalized medical technology consistently shown to guide psychiatrists to appropriate treatment for the most challenging patients.

- more - -

The CNS Response study, the largest in the company's history, was a randomized, blinded, controlled, parallel group, multicenter study. The patients in the study experienced depression treatment failure of one of more SSRIs and/or had failure with at least two classes of antidepressants. The patients fell into two groups: 1) those treated with rEEG medication guidance, and 2) those treated with the modified STAR*D treatment algorithm.

"This is the promise of personalized medicine, tailoring therapies to the unique medication response profile of each individual patient," said George Carpenter, chief executive officer of CNS Response, Inc., which developed the patented technology. "Those suffering from the most resistant forms of depression will now have an effective treatment option, and doctors will no longer have to play an extended and costly guessing game to see what works best."

About CNS Response

Today, most physicians are able to base treatment on objective test data, such as EKGs, MRIs, blood tests, etc. Broadly speaking, such advances have not yet come to those physicians practicing psychiatry.

CNS Response has developed a patented data-analysis capability that, with the help of a simple, non-invasive EEG, will analyze a patient's brain waves and compare the results to an extensive patient outcomes database. The process produces a rEEG® report providing a psychiatrist with guidance to personalize medication regimens for a patient, based on the patient's own brain physiology. To read more about the benefits this patented technology provides physicians, patients and insurers, please visit the CNS Response website, www.cnsresponse.com.

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995

Except for the historical information contained herein, the matters discussed are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. These statements involve risks and uncertainties as set forth in the Company's filings with the Securities and Exchange Commission. These risks and uncertainties could cause actual results to differ materially from any forward-looking statements made herein.

# # #

Referenced-EEG (rEEG) Efficacy Compared To STAR*D For Patients With Depression Treatment Failure:

First Look At Final Results

Charles DeBattista, M.D.[1]; Gustavo Kinrys, M.D.[2]; Daniel Hoffman M.D.[3]; Mark Schiller, M.D.[4]

[1]Stanford University School of Medicine, [2]Cambridge Hospital/Harvard Medical School, [3]CNS Response, Inc., [4]MindTherapy Clinic

BACKGROUND

Referenced-EEG (rEEG®) is a novel tool that provides medication guidance from a set of empirically derived biomarkers based on a quantitative electroencephalogram (QEEG). rEEG may have a role in guiding treatment for depressed patients. Several trials have investigated the use of rEEG efficacy in guiding Treatment Resistant patients with promising results. These studies were hampered, however, by their small sample sizes. A pilot study of rEEG (1), initiated in 2006, used the Texas Medication Algorithm Project (TMAP) algorithm as the control. Due to design problems the study blinding was compromised and the trial was stopped. A new design was developed using a modified medication algorithm based on the acute and long-term outcomes from the NIMH Sequenced Treatment Alternatives to Relieve Depression trial (STAR*D) (2). This standard was chosen because of its value in identifying the most effective antidepressants for treatment resistant patients.

OBJECTIVE

This study was designed to evaluate the efficacy of rEEG-based pharmacotherapy in comparison to medications guided by a leading standard (STAR*D) in the treatment of patients with depression treatment failure.

METHODS

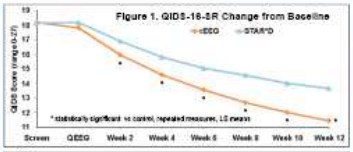
This was a randomized, controlled, single-blind, parallel group, multicenter study, of rEEG-guided medication recommendations *versus* the most successful treatment regimens from the STAR*D study. Patients were recruited at twelve centers across the US, and from two basic strata: patients with depression treatment failure of one or more Selective Serotonin Reuptake Inhibitors (SSRIs), and those with failure of at least two classes of antidepressants. Subjects were 18 years or older with Major Depressive Disorder (MDD). Subjects were required to have a Quick Inventory of Depressive Symptomatology-Self Report-16 (QIDS-16-SR) of ≥13 and a Montgomery-Åsberg Depression Rating Scale (MADRS) score of ≥26 at baseline. Potential subjects were excluded for medically relevant conditions, substance abuse, pregnancy or intent to become pregnant, lactation, or acute or chronic pain requiring prescription pain medication. All subjects underwent a washout of all current medications (except insulin, thyroxin, oral contraceptives, and hydrochlorothiazide) for a minimum of five half-lives prior to receiving a QEEG. The QEEG was analyzed utilizing rEEG technology. After the EEG, subjects were also excluded for reasons related to the EEG such as potential physiologic abnormalities or low abnormality in comparison to the current rEEG database. Also, subjects were excluded if the rEEG-guided treatment regimen would have been the same as the treatment regimen that the subject would receive if randomized to the control group. Subjects randomized to the rEEG group were assigned the treatment regimen that was based on the rEEG report. Subjects randomized to the control group were assigned a treatment regimen based upon the STAR*D algorithm. Control subjects who had failed SSRI's only were treated with a venlafaxine XR; and subjects who had failed on medications from two or more classes of antidepressants were assigned a treatment regimen starting with Step 2 of the modified STAR*D algorithm. The treatment period was 12 weeks with site visits at Week 1, 2, 4, 6, 8, 10, 12. The primary and secondary outcome measures are listed in Table 1. Safety was assessed through collection of vital signs and adverse events (AEs) at each visit.

METHODS, continued

RESULTS

Demography: A total of 485 subjects were screened and 114 subjects were randomized (57 rEEG, 57 STAR*D). Of these, 44 were from the SSRI-only stratum, and 70 were from the stratum that failed two or more antidepressants. This population was on average 44 years old, 180 pounds, 63.2% female, 66.8% Caucasian, 15.8% Hispanic, and 9.6% Black. A total of 32 of the 114 randomized subjects (16 per group) prematurely terminated for: AEs (4), lack of efficacy (13), withdrew consent (6), never took medications (3), and other reasons (6). The Modified Intent-to-Treat (MITT) population consisted of 104 subjects who were randomized and delivered valid data for the primary endpoints. The Per-Protocol (PP) population consisted of 89 MITT subjects who completed at least 2 weeks of treatment and fulfilled protocol criteria. Out of the 89 PP subjects analyzed for efficacy, 40 subjects were in the rEEG group and 49 subjects were in the STAR*D group (Table 1).

