Working2Walk 2018

Building Advocacy, Empowerment, and Unity towards Finding Cures for Paralysis

October 19 & 20, 2018
Vancouver, Canada

unite2fight paralysis

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PUSH to WALK
Redefining Possibilities for the
Spinal Cord Injury and Paralysis Community

Contents

What Are You Gonna Do When You Get Home?

October 19, 2018

This is the question we've been asking ourselves - and we want each of you to ask yourselves - as we've designed and developed our 13th annual Working 2 Walk Science & Advocacy Symposium.

We've developed a maxim that we hope breaks us out of the conference inertia cycle and instead creates more opportunities for your direct input. We call it **Context, Strategy, Voice**. Here's what it means:

• **Context:** the SCI Community must understand the broader context within which the scientific and clinical enterprise is operating. Relatedly, the Research Enterprise must better understand the context of the lived experience with SCI, so that the targets being sought match our Community's priorities. Without this interdependent context, we're all left swimming in a sea of press releases, donation requests and ambitious (and sometimes) misleading promises.

• **Strategy:** once we have a better and more realistic understanding of the context, we can then make intelligent and factually based decisions on strategic initiatives. How and in what areas do we place our people resources, our dollars and our efforts to ensure that we arrive at our goal of realizing cures? But also, how do we ensure that cures are available to all and optimized for all...across the planet?

• **Voice:** It is only with a good understanding of the context that we can develop realistic and effective strategies that build an effective chorus of voices from amongst the community and our various stakeholders. And it is with that effective and collective voice that we can demand the cures we seek.

We are foregoing our typical breakout sessions at W2W this year by replacing it with a facilitated SCI community-centric discussion.

We intend to identify strategies within the 4 areas listed below for the SCI community to become actively involved in effective advocacy:

Public Policy Initiatives (in 2 areas):
-Catalyzing the Research by involving and maturing the SCI community's Voice and building effective collaborations between the SCI community and our various stakeholders.
-Building Capacity for Exercise, Fitness and Rehabilitation/Recovery for the paralysis community to include health and well-being, preparation for curative interventions and post treatment optimization.

Bring our Advocacy Voice to the FDA: in anticipation of interventions for SCI for which there is currently no clear pathway. How do we start? Why is it necessary now? When?

Avoiding Tokenism: how can the SCI Community influence the Research Enterprise in a more meaningful way?

Increasingly, funders acknowledge that it is critical for the SCI Community to be a part of the research process. How can we develop research teams where the Community has a meaningful and active role in and throughout the research continuum; from defining research questions, developing protocols, through to dissemination and implementation?

Exploration of Areas for Complementary Work: How can SCI led/focused organizations reduce redundancy and competition in favor of amplifying our work in a more coordinated and strategic fashion? What are some practical ways that SCI led/focused organizations can effectively support the 4 initiatives above?

We trust that everyone here wants the same thing: more progress, and faster progress. We believe that we can help to make that happen - **Together**.

And finally - but importantly - **Don't Forget to Thank a Sponsor.** This conference happens because a few organizations write checks to underwrite expenses. Take a moment to speak to them. Let them know how much it means to you that they're here for us.

Onward!
Your friends at Unite 2 Fight Paralysis

SCHEDULE OF EVENTS

THURSDAY, OCTOBER 18, 2018
ARRIVAL DAY

5:00-7:00 pm
Early Registration & Check-In
Minoru Foyer

FRIDAY, OCTOBER 19, 2018

7:30-9:00 am
Registration & Full Plated Breakfast – ***Exhibitor Visits***
Minoru Foyer

8:45 am-5 pm
General Session
Grand Minoru Ballroom

8:50-9:10 am
Opening Remarks
Matthew Rodreick | Unite 2 Fight Paralysis
Bill Barrable, MHS | Rick Hansen Institute

9:10-9:30 am
So You've Suffered a Spinal Cord Injury, They Say You'll Never Walk Again, You Say You Will - Now What Are You Going to Do About It?
Barry Munro, BA, LLB | Canadian/American Spinal Research

9:30-9:50 am
Spinal Cord Neuromodulation for Restoration of Autonomic Cardiovascular Function in Individuals with Spinal Cord Injury
Andrei Krassioukov, MD, PhD, FRCPC | ICORD

9:50-10:00 am
Question & Answer Session

10:00-10:20 am
Activity and Physical Therapy After Incomplete SCI in the Rat
David Magnuson, PhD | University of Louisville

10:20-10:30 am
Question & Answer Session

10:30-11:00 am
Break – *Exhibitor Visits*

11:00-11:20 am
Spinal Cord Epidural Electrical Stimulation: An Update on Motor and Mobility Outcomes
Megan Gill, PT, DPT, NCS | Mayo Clinic

11:20-11:30 am
Question & Answer Session

FRIDAY, OCTOBER 19, 2018 (continued)

11:30-11:50 am — **Panel Discussion**
David Magnuson, PhD | University of Louisville
Andrei Krassioukov, MD, PhD, FRCPC | ICORD
Megan Gill, PT, DPT, NCS | Mayo Clinic
Lyn Jakeman, PhD | NINDS - Moderator

11:50-12:10 pm — **Table Discussion**

12:10-12:30 pm — **Follow-Up Panel Discussion**
David Magnuson, PhD | University of Louisville
Andrei Krassioukov, MD, PhD, FRCPC | ICORD
Megan Gill, PT, DPT, NCS | Mayo Clinic
Lyn Jakeman, PhD | NINDS - Moderator

12:30-1:30 pm — **Lunch – *Exhibitor Visits***

1:30-1:50 pm — **The Breadcrumb Path from Bench to Bedside**
Lyn Jakeman, PhD | NINDS

1:50 -2:00 pm — **Question & Answer Session**

2:00-2:20 pm — **Biomarkers of Acute Spinal Cord Injury**
Brian Kwon, MD, FRCSC, PhD | ICORD

2:20-2:30 pm — **Question & Answer Session**

2:30-2:50 pm — **Locomotor Recovery Following Moderate or Severe Contusive Spinal Cord Injury does not Require Oligodendrocyte Remyelination**
Wolfram Tetzlaff, MD, PhD | ICORD

2:50- 3:00 pm — **Question & Answer Session**

3:00-3:30 pm — **Break – *Exhibitor Visits***

3:30-3:50 pm — **Panel Discussion**
Brian Kwon, MD, FRCSC, PhD | ICORD
Wolfram Tetzlaff, MD, PhD | ICORD
Lyn Jakeman, PhD | NINDS - Moderator
Karim Fouad, PhD | University of Alberta

3:50-4:15 pm — **Table Discussions**

4:15-4:35 pm — **Follow-up Panel Discussion**
Lyn Jakeman, PhD | NINDS - Moderator
Brian Kwon, MD, FRCSC, PhD | ICORD
Wolfram Tetzlaff, MD, PhD | ICORD
Karim Fouad, PhD | University of Alberta

4:35-4:55 pm — **Welcome Message**
Rick Hansen, Rick Hansen Foundation

5:00-7:00 pm — **NETWORKING RECEPTION**
Cavu Bar & Lounge

Dinner on your own

SATURDAY, OCTOBER 20, 2018

8:00-8:45 am	**Registration & Full Plated Breakfast** – ***Exhibitor Visits*** Minoru Foyer
9:00-9:10 am	**Opening Remarks & Welcome** Matthew Rodreick | Unite 2 Fight Paralysis
9:10-9:30 am	**The Path to Resolving Bowel & Bladder Problems Following Spinal Cord Injury is Becoming Clear** Tracey Wheeler, PhD | Craig H. Neilsen Foundation
9:30-9:50 am	**Non-invasive Genital Nerve Stimulation for Neurogenic Bladder** Dennis Bourbeau, PhD | Cleveland FES Center
9:50-10:00 am	**Question & Answer Session**
10:00-10:20 am	**Nerve Transfer to Restore Bladder Function After Spinal Cord Injury** Justin Brown, MD | Massachusetts General Hospital
10:20-10:30 am	**Question & Answer Session**
10:30-11:00 am	**Break – *Exhibitor Visits***
11:00-11:20 am	**Sexual and Fertility Rehabilitation after SCI** Stacy Elliott, MD | ICORD
11:20-11:30 am	**Question & Answer Session**
11:30-11:50 am	**Panel Discussion** Stacy Elliott, MD | ICORD Dennis Bourbeau, PhD | Cleveland FES Center Justin Brown, MD | Massachusetts General Hospital Tracey Wheeler, PhD | Craig H. Neilsen Foundation - Moderator
11:50-12:15 pm	**Table Discussion**
12:15-12:30 pm	**Follow-up Panel Discussion** Stacy Elliott, MD | ICORD Dennis Bourbeau, PhD | Cleveland FES Center Justin Brown, MD | Massachusetts General Hospital Tracey Wheeler, PhD | Craig H. Neilsen Foundation - Moderator
12:30-1:30 pm	**Lunch – *Exhibitor Visits***

1:30-1:50 pm

Promoting the Effect of Rehabilitative Training following Spinal Cord Injury in Animal Models

Karim Fouad, PhD | University of Alberta

1:50-2:00 pm

Question & Answer Session

2:00-2:20 pm

Acute Intermittent Hypoxia: a Scientific and Personal Odyssey

Tommy Sutor, MS, CSCS | University of Florida

2:20-2:40 pm

Paying for After-Hospital Rehabilitation Through State Legislation

Dale Hull, MD, MPA | Neuroworx

2:40 -3:00 pm

Panel Discussion

Karim Fouad, PhD | University of Alberta
Tommy Sutor, MS, CSCS | University of Florida
Dale Hull, MD, MPA | Neuroworx
David Magnuson, PhD | University of Louisville - Moderator

3:00-3:30 pm

Break – *Exhibitor Visits*

3:30 pm

Context-Strategy-Voice: A Discussion on the SCI Community's Role in Expediting Cures

- Public Policy Initiatives
  a) Catalyzing the Research
  b) Building Capacity for Exercise, Fitness & Rehabilitation/Recovery
- Bring our Advocacy Voice to the FDA
- Avoiding Tokenism
- Exploration of Areas for Complementary Work

End of Conference

NOTES


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SPONSOR EXHIBITORS

Our sponsors help make Working 2 Walk possible - they also provide a tremendous array of resources, services and products for the SCI Community. Sponsors will be available at several exhibit tables in the Minoru Foyer area outside of the Minoru Ballroom. Please take a moment to stop by and learn more about their unique offerings for our Community.

GET CONNECTED

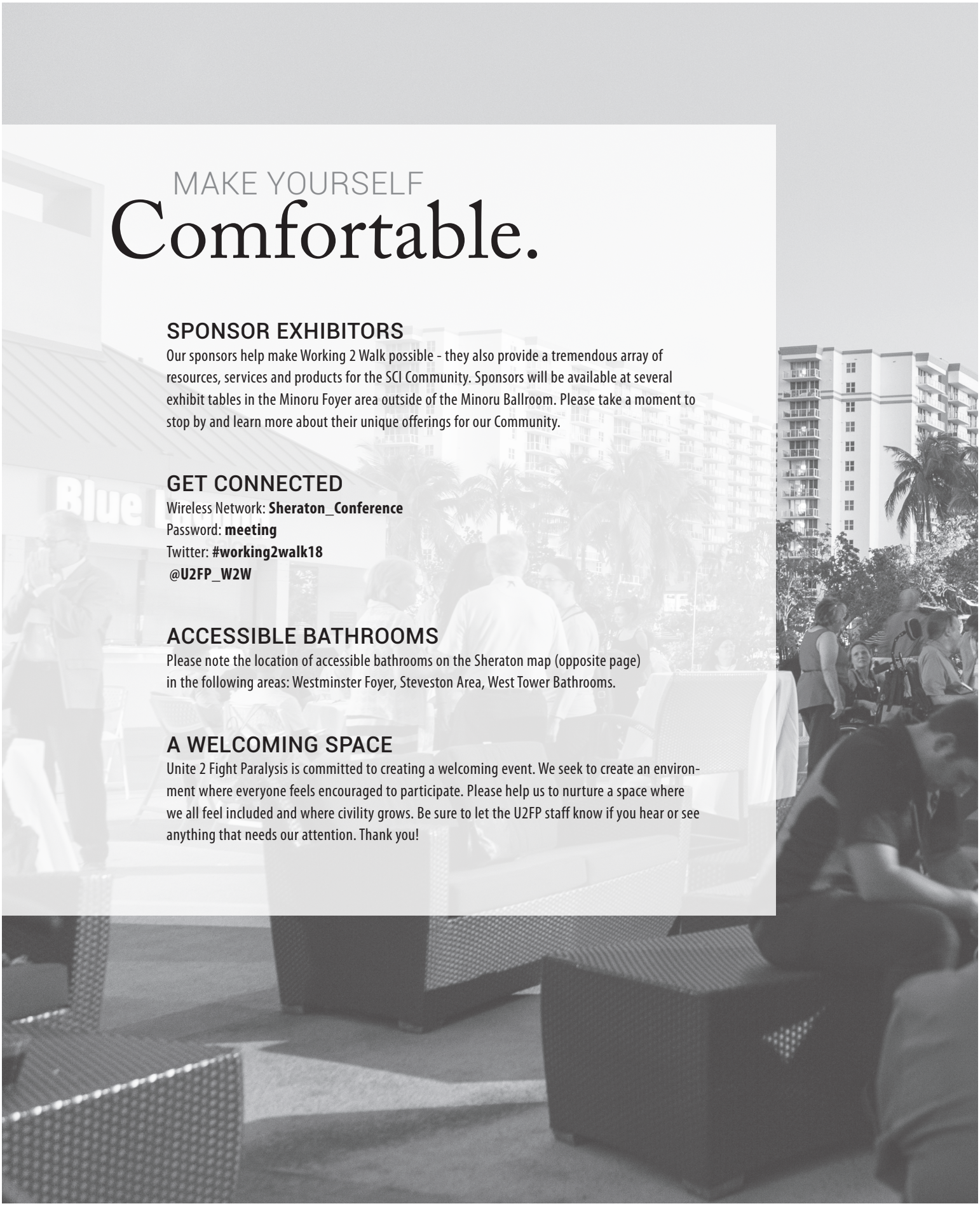
Wireless Network: **Sheraton_Conference**
Password: **meeting**
Twitter: **#working2walk18**
@U2FP_W2W

ACCESSIBLE BATHROOMS

Please note the location of accessible bathrooms on the Sheraton map (opposite page) in the following areas: Westminster Foyer, Steveston Area, West Tower Bathrooms.

A WELCOMING SPACE

Unite 2 Fight Paralysis is committed to creating a welcoming event. We seek to create an environment where everyone feels encouraged to participate. Please help us to nurture a space where we all feel included and where civility grows. Be sure to let the U2FP staff know if you hear or see anything that needs our attention. Thank you!



