



Program for SCOPE Workshop

**Functional Recovery after Spinal Cord Injury:
Implications of Different Spinal Injury Patterns
and Distinct Therapeutic Targets on Clinical Trial Outcomes**

Date: Friday, November 14th, 2008

Location: Washington, DC
Hyatt Regency Crystal City,
2799 Jefferson Davis Highway,
Arlington, Virginia, USA 22202
located close to Washington METRO subway (blue and yellow lines)
Tel: +1 703 418 1234

Stakeholders (representatives from):

- SCI Foundations (13 worldwide, non-governmental organizations)
- Representatives from the community of people living with SCI
- American Spinal Injury Association (ASIA, professional society)
- International Spinal Cord Society (ISCoS, professional society)
- Corporate Industry Representatives (drugs, biological, devices)
- Food and Drug Administration (US Govt. Regulatory Agency)
- National Institute on Disability and Rehabilitation Research (NIDRR)
- National Institutes of Health (US Govt. Agency)
- Veterans Administration (US Govt. Agency)
- Expert Scientists and Clinicians (worldwide)

Program Outline

8:00 – 8:15	Introduction: John Steeves, Chair of SCOPE
8:15 – 9:15	<p>Session 1: What is the natural history progression and spontaneous recovery from each type of spinal injury?</p> <p>Topics:</p> <ul style="list-style-type: none">• Different severities and spinal levels of injury• Functional potential based on level and severity of SCI• Spontaneous rates of recovery for each type of SCI <p>Chair: Dan Lammertse</p> <p>Speakers/Panel Members: James Fawcett Steve Kirshblum John Ditunno Dan Graves Bill Donovan Jim Guest</p>
9:15 – 10:00	<p>Session 2: What are the processes for assessing validity and sufficiency of preclinical findings for entry into human study?</p> <p>Topics:</p> <ul style="list-style-type: none">• Animal models of SCI• Preclinical validation of discovery/invention• Preclinical development prior to human study <p>Chair: Naomi Kleitman</p> <p>Speakers/Panel Members: Audrey Kalehua Alexander Rabchevsky Oswald Steward David Howells</p>
10:00 – 10:30	Break

<p>10:30 – 12:00</p>	<p>Session 3: Outcomes – Part A What are the appropriate sensitive, accurate, and reliable outcomes for different clinical targets and/or clinical trial phases?</p> <p>Topics:</p> <ul style="list-style-type: none"> • Outcome tools for specific clinical targets: <ul style="list-style-type: none"> - Motor/Sensory - Autonomic nervous system related functions (Cardiovascular, Bladder, Bowel, Sexual Function, Sudomotor) - Pain - Function (Activities of Daily Living) - Quality of Life <p>Chair: Marcalee Alexander</p> <p>Speakers/Panel Members: Ralph Marino Eric Bastings Allen Heineman MJ Mulcahey Nancy Shinowara Art Sherwood Ann Costello</p>
<p>12:00 – 13:00</p>	<p>Working Lunch with FDA presentation</p> <p>Topic:</p> <ul style="list-style-type: none"> • FDA regulatory framework, process, timelines. <p>Chair: Joel Myklebust</p> <p>Speaker: Carlos Pena</p>

<p>13:00 – 14:30</p>	<p>Session 4: Outcomes – Part B What is a clinically meaningful important change and how do you establish accurate clinical endpoints or thresholds?</p> <p>Topics:</p> <ul style="list-style-type: none"> • Thresholds and Responder Analysis • Surrogate versus Functional Outcome Tools • Defining Clinically Meaningful Important Change • Different Trial Designs <p>Chair: Andrew Blight</p> <p>Speakers/Panel Members: Beverley Walters Huub van Hedel Suzanne Groah Billy Dunn Kim Anderson</p>
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<p>14:30 – 15:00</p>	<p>Break</p>
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<p>15:00 – 15:45</p>	<p>Session 5: What are common adverse events after spinal cord injury and how should they be tracked?</p> <p>Topics:</p> <ul style="list-style-type: none"> • Concomitant injuries • Neurological • Inflammation and infection • Pulmonary and cardiovascular • Autonomic functions • Musculoskeletal, spasticity • Pain • Metabolic • Psychosocial <p>Chair: Fin Biering-Sorensen</p> <p>Speakers/Panel Members: William Bauman Yao Yao Zhu Lance Goetz Keith Tansey</p>
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<p>15:45 – 16:30</p>	<p>Session 6: What are the confounding factors that distort accurate interpretation of trial findings?</p> <p>Topics:</p> <ul style="list-style-type: none">• Surgery, medication• Concomitant injuries• Pain, spasticity• Rehabilitation therapy• Education, financial <p>Chair: Amie Jackson</p> <p>Speakers/Panel Members: Malvina Eydelman Diana Cardenas Kevin O'Connor Claire Kalpakjian</p>
<p>16:30 – 17:00</p>	<p>Summary Discussion</p> <p>Chair: John Steeves</p> <p>Panel Members: Jim Harrop Celia Witten Suzy Kim Ken Curley</p>