Efficacy Results: The primary endpoints (mean change from baseline for QIDS-16-SR and Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF) were both statistically significant (one-tailed, alpha = 0.05) in favor of the rEEG treatment group (Table 1, Figures 1 and 2). QIDS-16-SR scores were reduced by a mean of 6.77 points vs 4.51 points, for rEEG vs STAR*D, respectively. Q-LES-Q-SF % Maximum Satisfaction increased by a mean of 18 percentage points vs only 8.95 percentage points, for rEEG vs STAR*D, respectively. The following secondary endpoints (Table 1) were also statistically significant in favor of the rEEG treatment group: QIDS-16-SR response (reduction by 50%) (Figure 3) and remission (score of 5 or less); MADRS mean change and response; Clinical Global Impression of Improvement (CGI-I) of either a 2 or 1 (much improved or very much improved) as well as those ONLY reaching 1; Patient Health Questionnaire (PHQ-9) mean change and response; and CGI-S mean change. A summary of rEEG improvement over STAR*D is shown in Figure 4. Although the protocol was designed for a one-tailed analysis, a two-tailed analysis (alpha=0.025) of the primary endpoints was still statistically significant and 8 out of 12 secondary endpoints (Table 1) also met statistical significance.



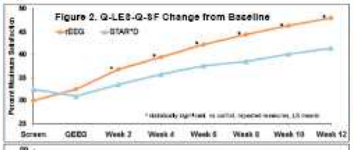


Table 1. Efficacy Results (Per Protocol Population)

	rEEG N=40	STAR*D N=49	p-value
Primary Measures			
QIDS-16-SR mean change (a)	-6.77	-4.51	<.0001
Q-LES-Q-SF mean change (a)	18.0	8.95	<.0001
Secondary Measures			
QIDS-16-SR response (c)	65.00%	38.78%	<.0001
QIDS-16-SR remission (c)	35.00%	26.53%	0.0077
MADRS mean change (b)	-21.85	-16.43	0.0093
MADRS response (d)	57.50%	44.90%	0.0238
MADRS remission (d)	40.00%	28.57%	0.0535
CGI-I mean change (a)	-1.75	-1.30	<.0001
CGI-I scores of 2 or 1 (c)	72.5%	53.06%	<.0001
CGI-I scores of 1 (c)	47.5%	20.41%	0.0008
PHQ-9 mean change (b)	-13.73	-9.40	0.0062
PHQ-9 response (d)	65.00%	48.98%	0.0058
PHQ-9 remission (d)	47.50%	36.73%	0.0545
CGI-Severity mean change (a)	-2.32	-1.48	0.0007

(a) Repeated measures, LS means/mixed procedure. (b) LS means from ANCOVA. (c) LS mean from GENMOD. (d) Logistic analysis.

CONCLUSIONS

This study demonstrated that rEEG-guided pharmacotherapy was highly effective in the treatment of subjects with depression treatment failure. rEEG efficacy was compared to STAR*D and demonstrated statistically significant superiority on nearly every parameter measured (QIDS-16-SR, QLESQ, MADRS, CGI, CGS and PHQ-9). This suggests that rEEG should be considered as a useful tool in the selection of medications for this difficult-to-treat population. These results warrant additional studies in the role of rEEG-guided psychopharmacology for this non-psychotic depressed psychiatric population.

REFERENCES

1. DeBattista C, Hoffman D, Schiller M, et. al., (Oct. 06), Referenced-EEG® Guidance of Medications for Treatment Resistant Depressed Patients – A Pilot Study, Poster #228, US Psychiatric and Mental Health Congress, San Diego, CA.

2. Rush JA, Trivedi MH, Wisniewski SR, et. al. Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR*D Report. Am J Psychiatry 2006;163:1905-1917.

This study was funded by CNS Response, Inc.

INFORMATION

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Investor Conference Call:
Top-line results from Depression Efficacy Trial

November 3, 2009

A new prescription:

rEEG® brings personalized medicine to Psychiatry

CNS Response

www.cnsresponse.com

Safe Harbor

The statements and discussions contained in this summary that are not historical facts constitute forward-looking statements, which can be identified by the use of forward-looking words such as "believes," "expects," "may," "intends," "anticipates," "plans," "estimates" and analogous or similar expressions intended to identify forward-looking statements. CNS Response wishes to caution the reader of this summary that these forward-looking statements and estimates as to future performance, estimates as to future valuations and other statements contained herein regarding matters that are not historical facts, are only predictions, and that actual events or results may differ materially. CNS Response cannot assure or guarantee you that any future results described in this summary will be achieved, and actual results could vary materially from those reflected in such forward-looking statements.

Information contained in this summary has been compiled by CNS Response from sources believed to be credible and reliable. However, CNS Response cannot guarantee such credibility and reliability. The forecasts and projections of events contained herein are based upon subjective valuations, analyses and personal opinions.

This summary shall not constitute an offer to sell or the solicitation of an offer to buy any securities. Such an offer or solicitation, if made, will only be made pursuant to an offering memorandum and subscription documents prepared by CNS Response specifically for such purposes.

Today's agenda

- **Background on rEEG**
  - Technology
  - Research
- **Depression Efficacy Trial**
  - Objective
  - Design
  - Investigators & locations
  - Review of results
  - Other views of the data
- **Closing Thoughts**
- **Questions**

Speakers:

George Carpenter, CEO, CNS Response
Charles DeBattista, MD, Stanford University School of Medicine
Daniel Hoffman, MD, Chief Medical Officer, CNS Response

CNS Response

www.cnsresponse.com

Trial & Error prescribing, explained

Psychiatry has relied on historical accounts, behavioral observations, and mental status examination as the basis for prescribing.

The psychopharm literature acknowledges that within any diagnostic category there is broad variation in patients' response to classes of medicines as well as specific agents within each class. This is a consequence of the DSM having been constructed as a behavioral sorting system and not as a pharmacotherapeutic response predictor.

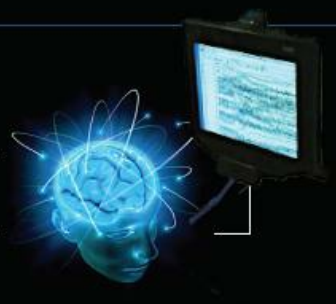
...This inductive leap may lead to a protracted trial and error process, requiring extreme patience and endurance of morbidity until a satisfactory treatment outcome is achieved.