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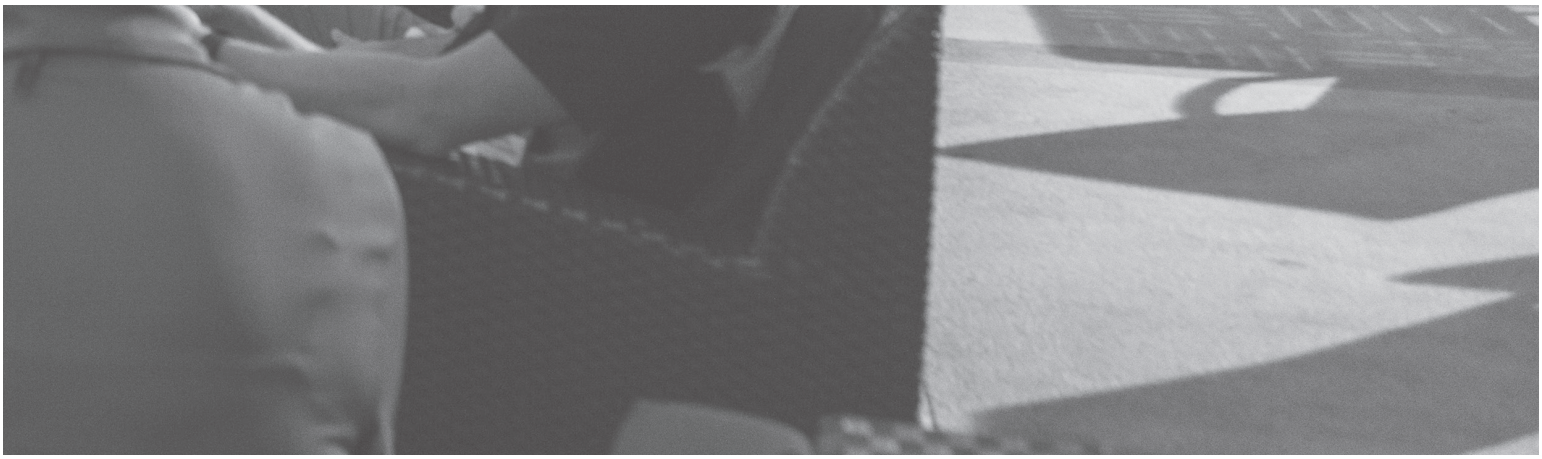


SPEAKER **BIOS**

A first-class line up of presenters from across the Scientific & Advocacy communities

Dennis Bourbeau, PhD |

Research Investigator, Louis Stokes Cleveland VA Medical Center; Staff Scientist, MetroHealth Medical System; Assistant Professor, Case Western Reserve University School of Medicine

Dennis Bourbeau is a research scientist with appointments at the Louis Stokes Cleveland VA Medical Center, the MetroHealth Medical Center, and Case Western Reserve University School of Medicine. Dr. Bourbeau's research focuses on understanding the neural mechanisms underlying control of pelvic autonomic functions, including bladder, bowel, and sexual function, and on developing approaches that use electrical stimulation to restore these functions when lost to spinal cord injuries or other neurological disorders. Such approaches would provide alternatives to surgeries or drugs. With his collaborators, he has conducted translational studies with human study participants with spinal cord injury using electrical stimulation to inhibit unwanted bladder contractions and improve urinary continence. Other projects include electrical stimulation to inhibit unwanted reflex sphincter contractions to improve bladder emptying; wireless bladder and bowel sensors for automatic control of these electrical stimulation approaches; and electrical stimulation to improve colonic motility for individuals with chronic constipation.

Justin Brown, MD |

Associate Professor of Neurosurgery at Massachusetts General Hospital; Director, Reconstructive Neurosurgery

Dr. Brown is a board-certified neurosurgeon focused on restoring movement following trauma and paralyzing injuries to the peripheral nerves, spinal cord and brain. He repairs nerves, optimizes function and recovers movement of the extremities. Dr. Brown began his career as a member of the Neurosurgery faculty of Washington University in St. Louis, where he helped lead the Center for Nerve Injury and Paralysis in collaboration with the Division of Plastic and Reconstructive Surgery. After that, he established the UC San Diego Paralysis Center, expanding the paralyzing disorders treated to include spinal cord injuries as well as stroke and brain injuries. This center was unique as a comprehensive paralysis center treating all forms of paralysis. Dr. Brown has recently relocated to Boston, where he is collaborating with other doctors at Harvard's Massachusetts General Hospital and Spaulding Rehabilitation Network to establish the East Coast's first comprehensive paralysis center.

Stacy Elliott, MD |

Medical Director, BC Centre for Sexual Medicine and Vancouver General Hospital; Professor, University of BC

Dr. Stacy Elliott is a Sexual Medicine Physician whose interests lie in the sexual and reproductive consequences of medical or surgical problems, particularly neurological disability. She is a Clinical Professor in the Departments of Psychiatry and Urologic Sciences, a PI at International Collaboration of Repair Discoveries (ICORD), University of British Columbia. Dr. Elliott is an internationally recognized expert in sexual rehabilitation and fertility following spinal cord injury, and in 2012, received the QE II Jubilee medal for her work. In 2014, she was also awarded the Rick Hansen Difference Maker Award for her continuing work in sexual rehabilitation for those with neurological disability. She sits on several national and international academic committees, advisory boards, and invited guideline consensus and clinical practice panels, teaches at the Medical School, and works with post-doctoral students in her research. She is the author of many peer-reviewed journal articles and book chapters.

Karim Fouad, PhD | *Professor, Rehabilitation Medicine Physical Therapy, University of Alberta*

Karim Fouad, PhD is a Canada Research Chair in Spinal Cord Injury and a professor in the Faculty of Rehabilitation Medicine at the UofA. He studied Biology in Germany, where he also did his PhD in neuroscience. This was followed by postdoctoral fellowships at the University of Alberta in Canada and the University and ETH in Zürich, Switzerland which focused on the control of locomotor function and neuronal regeneration following spinal cord injury respectively. He is experienced in in vivo electrophysiology and behavioral testing in a variety of animal models of injuries and diseases of the nervous system. His research focuses on understanding and promoting neuroplasticity following spinal cord injury and rehabilitative training in animal models.

Megan Gill, PT, DPT, NCS | *Physical Therapist, Mayo Clinic*

Megan is a clinician-researcher at Mayo Clinic, Rochester, Minnesota in the field of physical therapy for individuals with spinal cord injuries. She has worked with the SCI population for 14 years and currently works on research activities geared to recovery of motor activation and locomotion, specifically epidural stimulation and exoskeleton gait training. She is an active board member for two non-profit foundations, Chris Norton Foundation and the NeuroHospital House.

Rick Hansen | *Founder & CEO, Rick Hansen Foundation*

Rick Hansen, C.C., O.B.C., six-time Paralympic medalist, is a Canadian icon best known as the "Man In Motion" for undertaking an epic 26 month, 40,000 km journey around the world in his wheelchair. He is the Founder and CEO of the Rick Hansen Foundation, an organization committed to creating a world without barriers for people with disabilities.

Dale Hull, MD, MPA | *Executive Director, Neuroworx*

Dr. Dale Hull is a 1985 graduate of the University of Utah School of Medicine. This was followed by a residency in Obstetrics and Gynecology at the University of Utah Medical Center. He was in private practice from 1989 to 1999 in the Salt Lake City metropolitan area. In 1999, he experienced a spinal cord injury resulting in teraplegic paralysis. The next two and half years were spent with outpatient rehabilitation efforts working with physical therapist Jan Black. Unable to return to active practice, Hull and Black teamed up in 2004 to co-found Neuroworx, a not-for-profit, innovative, community-based, outpatient physical and occupational therapy clinic. The facility provides specialized and focused therapy for adults and children experiencing paralysis due to spinal cord injuries, brain injuries, stroke, cerebral palsy, and similar neurological conditions. Dr. Hull completed a Master of Public Administration degree in 2012. He currently serves as the Neuroworx Executive Director.

Lyn Jakeman, PhD | *Program Director, Repair and Plasticity, National Institute of Neurological Disorders and Stroke*

Lyn Jakeman earned her Ph.D. in Neuroscience from the University of Florida, and did postdoctoral research at Genentech, Inc. She then worked as a staff scientist at Syntex Research in Palo Alto, CA. From 1999-2013, Dr. Jakeman was on the faculty in the Department of Physiology and Cell Biology at the Ohio State University, where she ran a research lab seeking to understand the role of glial cells and the extracellular matrix in repair after spinal cord injury. Lyn currently works as a program director at the National Institutes of Health (NIH) in Bethesda MD.

Andrei Krassioukov, MD, PhD, FRCPC | *Professor, University of BC; Chair in Rehabilitation Research, ICORD*

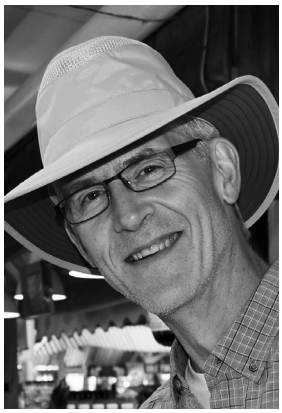
Andrei Krassioukov is a professor at the Department of Medicine, and Associate Director of the International Collaboration on Repair Discovery (ICORD) at the University of British Columbia, Vancouver. Dr. Krassioukov also holds an endowed Chair in Spinal Cord Rehabilitation Research. He is also a staff physician at the spinal cord injury program at the GF Strong Rehabilitation Centre. His research is focused on autonomic dysfunctions following spinal cord injury (SCI). His research is supported by grants from the Canadian Institute for Health Research, Heart and Stroke Foundation, Canadian Foundation for Innovation, Rick Hansen Institute/Foundation, Craig Neilsen Foundation, Christopher and Dana Reeve Foundation, Wings for Life and many others. Dr. Krassioukov's work in the area of SCI has been recognized through numerous national and international awards including the inaugural Alan Brown Award from ASIA. Just recently Dr. Krassioukov was inducted as a fellow of the Canadian Academy of Health Sciences. Presently, Dr. Krassioukov is a President–Elect of the American Spinal Injury Association (ASIA).

Brian Kwon, MD, FRCSC, PhD | *Canada Research Chair in SCI; Professor, University of BC; Associate Director, ICORD*

Dr. Kwon is a Professor in the Department of Orthopaedics at the University of British Columbia, the Canada Research Chair in Spinal Cord Injury, and holds the Dvorak Chair in Spine Trauma. He is an attending spine surgeon at Vancouver General Hospital, a level 1 trauma center and regional referral center for spinal cord injuries (SCI). He is also a research scientist at the International Collaboration on Repair Discoveries (ICORD). As a surgeon-scientist, he is particularly interested in the bi-directional process of translational research for spinal cord injury. He has worked extensively on establishing biomarkers of human SCI to understand the biology of human injury and to better stratify injury severity and improve the prediction of neurologic outcome. Dr. Kwon has led the development of a novel large animal model of SCI and is utilizing this for both bench-to-bedside and bedside-back-to-bench translational studies.

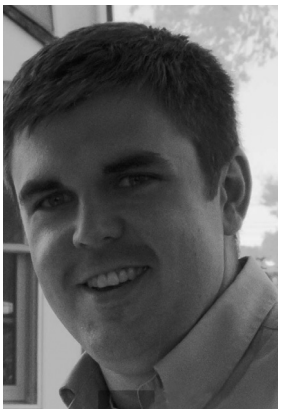
David Magnuson, PhD | *Friends for Michael Endowed Professor, University of Louisville*

After completing a BSc degree at the University of Victoria, Dr. Magnuson did postdoctoral research at University College London and at the University of Ottawa. After three years as a faculty member at the University of Manitoba, Dr. Magnuson joined the Department of Neurological Surgery at the University of Louisville and was a founding member of the Kentucky Spinal Cord Injury Research Center. In Louisville his research efforts have focused on spinal cord circuitry, the central pattern generator for locomotion, plasticity, rehabilitation and how activity influences functional recovery after SCI. Most recently his laboratory has explored the influence of activity & stretching on locomotor recovery and cardiovascular function after incomplete SCI.



Barry Munro, BA, LLB | *Chief Development Officer, CSRO*

Barry Munro is the Chief Development Officer of the Canadian Spinal Research Organization and the Ontario Neurotrauma Foundation and director of the American Spinal Research Organization. In 1987, Barry sustained a spinal cord injury in a diving accident, which resulted in quadriplegia. Barry has sat on multiple boards advocating for people with disabilities and particularly spinal cord injury research. Barry graduated from Law School in 1994 and was called to the Bar in 1996. Barry practiced personal injury law for over 10 years. Barry's legal experience combined with 30 years of practical experience living with a spinal cord injury make him a formidable advocate for the disabled community. Barry has dedicated the majority of his life to assisting people living with disabilities and improving their quality of living. Barry has also been instrumental as a Board Member with organizations such as Ontario Neurotrauma Foundation, the Canadian Spinal Research Organization and Charities First of Ontario.



Tommy Sutor, MS, CSCS | *PhD Candidate in Rehabilitative Science, University of Florida*

After initially pursuing a career in strength and conditioning, Tommy spent four years as an activity-based exercise trainer for people with spinal cord injuries. He was both intrigued and frustrated by how motor function and health outcomes from activity-based exercise were so variable – some people made more substantial gains than others. Tommy wanted to find a way to make activity-based exercise more effective and more efficient for more people, especially with chronic, functionally complete injuries. He is currently pursuing a PhD in rehabilitation science, investigating neuromodulation techniques to enhance the effects of activity-based training. His dissertation focuses on how acute intermittent hypoxia may enhance breathing, sitting, and standing function for people with chronic spinal cord injury. Tommy's overall career goal is to find ways to restore lost motor function, and to collaborate with people in other branches of science to work towards finding a cure for chronic spinal cord injury.

Wolfram Tetzlaff, MD, PhD | *John and Penny Ryan BC Leadership Chair in SCI Research; Professor, University of BC*

Wolfram Tetzlaff obtained his MD degree in Germany and his PhD in Canada. This was followed by faculty appointments at the Universities of Calgary, Ottawa and British Columbia, where he holds the John and Penny Ryan BC Leadership Chair in Spinal Cord Injury Research. He serves as the Director of ICORD, International Collaboration on Repair Discoveries and leads a research program focusing on experimental strategies for neuroprotection and neural repair after spinal cord injury (SCI). In particular, his group found that diets affect the cascades of secondary damage after spinal cord injury and can improve outcomes; and that a skin-derived progenitors when differentiated into Schwann cells can be used for neural repair in the chronically injured rodent spinal cord. More recently, he focused on the role of endogenous oligodendrocytes progenitor cells in spontaneous repair after SCI. Dr. Tetzlaff's work is funded by CIHR, Wings-for-Life, NSERC, Craig H. Neilsen, Spinal-Research and the MS Society.

Tracey Wheeler, PhD | *Program Officer, Craig H. Neilsen Foundation*

Tracey Wheeler, PhD., is a Program Officer at the Craig H. Neilsen Foundation. She manages the spinal cord injury (SCI) translational research portfolio which is designed to improve understanding and advance current treatment of SCI. The scope of this portfolio is broad, encompassing mechanistic, preclinical modeling, translational and/or clinical research to address gaps in the field and develop novel approaches. Tracey has over 18 years of experience in scientific program development, research evaluation, and program management of pre-clinical, translational, and clinical research. She worked as a scientific consultant and staff advisor at Defense Advanced Research Projects Agency (DARPA) in the areas of biomedical and biotechnology research, with a strong emphasis on technologies designed to communicate with the human nervous system. She has numerous publications on topics ranging from emerging brain-computer-interface technologies to bowel and bladder research priorities following spinal cord injury.

SPEAKER Abstracts

NON-INVASIVE GENITAL NERVE STIMULATION FOR NEUROGENIC BLADDER

Dennis Bourbeau, PhD | Research Investigator, Louis Stokes Cleveland VA Medical Center; Staff Scientist, MetroHealth Medical System; Assistant Professor, Case Western Reserve University School of Medicine

Neurogenic detrusor overactivity (NDO) following spinal cord injury (SCI) can cause urinary incontinence and reduced bladder capacity. It can also result in ureteric reflux and kidney damage, trigger episodes of autonomic dysreflexia, and significantly impact an individual's quality of life. Current clinical strategies for managing NDO are often limited by lack of effect, side effects, and invasiveness. Electrical stimulation of the genital nerves (GNS) has been shown to strongly inhibit reflex bladder contractions and acutely increase bladder capacity. However, it is unknown if chronic, take-home GNS can improve urinary continence or help meet individuals' bladder management goals during sustained use.

Five men with SCI and NDO were provided with portable stimulators for at-home GNS. Subjects completed a one-month control period without stimulation, followed by one month of using GNS at home to manage their bladders, and a finally another one-month period without stimulation. Subjects maintained a voiding diary; bladder capacity and quality of life assessments were conducted after each treatment period; and a satisfaction survey was completed at the end of the study.

