



www.scope-sci.org

ANNUAL REPORT

July 1, 2014 - June 30, 2015

MISSION:

To enhance the development of clinical trial and clinical practice protocols that will accurately validate therapeutic interventions for spinal cord injury (SCI) leading to the adoption of improved best practices, as well as improved understanding of related neurological disorders. (www.scope-sci.org).

PARTNERS:

SCOPE is an academic-industry-community organization that has been operating for over 8 years.

SCOPE is currently co-chaired by Drs. John Steeves (ICORD, Vancouver, BC) and Andrew Blight (Acorda Therapeutics, Ardsley, NY), with administrative services (Lesley Hudson) provided under a contract with the ASIA central office (Atlanta, GA). SCOPE consists of representatives from:

- Corporate partners, including - Acorda Therapeutics, Asubio Pharmaceuticals, StemCells Inc., Asterias Biotherapeutics, DP Clinical
- Foundations - Craig H. Neilsen Foundation (CHN), Wings for Life Foundation (WFL), European Multicenter Study on SCI (EMSCI),
- Federal US agencies - (NIDRR, NIH, VA R&D, DoD);
- Clinical and scientific experts from various academic institutions and hospitals across the world

2014-2015 ACHIEVEMENTS

During the past fiscal year, SCOPE activities have escalated along several fronts, including:

1. Ongoing incomplete SCI (iSCI) Project (in conjunction with Dr. Armin Curt at Balgrist Hospital in Zurich and members of EMSCI): This long-term program of investigations is to develop mechanisms for inclusively enrolling trial participants with complete and incomplete SCI. It involves analysis of the EMSCI database (~3200 people), which is the world's most comprehensive SCI dataset tracking the patterns of neurological and functional recovery over the first year after injury. The goal is to determine objectively: (1) inclusion/exclusion criteria for iSCI trial participants; (2) to create mechanisms for stratifying participants into relatively homogenous study cohorts; and (3) to model (test) potential neurological and functional outcome measures for Phase II trials. Two publications (Tanadini et al. 2014, 2015) have been completed and more are in progress. The intent is to build a comprehensive study matrix for all types of traumatic SCI.

2. A meeting was held in New York City in February 2014 to discuss and debate whether a minimal clinically important difference (MCID) can be defined for SCI. The following topics were addressed: (1) concepts and constraints for the determination of MCID, (2) the contrasts between MCID and minimal detectable difference (MDD), (3) MCID within the different domains of International Classification of Functioning, disability and health, (4) the roles of clinical investigators and clinical participants in defining MCID and (5) the implementation of MCID in acute versus chronic spinal cord injury (SCI) studies. Estimation of an MCID for SCI remains elusive. In the interim, if the target of a therapeutic is the injured spinal cord, it is most desirable that any improvement in neurological status be correlated with a functional (meaningful) benefit.
3. SCOPE led 2 workshops in 2014 (ASIA and ISCoS annual meetings). The ASIA workshop (May 15, 2014) provided an update on the status of several ongoing clinical trials. The ISCoS workshop (September 3, 2014) focused on a public discussion and debate surrounding MCID (see above).
4. SCOPE partnered with the Craig H. Neilsen (CHN) Foundation to coordinate a 2-day workshop in Philadelphia (January 9-10, 2015) on functional upper extremity (UE) outcome measures for clinical trials. A peer-reviewed manuscript will be submitted for publication. Some of the preliminary findings were: (1) there are several available and somewhat overlapping tools to track functional UE outcomes after SCI. (2) there is a lack of outcome tools to adequately track volitional performance recovery after mild (AIS-D) SCI. (3) Beyond surveys, outcome tools for other therapeutic targets, such as bladder, bowel, and sexual functions have yet to be incorporated into clinical trials. (4) Rasch modeling may help determine which outcome items are accurately tracking functional transitions after SCI.
5. In collaboration with Asubio Pharmaceuticals, SCOPE has incorporated a new project focused on Rasch modeling of neurological and functional outcomes after SCI. This project is being directed out of Vancouver by Dr. Steeves. The intent is to develop a “ruler” that might be used to track and measure clinical trials outcomes across an inclusive range of SCI types. The preliminary data looks promising. To date, tetraplegic and paraplegic SCI participants with both complete and incomplete SCI can be fitted to and tracked along a common “ability ruler” measuring change in volitional performance after SCI. Improvements in volitional performance are considered a valuable clinical endpoint for detecting therapeutic benefit for treatments targeted to the CNS.
6. SCOPE will hold a workshop in Montreal on May 17, 2015 (immediately after the joint ISCoS –ASIA annual meeting) to discuss lower extremity (LE) functional outcome measures. This workshop will have similar goals to those outlined above for UE functional outcomes.
7. SCOPE continues to provide quarterly online updates (www.scope-sci.org) by Dr. Dan Lammertse of ongoing SCI clinical trials that are formatted into two separate tables:
 - a. Current SCI Clinical Trials of Drug, Cell, and Surgical Interventions to Improve Neurological and Related Functional Outcomes
 - b. Current SCI Clinical Trials of Rehabilitation and Technological Interventions to Improve Functional Outcomes
8. SCOPE participated in a NINDS/NIH-coordinated effort to define Common Data Elements (CDEs) for various outcomes after SCI to improve comparisons across different studies. The CDEs are available online (www.commondataelements.ninds.nih.gov)