Suffin & Emory, Clinical Electroencephalography, 1995 vol. 26 no. 2

CNS Response

The referenced-EEG® process

How rEEG® works:



Standard Digital EEG

+

Analysis [1]
Compare to "normal" database to stratify

+

Analysis [2]
Compare to CNSR outcomes database
(17,000 outcome correlations)

= rEEG®
Medical Correlations

CNS Response

The rEEG® Report

Section A

Comparison with Normal people of same age and sex

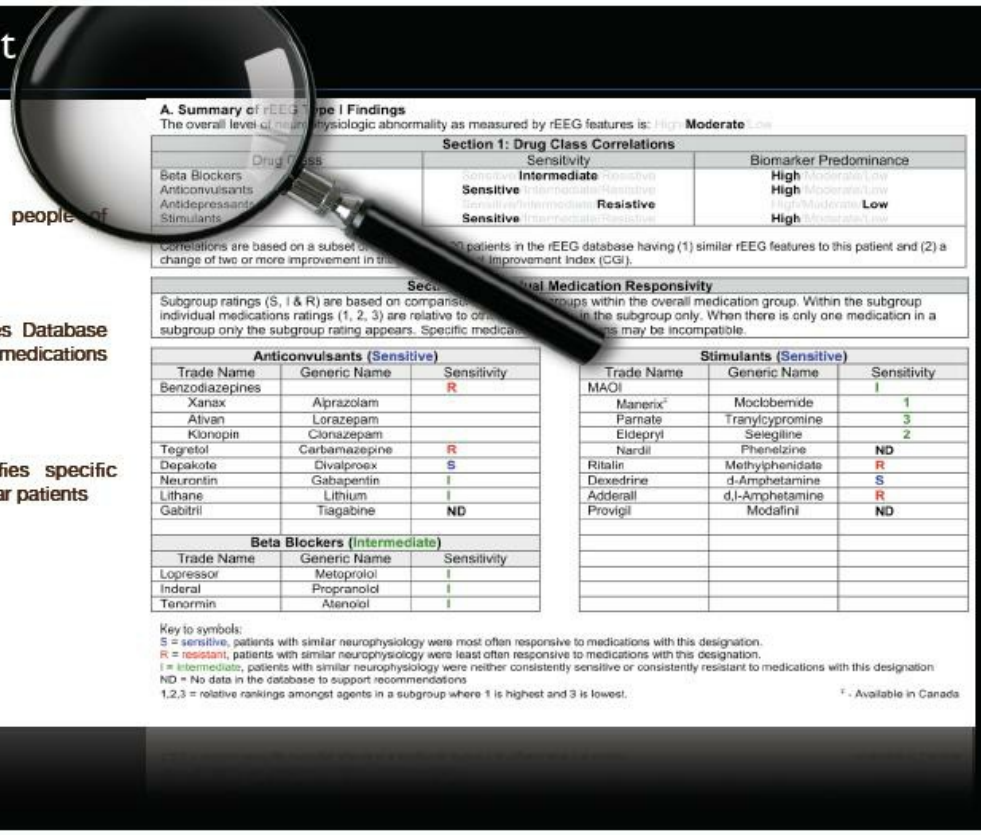
Section 1

Comparison with Outcomes Database to identify categories of medications helpful to similar patients

Section 2

Within categories, identifies specific medications helpful to similar patients

S = Sensitive
R = Resistant
I = Intermediate
1,2,3 = relative rankings within a subgroup



A. Summary of rEEG Type I Findings

The overall level of neurophysiologic abnormality as measured by rEEG features is: High **Moderate** Low

Section 1: Drug Class Correlations

Drug Class	Sensitivity	Biomarker Predominance
Beta Blockers	**Intermediate**	**High** Moderate/Low
Anticonvulsants	**Sensitive** Intermediate/Resistive	**High** Moderate/Low
Antidepressants	Sensitive/Intermediate **Resistive**	High/Moderate **Low**
Stimulants	**Sensitive** Intermediate/Resistive	**High** Moderate/Low

Correlations are based on a subset of patients in the rEEG database having (1) similar rEEG features to this patient and (2) a change of two or more improvement in the Improvement Index (CGI).

Section 2: Individual Medication Responsivity

Subgroup ratings (S, I & R) are based on comparisons of groups within the overall medication group. Within the subgroup individual medications ratings (1, 2, 3) are relative to others in the subgroup only. When there is only one medication in a subgroup only the subgroup rating appears. Specific medications may be incompatible.

Anticonvulsants (Sensitive)

Trade Name	Generic Name	Sensitivity
Benzodiazepines		R
Xanax	Alprazolam	
Ativan	Lorazepam	
Klonopin	Clonazepam	
Tegretol	Carbamazepine	R
Depakote	Divalproex	S
Neurontin	Gabapentin	I
Lithane	Lithium	I
Gabitril	Tiagabine	ND

Beta Blockers (Intermediate)

Trade Name	Generic Name	Sensitivity
Lopressor	Metoprolol	I
Inderal	Propranolol	I
Tenormin	Atenolol	I

Stimulants (Sensitive)

Trade Name	Generic Name	Sensitivity
MAOI		I
Manerix[F]	Moclobemide	1
Parnate	Tranylcypromine	3
Eldepryl	Selegiline	2
Nardil	Phenelzine	ND
Ritalin	Methylphenidate	R
Dexedrine	d-Amphetamine	S
Adderall	d,l-Amphetamine	R
Provigil	Modafinil	ND

Key to symbols:
S = sensitive, patients with similar neurophysiology were most often responsive to medications with this designation.
R = resistant, patients with similar neurophysiology were least often responsive to medications with this designation.
I = intermediate, patients with similar neurophysiology were neither consistently sensitive or consistently resistant to medications with this designation
ND = No data in the database to support recommendations
1,2,3 = relative rankings amongst agents in a subgroup where 1 is highest and 3 is lowest.

[F] - Available in Canada

CNS Response

3rd Party Evidence Review--2008

UBC
United BioSource Corporation

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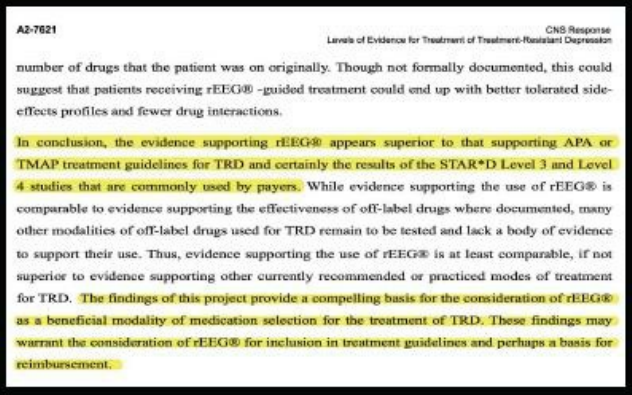
Comparing Levels of Evidence for Treatment of Treatment-Resistant Depression with Referenced-EEG® to Current Practice

Prepared by

Mkaya Mwamburi, MD, PhD
Marisol Hernandez-Medina, MD, MPH

October 17, 2008



A2-7621

CNS Response
Levels of Evidence for Treatment of Treatment-Resistant Depression

number of drugs that the patient was on originally. Though not formally documented, this could suggest that patients receiving rEEG® -guided treatment could end up with better tolerated side-effects profiles and fewer drug interactions.