Subjects applied GNS either continuously or on-demand for 5-30 minutes per use 2.3±2.8 times per day. Leakage events significantly decreased during the stimulation period, from 1.0±0.5 to 0.1±0.4 leaks per day (n=4). One subject, who used a condom catheter and leg bag, did not record incontinence episodes in any period, but reported no unintentional voiding into his leg bag. All subjects were satisfied that GNS met their bladder goals; wanted to continue using GNS; and would recommend it to others.

In conclusion, short term GNS at home can help reduce urinary incontinence and help subjects meet their bladder management goals. The feasibility and effectiveness of long-term chronic GNS to improve bladder control for individuals with SCI and NDO needs to be further tested.

SURGICAL NERVE TRANSFER APPROACH TO POTENTIAL BLADDER REINNERVATION

Justin Brown, MD | Associate Professor of Neurosurgery at Massachusetts General Hospital; Director, Reconstructive Neurosurgery

The lower urinary tract is controlled by a complex neural circuit between the brain, spinal cord, inferior mesenteric ganglia and peripheral pelvic plexus that coordinates urine storage and emptying. Severe spinal cord injuries can result in loss of bladder control and often a spastic bladder. When this injury is within the lumbar spine, involving the conus or cauda equina or even the pelvic plexus just outside of the spine, this can cause a lower motor neuron lesion leading to a flaccid bladder with detrusor areflexia. Long-term consequences of either scenario can be as severe as renal failure and recurrent urinary infections are common. Epidemiological studies suggest that regaining bladder continence in patients with spinal cord injury improves quality of life, aids reintegration into the community and helps prevent clinical complications.

Studies show that while transfer of either a mixed sensory and motor nerve or a primarily motor nerve can reinnervate the bladder, using a primarily motor nerve provides greater return of nerve-evoked detrusor contraction. This surgical approach may be useful for patients with either upper or lower motor injury to accomplish bladder emptying.

SEXUAL AND FERTILITY REHABILITATION AFTER SPINAL CORD INJURY

Stacy Elliott, MD | Medical Director, BC Centre for Sexual Medicine and Vancouver General Hospital; Professor, University of BC

Sexual function is a huge priority for persons with spinal cord injury (SCI), ranked either first or second in terms of importance in quality of life after SCI. This relatively neglected area of rehabilitation has been highlighted with the advent of Viagra and the rise

of social media. For men, the use of PDE5i and penile injections has mainly resolved the issue of unreliable erectile function, but ejaculation and orgasm still remain elusive to more than 75% and 50%, respectively. For women, there is no specific medication for arousal disorders or orgasmic dysfunction after SCI. Experience over time, having an intimate partner, and having an incomplete injury versus complete injury bode better for orgasmic release for both sexes. Some persons experience autonomic dysreflexia with sexual practices (particularly with ejaculation and orgasm) which may require prophylactic medications, while others experience mild to moderate dysreflexia which over time can be morphed into more erotic feelings. Ejaculation has been utilized not only for sexual and fertility purposes, but anecdotally has improved bladder and bowel control. While not formally studied, improved walking skills with Exoskeleton and pelvic floor strengthening, may enhance sexual function in some. Fertility is most affected in men after SCI with the ejaculatory difficulties, of which sperm retrieval methodology exists. However, semen quality is invariably affected by the cytokines found in seminal fluid, significantly altering sperm quality. Women's fertility is not affected after SCI, but contraception may need to be modified. Women with SCI can safely carry a pregnancy and most deliver vaginally. A multidisciplinary team must be in place for women to assist with pregnancy, labour, delivery and postpartum issues (including breastfeeding). A positive outlook and interest toward sexual and fertility rehabilitation is finally here!

PROMOTING THE EFFECT OF REHABILITATIVE TRAINING FOLLOWING SPINAL CORD INJURY IN ANIMAL MODELS

Karim Fouad, PhD | Professor, Rehabilitation Medicine Physical Therapy, University of Alberta

Rehabilitative training is currently one of the best treatments to moderately recover motor function after a spinal cord injury. In this presentation we will discuss two new approaches that evolved in animal models to enhance the ability to train successfully. One idea is based on the finding that the spinal cord below the level of the injury has a reduction in the blood flow of small blood vessels. This dampens the activity in neuronal networks and thus makes it more difficult to activate them. Understanding and manipulating the process that reduces blood flow, or increasing spinal cord oxygenation are potential mechanisms to enhance motor activity and thus enable training. The second approach is based around the finding that neuroplasticity and consequently rehabilitative training efficacy following spinal cord injury decrease over time. This has likely various reasons, however we found that providing a mild inflammatory stimulus can partially restore neuroplasticity. Despite the obvious concerns regarding inflammation, these results warrant further investigations into the detailed mechanism of this effect and the exploration of clinically relevant approaches to manipulate inflammatory pathways in chronic SCI.

SPINAL CORD EPIDURAL ELECTRICAL STIMULATION: AN UPDATE ON MOTOR AND MOBILITY OUTCOMES

Megan Gill, PT, DPT, NCS | Physical Therapist, Mayo Clinic

Epidural spinal cord stimulation has shown to be an effective tool for regulating locomotor behavior and can allow for regaining voluntary control of movements by paralyzed patients. Recent literature continues to demonstrate intentional modulation of motor activation translating to functional mobility such as standing and stepping in individuals with severe, clinically complete diagnosed spinal cord injuries. Motor outcomes and movement patterns enabled by epidural electrical stimulation will be reviewed; additionally, potential existing rehabilitation strategies and/or technology available today to mitigate the barriers of translation will also be discussed.

WELCOME MESSAGE

Rick Hansen | Founder & CEO, Rick Hansen Foundation

Rick is honoured to provide welcoming remarks at the Working 2 Walk Science & Advocacy Symposium here in Vancouver. Through the power of his own story and the inspiration he's found in others, Rick Hansen believes that it's not what happens to you, but what you do with it that counts. Everyone has the ability to make a difference, and anything is possible if you have the courage to try. Rick believes that collaborative, global research is the key to improving the health and quality of life for people with disabilities. The Rick Hansen Foundation continues to invest in spinal cord injury research through partnerships with the Rick Hansen Institute (RHI) and the International Collaboration on Repair Discoveries (ICORD) as part of its ongoing work to raise awareness about accessibility, inclusion, and the potential of people with disabilities.

SPEAKER Abstracts

PAYING FOR AFTER-HOSPITAL REHABILITATION THROUGH STATE LEGISLATION

Dale Hull, MD, MPA | Executive Director, Neuroworx

Individuals affected by paralysis often do not have access to extended therapy after being discharged from the hospital because of financial issues. Either their insurance benefits are short-lived, they can't qualify for other assistance or they lack the personal resources to pay privately. Yet many of those individuals could progress to a higher level of functional mobility, greater personal independence, better health, and have an enhanced quality of life if they were able to obtain more rehabilitative therapy. An advocacy effort resulted in the State of Utah passing legislation in 2012 that created the SCI/BI Rehabilitation Fund to provide after-hospital physical, occupational, and speech therapy for individuals experiencing a spinal cord injury or brain injury who have the potential to make progress but do not have adequate resources to access the appropriate care. The individuals must be a Utah State resident and the fund functions as a payer-of-last-resort. The success of the program led to additional funding in 2017. Program monies are generated through DUI vehicle impound fees and the registration of motorcycles and off-highway vehicles. The fund is administered by a seven member committee made up of legislators, state administrators, and citizens appointed by the governor with oversight by the Utah Department of Health. Services are provided by rehabilitation clinics that meet the requirements specified in the legislation. Reimbursement is made directly to the clinics on a fee-for-service basis. During the first five years, funded individuals met or exceeded the functional goals and outcomes established by the oversight committee.

THE BREADCRUMB PATH FROM BENCH TO BEDSIDE

Lyn Jakeman, PhD | Program Director, Repair and Plasticity, National Institute of Neurological Disorders and Stroke

Drugs, cells, gene therapies, and devices are under investigation around the world with hopes of determining safety and effectiveness to improve or enhance recovery after injury. Meanwhile, advances in tools and technology in biology, engineering and communications have vastly accelerated neuroscience discoveries. Yet, many basic research studies end with some new knowledge and scientific publications, but no product has been found, no treatment identified. Early stage clinical trials also often end with no definitive answers, or do not finish at all. Why does this happen? Is it inevitable? Are there exceptions? How do we ensure that investments in research will benefit patients and consumers? These are questions that funding agencies grapple with all of the time. In this presentation, I will discuss the often spotted and twisted path from fundamental research to translation of ideas into therapies, and I will outline some of the existing programs targeted at helping projects get to the next step. In closing, I will present some ideas for how diverse stakeholders can work together to identify and respond to potential research advances that are poised at the intersection of scientific, technological and community readiness. I hope to encourage discussion of the approaches and language that can can be employed to foster cooperative efforts across the translational spectrum.

SPINAL CORD NEUROMODULATION FOR RESTORATION OF AUTONOMIC FUNCTIONS AFTER SCI

Andrei Krassioukov, MD, PhD, FRCPC | Professor, University of BC; Chair in Rehabilitation Research, ICORD

During the last decade we have seen growing evidence that electrical spinal cord stimulation (SCS) improves motor functions in individuals with spinal cord injury (SCI). Interestingly, SCS (both invasive/epidural and non-invasive/transcutaneous stimulation) also has potential for the modulation of autonomic functions. Remarkably, autonomic recovery is among the highest priorities among individuals with SCI. However, based on an examination of the registered clinical trials (https://clinicaltrials.gov) only 10% of the trials included evaluation of autonomic dysfunctions as primary or as secondary outcomes. During this presentation participants will learn about the potential benefits of the epidural/transcutaneous SCS on various autonomic dysfunctions that negatively impact the health and quality of life of individuals with SCI. The issues of optimization of stimulation parameters and protocols for activation of voluntary (motor) functions versus non-voluntary (autonomic) functions will be also discussed. Finally, the need and intensity of rehabilitation prior/post initiation of SCS will be discussed.

BIOMARKERS OF ACUTE SCI

Brian Kwon, MD, FRCSC, PhD | Canada Research Chair in Spinal Cord Injury; Professor, University of BC; Associate Director, ICORD

The concept of identifying and then using biomarkers in SCI clinical trials is related to some of the very fundamental challenges in neurotrauma where interventions are tested in a human population that is inherently very heterogeneous with high variability in outcomes. These challenges include understanding and monitoring SCI pathophysiology and how these affect critical spinal functions. Reflecting injury processes, SCI biomarkers can help categorize and stratify patients' initial severity of neurologic impairment and predict the extent of spontaneous/natural neurological and functional recovery. Biomarkers may also be used to track SCI progression and as measures of biological responses to treatment throughout the lifetime of a person with SCI. To this end, this presentation will describe the basic principles behind the application of biomarkers for SCI and how such biomarkers may help to overcome these challenges.

ACTIVITY AND PHYSICAL THERAPY AFTER INCOMPLETE SCI IN THE RAT

David Magnuson, PhD | Friends for Michael Endowed Professor, University of Louisville

The Consortium for Spinal Cord Medicine has prescribed that all spinal cord injured patients receive stretching therapies beginning within the first week post-injury. This therapy is targeted at preventing joint and muscle problems that many spinal cord injured individuals develop. These include contractures, where the range-of-motion of a joint is reduced, muscle shortening (often associated with contractures), and muscle wasting (loss of mass and strength). Maintaining muscle and joint health early after injury is critical to long-term health and for participation in rehabilitation efforts. Despite the fact that essentially all patients with spinal cord injuries receive significant levels of stretch-based physical therapy, stretching has not been studied systematically in animal models and has been studied very little in human subjects. For several years we have been studying activity-based rehabilitation in animal models. Using strategies to increase or decrease post-injury activity, including the use of a "rat wheelchair" we observed that some of our animals developed contractures when their hindlimbs were immobile. We then developed a stretching protocol that had two surprising outcomes; it did not prevent contractures and it had a negative impact on locomotor function. Since then we have gained a good understanding of the phenomenon, and are beginning to understand the underlying causes. The goal of this talk is to describe the phenomenon, to demonstrate how and perhaps why stretching interferes with locomotion even when muscles are not damaged. We will also discuss the potential clinical relevance and try to put this work into the larger context of post-injury changes in the spinal cord and the roles of exercise, rehabilitation and physical therapy.

SO YOU'VE SUFFERED A SCI; THEY SAY YOU'LL NEVER WALK AGAIN - YOU SAY YOU WILL. NOW WHAT ARE YOU GOING TO DO ABOUT IT?

Barry Munro, BA, LLB | Chief Development Officer, CSRO

Barry Munro will share his journey of a quest for a cure that has been going on for 31 years, since his injury in 1987. He will share his experiences and comment on the attitudinal changes in the world in relation to finding a cure for spinal cord injuries. He will explore and look back on the chronology of events from Rick Hansen's tour around the world and Christopher Reeve's passion to find a cure, to the passing of a proverbial torch of cure now carried by U2FP and other organizations around the world. This will be the tale of history and the recommendations of a playbook for the future in continuing the quest to find a cure for paralysis.

ACUTE INTERMITTENT HYPOXIA: A SCIENTIFIC AND PERSONAL ODYSSEY

Tommy Sutor, MS, CSCS | PhD Candidate in Rehabilitative Science, University of Florida

Tommy Sutor did not find the movement to cure spinal cord injuries, but rather, it found him. Having originally thought he wanted to pursue a career as a strength and conditioning or track and field coach, Tommy took a job as an activity-based exercise trainer and was thrust into the movement to cure spinal cord injury. Fascinated by both the science and the realities of everyday life for people with spinal cord injuries, he knew he wanted to play some part in this movement, but didn't see how since he was not a doctor nor someone who knew how to do animal or cellular experiments. Eventually, Tommy realized that much of his knowledge about how to train ath-

letes overlapped with neurorehabilitation. Additionally, it served as a good foundation of knowledge to seek answers to unanswered questions. He decided to pursue a PhD in rehabilitation science so that he could investigate ways to enhance motor function in people with chronic spinal cord injury, while at the same time getting a better understanding of basic research and what it will ultimately take to heal an injured spinal cord.

Tommy is currently studying acute intermittent hypoxia and its uses for enhancing rehabilitation after spinal cord injury. He will be discussing the history of acute intermittent hypoxia, current and ongoing research from the University of Florida (including preliminary findings from his own dissertation), and future directions for acute intermittent hypoxia as a way to enhance rehabilitation and motor function after chronic spinal cord injury.

LOCOMOTOR RECOVERY FOLLOWING MODERATE OR SEVERE CONTUSIVE SCI DOES NOT REQUIRE OLIGODENDROCYTE REMYELINATION

Wolfram Tetzlaff, MD, PhD | John and Penny Ryan BC Leadership Chair in Spinal Cord Research; Professor, University of BC

Spinal cord injury (SCI) can lead to severe and permanent motor, sensory and autonomic dysfunction due to the adult mammalian spinal cord's inability to regenerate lost neurons and their connections. Most SCIs in humans do not result in the complete transection of the spinal cord but instead axons are spared at the lesion epicenter and a period of limited functional improvement commences soon after SCI despite axon regeneration failure. Enhancing the functional connectivity of the spared circuitry may be a viable means of promoting functional improvements following SCI. However, oligodendrocyte death in the weeks after SCI presumably results in the demyelination of spared axons, which could diminish the functionality of spared circuits. Demyelination impairs the amplitude and speed of electrical conductance and oligodendrocyte loss may leave axons vulnerable to degeneration. For these reasons, strategies to enhance oligodendrocyte remyelination of spared axons have been hypothesized to promote functional improvements following SCI. However, the extent of remyelination and its role of myelin regeneration in locomotor recovery has never been tested directly. Our data indicates that while spontaneous remyelination is extensive following SCI, it is not associated with improvements in hindlimb motor function during spontaneous recovery in our contusion models. This questions the interpretation/validity of rodent models used in support of clinical trials of transplantation of oligodendrocytes precursor cells.

