Issue #1
August 2011

INSTRIDE

The newsletter for the Innovative Neurotronics, INSTRIDE study

In this issue:

Welcome

Innovative Neurotronics, Inc. with Medpace Medical Device would like to welcome you to the INSTRIDE study. We are happy to provide you with the first official INSTRIDE study newsletter containing essential study updates, reminders, and more.

As of August 23, 2011, there are 16 active sites and 178 subjects randomized. Thank you all for your contributions to the study and please let us know how we can support you and your staff to continue making the study a success!

Study Enrollment

As of August 23, 2011

PI Name	Site Name	Subjects Enrolled
Noel Rao, MD	027 Marianjoy	39
Bruce Solomon, DO	009 FirstHealth of the Carolinas	33
Karen Nolan, PhD	012 Kessler Foundation Research Center	31
William Pease, MD	020 Ohio State University Medical Center	11
Mark Gudesblatt, MD	008 South Shore Neurologic	12
Aamir Rasheed, MD	017 United Health Services	10
Jason Greenberg, MD	028 Helen Hayes Hospital	10
Margaret Turk, MD	004 SUNY Upstate Medical University	11
David Wiersma, DO	007 St. Mary's of Michigan	9
Thiru Annaswamy, MD	002 Dallas VA	9
Gary Abrams, MD	013 San Francisco VA	2
Murray Brandstater, MD	016 Loma Linda University	1
Pramodkumar Sethi, MD	005 Guilford Neurologic Associates	0
Roi Ann Wallis, MD	003 Los Angeles VA	0
Total Enrollment		**178**

Congratulations to the following sites on their recent activation!

- Dr. Roi Ann Wallis – Los Angeles VA
- Dr. Pramodkumar Sethi – Guilford Neurologic Associates
- Dr. Murray Brandstater – Loma Linda University

GOAL:
Aim to enroll at least 12 subjects in the next 3 months at each site by the time of the next study newsletter!

NEUROTRONICS
"INDEPENDENCE, ONE STEP AT A TIME"

MEDPACE
Medical Device

INSTRIDE is a publication prepared by Medpace for the Innovative Neurotronics, INSTRIDE study.
Contributions or suggestions for future issues are welcome and encouraged. If you have an item you wish to have included in *INSTRIDE*, please email it to Phil Ghizoni at p.ghizoni@medpace.com.

Subject Screening

- Subjects with a history of seizure disorder will be excluded from the study per protocol exclusion criteria. Subjects who have been taking anti-seizure medications to prevent seizures would likely be excluded because a seizure could occur if the subject did not take their medications. However, taking anti-seizure medications does not itself exclude a potential subject, nor does one or two seizures secondary to stroke necessarily qualify as a history of seizure disorder. Ultimately, it will be the Principle Investigator's decision, after reviewing each subject's history, as to whether he or she truly has a history of a seizure disorder, and therefore whether enrollment in the study is permissible.
- Sites should determine that potential subjects considered for enrollment in the study will be able to complete the Baseline and Follow-Up ambulation exams and questionnaires at their Screening Visit. Assess subjects closely for their likely ability to perform the required study tests (e.g., 6-minute walk, Modified Emory Functional Ambulation Profile, GAITRite data capture, Berg Balance Assessment) prior to enrollment. If a potential subject is very unlikely to be able to perform the required testing at the Baseline and Follow-up visits, consideration should be given as to whether indeed to pursue enrollment.