In conclusion, the evidence supporting rEEG® appears superior to that supporting APA or TMAP treatment guidelines for TRD and certainly the results of the STAR*D Level 3 and Level 4 studies that are commonly used by payers. While evidence supporting the use of rEEG® is comparable to evidence supporting the effectiveness of off-label drugs where documented, many other modalities of off-label drugs used for TRD remain to be tested and lack a body of evidence to support their use. Thus, evidence supporting the use of rEEG® is at least comparable, if not superior to evidence supporting other currently recommended or practiced modes of treatment for TRD. The findings of this project provide a compelling basis for the consideration of rEEG® as a beneficial modality of medication selection for the treatment of TRD. These findings may warrant the consideration of rEEG® for inclusion in treatment guidelines and perhaps a basis for reimbursement.

Referenced-EEG was associated with relatively high remission rates in Treatment Resistant Depression with reasonable levels of evidence. ...In conclusion, the evidence supporting rEEG® appears **superior** to that supporting APA or TMAP treatment guidelines for TRD and certainly the results of the STAR*D Level 3 and Level 4 studies that are commonly used by payers.

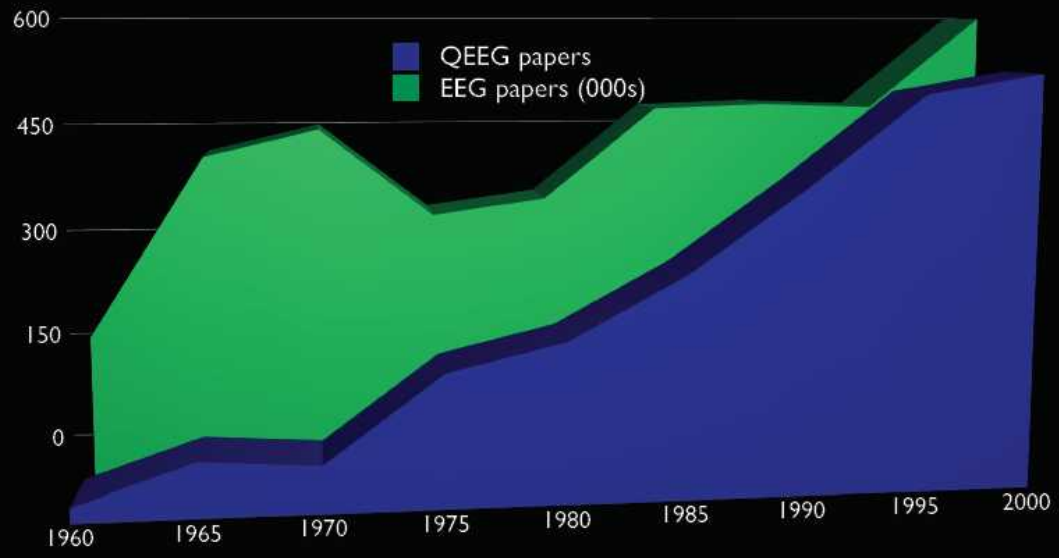
Center for Health Economics, Epidemiology, and Science Policy, UBC, July 2008

CNS Response


prior research
CNS Response

Progressive research interest in EEG/Quantitative EEG

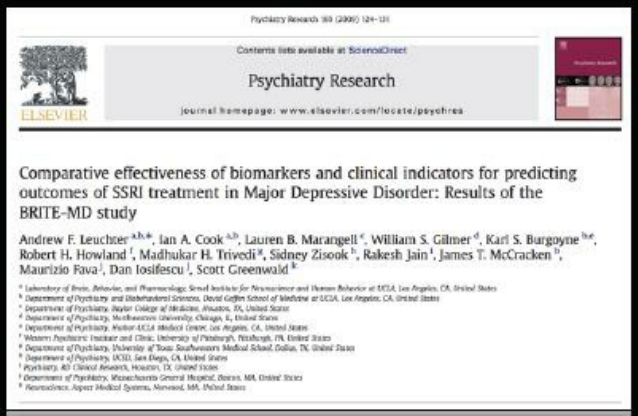
Journal publications indexed in PubMed as "quantitative EEG" or "EEG" since 1960



CNS Response

From "What is Quantitative EEG?", David A. Kaiser, Ph.D. Rochester Institute of Technology

Comparable studies -- Aspect Medical, 2009



Psychiatry Research 169 (2009) 124–131

Contents lists available at ScienceDirect

Psychiatry Research

journal homepage: www.elsevier.com/locate/psychres

Comparative effectiveness of biomarkers and clinical indicators for predicting outcomes of SSRI treatment in Major Depressive Disorder: Results of the BRITE-MD study

Andrew F. Leuchter [a,b,*], Ian A. Cook [a,b], Lauren B. Marangell [c], William S. Gilmer [d], Karl S. Burgoyne [b,e], Robert H. Howland [f], Madhukar H. Trivedi [g], Sidney Zisook [h], Rakesh Jain [i], James T. McCracken [j], Maurizio Fava [l], Dan Iosifescu [l], Scott Greenwald [k]

BRITE Study:

- n = 375
- Biomarker = "cordance"
- 5-lead EEG
- Design: Dose-loading at 1 week
- Successfully predicted response to a single antidepressant

CNS Response

rEEG® Clinical Research

Journal of American Physicians and Surgeons Vol. 12, No 4, Winter 2007

Suffin & Emory, Journal of Clinical Electroencephalography, 1995

Controlled Trials	Population	rEEG Efficacy	Control Group
Multi-site Depression Efficacy Trial -- 2009	114	65%	39%
ADD & Depression Blinded Trial[1,3]	100	68%	22%
VA Blinded Study[3,5]	13	85%	17%
TRD Pilot -- post hoc	18	58%	0%

Open Label Case Series	Population	Efficacy
Dr. Greenblatt Scientific Pres APA 2008[7]	13	92%
CIGNA-Atlanta Pilot[3]	56	70%
Dr. Davis Case Series[3]	15	100%
Monte Nido Case Series[2,3]	104	83%
Dr. Hamilton Case Series[3]	34	78%
Dr. Hoffman Case Series[3]	74	76%
Rancho L'Abri Case Series[3,4]	58	93%
Dr. Schiller Case Series[7]	19	89%

CNS Response

1 Clinical EEG and Neurosciences, 1995
2 NCDEU Poster at Annual Meeting 2004
3 APA Poster at Annual Meeting 2005
4 APA Poster at Annual Meeting 2005
5 American College of Physicians & Surgeons, 2007
6 CPDD Poster at Annual Meeting 2008
7 2008 US Psychiatric & Mental Health Congress 2008

What STAR*D proved: Treatment Resistant Depression is tough

TABLE 1: Failed Trials' Progressive *"Poisoning of the Well"* Effect as Documented by STAR*D

MEDICATION STEP	DECREASING REMISSION RATES [1] (TABLE 4 PAGE 1911)	DECREASING RESPONSE RATES [1] (TABLE 4 PAGE 1911)	INCREASING RELAPSE RATES [1] (TABLE 5 PAGE 1912)	INCREASING DROPOUT RATES [1] (FIGURE 1 PAGE 1903)
Step 1	36.8%	48.6%	40.1%	20.1%
Step 2	30.6%	28.5%	55.3%	29.7%
Step 3	13.7%	16.8%	64.6%	44.8%
Step 4	13.0%	16.3%	71.1%	60.1%

The STAR*D trial provides robust, real-world data that can be applied broadly to both primary and specialty care settings. The study confirms that different people respond to different treatment strategies, but it does not pinpoint what treatments work best for whom. The STAR*D team concluded that future research should be targeted to identify the best multi-step treatment options for individuals, especially those with treatment-resistant depression.