THE PATH TO RESOLVING BOWEL AND BLADDER PROBLEMS FOLLOWING SCI IS BECOMING CLEAR

Tracey Wheeler, PhD | Program Officer, Craig H. Neilsen Foundation

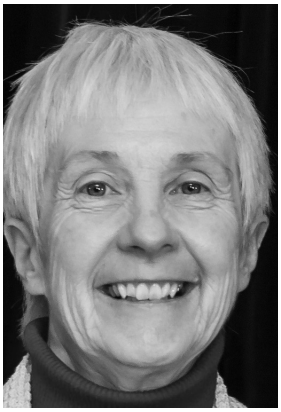
The inability to control one's own bowel and bladder impacts every aspect of daily life. The indignities faced after spinal cord injury (SCI) range from loss of independence and privacy in these basic functions to perpetual fear of "having an accident." It is consistently one of the foremost challenges identified by people with SCI; yet there have been few attempts to coordinate resources to improve bowel and bladder management. In March of 2017, the Craig H. Neilsen Foundation convened a workshop to provide leadership and focus attention on this fundamental need. Participants included a highly selective group of approximately 40 experts including clinicians, researchers, patient advocates, government agencies and potential funding partners to identify a path forward.
With the support of an International Advisory Committee, plans were crafted to develop a program that would build collective momentum towards identifying the most promising approaches to pursue, assuming a 10-year translational timeline as a reasonable and achievable goal. To frame the working discussions that were the core of the workshop, currently available tools, knowledge and treatments were reviewed. Participants presented compelling descriptions of the challenges they face as physicians and consumers, and in addressing translational issues faced in improving on current technologies.

This presentation reviews the 5 core recommendations from this effort and provides an update on the progress made since to address the pressing needs of people with SCI. 1) Neuromodulation 2) Clinical Practice Guidelines 3) Bowel Physiology 4) Sensation/Feedback 5) Rehabilitation/Activity/Exercise

LEADERSHIP **TEAM**

The Board & Staff of Unite 2 Fight Paralysis

BOARD OF DIRECTORS



Marilyn Smith, *President*

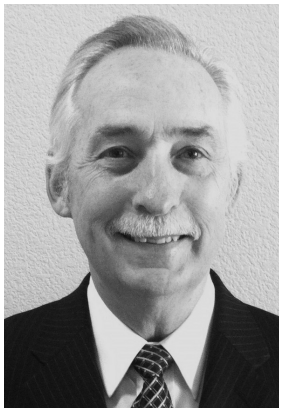
Marilyn (of Hood River, Oregon) is a graduate of the University of Michigan and brings a wide variety of skills to her work with Unite 2 Fight Paralysis. She has many years of experience as a fundraiser, event planner, and volunteer coordinator for nonprofit organizations. She has also worked as a tax consultant, webmaster, and office manager in the for-profit world. When her son was paralyzed in 2002 by a wheel that flew off of an oncoming vehicle, she immediately went to work to help him make the best of his situation. Following the "Spring Into Action" Rally in Washington, DC, in 2005, Marilyn carried her organizational skills over to U2FP, and gave thousands of volunteer hours to oversee the successful launch of the organization. She is one of the co-founders of U2FP, and served as Executive Director from 2009-2017 before moving into the role of Board President.

Barry Munro

Barry (of Toronto, Canada) is the Chief Development Officer of the Canadian Spinal Research Organization and the Ontario Neurotrauma Foundation; he also serves as director of the American Spinal Research Organization. In 1987, Barry sustained a spinal cord injury in a diving accident, which resulted in quadriplegia. He has sat on multiple boards advocating for people with disabilities and particularly spinal cord injury research. Barry graduated from Law School in 1994 and was called to the Bar in 1996. He practiced personal injury law for over 10 years. His legal experience combined with 30 years of practical experience living with a spinal cord injury make him a formidable advocate for the disabled community. Barry has dedicated his life to assisting people living with disabilities and improving their quality of life.

Mike Burris, *Secretary*

Mike (of Colorado Springs, Colorado) received his B.A. from the University of Iowa and has an M.S. in Systems Management from the University of Southern California. Mike has more than 35 years of experience in the world of space exploration. He served as an Air Force intelligence officer from 1977-1982. After he left the Air Force, he went to work at Science Applications International Corp. (SAIC) before retiring as an Assistant Vice President at the end of 2011. During his career, he worked on several space related activities such as the building of the Air Force's Consolidated Space Operations Center, the Air Force Satellite Control Network, NASA's X-43 hypersonic research vehicles, and the replacement for the Space Transportation System. Prior to joining the U2FP Board he served on three boards; he served 10-years as a school board member for the Lewis-Palmer School District #38 in Colorado during the 1990s, he was a member of the International Astronautical Congress (IAC) Space Transportation Committee from 2004-2011, and he is currently a member of Rehabilitation Institute of Chicago (RIC) Foundation Board. In July 2009 while body surfing Mike suffered a C4 incomplete SCI that, although he is ambulatory, still impacts him today. Being on the U2FP Board provides him the opportunities to advance the goals of our community and advocate for all of us to live our best possible lives.



Michele "Shelly" Towle

Michele (of Bismark, North Dakota) is the Assistant Director of the Spinal Cord Injury Program at DP Clinical, Inc., located in Rockville, MD. Michele has 18 years of experience in SCI clinical research. She became a study coordinator starting in 1999 when she began working with spinal cord injured patients enrolled in clinical trials. Through this early experience she came to understand the impact of a spinal cord injury, not only for individuals but also for their families and communities. Michele then moved on to monitor and manage SCI clinical trials for DP Clinical since 2003. DP Clinical is a Contract Research Organization (CRO) specializing in Spinal Cord Injury (SCI) Phase I-IV clinical programs for pharmaceutical, biotech, and medical device companies. Over the years, Michele has seen many SCI clinical trials halted due to slow enrollment and the prohibitive cost, leaving SCI patients without a potentially beneficial new therapy. Research needs to succeed, and there remains a need for meaningful contribution to the efforts in spinal cord research. Michele advocates for better-designed protocols and validated efficacy tools to be used in clinical trials. Working with so many talented individuals with SCI expertise and a commitment to research, makes Michele ask, "how can I as a non-scientist help to advance research and clinical trials that will provide a breakthrough for spinal cord injuries?"

Alexandar "Sasha" Rabchevsky

Alexander "Sasha" Rabchevsky (of Lexington, Kentucky) is a tenured Professor of Physiology at the University of Kentucky, College of Medicine and is a core member of the Spinal Cord & Brain Injury Research Center. He is, himself, paralyzed from the chest down as the result of a motorcycle accident in 1985 which fractured his sixth thoracic vertebrae rendering him a complete T5 paraplegic. His research efforts have ensured continued extramural funding while gaining him international recognition as a leading expert in both mitochondrial dysfunction and autonomic pathophysiology following spinal cord injury, particularly the development of a hypertensive syndrome termed autonomic dysreflexia. It is the latter condition that he himself experiences on a regular basis, and his studies have advanced our understanding of how to monitor and treat such an insidious disorder. He has and continues to serve on various study sections, both federal and private, is associate editor and reviewer of various scientific journals, and his distinct studies have been funded by the National Institutes of Health, the International Spinal Research Trust, the Paralyzed Veterans Administration, the Craig H. Neilsen Foundation, the Commonwealth of Kentucky, and the University of Kentucky.

STAFF

Matthew Rodreick *Executive Director*

Matthew (of Minneapolis, Minnesota) entered the SCI community after his son Gabe sustained a C5 injury while body surfing in Costa Rica. After leaving his position as Emergency Department Operations Supervisor for the Fairview Health System, he and Gabe traveled the world in search of the best therapeutic options, only to end up back in Minnesota advocating for cure research. Matthew led a coalition of Minnesota SCI community advocates and researchers to leverage the state legislature in pursuit of public funding for SCI research. In 2012 he made a short documentary film featuring then Minnesota Viking punter and Twitter celebrity Chris Kluwe, spending a day in a wheelchair. The screening of "Chris Kluwe Rolls A Mile In Someone Else's Wheels" kicked off their 2013 legislative campaign. The bill was passed in 2015 as the MN SCI/TBI Research Grant Program, and Matthew is now working with advocates in Washington and Pennsylvania to pass similar legislation. He credits U2FP and Working 2 Walk with providing the knowledge, focus and energy to see the real possibility of an end to the debilitating effects of paralysis.

Donna Sullivan *Special Projects Director*

Donna (of Dublin, Ohio) joined the paralysis community in 2005 when her son sustained a spinal cord injury. The following year, she attended W2W; since that time she committed herself to the mission of U2FP. Her belief is whether you're advocating for specific research or legislation to support it, individuals must first understand that a spinal cord injury is more than a chronic condition – its complications are life threatening. Her role as Project Director includes following research and developing the program for the Working 2 Walk Science & Advocacy Symposium. Her efforts bring together top international researchers and advocates to collaborate on the latest developments. She was instrumental in developing the U2FP Scientific Advisory Board (SAB) and works with an international group of organizations in an effort to provide them with SAB oversight on their funding decisions. Previously, she worked as the Operations Manager for GTE/Sylvania Hospital Products Division and as an elementary school Enrichment Coordinator. Working alongside gifted researchers and determined advocates fuels her commitment to advancing a cure for spinal cord injuries.

Christal Powell *Research Consultant*

Christal (of Alliance, Nebraska) owns and operates a residential real estate business and works on the family farm. She is married and has two children. Christal entered the paralysis community after her son sustained a spinal cord injury in 2005. They met other members of the community in Washington D.C. at the Working 2 Walk conference in 2008. They began holding local fundraisers and advocating for research on a national level. Prior to her son's injury, she worked as a Front Desk Manager for Heartland Pointe, LLC. Chris believes anyone advocating for spinal cord injury legislation, research and funding can make a difference in bringing regenerative medicine to the clinic as soon as possible. Chris is deeply honored to serve on a national level for Unite 2 Fight Paralysis.

Kathryn Mahoney
Team U2FP Director

Kathryn (of Western Springs, Illinois) was in her senior season as a gymnast at Michigan State University when she sustained a C6 spinal cord injury from a fall during practice. She returned to MSU and graduated with a B.S. in Chemical Engineering in 2013. In 2017, she completed her M.S. in Business Analytics. An athlete her whole life, Kathryn craved physical activity and was soon introduced to adaptive sports. She has now been handcycling and playing wheelchair rugby for the last two years, and believes the mental and physical benefits of adaptive sports and the surrounding community are immeasurable. She also attends NextSteps Chicago, where the focus is on activity-based therapies. Kathryn is excited to share the mission of U2FP and facilitate the development of Team U2FP, which encourages runners and wheelchair athletes to support the search for a cure by racing in any event, from 5k's to marathons. Additionally, she motivates and assists the athletes to meet their training and fundraising goals.

Jake Beckstrom
C.A.N. Manager

Jake Beckstrom is from Watertown, Minnesota. At the age of 16, Jake had a diving accident in a backyard pool and sustained a C4-6 spinal cord injury. A lifelong love of hunting, fishing, and the outdoors led him to pursue a path of environmental sustainability. He received a B.S. in Environmental Science at Southwest Minnesota State University, and in 2015, he received a law degree and master's degree in Environmental Law and Policy at Vermont Law School. Jake is eager to use his experience in public policy and advocacy to work with the Cure Advocacy Network to lobby for smarter spinal cord injury research funding and find a cure for paralysis.

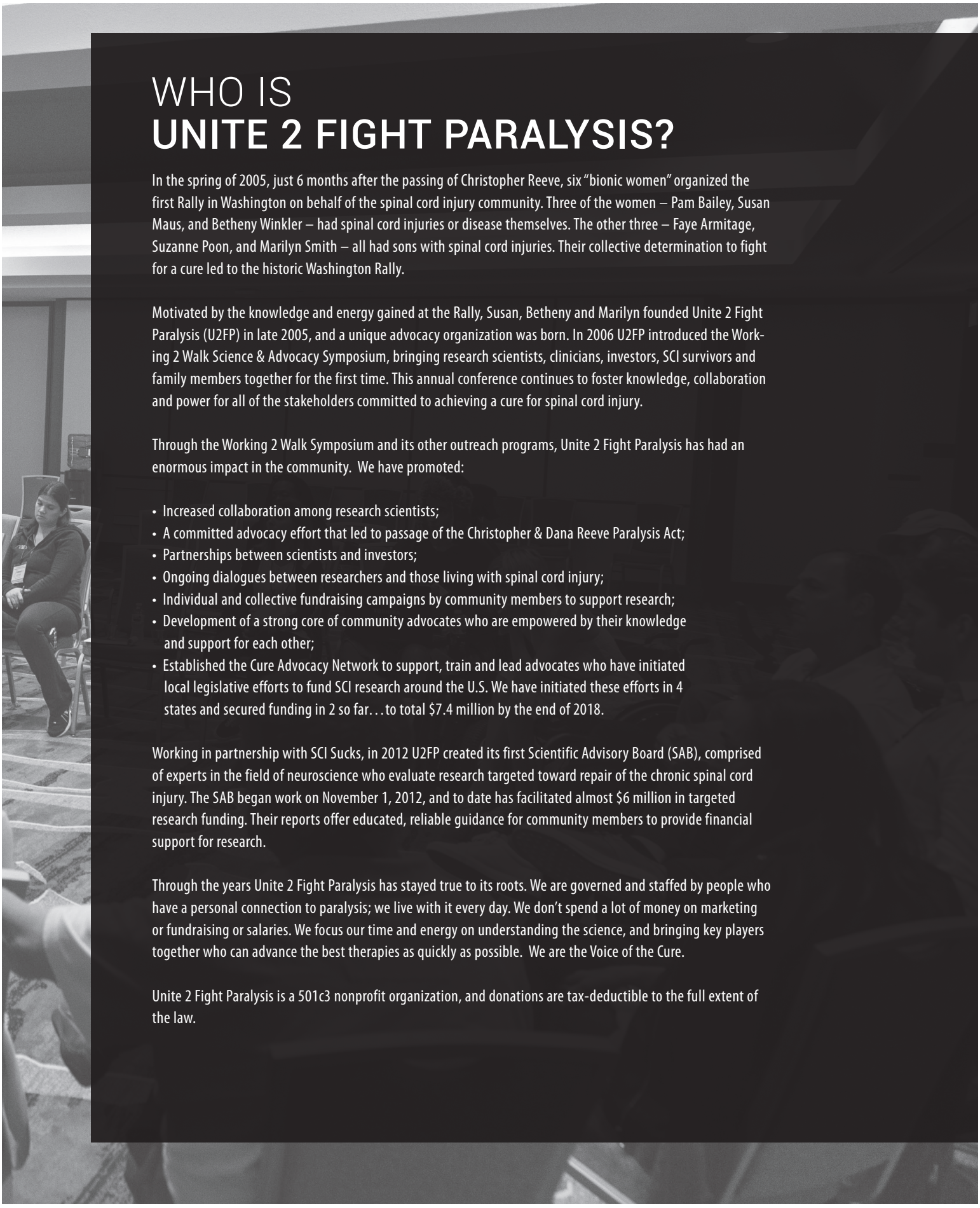
Ryan Romine
Program Manager

Ryan (of Minneapolis, Minnesota) has worked in managerial and administrative roles at mission driven organizations for the last 15 years. He has a strong background in communications, customer service, and project management. Impressed by U2FP's vision to end paralysis rather than simply accommodate it, Ryan is honored to lend his efforts in the comprehensive fight for a cure.

