

# The NeuroStar Outcomes Registry Update

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- ThriveLogic TMS + NeuroHealth
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- Private practice -1986-present



## Topics

- Overview
- Data Acquisition
- National Outcomes
- ThriveLogic Outcomes
- Conclusion
- Q&A



## NeuroStar - Indication for Use

"NeuroStar Advanced Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode"



## Contraindication

- NeuroStar TMS Therapy is contraindicated in patients with non-removable conductive metal in or near the head
- Refer to <u>www.NeuroStar.com</u> for complete product safety information



## What is the NeuroStar Outcomes Registry?

- Registry of de-identified Major Depressive Disorder patient treatment and result data
- Opted-in by NeuroStar physicians
- On track to become the largest registry of treatment resistant depression
  - STAR\*D trial included 2,876 evaluable patients
  - NeuroStar Outcomes Registry is expected to have 6,000 evaluable patients by the end of 2019



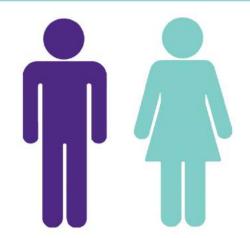
# Why do a NeuroStar Registry?

- Create confidence in Transcranial Magnetic Stimulation in the psychiatry and payor communities
- Quality measures/Continuous quality improvement
  - MACRA
  - JCAHO
- Continue to study Transcranial Magnetic Stimulation to advance the science and inform future areas of study and research and development.
  - New Indications
  - Alternative treatment paradigms
  - Combination therapies
- Opportunity to examine NeuroStar results in real world practice
  - Practices have used their data to build confidence in their office for referring physicians



# NeuroStar Outcomes Registry Data Acquisition

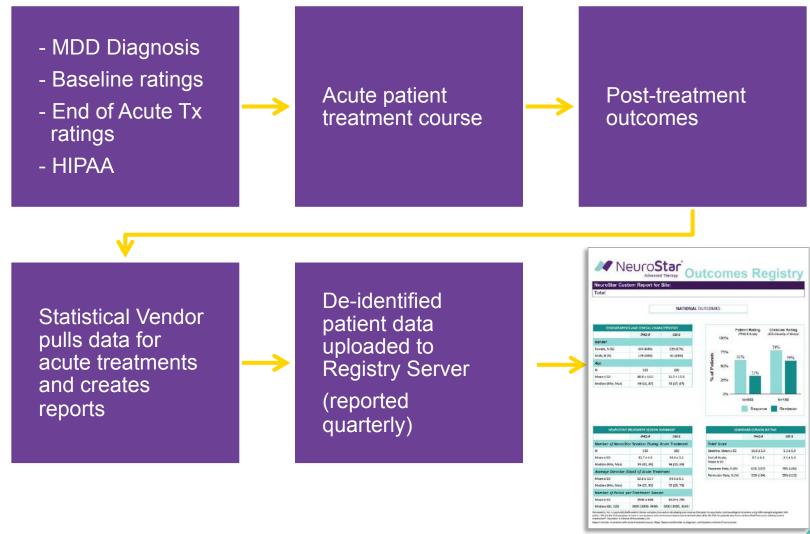
- Major Fields:
  - Demographic Elements
  - Treatment Elements
  - Outcome Measure Elements



- Data Sources:
  - Obligatory fields Age, Gender
  - Automatic capture by NeuroStar Treatment parameters
  - User entered data Diagnosis, Ratings



# NeuroStar Outcomes Registry Data Collection and Flow



# NeuroStar Outcomes Registry Patient Ratings

- Patient Rated PHQ-9
- Clinician Rated CGI-S
- Baseline Rating
  - first rating +/- 4 days from relative to first treatment date
- End of Acute Rating
  - last rating +/- 4 days relative to End of Acute
     (EOA) treatment date



## NeuroStar Outcomes Registry National Results

DEMOGRAPHICS AND CLINICAL CHARACTERISTICS		
	PHQ-9	CGI-S
Gender		
Female, N (%)	975 (65%)	364 (65%)
Male, N (%)	530 (35%)	193 (35%)
Other, N (%)	1 (0%)	0 (0%)
Age		
N	1506	557
Mean ± SD	46.8 ± 15.9	48.9 ± 16.0
Median (Min, Max)	48 (0, 87)	50 (0, 87)

All results are as of April 18, 2018 Unmonitored data – age of 0 may be reported for incorrectly entered date of birth

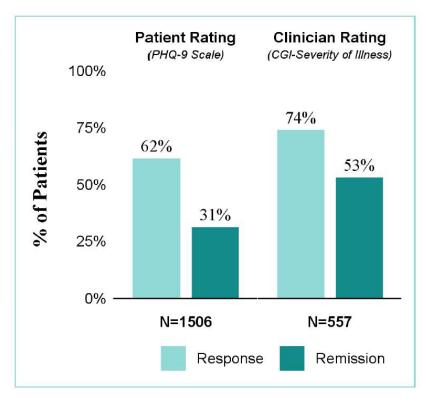


# NeuroStar Outcomes Registry National Results

NEUROSTAR TREATMENT SESSION SUMMARY			
	PHQ-9	CGI-S	
Number of NeuroStar Sessions During Acute Treatment			
N	1506	557	
Mean ± SD	33.2 ± 4.2	35.0 ± 2.9	
Median (Min, Max)	36 (20, 39)	36 (20, 39)	
Average Duration (days) of Acute Treatment			
Mean ± SD	54.0 ± 10.5	56.7 ± 8.5	
Median (Min, Max)	55 (19, 94)	56 (27, 86)	
Number of Pulses per Treatment Session			
Mean ± SD	3415 ± 1191	3295 ± 1415	
Median (Q1, Q3)	3000 (3000, 4200)	3000 (3000, 4600)	