"This new STAR*D report reminds us that treating depression remains a formidable challenge," said NIMH Director Thomas Insel M.D. "While roughly two-thirds of patients report remission, many subsequently relapse. We need new treatments that are rapid, enduring, and individualized to facilitate recovery."

CNS Response

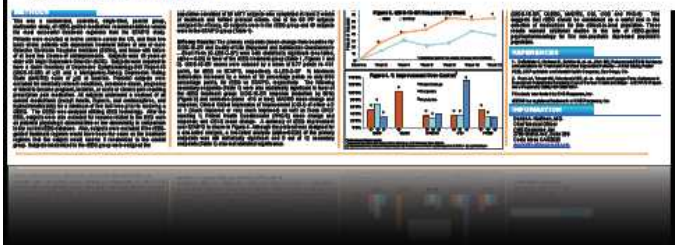
National Institute of Mental Health, **Science Update**, 11/1/06


Multi-site Depression Efficacy Trial -- 2009
Top-line results
CNS Response

Multi-site Depression Efficacy Trial -- Objective

OBJECTIVE

This study was designed to evaluate the efficacy of rEEG-based pharmacotherapy in comparison to medications guided by a leading standard (STAR*D) in the treatment of patients with depression treatment failure.



Referenced-EEG (rEEG) Efficacy Compared To STAR*D For Patients With Depression Treatment Failure: *First Look At Final Results*

Charles DeBattista, M.D.1; Gustavo Kinrys, M.D.2; Daniel Hoffman M.D.3; Mark Schiller, M.D.4
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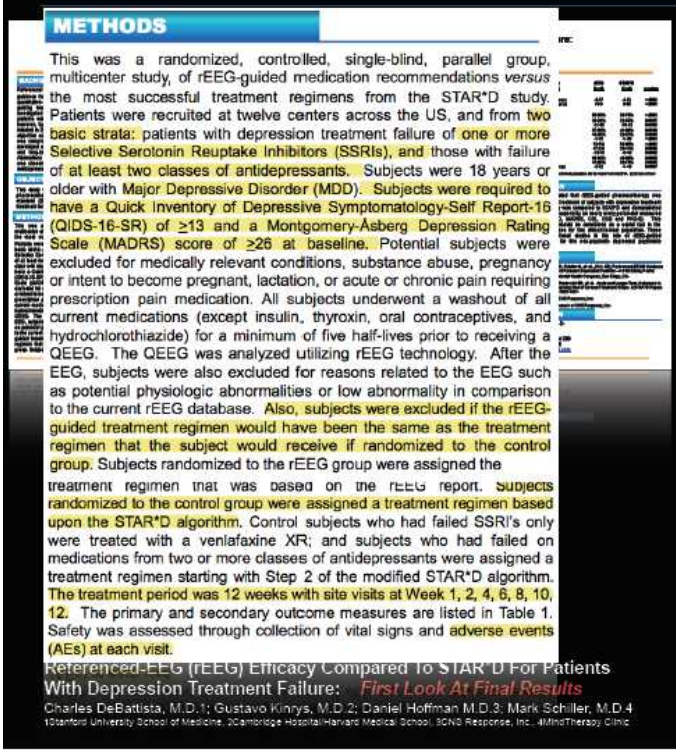
Multi-site Depression Efficacy Trial -- Design



METHODS

This was a randomized, controlled, single-blind, parallel group, multicenter study, of rEEG-guided medication recommendations *versus* the most successful treatment regimens from the STAR*D study. Patients were recruited at twelve centers across the US, and from two basic strata: patients with depression treatment failure of one or more Selective Serotonin Reuptake Inhibitors (SSRIs), and those with failure of at least two classes of antidepressants. Subjects were 18 years or older with Major Depressive Disorder (MDD). Subjects were required to have a Quick Inventory of Depressive Symptomatology-Self Report-16 (QIDS-16-SR) of ≥13 and a Montgomery-Åsberg Depression Rating Scale (MADRS) score of ≥26 at baseline. Potential subjects were excluded for medically relevant conditions, substance abuse, pregnancy or intent to become pregnant, lactation, or acute or chronic pain requiring prescription pain medication. All subjects underwent a washout of all current medications (except insulin, thyroxin, oral contraceptives, and hydrochlorothiazide) for a minimum of five half-lives prior to receiving a QEEG. The QEEG was analyzed utilizing rEEG technology. After the EEG, subjects were also excluded for reasons related to the EEG such as potential physiologic abnormalities or low abnormality in comparison to the current rEEG database. Also, subjects were excluded if the rEEG-guided treatment regimen would have been the same as the treatment regimen that the subject would receive if randomized to the control group. Subjects randomized to the rEEG group were assigned the treatment regimen that was based on the rEEG report. Subjects randomized to the control group were assigned a treatment regimen based upon the STAR*D algorithm. Control subjects who had failed SSRI's only were treated with a venlafaxine XR; and subjects who had failed on medications from two or more classes of antidepressants were assigned a treatment regimen starting with Step 2 of the modified STAR*D algorithm. The treatment period was 12 weeks with site visits at Week 1, 2, 4, 6, 8, 10, 12. The primary and secondary outcome measures are listed in Table 1. Safety was assessed through collection of vital signs and adverse events (AEs) at each visit.