Kate Willette
Writer & CureCast host

Kate (of Bellevue, Washington) is a writer and activist. She holds an M.Ed and a BA in mathematics, both from the University of Washington in Seattle. When her husband broke his neck skiing in the spring of 2001, she gradually became determined to use her skills to further the cause of a cure for spinal cord injury. She published a memoir (Some Things Are Unbreakable) in 2003 that has won high praise from editors and readers alike. Her articles about the state of research science and the men and women who are engaged in it have been published in the United States, Norway, and online. In recent years she's enjoyed writing colorful, reliable, real-time narratives of U2FP events with a series of live blogs that are widely read and disseminated in the spinal cord injury community. In September of 2015 she published **Don't Call It a Miracle: The Movement to Cure Spinal Cord Injury** . This book is a must-read for advocates, a lay-friendly, beautifully illustrated summary of the scientific, regulatory, and funding problems to be solved, and what you can do to speed things along.forward.

OUR Mission



WHO IS
UNITE 2 FIGHT PARALYSIS?

In the spring of 2005, just 6 months after the passing of Christopher Reeve, six "bionic women" organized the first Rally in Washington on behalf of the spinal cord injury community. Three of the women – Pam Bailey, Susan Maus, and Betheny Winkler – had spinal cord injuries or disease themselves. The other three – Faye Armitage, Suzanne Poon, and Marilyn Smith – all had sons with spinal cord injuries. Their collective determination to fight for a cure led to the historic Washington Rally.

Motivated by the knowledge and energy gained at the Rally, Susan, Betheny and Marilyn founded Unite 2 Fight Paralysis (U2FP) in late 2005, and a unique advocacy organization was born. In 2006 U2FP introduced the Working 2 Walk Science & Advocacy Symposium, bringing research scientists, clinicians, investors, SCI survivors and family members together for the first time. This annual conference continues to foster knowledge, collaboration and power for all of the stakeholders committed to achieving a cure for spinal cord injury.

Through the Working 2 Walk Symposium and its other outreach programs, Unite 2 Fight Paralysis has had an enormous impact in the community. We have promoted:

- Increased collaboration among research scientists;
- A committed advocacy effort that led to passage of the Christopher & Dana Reeve Paralysis Act;
- Partnerships between scientists and investors;
- Ongoing dialogues between researchers and those living with spinal cord injury;
- Individual and collective fundraising campaigns by community members to support research;
- Development of a strong core of community advocates who are empowered by their knowledge and support for each other;
- Established the Cure Advocacy Network to support, train and lead advocates who have initiated local legislative efforts to fund SCI research around the U.S. We have initiated these efforts in 4 states and secured funding in 2 so far. . . to total $7.4 million by the end of 2018.

Working in partnership with SCI Sucks, in 2012 U2FP created its first Scientific Advisory Board (SAB), comprised of experts in the field of neuroscience who evaluate research targeted toward repair of the chronic spinal cord injury. The SAB began work on November 1, 2012, and to date has facilitated almost $6 million in targeted research funding. Their reports offer educated, reliable guidance for community members to provide financial support for research.

Through the years Unite 2 Fight Paralysis has stayed true to its roots. We are governed and staffed by people who have a personal connection to paralysis; we live with it every day. We don't spend a lot of money on marketing or fundraising or salaries. We focus our time and energy on understanding the science, and bringing key players together who can advance the best therapies as quickly as possible. We are the Voice of the Cure.

Unite 2 Fight Paralysis is a 501c3 nonprofit organization, and donations are tax-deductible to the full extent of the law.

VOICE OF THE Cure A U2FP **VISION**

What is the Cure? Defining a Vision

Unite 2 Fight Paralysis uses the tagline, "Voice of the Cure". What does the word "cure" mean to us? Our vision of a cure includes:

1. Restoration of one's fully functional and healthy body, including relief from pain and spasms, return of bowel, bladder and sexual function, and recovery of normal sensation in addition to motor control. Once cured a person should be able to live independently, free of assistive devices, caregivers, catheters, etc.

2. Belief that curative therapies will come in stages, and support for advancing research into each stage as it becomes more promising.

3. Understanding that recovery will come through combinations of therapies that may vary just as much as the nature of spinal cord injuries. To this end we promote and support collaborations amongst scientists, investors, advocates, clinicians, and regulatory agencies.

4. Commitment over the long term to successive stages of recovery, refusing to be satisfied until all bodily functions are restored.

What is the Cure? Navigating the Vision

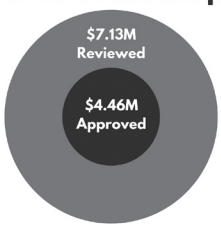
U2FP fights for a cure for the invisible ones, the severely disabled, the families who support them, and everyone who believes that it's possible, and more importantly urgent, to restore health and opportunity to these compromised lives.

A cure does not mean that a person receives a "magic potion" injection one day and is up and running around the next. We know that after any kind of intervention to stimulate regeneration, extensive rehabilitation will be required to properly connect the motor and sensory pathways and restore function.

Let us never forget about those with complete injuries and little or no return, those who cannot use their hands or live independently, those who have no family support and are shuffled off to nursing homes, those on ventilators who require 24/7 assistance, those who do not have the time and/or money to spend the hours necessary to maximize recovery.

We don't want to start a "pity party", but we do want to increase awareness of these realities. Decision-makers need to understand that paralysis is a progressive and burdensome condition, that research science shows great promise and needs financial support, that restoring function will save millions of dollars for SCI survivors, their families, and society.

Research Grant Requests



*numbers as of September 2018

SCIENTIFIC ADVISORY **BOARD**

Cure research can be overwhelming and confusing. Many smaller foundations want to fund promising research, but lack the scientific expertise to vet their funding decisions. The U2FP Scientific Advisory Board is here to fill this gap. We make that expertise available to these important members of the paralysis community.

The U2FP Scientific Advisory Board (SAB) is directing dollars from SCI foundations to research that is Relevant to Chronic Injury, Replicable, Translatable and Innovative.

Relevant to Chronic Injury Giving preference to chronic injury research allows for a greater impact to the vast majority of individuals currently living with a spinal cord injury.

Replicable Research needs to be replicated in order to move toward clinical trials. We want to identify opportunities to replicate research that shows promise for innovative treatments.

Translatable Research that is applicable to the chronic injury and has the potential to move from animal models to human trials.

Innovative We wish to identify research that is asking bold questions with conservative interpretations, rather than conservative questions with bold interpretations.

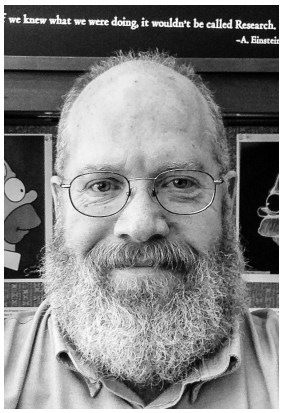
Moses V. Chao, PhD

Dr. Chao is a Professor of Cell Biology, Physiology, and Neuroscience, and professor of Psychiatry at the York University School of Medicine. He is the former President of the 42,000-member Society for Neuroscience (SFN), made up of the world's leading brain and spinal cord scientists. Dr. Chao's lab at the Skirball Institute of Biomolecular Medicine focuses on the study of molecular neurobiology and understanding the mechanisms that lead to a. the generation of neural cells and their targets, and b. the mechanisms that allow axons to project to their targets, form synapses, and signal to one another. Dr. Chao believes strongly in the necessity for more discovery science to solve the challenges of neurodegenerative disease and trauma. He brings a wealth of knowledge and experience in the field of neuroscience to our Advisory Board, and we appreciate his service.

Phillip G. Popovich, PhD, *Chair*

Dr. Popovich is the Chair and Professor in the Department of Neuroscience and Director of the Center for Brain and Spinal Cord Repair at Ohio State University. His laboratory is an interdisciplinary research group dedicated to studying the complexities of CNS injury, inflammation and tissue repair. Inflammation can have devastating consequences in the spinal cord, and the lab is striving to develop novel therapies that will manipulate or over-ride normal immune function. In addition, the Popovich lab performs replication work for the NIH. Replication is a core principle of the scientific method. To establish validity, the results of an experiment performed by one group of scientists must be evaluated by an independent group of scientists. The second group attempts to repeat the experiment of the first group, based on the original description. If the outcomes are similar, replication has been achieved and the first experiment is validated. Dr. Popovich's work in the replication process will bring a detail-oriented perspective to evaluating scientific projects.

Keith Tansey, MD, PhD



Dr. Tansey earned his BS and MS in Biology and Biomechanics from Stanford University and his MD and PhD in Neuroscience from the University of Texas Southwestern Medical Center. He then completed his Residency in Neurology at Washington University in St. Louis and then Fellowships there and at the University of California at Los Angeles in Neurorehabilitation and Spinal Cord Injury Research. He was board certified in Neurology and then subspecialty board certified in Spinal Cord Injury Medicine and Neural Repair and Rehabilitation. Dr. Tansey serves on the Board of the American Society for Neurorehabilitation and as a Board Officer for the American Spinal Injury Association and the International Society for Restorative Neurology. He is currently editing a book, "Neurological Aspects of Spinal Cord Injury" with two colleagues from Heidelberg Germany. Dr. Tansey has grants to study neural plasticity after spinal cord injury in animal models and humans from the National Institutes of Disability and Rehabilitation Research, the Department of Defense, the Veterans Administration, and the Neilsen Foundation.

Steven Kirshblum, MD

Dr. Kirshblum is nationally recognized for his work in the area of spinal cord injury rehabilitation and research. He joined Kessler Institute in 1990 and currently serves as Medical Director of the West Orange campus, as well as the Director of the Spinal Cord Injury Program. Dr. Kirshblum received his medical degree from the University of Health Sciences/Chicago Medical School and completed a residency in physical medicine and rehabilitation at Mt. Sinai Hospital in New York City, where he was a chief resident. He became board certified in 1991 and was one of the first physicians in the country to receive special certification in spinal cord injury medicine in 1998. One of the most widely respected physicians in his field, Dr. Kirshblum has delivered more than 500 lectures nationally and internationally. He is the President of the Academy of Spinal Cord Injury Professionals, Chair of the International Standards Committee for the American Spinal Association and a member of numerous advisory boards and foundations for spinal cord research.

Brian Kwon, MD, PhD, FRCSC

Dr. Kwon is the Canada Research Chair in Spinal Cord Injury and a Professor in the Department of Orthopaedics at the University of British Columbia (UBC). As a surgeon-scientist, he is particularly interested in the bi-directional process of translational research for spinal cord injury – both "bench to bedside" and "bedside back to bench". He has worked extensively on establishing biomarkers of human SCI to facilitate human trials and is leading a national biobanking effort in acute SCI. In his laboratory he has developed novel preclinical small and large animal models of SCI that can serve as the testing ground for therapeutic strategies and for conducting bedside back to bench translational studies. He has also led initiatives to establish a framework for how promising therapies for SCI should be evaluated in the laboratory setting prior to translation into human patients.

John Houle, PhD

Dr. Houle is a professor in the Department of Neurobiology & Anatomy at Drexel University College of Medicine, and director of the Spinal Cord Research Center. Prior to coming to Drexel, he taught at the University of Arkansas for Medical Sciences (UAMS), also serving as the director of the Division of Cellular and Molecular Neurobiology and the Neuroscience Research Core Facilty at UAMS. Dr. Houle has long been interested in neurotransplantation strategies to promote structural and functional recovery after spinal cord injury. Research in his laboratory is designed to examine multiple aspects of the neuronal and glial cell response to spinal cord injury, with the intent of designing a combinatorial treatment strategy for regeneration leading to functional recovery. Dr. Houle's career has been a pursuit of understanding how the regenerative response of injured neurons is regulated, why some neuron groups are strong regenerators while others exhibit very limited regenerative effort, and how we might enhance regeneration in acute and chronic injury conditions.

Jean de Vellis, PhD *(In Memoriam)*

Dr. de Vellis was a Distinguished Professor in the Department of Neurobiology at the University of California, Los Angeles. His laboratory is interested in the genetic and epigenetic molecular mechanisms that fashion the progression of stem cells into the amazing cellular phenotypic diversity of the central nervous system. His research helped to define at the molecular level the plasticity of brain cells and their potential for regeneration in neurodegenerative diseases. A main focus of his laboratory is on the development of oligodendrocytes, the myelin forming cells in the central nervous system and a key cell in brain iron homeostasis. In 2008 Dr. de Vellis received the Bernard Haber Award from the American Society of Neurochemistry, recognizing his outstanding leadership and contributions in the field of neurochemistry. We were honored to have his valuable input and experience on our Scientific Advisory Board.

BACKGROUND

In September of 2012, Unite 2 Fight Paralysis - in partnership with SCI Sucks - initiated a Scientific Advisory Board. Its purpose was and is to provide investors in the SCI community with peer-reviewed recommendations on where to direct critical funding and information on specific research interests.

The SAB is made possible, in part, due to contributions from The Allergan Foundation, Cure Medical and the Hong Kong Spinal Cord Injury Foundation.

NSCISC
NATIONAL SPINAL CORD INJURY STATISTICAL CENTER

Spinal Cord Injury Facts and Figures at a Glance

2018 SCI Data Sheet

This data sheet is a quick reference on demographics and the use of services by people with spinal cord injury in the United States.

The National Spinal Cord Injury Database is a prospective longitudinal multicenter study that currently captures data from an estimated 6% of new SCI cases in the United States. The database has demographic and condition status data through 2017 for 32,727 people with SCI.

National SCI Statistical Center
515 Spain Rehabilitation Center
1717 6th Avenue South
Birmingham, AL 35233-7330

For Statistics: 205-934-3342
For Business: 205-934-3320
TDD: 205-934-4642
FAX: 205-934-2709
E-mail: NSCISC@uab.edu
Website: uab.edu/NSCISC

Incidence

Given the current U.S. population size of 327 million people, a recent estimate showed that the annual incidence of spinal cord injury (SCI) is approximately 54 cases per one million people in the United States, or about 17,700 new SCI cases each year. New SCI cases do not include those who die at the location of the incident that caused the SCI.

Prevalence

The number of people with SCI living in the United States is currently estimated to be approximately 288,000 persons, with a range from 247,000 to 358,000 persons.

Age at Injury

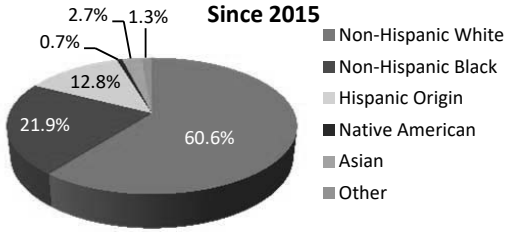
The average age at injury has increased from 29 years during the 1970s to 43 years currently.

Gender

About 78% of new SCI cases are male.

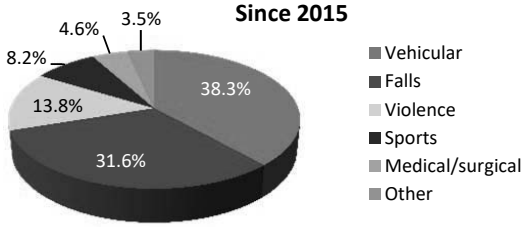
Race/Ethnicity

About 22% of injuries have occurred among non-Hispanic blacks since 2015, which is higher than the proportion of non-Hispanic blacks in the general population (12%).



Cause

Vehicle crashes are currently the leading cause of injury, closely followed by falls. Acts of violence (primarily gunshot wounds) and sports/recreation activities are also relatively common causes.

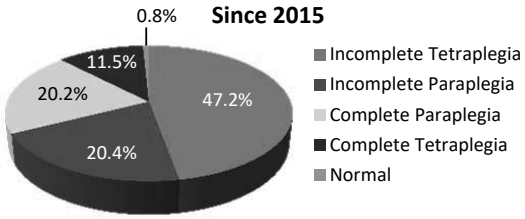


Lengths of Stay

Lengths of stay in the hospital acute care unit have declined from 24 days in the 1970s to 11 days currently. Rehabilitation lengths of stay have also declined from 98 days in the 1970s to 34 days currently.