Core Laboratory Reminders

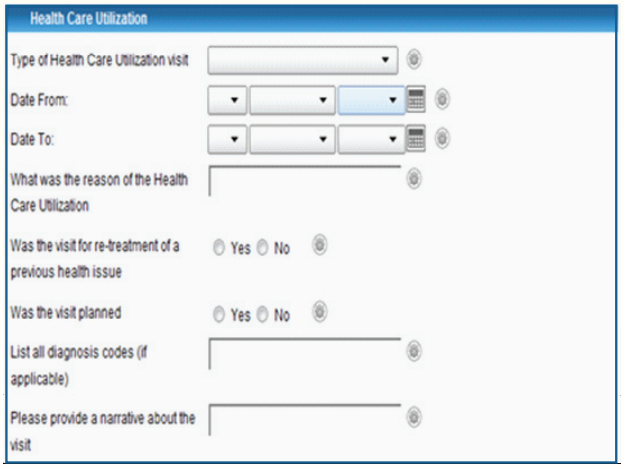
Continue to capture the GAITRite data for Baseline, 1M, 3M, 6M, and 12M follow-ups. Send the file to Dr. Besser at the Core Laboratory upon completion of the exam on the day of the subject's visit. This ensures the data is not outstanding for an extended amount of time and allows the Core Laboratory ample time to review the data.

Study Reminders

- Potential subjects who are screened and do not meet eligibility criteria at the Screening Visit are still given a $35 gift card for the travel associated with the screening visit (i.e., a screen failure).
- Sub-Investigators are required to complete necessary documentation prior to participation. This includes:
  - » Curriculum vitae signed and dated
  - » Financial disclosure provided in the INSTRIDE Study Binder
  - » Sub-Investigator agreement (by way of protocol signature page) provided in the INSTRIDE Study Binder
  - » Study training by an authorized study representative (Medpace, Monitor, or Innovative Neurotronics)
  - » Delegation of authority log (added by Primary Investigator) provided in the INSTRIDE Study Binder

Monitoring, EDC, and Safety

- Report Adverse Events (AEs) and Serious Adverse Events (SAEs) on the AE page in the Electronic Data Capture (EDC). Report AEs within 7 calendar days of notification of an event and SAEs within 24 hours of notification.
- Enter data into the Merge (previously "KIKA") EDC system when a study visit is complete. This data allows us to appropriately track the visits completed to date and assess study visit compliance on a site-by-site basis. If you have any questions on how to enter this information into the Merge EDC, contact your Medpace Clinical Study Associate.



Health Care Utilization (HCU)

Continue to make attempts to collect Health Insurance Claim Form (HCFA) and Uniform Billing Form (UB04) to list all necessary diagnosis codes on the form. If these are not obtained, enter a comment in the narrative section of the efforts made to unsuccessfully retrieve this information or N/A in the diagnosis codes section. Enter this information on the HCU form in the sections identified by arrows in the image in the EDC.

Study Time and Events Table

Investigational Plan Version 4

	Screening/ Randomization	Fitting	Baseline	1 Month	3 Month	6 Month	12 Month	Unscheduled Visit
		7 days (+/- 2)	14 days (+/- 2)	30 days from baseline (+/- 7)	90 days from baseline (+/- 14)	180 days from baseline (+/- 14)	365 days from baseline (+/- 28)	
Inclusion/Exclusion	X							
Informed Consent	X							
Randomization	X							
Demographics	X							
Body Weight/BMI	X		X	X	X	X	X	
Stroke History	X							
Physician Screening	X							
Medical History	X							
Medications	X		X	X	X	X	X	
Co-Morbidity	X							
Nerve Stimulation Test	X	X						
Device Fitting/Programming		X						
Review Device Parameters/ AFO Confirmation			X	X	X	X	X	X
Neurological Assessment	X							
Mental Status Exam	X							
Depression Scale	X							
SIS			X	X	X	X		
SSQoL			X			X		
Berg Balance			X			X		
6-Min Walk			X	X	X	X	X	
10-Meter Walk	X		X	X	X	X	X	
mEFAP			X	X	X	X	X	
GAITRite Data Capture			X	X	X	X	X	
Adverse Events		X	X	X	X	X	X	X
Protocol Deviations	X	X	X	X	X	X	X	X
HCU			X	X	X	X	X	X
Patient Diary			X	X	X	X	X	
Study Exit							X	

Project Team

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