Referenced-EEG (rEEG) Efficacy Compared To STAR*D For Patients With Depression Treatment Failure: *First Look At Final Results*

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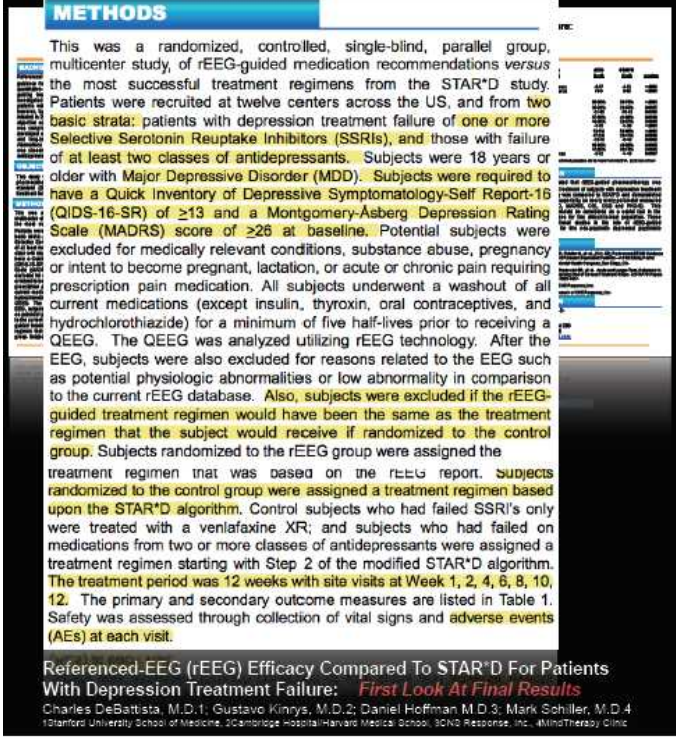
- A randomized, controlled, single-blind, parallel group, multicenter study
- Patients with Major Depressive Disorder treatment failure
- rEEG medication guidance vs most successful treatments from STAR*D
- Two basic strata (patient groups):
  - failure on one or more Selective Serotonin Reuptake Inhibitors (SSRIs)
  - failure of at least two classes of antidepressants in the current episode
- Subjects required to have both:
  - Quick Inventory of Depressive Symptomatology-Self Report-16 (QIDS-16-SR) of >13
  - Montgomery-Åsberg Depression Rating Scale (MADRS) score of >26 at baseline

Multi-site Depression Efficacy Trial -- Design (cont'd)



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- All subjects underwent a washout of all current meds for minimum of five half-lives
- Subjects were excluded if rEEG-guided treatment regimen would have been identical if randomized to the control group – this occurred in __% of screened cases
- Treatment protocol:
  - Subjects randomized to rEEG group were assigned the treatment regimen that was based on the rEEG report
  - Subjects randomized to the control group were assigned a treatment regimen based upon the OPTIMIZED STAR*D algorithm
    - Control subjects who had failed SSRI's only were treated with venlafaxine XR
    - Subjects who had failed on medications from two or more classes of antidepressants were assigned a treatment regimen starting with Step 2 of the Optimized STAR*D algorithm

Multi-site Depression Efficacy Trial -- Investigators & Locations

Investigators:

Charles DeBattista, MD
Gustavo Kinrys, MD
Martin Teicher, MD
James Kocsis, MD
Steven Potkin, MD
Corey Goldstein, MD

Locations:

Stanford University Medical Center
Harvard/Cambridge Hospital
Harvard/McClean Hospital
Cornell University
UCI Medical Center
Rush Medical Center

and 6 commercial sites

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rEEG® Multi-site Depression Efficacy Trial -- Clinical Endpoints

Table 1. Efficacy Results (Per Protocol Population)	rEEG	STAR*D
Primary Measures		
QIDS-16-SR mean change (a)		
Q-LES-Q-SF mean change (a)		
Secondary Measures		
QIDS-16-SR response (c)		
QIDS-16-SR remission (c)		
MADRS mean change (b)		
MADRS response (d)		
MADRS remission (d)		
CGI-I mean change (a)		
CGI-I scores of 2 or 1 (c)		
CGI-I scores of 1 (c)		
PHQ-9 mean change (b)		
PHQ-9 response (d)		
PHQ-9 remission (d)		
CGI-Severity mean change (b)		

(a) Repeated measures, LS means/mixed procedure. (b) LS means from ANCOVA. (c) LS means from GENMOD. (d) Logistic analysis.

Primary outcome measures were a 1-tailed assessment of change from baseline for:

- QIDS-16-SR (Quick Inventory of Depression Symptoms)
- Q-LES-Q-SF (Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form)
- These were chosen to match closely to the original STAR*D study

Secondary outcome measures were:

- QIDS-16-SR response and remission
- MADRS mean change, response & remission
- PHQ-9 (Patient Health Questionaire) mean change, response & remission
- CGI-S (Severity) mean change
- CGI-I (Improvement) of 2 or 1 (much improved or very much improved)
- CGI-I only (very much improved)

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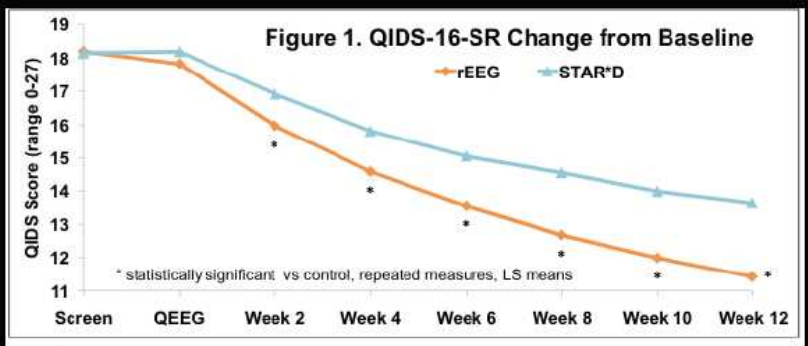
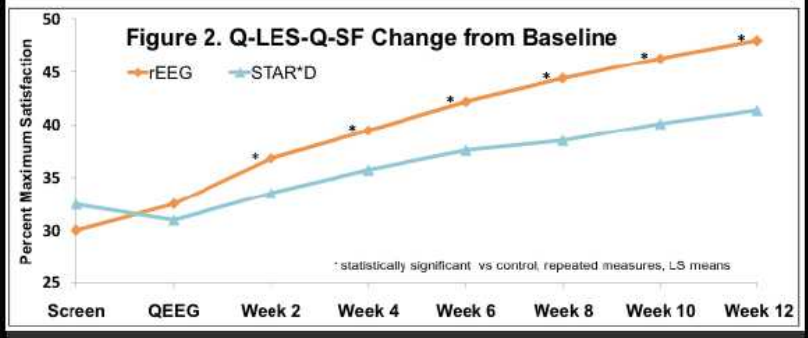
Multi-site Depression Efficacy Trial -- Results





PRIMARY endpoints -- both statistically significant for the rEEG group:

