



**INITIATIVE ON METHODS, MEASUREMENT, AND PAIN ASSESSMENT IN CLINICAL TRIALS / INSTITUTE OF NEUROMODULATION /
INTERNATIONAL NEUROMODULATION SOCIETY**

RESEARCH DESIGN CONSIDERATIONS FOR RANDOMIZED CLINICAL TRIALS OF SPINAL CORD STIMULATION FOR PAIN

NOVEMBER 14-16, 2018

WESTIN GEORGETOWN, WASHINGTON, DC

AGENDA

Wednesday, November 14, 2018

7:00 – 9:00 PM

Welcome Reception/Dinner

Location: Mayfair Court

Thursday, November 15, 2018

7:15-8:00 AM

Breakfast

Location: Washington Ballroom Foyer

8:00-8:15 AM

Welcome and introductions

Location: Washington Ballroom

- Richard North, MD, Simon Thomson, MD,
and Dennis Turk, PhD

8:15-9:00 AM

The history of research on the mechanisms, efficacy, and safety of spinal cord stimulation

- Richard North, MD

9:00-9:45 AM

SCS clinical trial objectives and research designs, including comparison groups and testing superiority vs. non-inferiority

- Rod Taylor, PhD

9:45-10:15 AM

Sources of bias in RCTs of SCS and their mitigation

- Nathaniel Katz, MD

10:15-10:45 AM

Break

10:45-11:15 AM

Evidence standards for device approval: regulatory perspectives

- Carlos Peña, PhD (CDRH)
- Rahul Singh, MD (MHRA)

11:15 AM -12:30 PM	<p>Group discussion: study objectives, designs, and bias</p> <ul style="list-style-type: none"> • Moderators: Salim Hayek, MD, and Nathaniel Katz, MD • Panelists: Richard North, MD; Carlos Peña, PhD; Rahul Singh, MD; Rod Taylor, PhD
12:30-1:30 PM	<p>Lunch Location: Mayfair Court</p>
1:30-2:00 PM	<p>Systematic review of methodologic characteristics and outcomes in RCTs of SCS for pain</p> <ul style="list-style-type: none"> • Ewan McNicol, PharmD
2:00-2:30 PM	<p>Inclusion/exclusion criteria (e.g., diagnoses, pain severity, pain duration, psychosocial vulnerabilities; treatment history, concomitant analgesics)</p> <ul style="list-style-type: none"> • John Markman, MD
2:30-3:00 PM	<p>Primary and secondary outcomes (e.g., pain, function, opioid sparing; duration of follow up)</p> <ul style="list-style-type: none"> • Ali Rezai, MD
3:00-3:30 PM	<p>Break</p>
3:30-4:00 PM	<p>Adverse events: assessment and reporting</p> <ul style="list-style-type: none"> • Salim Hayek, MD
4:00-5:30 PM	<p>Group discussion: inclusion/exclusion criteria, outcomes, and safety</p> <ul style="list-style-type: none"> • Moderator: Nathaniel Katz, MD, and Richard North, MD • Panelists: Salim Hayek, MD; John Markman, MD; Ewan McNicol, PharmD; Ali Rezai, MD
7:00 – 9:00 PM	<p>Dinner Location: Thomas Boardroom</p>

Friday, November 16, 2018

7:15-8:00 AM	<p>Breakfast Location: Washington Ballroom Foyer</p>
8:00-8:30 AM	<p>Study execution (e.g., controlling non-specific factors; programming standards; sponsor involvement; site and patient training; outcome assessment procedures) Location: Washington Ballroom</p> <ul style="list-style-type: none"> • Simon Thomson, MD

8:30-9:00 AM	Data analysis, interpretation, and reporting (e.g., pre-specification, estimands, missing data, multiplicity, clinical meaningfulness; responder definitions; “discerning hype from substance”) <ul style="list-style-type: none"> Jennifer Gewandter, PhD
9:00-9:30 AM	Economic outcomes and cost-effectiveness analyses <ul style="list-style-type: none"> Brian Kopell, MD
9:30-10:00 AM	Special issues in RCTs of SCS, including sham stimulation and programming comparisons <ul style="list-style-type: none"> Sam Eldabe, MD
10:00-10:30 AM	Break
10:30 AM -12:00 PM	Group discussion: study execution, analysis, interpretation and reporting <ul style="list-style-type: none"> Moderator: Nathaniel Katz, MD, and Ali Rezai, MD Panelists: Sam Eldabe, MD; Jennifer Gewandter, PhD; Brian Kopell, MD; Simon Thomson, MD
12:00-1:30 PM	Lunch Location: Thomas Boardroom
1:30-4:00 PM	Group discussion: recommendations for research methods, study execution, and reporting of RCTs of SCS Location: Washington Ballroom <ul style="list-style-type: none"> Moderators: Robert Dworkin, PhD, Nathaniel Katz, MD, and Rod Taylor, PhD
4:00 PM -	Departures