CONTINUING GOALS:

1. To facilitate communication and coordination of effort among basic scientists, clinical researchers, academic institutions, industry, government agencies, and not-for-profit foundations.
2. To foster collaboration among all stakeholders in their common goal to improve functional outcomes and quality of life for people living with SCI so they may participate more fully within society.

3. To identify accurate, sensitive, and reliable outcome tools that measure a clinically meaningful benefit for specific body functions, daily activities, community participation, and quality of life that have been altered by SCI.
4. To foster clinical trial protocols that lead to the adoption of the most effective best practices for the treatment and care of individuals living with SCI. Where warranted, to facilitate and establish guidelines for clinical trial protocols and outcomes, clinical practice, and community access and integration.
5. To continually track and provide online updates of relevant SCI clinical trials and where possible, integrate new knowledge (e.g. relevant datasets) into SCOPE activities.
6. To disseminate widely the teaching of valid therapeutic interventions for SCI through all available media.

CURRENT SCOPE COMMITTEE MEMBERS

- John Steeves, Ph.D., Co-Chair, ICORD, Vancouver, BC
- Andrew Blight, Ph.D., Co-Chair, Acorda Therapeutics
- Lesley M. Hudson, M.A., ASIA/SCOPE Executive Director
- Kim Anderson, Ph.D., University of Miami
- Theresa Cruz, Ph.D., National Center for Medical Rehabilitation Research (NCMRR)
- Kenneth Curley, M.D., US Department of Defense
- Armin Curt, M.D., Balgrist Research Hospital, Zurich and EMSCI
- James Guest, M.D, Ph.D., University of Miami
- Stephen Huhn, M.D., StemCells, Inc.
- Lyn Jakeman, Ph.D., NINDS/NIH
- Linda Jones, MS, PT, Craig H. Neilsen Foundation
- Steven Kirshblum, M.D., Kessler Institute for Rehabilitation
- Naomi Kleitman, Ph.D., Craig H. Neilsen Foundation
- Audrey Kusiak, Ph.D., Veterans Administration R&D
- Daniel P. Lammertse, M.D., Craig Hospital
- Benjamin Levinson, M.D., Asubio Pharmaceuticals
- MJ Mulcahey, OTR/L, Ph.D., Thomas Jefferson Medical University
- Devinder Poonian, DP Clinical
- Jan Schwab. M.D., Wings for Life
- Arthur Sherwood, P.E., Ph.D., International Society for Restorative Neurology
- Edward Wirth, M.D., Asterias BioTherapeutics

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