- QIDS-16-SR scores were reduced by a mean of 6.77 points vs 4.51 points, for rEEG vs STAR*D for a 50% improvement over control
- Q-LES-Q-SF % Maximum Satisfaction increased by a mean of 18 percentage points vs only 8.95 percentage points, for rEEG vs STAR*D, respectively for 101% improvement over control

Referenced-EEG (rEEG) Efficacy Compared To STAR*D For Patients With Depression Treatment Failure: *First Look At Final Results*

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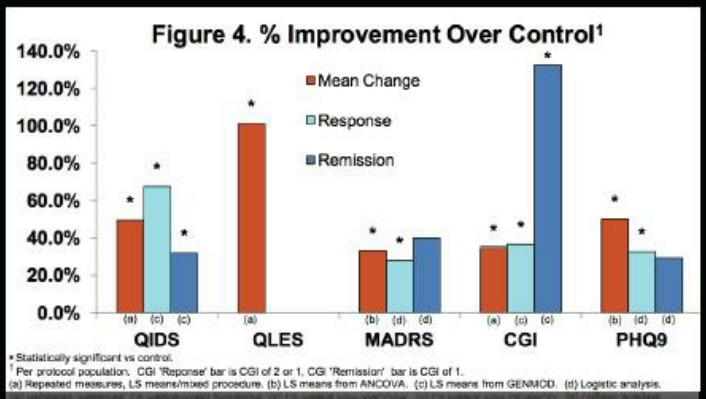
rEEG® Multi-site Depression Efficacy Trial -- All Endpoints



- QLESQ: The mean change for the Experimental group (rEEG) was 18 point vs. 8.95 for the Control group (StarD) or a 100% improvement
- This was statistically significant at < .0001. This means that there is a greater than 99.99% chance that rEEG really is better than the StarD
- The QIDS Response rate for the rEEG group was 65% vs. 39% for the Control which is a spread of 26 percentage points and a 68% improvement over control (i.e. 26%/39%)
- The QIDS remission rate for the experimental group was 35% vs. 27% for Control for a spread of 8 points or an improvement of 32%
- The percentage of subjects who achieved a CGI of 1 for the rEEG group was 48% vs 20% for the control for a spread of 28% or a percent improvement of 133%
- QIDS mean change from baseline was 50%

Referenced-EEG (rEEG) Efficacy Compared To STAR*D For Patients With Depression Treatment Failure: ***First Look At Final Results***

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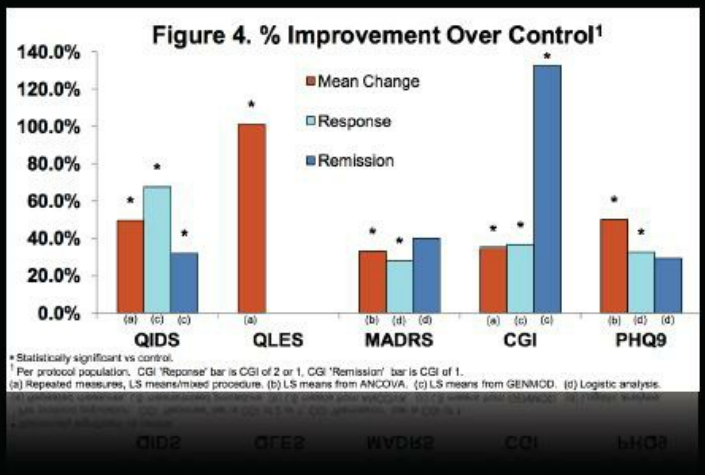
rEEG® Multi-site Depression Efficacy Trial -- All Endpoints



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SECONDARY: % improvement over control (i.e., rEEG 12 week improvement – Control 12 week improvement /Control improvement x 100)

- QIDS-16-SR response (reduction by 50%) and remission (score of 5 or less); RESPONSE WAS 68% AND REMISSION WAS 32%
- MADRS mean change and response were statistically significant with mean change being 33.3%, response was 28%. Remission was 40%
- Clinical Global Impression of Improvement (CGI-I) of either a 2 or 1 (much improved or very much improved) had a 36.6% improvement over control as well as those ONLY reaching 1 – a more difficult measurement – of 133% improvement over control
- Patient Health Questionnaire (PHQ-9) mean change was 50% and response was 33% - both were statistically significant; remission was 29%
- CGI-S mean change was 49% and significant

rEEG® Multi-site Depression Efficacy Trial -- Results

Table 1. Efficacy Results (Per Protocol Population)	rEEG N=40	STAR*D N=49	p-value
Primary Measures			
QIDS-16-SR mean change (a)	-6.77	-4.51	**<.0001**
Q-LES-Q-SF mean change (a)	18.0	8.95	**<.0001**
Secondary Measures			
QIDS-16-SR response (c)	65.00%	38.78%	**<.0001**
QIDS-16-SR remission (c)	35.00%	26.53%	**0.0077**
MADRS mean change (b)	-21.85	-16.43	**0.0383**
MADRS response (d)	57.50%	44.90%	**0.0228**
MADRS remission (d)	40.00%	28.57%	0.0635
CGI-I mean change (a)	-1.75	-1.30	**<.0001**
CGI-I scores of 2 or 1 (c)	72.5%	53.06%	**<.0001**
CGI-I scores of 1 (c)	47.5%	20.41%	**0.0008**
PHQ-9 mean change (b)	-13.73	-9.40	**0.0062**
PHQ-9 response (d)	65.00%	48.98%	**0.0055**
PHQ-9 remission (d)	47.50%	36.73%	0.0645
CGI-Severity mean change (b)	-2.32	-1.46	**0.0007**

(a) Repeated measures, LS means/mixed procedure. (b) LS means from ANCOVA. (c) LS means from GENMOD. (d) Logistic analysis.

Referenced-EEG (rEEG) Efficacy Compared To STAR*D For Patients With Depression Treatment Failure: *First Look At Final Results*

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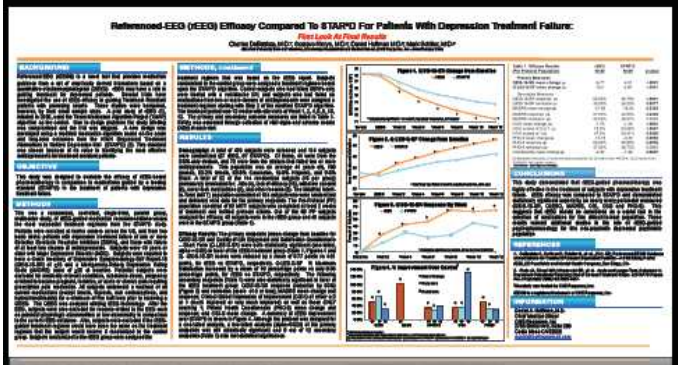
- TWO-TAILED: a two-tailed analysis of the primary endpoints was still statistically significant and 9 out of 12 secondary endpoints also met statistical significance