Neurological Level and Extent of Lesion

Incomplete tetraplegia is currently the most frequent neurological category. The frequency of incomplete and complete paraplegia is virtually the same. Less than 1% of persons experienced complete neurological recovery by the time of hospital discharge.



Spinal Cord Injury Model System
NIDILRR
National Institute on Disability, Independent Living, and Rehabilitation Research

MSKTC SCI · TBI · BURN | Model Systems Knowledge Translation Center

Marital Status

More than half of persons with SCI are single/never married at the time of their injury. The percentage of persons who are married slowly increases over time, as does divorce.

Status (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
Single	51.2	50.0	41.1	36.1	30.5	25.1
Married	32.9	32.5	33.6	35.1	38.2	43.9
Divorced	9.5	11.2	19.3	23.2	23.9	20.7

Occupational Status

At one year after injury, about 12% of persons with SCI are employed. About one third is employed by 20 years post-injury.

Status (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
Employed	57.7	12.4	26.9	33.2	32.1	31.5
Student	14.6	15.0	6.5	2.4	0.6	0.0

Education

More than half of persons with SCI are high school graduates at the time of their injury. Level of education slowly increases over time.

Education (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
High School Only	51.5	54.0	51.1	47.0	43.6	32.3
College or Higher	11.6	12.9	22.1	28.3	35.7	47.3

Re-Hospitalization

About 30% of persons with SCI are re-hospitalized one or more times during any given year following injury. Among those re-hospitalized, the length of hospital stay averages about 22 days. Diseases of the genitourinary system are the leading cause of re-hospitalization, followed by disease of the skin. Respiratory, digestive, circulatory, and musculoskeletal diseases are also common causes.

Lifetime Costs

The average yearly expenses (health care costs and living expenses) and the estimated lifetime costs that are directly attributable to SCI vary greatly based on education, neurological impairment, and pre-injury employment history. These estimates do not include any indirect costs such as losses in wages, fringe benefits, and productivity (indirect costs averaged $74,509 per year in 2017 dollars).

	Average Yearly Expenses (in 2017 dollars)		Estimated Lifetime Costs by Age at Injury (discounted at 2%)	
Severity of Injury	First Year	Each Subsequent Year	25 years old	50 years old
High Tetraplegia (C1–C4) AIS ABC	$1,102,403	$191,436	$4,891,398	$2,688,229
Low Tetraplegia (C5–C8) AIS ABC	$796,583	$117,437	$3,573,960	$2,198,305
Paraplegia AIS ABC	$537,271	$71,172	$2,391,872	$1,569,714
Motor Functional at Any Level AIS D	$359,783	$43,700	$1,634,139	$1,153,420

Data Source: Economic Impact of SCI published in the journal *Topics in Spinal Cord Injury Rehabilitation,* Volume 16, Number 4, in 2011. ASIA Impairment Scale (AIS) is used to grade the severity of a person's neurological impairment following spinal cord injury.

Life Expectancy

The average remaining years of life for persons with SCI have not improved since the 1980s and remain significantly below life expectancies of persons without SCI. Mortality rates are significantly higher during the first year after injury than during subsequent years, particularly for persons with the most severe neurological impairments.

		Life Expectancy (years) for Post-Injury by Severity of Injury and Age at Injury									
		For Persons Who Survive the First 24 Hours					For Persons Surviving at Least 1 Year Post-Injury				
Age at Injury	No SCI	AIS D—Motor Functional at Any Level	Para	Low Tetra (C5–C8)	High Tetra (C1–C4)	Ventilator Dependent Any Level	AIS D—Motor Functional at Any Level	Para	Low Tetra (C5–C8)	High Tetra (C1–C4)	Ventilator Dependent-Any Level
20	59.6	52.9	45.7	40.3	34.0	11.3	53.2	46.2	41.2	35.2	19.0
40	40.7	35.2	29.7	24.9	20.9	8.7	35.4	30.2	25.7	22.1	13.3
60	23.2	19.5	16.1	13.2	11.1	3.7	19.7	16.5	14.0	12.5	7.9

Cause of Death

Persons enrolled in the National SCI Database since its inception in 1973 have now been followed for 40 years after injury. During that time, the causes of death that appear to have the greatest impact on reduced life expectancy for this population are pneumonia and septicemia. Mortality rates are declining for cancer, heart disease, stroke, arterial diseases, pulmonary embolus, urinary diseases, digestive diseases, and suicide. However, these gains are being offset by increasing mortality rates for endocrine, metabolic and nutritional diseases, accidents, nervous system diseases, musculoskeletal disorders, and mental disorders. There has been no change in the mortality rate for septicemia in the past 40 years, and there has only been a slight decrease in mortality due to respiratory diseases.

 The contents of this publication were developed under grants from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant numbers 90DP0083 and 90DP0082). NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this publication do not necessarily represent the policy of NIDILRR, ACL, HHS, and you should not assume endorsement by the Federal Government.

Data from the National SCI Database is from 29 federally funded SCI Model Systems since 1973. Presently, there are 14 systems and 5 Form II (follow up) centers sponsored by NIDILRR. For a complete list of current SCI Model Systems, go to www.msktc.org/sci/model-system-centers.

Citation: National Spinal Cord Injury Statistical Center, Facts and Figures at a Glance. Birmingham, AL: University of Alabama at Birmingham, 2018.

THE Basics

NIH CLINICAL RESEARCH TRIALS **AND YOU**

Source: nih.gov/health-information/nih-clinical-research-trials-you/basics

What are clinical trials and why do people participate?

Clinical research is medical research that involves people like you. When you volunteer to take part in clinical research, you help doctors and researchers learn more about disease and improve health care for people in the future. Clinical research includes all research that involves people. Types of clinical research include:

- Epidemiology, which improves the understanding of a disease by studying patterns, causes, and effects of health and disease in specific groups.
- Behavioral, which improves the understanding of human behavior and how it relates to health and disease.
- Health services, which looks at how people access health care providers and health care services, how much care costs, and what happens to patients as a result of this care.
- Clinical trials, which evaluate the effects of an intervention on health outcomes.

What are clinical trials and why would I want to take part?

Clinical trials are part of clinical research and at the heart of all medical advances. Clinical trials look at new ways to prevent, detect, or treat disease. Clinical trials can study:

- New drugs or new combinations of drugs
- New ways of doing surgery
- New medical devices
- New ways to use existing treatments
- New ways to change behaviors to improve health
- New ways to improve the quality of life for people with acute or chronic illnesses.

The goal of clinical trials is to determine if these treatment, prevention, and behavior approaches are safe and effective. People take part in clinical trials for many reasons. Healthy volunteers say they take part to help others and to contribute to moving science forward. People with an illness or disease also take part to help others, but also to possibly receive the newest treatment and to have added (or extra) care and attention from the clinical trial staff. Clinical trials offer hope for many people and a chance to help researchers find better treatments for others in the future.

How does the research process work?

The idea for a clinical trial often starts in the lab. After researchers test new treatments or procedures in the lab and in animals, the most promising treatments are moved into clinical trials. As new treatments move through a series of steps called phases, more information is gained about the treatment, its risks, and its effectiveness.

What are clinical trial protocols?

Clinical trials follow a plan known as a protocol. The protocol is carefully designed to balance the potential benefits and risks to participants, and answer specific research questions. A protocol describes the following:

- The goal of the study
- Who is eligible to take part in the trial
- Protections against risks to participants
- Details about tests, procedures, and treatments
- How long the trial is expected to last
- What information will be gathered

A clinical trial is led by a principal investigator (PI). Members of the research team regularly monitor the participants' health to determine the study's safety and effectiveness.

What is an Institutional Review Board?

Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are reduced and are outweighed by potential benefits. IRBs are committees that are responsible for reviewing research in order to protect the rights and safety of people who take part in research, both before the research starts and as it proceeds. You should ask the sponsor or research coordinator whether the research you are thinking about joining was reviewed by an IRB.

What is a clinical trial sponsor?

Clinical trial sponsors may be people, institutions, companies, government agencies, or other organizations that are responsible for initiating, managing or financing the clinical trial, but do not conduct the research.

What is informed consent?

Informed consent is the process of providing you with key information about a research study before you decide whether to accept the offer to take part. The process of informed consent continues throughout the study. To help you decide whether to take part, members of the research team explain the details of the study. If you do not understand English, a translator or interpreter may be provided. The research team provides an informed consent document that includes details about the study, such as its purpose, how long it's expected to last, tests or procedures that will be done as part of the research, and who to contact for further information. The informed consent document also explains risks and potential benefits. You can then decide whether to sign the document. Taking part in a clinical trial is voluntary and you can leave the study at any time.

What are the types of clinical trials?

There are different types of clinical trials.

- **Prevention trials** look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning. Approaches may include medicines, vaccines, or lifestyle changes.
- **Screening trials** test new ways for detecting diseases or health conditions.
- **Diagnostic trial**s study or compare tests or procedures for diagnosing a particular disease or condition.
- **Treatment trials** test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
- **Behavioral trials** evaluate or compare ways to promote behavioral changes designed to improve health.
- **Quality of life trials** (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with conditions or illnesses.

What are the phases of clinical trials?

Clinical trials are conducted in a series of steps called "phases." Each phase has a different purpose and helps researchers answer different questions.

- **Phase I trials:** Researchers test a drug or treatment in a small group of people (20–80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.
- **Phase II trials:** The new drug or treatment is given to a larger group of people (100–300) to determine its effectiveness and to further study its safety.
- **Phase III trials:** The new drug or treatment is given to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.
- **Phase IV trials:** After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment's benefits, and optimal use.

What do the terms placebo, randomization, and blinded mean in clinical trials?

In clinical trials that compare a new product or therapy with another that already exists, researchers try to determine if the new one is as good, or better than, the existing one. In some studies, you may be assigned to receive a **placebo** (an inactive product that resembles the test product, but without its treatment value).

Comparing a new product with a placebo can be the fastest and most reliable way to show the new product's effectiveness. However, placebos are not used if you would be put at risk — particularly in the study of treatments for serious illnesses — by not having effective therapy. You will be told if placebos are used in the study before entering a trial.

Randomization is the process by which treatments are assigned to participants by chance rather than by choice. This is done to avoid any bias in assigning volunteers to get one treatment or another. The effects of each treatment are compared at specific points during a trial. If one treatment is found superior, the trial is stopped so that the most volunteers receive the more beneficial treatment.

"Blinded" (or **"masked"**) studies are designed to prevent members of the research team and study participants from influencing the results. Blinding allows the collection of scientifically accurate data. In **single-blind** (**"single-masked"**) studies, you are not told what is being given, but the research team knows. In a double-blind study, neither you nor the research team are told what you are given; only the pharmacist knows. Members of the research team are not told which participants are receiving which treatment, in order to reduce bias. If medically necessary, however, it is always possible to find out which treatment you are receiving.

Who takes part in clinical trials?

Many different types of people take part in clinical trials. Some are healthy, while others may have illnesses. Research procedures with healthy volunteers are designed to develop new knowledge, not to provide direct benefit to those taking part. Healthy volunteers have always played an important role in research.

Healthy volunteers are needed for several reasons. When developing a new technique, such as a blood test or imaging device, healthy volunteers help define the limits of "normal." These volunteers are the baseline against which patient groups are compared and are often matched to patients on factors such as age, gender, or family relationship. They receive the same tests, procedures, or drugs the patient group receives. Researchers learn about the disease process by comparing the patient group to the healthy volunteers.

Factors like how much of your time is needed, discomfort you may feel, or risk involved depends on the trial. While some require minimal amounts of time and effort, other studies may require a major commitment of your time and effort, and may involve some discomfort. The research procedure(s) may also carry some risk. The informed consent process for healthy volunteers includes a detailed discussion of the study's procedures and tests and their risks.

A **patient volunteer** has a known health problem and takes part in research to better understand, diagnose, or treat that disease or condition. Research with a patient volunteer helps develop new knowledge. Depending on the stage of knowledge about the disease or condition, these procedures may or may not benefit the study participants.

Patients may volunteer for studies similar to those in which healthy volunteers take part. These studies involve drugs, devices, or treatments designed to prevent,or treat disease. Although these studies may provide direct benefit to patient volunteers, the main aim is to prove, by scientific means, the effects and limitations of the experimental treatment. Therefore, some patient groups may serve as a baseline for comparison by not taking the test drug, or by receiving test doses of the drug large enough only to show that it is present, but not at a level that can treat the condition.

Researchers follow clinical trials guidelines when deciding who can participate, in a study. These guidelines are called **Inclusion/Exclusion Criteria**. Factors that allow you to take part in a clinical trial are called "inclusion criteria." Those that exclude or prevent participation are "exclusion criteria." These criteria are based on factors such as age, gender, the type and stage of a disease, treatment history, and other medical conditions. Before joining a clinical trial, you must provide information that allows the research team to determine whether or not you can take part in the study safely. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe, and to help ensure that researchers can find new information they need.

What do I need to know if I am thinking about taking part in a clinical trial?

Risks and potential benefits

Clinical trials may involve risk, as can routine medical care and the activities of daily living. When weighing the risks of research, you can think about these important factors:

- The possible harms that could result from taking part in the study
- The level of harm
- The chance of any harm occurring

Most clinical trials pose the risk of minor discomfort, which lasts only a short time. However, some study participants experience complications that require medical attention. In rare cases, participants have been seriously injured or have died of complications resulting from their participation in trials of experimental treatments. The specific risks associated with a research protocol are described in detail in the informed consent document, which participants are asked to consider and sign before participating in research. Also, a member of the research team will explain the study and answer any questions about the study. Before deciding to participate, carefully consider risks and possible benefits.

Potential benefits

Well-designed and well-executed clinical trials provide the best approach for you to:

- Help others by contributing to knowledge about new treatments or procedures.
- Gain access to new research treatments before they are widely available.
- Receive regular and careful medical attention from a research team that includes doctors and other health professionals.

Risks

Risks to taking part in clinical trials include the following:

- There may be unpleasant, serious, or even life-threatening effects of experimental treatment.
- The study may require more time and attention than standard treatment would, including visits to the study site, more blood tests, more procedures, hospital stays, or complex dosage schedules.

What questions should I ask if offered a clinical trial?

If you are thinking about taking part in a clinical trial, you should feel free to ask any questions or bring up any issues concerning the trial at any time. The following suggestions may give you some ideas as you think about your own questions.

The study

- What is the purpose of the study?
- Why do researchers think the approach may be effective?
- Who will fund the study?
- Who has reviewed and approved the study?
- How are study results and safety of participants being monitored?
- How long will the study last?
- What will my responsibilities be if I take part?
- Who will tell me about the results of the study and how will I be informed?

Risks and possible benefits

- What are my possible short-term benefits?
- What are my possible long-term benefits?
- What are my short-term risks, and side effects?
- What are my long-term risks?
- What other options are available?
- How do the risks and possible benefits of this trial compare with those • options?

Participation and care

- What kinds of therapies, procedures and/or tests will I have during the trial?
- Will they hurt, and if so, for how long?
- How do the tests in the study compare with those I would have outside of the trial?
- Will I be able to take my regular medications while taking part in the clinical trial?
- Where will I have my medical care?
- Who will be in charge of my care?

Personal issues
- How could being in this study affect my daily life?
- Can I talk to other people in the study?

Cost issues
- Will I have to pay for any part of the trial such as tests or the study drug?
- If so, what will the charges likely be?
- What is my health insurance likely to cover?
- Who can help answer any questions from my insurance company or health plan?
- Will there be any travel or child care costs that I need to consider while I am in the trial?

Tips for asking your doctor about trials
- Consider taking a family member or friend along for support and for help in asking questions or recording answers.
- Plan what to ask — but don't hesitate to ask any new questions.
- Write down questions in advance to remember them all.
- Write down the answers so that they're available when needed.
- Ask about bringing a tape recorder to make a taped record of what's said (even if you write down answers).