## NeuroStar Outcomes Registry National Results

STANDARD CLINICAL RATING		
	PHQ-9	CGI-S
Total Score		
Baseline, Mean ± SD	19.3 ± 4.7	5.4 ± 0.9
End of Acute, Mean ± SD	8.8 ± 6.4	2.6 ± 1.4
Response Rate, % (N)	62% (927)	74% (413)
Remission Rate, % (N)	31% (471)	53% (296)



**SITE OUTCOMES** 

#### **NATIONAL OUTCOMES**

	MDD <sup>2</sup>
Gender	
Female, N (%)	49 (69%)
Male, N (%)	22 (31%)
Other, N (%)	0 (0%)
Age	
N	71
Mean ± SD	51.3 ± 16.8
Median (Min, Max)	54 (16, 82)

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#### **SITE OUTCOMES**

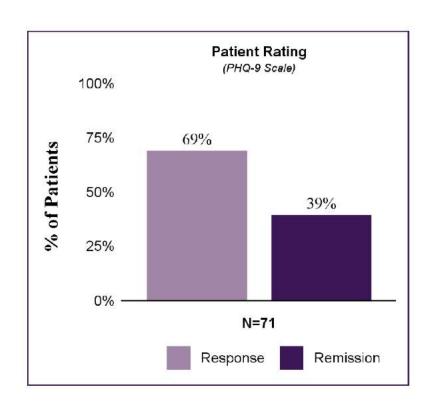
NEUROSTAR TREATMENT SESSION SUMMARY		
	MDD <sup>1</sup>	
Number of NeuroStar Sessions During Acute Treatment		
N	71	
Mean ± SD	29.9 ± 4.4	
Median (Min, Max)	30 (20, 38)	
Average Duration (days) of Acute Treatment		
Mean ± SD	47.0 ± 10.1	
Median (Min, Max)	46 (19, 69)	
Number of Pulses per Treatment Session		
Mean ± SD	2922 ± 1056	
Median (Q1, Q3)	3000 (3000, 3120)	

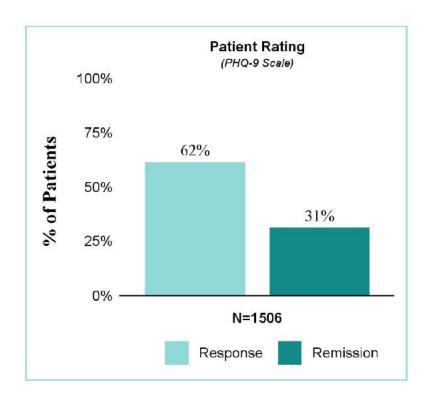
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#### **SITE OUTCOMES**

#### **NATIONAL** OUTCOMES





**SITE OUTCOMES** 

#### **NATIONAL OUTCOMES**

STANDARD CLINICAL RATING		
	Patient Clinical Rating	
Baseline, Mean ± SD	16.3 ± 6.1	
End of Acute, Mean ± SD	7.3 ± 5.9	
Response Rate, % (N)	69% (49)	
Remission Rate, % (N)	39% (28)	

STANDARD CLINICAL RATING		
	Patient Clinical Rating	
Baseline, Mean ± SD	19.3 ± 4.7	
End of Acute, Mean ± SD	8.8 ± 6.4	
Response Rate, % (N)	62% (927)	
Remission Rate, % (N)	31% (471)	

## Keys to success

- Patient selection
- Patient engagement
- Staff training



# NeuroStar Outcomes Registry Conclusions

- Over 1500 patients entered in NeuroStar Outcomes Registry since Q4 2016
- NeuroStar Outcomes Registry is expected to reach 6000 outpatients from more than 50 clinical sites at 36 months.
- Treatment outcomes consistent with NeuroStar open-label study data (Carpenter, 2012)
  - 2/3 Respond
  - 1/3 Remit
- Patient treatment courses consistent with labeled indication
- TrakStar makes large scale data collection feasible

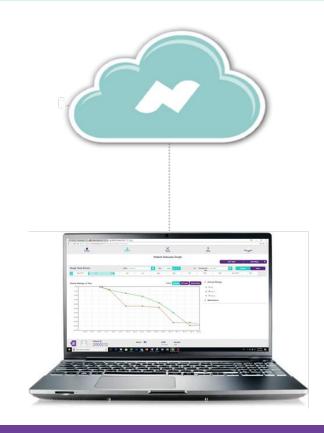


## TrakStar™ Cloud

### Powerful Web-Enabled Patient Data Management System

# Only TrakStar Cloud can automatically and securely Track, Manage, Report your clinical success:

- MANAGE treatment protocols for consistent, optimized dosing .Web-based technology for centralized, easy-to-access database – available to multiple NeuroStar facilities, allowing for treatment flexibility
- TRACK treatment history and outcomes automatically from NeuroStar®
- REPORT easily produced patient records, reimbursement claims, referring physician communication



# **Convenient Treatment Session** delivery

 Orders automatically sync to NeuroStar System





**Questions & Answers** 



Thank you!