Multi-site Depression Efficacy Trial -- 2009


Referenced-EEG (rEEG) Efficacy Compared To STARD For Patients With Depression Treatment Failure:
First Look At Final Results

Take-aways:

1. Remarkably consistent with previous trials:
   rEEG predicted medication response 65% of the time
2. Statistically significant improvement over control group on all primary & most secondary endpoints (9/12 - two tailed)
3. STAR*D is a tough control group:
   only 10% of MDs offer this level of treatment in US
4. Significant separation (50-100% on primary endpoints)
   - well above typical antidepressant trial (<10%)
   - response was early, durable, & still growing at week 12
5. Strong statistical significance -- adequately powered to show a significant difference

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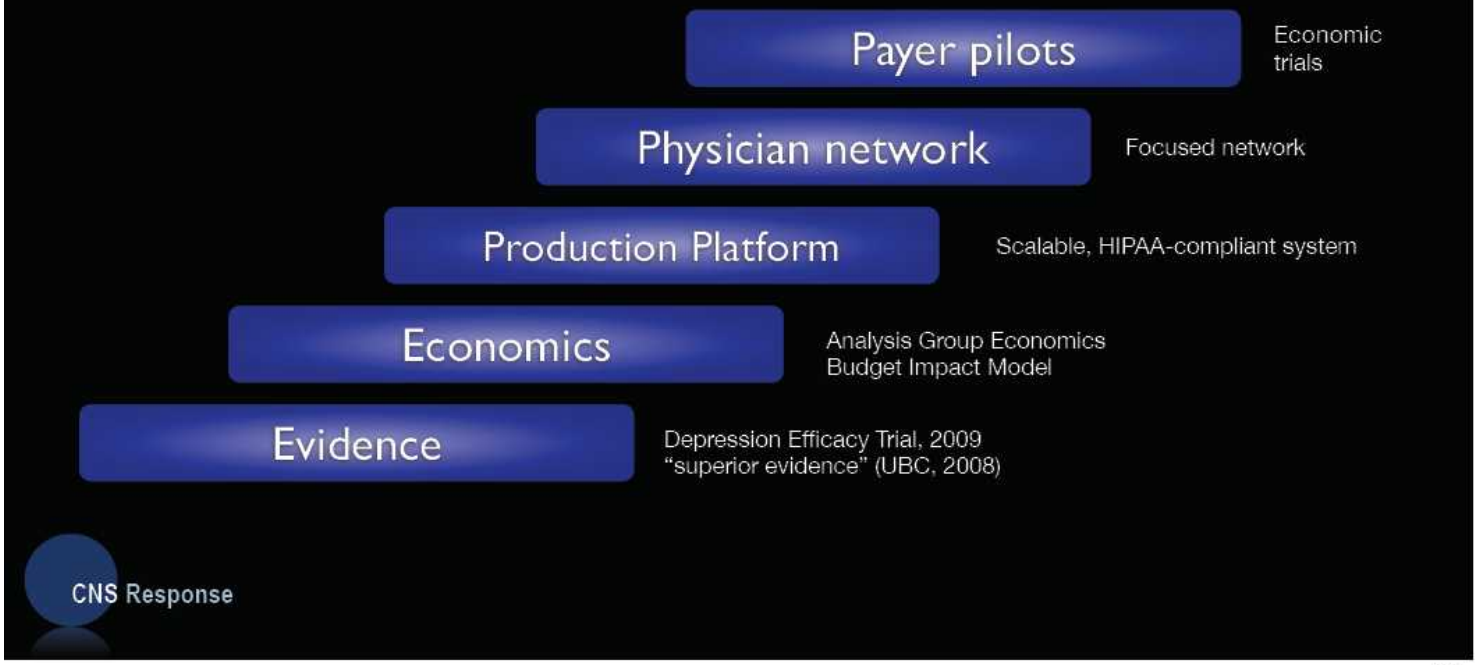
closing thoughts
CNS Response

Foundation for growth



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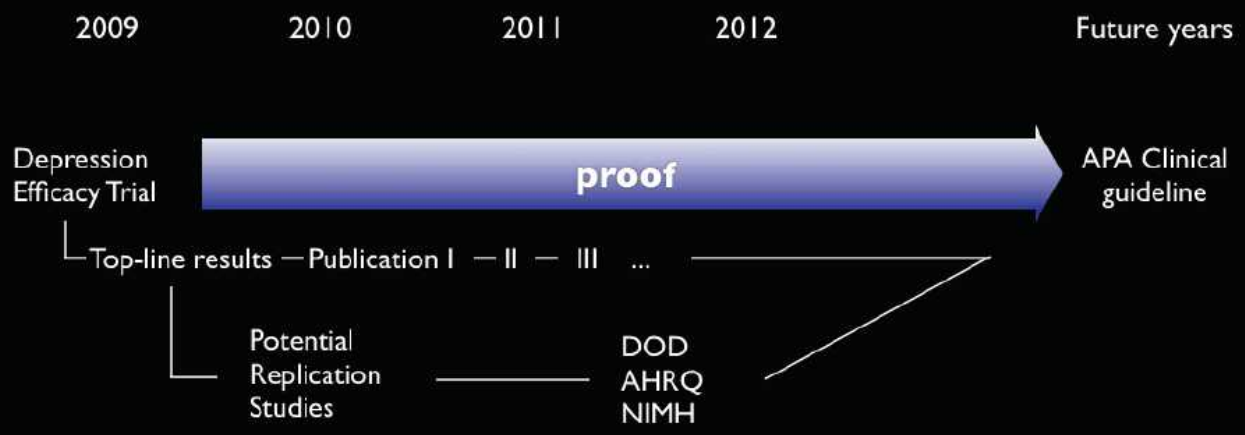
Future research:



CNS Response

Mental Health Parity

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343)

- Reimbursement of behavioral therapies must be on same basis as physical medicine
- Parity will increase behavioral spending -- 1-3% increase in total health care spend

CNS Response

Health Care Reform

Roughly $700 billion each year goes to health-care spending that can't be shown to lead to better health outcomes, according to the non-partisan Congressional Budget Office.

Comparative effectiveness quite simply means comparing two or more treatments for a given condition. Studies may compare similar treatments, such as two drugs, or may analyze very different approaches, such as surgery and drug therapy.

In some cases, a given treatment may prove to be more effective clinically or more cost-effective for a broad range of patients, but frequently a key issue is determining **which specific types of patients would benefit most from it.**

Consumer Reports, 2/10/09


Questions
CNS Response

Corporate Information

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