This information courtesy of Cancer.gov.

How is my safety protected?

Ethical guidelines

The goal of clinical research is to develop knowledge that improves human health or increases understanding of human biology. People who take part in clinical research make it possible for this to occur. The path to finding out if a new drug is safe or effective is to test it on patients in clinical trials. The purpose of ethical guidelines is both to protect patients and healthy volunteers, and to preserve the integrity of the science.

Informed consent

Informed consent is the process of learning the key facts about a clinical trial before deciding whether to participate. The process of providing information to participants continues throughout the study. To help you decide whether to take part, members of the research team explain the study. The research team provides an informed consent document, which includes such details about the study as its purpose, duration, required procedures, and who to contact for various purposes. The informed consent document also explains risks and potential benefits.

If you decide to enroll in the trial, you will need to sign the informed consent document. You are free to withdraw from the study at any time.

IRB review

Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are minimal when compared with potential benefits. An IRB is an independent committee that consists of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are protected. You should ask the sponsor or research coordinator whether the research you are considering participating in was reviewed by an IRB.

Further reading

For more information about research protections, see:
- Office of Human Research Protection
- Children's Assent to Clinical Trial Participation

For more information on participants' privacy and confidentiality, see:
- HIPAA Privacy Rule
- The Food and Drug Administration, FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective

For more information about research protections, see:
About Research Participation (hhs.gov/ohrp/education-and-outreach/about-research-participation/index.html)

What happens after a clinical trial is completed?

After a clinical trial is completed, the researchers carefully examine information collected during the study before making decisions about the meaning of the findings and about the need for further testing. After a phase I or II trial, the researchers decide whether to move on to the next phase or to stop testing the treatment or procedure because it was unsafe or not effective. When a phase III trial is completed, the researchers examine the information and decide whether the results have medical importance.

Results from clinical trials are often published in peer-reviewed scientific journals. **Peer review** is a process by which experts review the report before it is published to ensure that the analysis and conclusions are sound. If the results are particularly important, they may be featured in the news, and discussed at scientific meetings and by patient advocacy groups before or after they are published in a scientific journal. Once a new approach has been proven safe and effective in a clinical trial, it may become a new standard of medical practice.

Ask the research team members if the study results have been or will be published. Published study results are also available by searching for the study's official name or Protocol ID number in the National Library of Medicine's PubMed® database.

How does clinical research make a difference to me and my family?

Only through clinical research can we gain insights and answers about the safety and effectiveness of treatments and procedures. Groundbreaking scientific advances in the present and the past were possible only because of participation of volunteers, both healthy and those with an illness, in clinical research. Clinical research requires complex and rigorous testing in collaboration with communities that are affected by the disease. As research opens new doors to finding ways to diagnose, prevent, treat, or cure disease and disability, clinical trial participation is essential to help us find the answers.

Unite 2 Fight Paralysis does not imply or infer an endorsement or recommendation of the below mentioned research. Find updated Clinical Trials charts on our website: https://u2fp.org/get-involved/resources.html

ACRONYM CHART

ABT	**Activity Based Therapy**
ADSC	**Adipose Derived Stem Cells (Body Fat)**
ahSC	**Autologous Human Schwann Cells**
AIS	**American Spinal Injury Association Impairment Scale (AIS): International Standards for Neurological Classification of Spinal Cord Injury**
ALS	**Amyotrophic Lateral Sclerosis**
BMSC	**Bone Marrow Stromal or Stem Cell**
BMMNC	**Bone Marrow Mononuclear Cell**
BMPC	**Bone Marrow Progenitor Cells**
BMI	**Brain Machine Interface**
CPG	**Central Pattern Generator**
DOD	**Department of Defense (US)**
DTI	**Diffusion Tensor Imaging**
ECoG	**Electrocorticography**
EES	**Epidural Electrical Stimulation**
EMG	**Electromyographic**
FES	**Functional Electrical Stimulation**
FGF	**Fibroblast Growth Factor**
FDA	**Food & Drug Administration**
GRNOPC1	**Geron Oligodendrocyte Progenitor Cell**
hESC	**Human Embryonic Stem Cell**
hOESC	**Human Olfactory Ensheathing Stem Cell**
HUCB-MNC	**Human Umbilical Cord Blood Mononuclear Cells**
HNSC	**Human Neural Stem Cell**
HSSC	**Human Spinal Cord Stem Cell**
IDE	**Investigational Device Exemption**
IND	**Investigational New Drug**
iPSC	**Induced Pluripotent Stem Cell**
MSC	**Mesenchymal Stem Cell**
NIH	**National Institutes of Health**
OLP	**Olfactory Lamina Propria**
OPC	**Oligodendrocyte Progenitor Cells**
PI	**Principal Investigator**
rhHGF	**Recombinant Human Hepatocyte Growth Factor**
rTMS	**Repetitive Transcranial Magnetic Stimulation**
SCI	**Spinal Cord Injury**
SMA	**Spinal Muscular Atrophy**
TMS	**Transcranial Magnetic Stimulation**
UC-MSC	**Human Umbilical Cord-derived Mesenchymal Stem Cells**

Questions and comments are welcome at trials@u2fp.org

ONGOING CLINICAL TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
Albany Medical College	Jamboxx Respiratory Therapy Device	NCT03533400	quadriplegia	US	Not yet recruiting
AOSpine Europe	Surgical Decompression	NCT01674764	Acute <14 days post	Sites in Europe	Recruiting
AOSpine North American	Riluzole Oral Therapy	Ph II&III NCT01597518	Acute <24 hrs post Video presentation	US/Canada	Recruiting News
Aristotle University Of Thessaloniki	Brainwave Control of a Wearable Robotic Arm	NCT02443558	Cervical SCI	Greece	Active, Not Recruiting
Asterias Biotherapeutics	AST-OPC1	Ph I & II NCT02302157	ASI A&B C5 -C7 Complete < 25 days post	US	Active, Not Recruiting Shepherd Ctr Report Report 1-24-17
Baylor College of Medicine	Injection vs oral Botox	NCT01050114	Stable injury >6 mos neurogenic bladder	US	Recruiting
BioArtic Neuroscience	Fibroblast Growth Factor 1	Ph I & II NCT02490501	ASI A T2 - T11 4 - 48 mos post	Sweden	Recruiting
Brooks Rehabilitation Ctr.	Hybrid Assistive Limb (HAL)	NCT03504826	ASI B, C or D >1 yr post injury	US	Not yet recruiting
Burke Med Research Institute	Non-Invasive Stim & Anklebot	NCT03592173	> 6 mos post function in ankle flexor and extensors	US	Recruiting
	Robotic Training and tDCS	NCT03555838	ASI B,C or D Cervical >6 mo post	US	Recruiting
California Institute of Tech	Brain Machine Interface	NCT 01964261	High cervical injury	US 3 locations	Recruiting
Case Western Reserve Metro Health Center	Multi-functional Neuroprosthetic	NCT02329652	C4-C8 >6 mos post All AIS grades	US	Recruiting
	IST-16 Implanted Stimulator	NCT00623389	> 6 mos post C6 - T12	US	Recruiting
	Neuroprosthesis for Posture and Trunk Control	NCT01474148	>6 mos post C4-T12 ASI A-C	US	Recruiting
	Stimulation to restore cough	NCT01659541	C8 or above 12 mo post incomplete 6 mo post complete	US	Recruiting
	Implant Myoelectric Control	NCT00583804	Chronic pediatric	US	Active, not recruiting
Centre Hospitalier Universitaire Vaudois	Epidural Elec Stimulation w/Robotic Rehab (STIMO)	NCT02936453	ASI C&D T8 & above >12 mos post	SUI	Recruiting Add'tl Info U2FP Video
Centre Hospitalier Universitaire de Saint Etienne	Brain Reorganization in Neuropathic Pain	NCT02858466	Neuropathic pain	France	Recruiting
Chinese Academy of Sciences	NeuroRegen Scaffold™	Ph I NCT02352077	ASI A C5 - T12 Chronic	China	Recruiting by invite only
	Collagen Scaffold Transplantation	Ph 1 NCT02510365	<21 days post C5 - T12 Acute	China	Recruiting
	NeuroRegen Scaffold™ w/stem cells	NCT02688049	C5 - T12 Chronic ASI A	China	Recruiting
	NeuroRegen Scaffold™ w/BMSCs vs. Intradural Decompression	NCT02688062	Thoracic Chronic ASI A	China	Recruiting

ONGOING CLINICAL TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
Cleveland Clinic	Non-invasive brain stimulation	NCT01539109	Incomplete Chronic >6 mos post	US	Recruiting
Clinique Romande de Readaptation	Body Weight Support Robot LEAP	NCT03458169	Detailed criteria	SUI	Recruiting
Craig Hospital	Simvastatin to treat bone loss	NCT02946424	<3 mo post Acute AIS A-C	US	Recruiting
Da Nang Hospital	Bone Marrow-derived Mononuclear Cells	NCT02923817	3 wks -1 yr post ASI A or B	Vietnam	Recruiting
École Polytechnique Fédérale de Lausanne	STIMO EES w/Robot-assisted Rehab	NCT02936453	ASI C&D T10 & above 12 mo post	Switzerland	Recruiting
	LEAP: Overground Body Weight Support Robot	NCT03458169	Detailed criteria	Switzerland	Recruiting
Ekso Bionics	Lower extremity exoskeleton	NCT02566850	Be able to balance with arms	US	Recruiting by invitation
	Exoskeleton (WISE)	NCT02943915	C1-T10 AIS C&D	US	Recruiting
Erenköy Physical Therapy and Rehabilitation Hospital	exsoskeleton vs robotic training	NCT03544398	previous robotic training	Turkey	Not yet recruiting
Eusol Biotech Co., Ltd.	ES135 (rhFGF1) Fibroblast growth factor	PhIII NCT03229031	ASI A	Taiwan 3 locations	Recruiting
Fed. Research Clinical Ctr Novagenesis Fdn/Fortuna Fix	Neural Stem Cells	Ph I & II NCT02326662	ASI A or B Acute & Chronic	Russia	Active, not recruiting
Federal Univ of Pernambuco	rTMS w/Treadmill Training	NCT03394560	AIS C or D Below T1 >8 mos post	Brazil	Not yet recruiting
Ferrer Internacional S.A.	Allogeneic Adipose Derived Adult Mesenchymal Stem Cells	NCT02917291	Two phases each with detailed criteria	Spain	Recruiting
Groupe Hospitalier Paris Saint Joseph	Artificial Intelligence Engine (IA) Eclipse Nim, Medtronic®	NCT02833428	Acute C2 - T12	France	Recruiting
Helsinski Univ Central Hosp	Transcranial Magnetic & Peripheral Nerve Stim	NCT03045744	Incomplete	Finland	Recruiting by invite only
	Transcranial magnetic stimulation	NCT03104803	Incomplete Non traumatic	Finland	Recruiting by invite only
	Paired associative stimulation	NCT03459885	Cervical incomplete	Finland	Recruiting by invite only
Hospital Nacionalde Parapléjicos de Toledo	Autoantibodies	NCT02493543	<45 days post	Spain	Active, Not Recruiting
	Exoskeleton	NCT03477123	ASI C - D 6 wks -18 mo post	Spain	Recruiting by invite only
Hospital Sao Rafael	Autologous Mesenchymal SCs	PH II NCT02574585	Thoracolumbar Chronic and Complete	Brazil	Not yet recruiting
	Autologous Mesenchymal SCs	Ph I NCT02574572	C5 - C7 >12 mos post ASI A	Brazil	Recruiting
Institut Guttmann	Intrathecal Wharton's Jelly Mesenchymal SCs	NCT03003364	T2-T11 AIS A Chronic 1-5yrs post	Spain	Active, Not Recruiting
Instituto Nacional de Rehabilitacion	Robotic Gait Training	NCT02749357	>6 mos post ASI C or D	Mexico	Recruiting
InVivo Therapeutics	Biopolymer Scaffolding INSPIRE Study	Ph III NCT02138110	ASI A Acute T2 - T12/L1	US 19 Locations	Ongoing not recruiting U2FP Video
Ipsen Innovations	Dysport® Urinary Incontinence	PH III NCT02660138	6 mos post T1 or below	US & Canada	Recruiting
	Dysport® Study 2	NCT02660359	6 mos post T1 or below	US & Canada	Recruiting
	FES Arm & Shoulder	Ph I & II NCT01005615	Chronic C1-C6	US	Active, not recruiting

ONGOING CLINICAL TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
Kennedy Krieger Institute	Aquatic vs. Land Locomotor Training	NCT02774603	C1-C7 ASI C or D >12 mos post	US	Recruiting
	Transcutaneous Stimulation (TSCS) and Gait Training	NCT03384017	>1 yr post T10 and above	US	Recruiting
Kessler Foundation	Testosterone, Standing and Estim	NCT02317640	Male, C6 - T10 ASI A, B or C	US	Recruiting
	Micro-fragmented adipose tissue (Lipogems®)	NCT03167138	>12 mos post C5-L5 Shoulder pain	US	Recruiting
	Robotic Exoskeleton	NCT02324322	>1 yr post C6-T10	US	Recruiting
	MRI to study plasticity	NCT03069222	< 3 wks post injury	US	Recruiting
	Mirabegron and Oxybutynin (MOSET-SCI)	NCT03187795	At least 12 mo post ASI A-D	US	Not recruiting
	Exoskeleton and Spinal Cord Stimulation	NCT03096197	Varied criteria	US	Recruiting
Kringle Pharma	Hepatocyte GF (KP-100IT)	Ph I & II NCT02193334	Acute below C3 < 72 hrs after injury	Japan	Recruiting
Kunming Tongren Hospital	Decompression Surgery+Rehab vs Surgery alone	NCT02663310	>12 mos post T1 - T12 ASI A	Hong Kong	Recruiting
Lille Catholic University	Ejaculatory Dyssynergia by Electronic Microsensors (EDGE)	NCT02974673	Male	France	Recruiting
Loewenstein Hospital	Transcranial direct current stim tDCS -Pain & Function	NCT03052244	Hebrew/Neuro pain	Israel	Not yet recruiting
Massachusetts Gen'l Hosp Case Western Reserve - Stanford - Providence	BrainGate2	NCT 00912041	Complete/incomplete quadriplegia	US 4 Locations	Recruiting
Mayo Clinic	Epidural Stimulation	NCT02592668	2 yrs post ASI A or B C7 - T10	US	Ongoing not recruiting Info/Videos
	Adipose-derived mesenchymal stem cells (AD-MSCs)	NCT03308565	2 wks - 1 yr post	US	Recruiting
McGuire Research Institute VA Medical Center	Exoskeleton and Spinal Cord Injury (EXTra-SCI)	NCT03410550	>1 yr post	US	Recruiting
MD Stem Cells The Healing Institute	BMSCs Exoskeleton & Virtual Reality (SciExVR)	NCT03225625	Medically stable SCI	US	Recruiting
Medical University of Graz	Hyperbaric Oxygenation	NCT03101982	Complete & Incomplete	Austria	Not yet recruiting
Miami Project to Cure Paralysis	ahSC Transplantation	NCT02354625	C5 - T12 <12 mos post	US	Recruiting
	Neural Control of Bilateral Movements	NCT02446210	Detailed criteria	US	Recruiting U2FP Report
	Corticospinal Function	NCT02451683	>6 mos post C8 & above	US	Recruiting
Moleac - Kebangsaan Malaysia Med Ctr	NeuroAiD drug w/rehab	NCT02537899	3 days - 4 wks post ASI A or B	Malaysia	Link Recruiting
Montecatone Rehab Inst	Exoskelton	NCT03443700	1-5 years post T1-L1 ASI C or D	Italy	Not yet recruiting
	Robotic anthropomorphic exoskeleton (EKSO-GT)	NCT03443700	ASI C or D T1-L1 1-5 yrs post	Italy	Not yet recruiting
	Pain - Acupuncture vs Aspecific Needle Skin Stimulation	NCT03170557	ASI A,B,C or D >1 mo post	Italy	Recruiting

ONGOING CLINICAL TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
Mt. Sinai Hospital	Botox to treat pain	NCT02736890	Pain at level of SCI	US	Recruiting
MyndTec Inc.	Reaching/Grasping MyndMove® Neuromodulation	NCT03439319	AIS B-D C4-C7 >4 mo & <12 mo post	US & Canada	Not yet recruiting
Neuralstem	Neural stem cell (HSSC)	NCT01772810	>1 yr, < than 2 T2-T12 & C5-C7	US	Recruiting News Link
Nantes University Hospital	Upper limb tendon transfer	NCT03513783	At St. Jacques Hosp C5 - C6 w/health ins	France	Not yet recruiting
	Delay in Surgery Cervical Central Cord Injury in Canal Stenosis	NCT02673320	AIS A-D C2 - T1	4 Locations France	Not yet recruiting
Neurogen Brain & Spine Institute	Autologous BMSCs	Ph II NCT02009124	All AIS and Injury levels	India	Recruiting
NHS Greater Glasgow and Clyde	Neuro feedback for Neuropathic pain	NCT02678494	C5 - T12	UK	Recruiting
	Neuro feedback for Neuropathic pain	NCT02178917	C5-T12	UK	Recruting
	Brain Control Interface & FES for hand function	NCT 03257982	C2-C7 <1yr post	UK	Recruiting
	Muscle fatigue related to FES	NCT03254862	Incomplete	UK	Recruiting
Northwell Health	Brain Control Interface & FES for hand function	NCT01852279	ASI B-C C4-C8	UK	Recruiting
	Biomarkers of Spontaneous Recovery	NCT02731027	0 -3 days post C4-T10 ASI A-D	US 3 Locations	Recruiting
	Neuromuscular Stim for Hands	NCT03385005	Various criteria	US	Recruiting
Northwestern University	Zoledronic Acid for bone loss	NCT02325414	<120 days post	US	Recruiting
	Teriparatide for bone loss	Ph II NCT02025179	Acute & Chronic Observational Study	US	Active, not recruiting
Ohio State University	Neural Bridge Implant System	NCT01997125	Tetraplegic C4- C6 ASIA A: 12 mo post	US	Recruiting
Oslo University Hospital	Botox for bladder dysfunction	Ph 4 NCT01698138	C6 - T11 <4 wks post	Norway	Recruiting
Ottawa Hospital Research Institute/Washington Univ	Nerve Transfers to Restore Hand Function	NCT02861612	C5 to C7	US	Recruiting
Parker - Hannifin	Indego Exoskeleton	NCT02793635	>1 year post LE function	US 3 locations	Recruiting
Recordati Industria Chimica e Farmaceutica	Drug therapy Neurogenic Detrusor Overactivity	NCT03482037	Below C6 ASI A, B or C >1 yr incontinenace	France	Recruiting
Rehab Inst. of Chicago (RIC) Shirley Ryan AbilityLab	Drug Lexapro	Ph I NCT01753882	C1 - T10 ASI C or D 1 - 9 mos post injury	US	Active Not recruiting
	Hypoxia & upper limb training	NCT03262766	C3-T1 >1 yr post motor incomplete	US	Recruiting
	ReWalk Exsoskeleton	Ph II NCT02104622	Sub-acute incomplete C1 - T10	US	Active, not recruiting
	Ekso Exoskeleton	NCT01701388	C6 - L5	US	Not recruiting
	Robotic or treadmill training w/transcutaneous estim	NCT02991248	C4 - T10	US	Not yet recruiting
	Motor learning in a customized Body-Machine interface	NCT01608438	C3-C6 ASI A,B or C	US	Recruiting
St. George's Univ of London	Spinal Cord Pressure (ISCoPE)	NCT02721615	AIS A-C <72 hrs post	UK	Recruiting

ONGOING CLINICAL TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
	Human Olfactory Ensheathing Stem Cells (hOESC)	NCT02870426	Brain dead donors to donate olfactory bulbs	UK	Recruiting
Seoul National Univ Hospital	Transcutaneous Stimulation	NCT02863315	Cervical/High thoracic >6 mos post	So Korea	Active, Not Recruiting
Shepherd Center	Stimulation 3 types	NCT02611375	C1-C8 Limited hand function	US	Recruiting
	Transcranial direct current stimulation (tDCS)	NCT03237091	Cervical C1-C8 at least 6 mo post ASI A-D	US	Recruiting
	Transcranial direct current stimulation (tDCS)	NCT03237234	C3-T10 >12 mo post ASI C or D	US	Recruiting
	Impact of Whole Body Vibration on Spasticity	NCT02340910	>5 mos post Injury T12 & higher	US	Recruiting
	Stimulation to Augment ABT	NCT03240601	All SCI	US	Recruiting
Spaulding Rehab Hospital	Intermittent hypoxia	NCT02632422	C4-T12 AIS B-D 2-4 mo post	US	Recruiting
	Intermittent hypoxia	NCT02323945	C2-T12 incomplete >1 yr post	US	Recruiting
	Non-invasive ventilation	NCT02865343	Chronic AIS A,B or C T3 or above	US	Recruiting
	Non-invasive ventilation(NIV) w/FES Row training	NCT03267212	AIS A, B or C C5-T12	US	Recruiting
	Hypoxia on Leg Function	NCT02274116	C4-T12 >1 yr post incomplete	US	Recruiting
	Caffeine & Low Oxygen	NCT02323698	below C2 and above T12 > 1 yr post	US	Recruiting
SCI Center of Western Denmark	LION Procedure - Implanted ES device	NCT03441256	T5-L2 AIS A or B <12 mos post	Denmark	Recruiting by invite only
Stem Cells Arabia	Autologous BMSCs or Leukapheresis-Derived SCs	Ph I&II NCT02687672	6 - 60 mos. post	Jordan	Recruiting
Swiss Paraplegic Centre	Rivaroxaban to treat thromboemlism	NCT02970773	AIS A >3 mos post	SUI	Recruiting
	Electrostimulation on Denervated Muscles	NCT02265042	>2 yrs post T10-L5 ASI A	SUI	Recruiting
	Optimal FES Training Characteristics	NCT03621254	>6 wks - <12 wks post C7-T10 ASI A&B	SUI	Not yet recruiting
	Respiratory strength related to complications RESCOM	NCT02891096	C1-T12 ASI A,B,C&D	SUI	Recruiting
	FES Reconstructive Hand & Arm Surgery	NCT03048331	C4 - T1 >6mos post All ASI levels	SUI	Recruiting
Taipei Veterans General Hospital, Taiwan	Freewalk Exoskeleton	NCT03548649	AIS A-D C7-L5	Taiwan	Enrolling by invite
Taris Biomedical	Trospium-Releasing Intravesical System	NCT03168828	Neurogenic Bladder >6 mo post	US 3 locations	Recruiting
The 3rd Affiliated Hospital of Sun Yat-sen University	UC Mesenchymal SCs	PhI&II NCT02481440	2 wks - 1 yr post All injury and ASI levels	China	Recruiting
		PHII NCT03505034	ASI A-D >1yr post injury	China	Recruiting
		PhII NCT03521336	ASI A-D 2 wks-2 mo post	China	Recruiting
		PhII NCT03521323	ASI A-D 2 mo - 12 mo post	China	Recruiting
Thomas Jefferson University	Zoledronic Acid for Bone Loss	NCT01642901	C4-T10 ASI A	US	Active, Not Recruiting

ONGOING CLINICAL TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
Toronto Rehab Institute	Electrical Stimulation	Ph III NCT01292811	Chronic T10-L5 ASI A	Canada	Active, not recruiting
University of Aarhus	Biomarkers	NCT03505463	<72 hrs post C1-LI ISNCSCI A-C	Denmark	Not yet recruiting
University College London	Transcutaneous estim	NCT03536338	>1 yr post C5-T12 ASI A-D	UK	Not yet recruiting
University of Alabama-Birmingham	Neuromuscular estim	NCT03204240	C5-T12 AIS A < 14 days post	US	Recruiting
University of Alberta	Exoskeleton - Rewalk	NCT02322125	>1 yr post	Canada	Recruiting
University of Calgary	Minocycline-Decompression	Ph III NCT01828203	C7 - S1	Canada	Recruiting
Univ of British Columbia	Arm nerve transfer	Ph IV NCT01579604	Chronic Cervical	Canada	Recruiting
	Fesoterodine for AD	NCT02676154	T6 & above >1yr post	Canada	Recruiting
	Upper limb MyndMove Study	NCT02799966	10 days - 6 mo post ASI B&D C4-C7	Canada	Recruting
	Changes to Gut Bacteria	NCT02903472	SCI	Canada	Recruiting
	CSF Monitoring and Biomarker Study (CAMPER)	NCT01279811	Acute within 48 hrs Cervical and Thoracic	US & Canada	Recruiting
University of CA - Los Angeles	Neuromodulation Arm	NCT02313194	C1 - C5 >12 mos post	US	Recruiting U2FP Report
	Neuromodulation Bladder	NCT02331979	C2 - C8 >12 mos post	US	Recruiting
UCLA CalTech Casa Colina	Brain Implant for Neural Control of a Computer	NCT01958086	High cervical injury	US	Recruiting @ Casa Colina
Univ of CA San Francisco	Deep Brain Stimulation (DBS)	NCT 03029884	>1 yr neuropathic pain	US	Recruiting
University of Florida	Intermittent Hypoxia	NCT03071393	>6 mos post C4-T12	US	Recruiting
	Intermittent Hypoxia	NCT03029559	Detailed Exclusion Criteria	US	Recruiting
	Corticospinal Control of Walking	NCT02132650	Detailed criteria	US	Recruiting
	Diaphragm Pacing	NCT02556125	Acute Cervical	US	Recruiting
University Hospital Inselspital, Berne	microRNA Expression in Obstructive & Neurogenic Bladder	NCT02410876	<6 wks post injury	SUI	Recruiting
University of Hong Kong	Tailored-made EMG driven soft-robotic hand	NCT03483766	Tetraplegia	HK	Active, Not Recruiting
University of Jordan	BM-MSC vs AT-MSC	NCT02981576	AIS A,B or C >2wks post	Jordan	Active, not recruiting
University of Louisville	Epi Stim	NCT02339233	Above T10	US	Recruiting
	Recovery of Bladder & Sexual Function through ABTs	NCT03036527	Medically stable	US	Recruiting
	Task-specific Epidural Stimulation Study (TS EPI)	NCT03364660	At least 2 yrs. post SCI	US	Recruiting
	SPARC Bladder Mapping and Training Study	NCT03452007	AIS A-B >2 yrs post	US	Not yet recruiting

ONGOING CLINICAL TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
	Epidural Stimulation for Cardiovascular Function	NCT02037620	AIS A,B or C Cervical injury	US	Active, Not Recruiting
	Pediatric locomotor bladder study	NCT03559036	Supra-sacral, non-progressive SCI	US	Recruiting
University of Maryland	Transcranial therapy	NCT03111277	>6 mo neuro pain	US	Recruiting
University of Miami	Corticospinal Function	NCT02451683	≥ 6 months post C8 and above	US	Recruiting
	Intermittent Hypoxia on Metabolism and Dysglycemia	NCT 02973438	C5 or below >1 yr post BMI requirements	US	Recruiting
	TENS to prevent neuro pain	NCT03267810	< 4mo post	US	Recruiting
	Vagal Nerve Stim to Reduce Inflammation & Hyperadrenergia	NCT02983266	Detailed criteria	US	Recruiting
	Systemic Hypothermia	NCT02991690	ASI A-C <24 hr post	US	Recruiting
	D-Cycloserine and stimulation	PhIV NCT02635893	Above L5 >1 mo post dorsi/hip flexors	US	Recruiting
	Medtronic Activa PC+S Brain Machine Interface	NCT02564419	C5 - C6 Chronic A or B	US	Recruiting
	Magnetic Stimulation	NCT02446210	Detailed criteria	US	Recruiting
	Distal Gut Microbiome	NCT03319225	>1yr post C5-T6 ASI A-C	US	Recruiting
	Intermittent Hypoxia	NCT03433599	> 6mo post AIS C-D C3 - T1	US	Not yet recruiting
	Therapeutic Hypothermia (ARTIC)	Ph I NCT01739010	Acute	US	Active, Not Recruiting
	Vibration for muscle spasms	NCT03598504	> 1 year ASI A,B & C	US	Recruiting
	Male Fertility Program	NCT01467869	Male	US	Recruiting
University of Michigan	Gentamicin Sulfate for bladder infections	NCT03503513	Detailed criteria	US	Not yet recruiting
University of Minnesota	Epidural Stimulation After Neurologic Damage (E-STAND)	NCT03026816	C6 and T10 - ASI A or B Motor complete Chronic	US	Recruiting U2FP Video
University of Nove de Julho	Low-level Laser Therapy	NCT03031223	C3-L5 <1 yr post	Brazil	Recruiting
University of Pernambuco	Transcranial Magnetic Stimulation	NCT03014999	Detailed criteria	Brazil	Recruiting
University of Pittsburgh	Microelectrode Brain-Machine Interface	NCT01364480	>1 yr post Cervical injury	US	Recruiting
	Effect of Vibration Exercise on Upper Limb	NCT02998021	T2 or lower >1yr post	US	Recruiting
	Brain-Machine Interface Blackrock Microsystems	NCT01894802	Tetraplegia	US	Recruiting
University of Sao Paulo	tDCS and Lokomat Training	NCT02562001	ASI C&D 1-36 mo post	Brazil	Recruiting
	Transcranial Magnetic Stimulation	NCT02899637	Incomplete, nonprogressive etiology	Brazil	Not yet recruiting
University of So. California	NeuroPort Array Brain-Machine Interface (BMI)	NCT01849822	High cervical injury	US	Ongoing not recruiting

ONGOING CLINICAL TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
California Institute of Tech.	Neural Prosthetic System 2	NCT01964261	High cervical injury	US 3 locations	Recruiting
Univ of Texas - San Antonio	Capsaicin 8% Patch Low Dose Capsaicin 0.04% gel	NCT02441660	Neuropathic pain	US	Recruiting
	Anticholinergic Agent vs. Mirabegron (SCIMYR)	NCT03612401	Neurogenic bladder age >60 years	US	Not yet recruiting
University of Texas - Houston	Transcutaneous Stimulation	NCT03249454	T8-T9 >6mo post ASI C&D	US	Recruiting
	Robotic Gait Training	NCT03057652	> 6 mo post	US	Recruiting
	Transcutaneous Tibial Nerve Stim of bladder	NCT03458871	Stable SCI for 6 months	US	Recruiting
	Nerve transfers for hand function	NCT03451474	AIS A, B or C >6 mo post	US	Recruiting
Univ of Texas - Dallas	Technology Upper Extremity RePlay	NCT03621969	Upper limb impairment	US	Recruiting
University of Utah	Implantable sacral neuromodulator for bladder	NCT 03083366	ASI A - B t12 or above <12 wks post	US	Recruiting
	Micro-Electrodes Implanted in a Human Nerve	NCT02034461	peripheral nerve injury	US	Enrolling by invite
University of Washington	Transcutaneous Elec Spinal Stim (ADDRESS)	NCT03184792	C7 and above >1yr post	US	Recruiting
	Transcutaneous Stimulation	NCT03509558	T12 or above	US	Recruiting
University of Zurich	Deep Brain Stimulation	NCT03053791	Incomplete T10 and up > 6 mos post	SUI	Recruiting
	Body Weight Supported Training Study	NCT03534518	>6 mos post ASI C or D Above T12 injury	SUI	Recruiting
	Upper Limb Activity	NCT02098122	<90 days post	SUI	Recruiting
	Probing Neural Circuitry for the Control of Movement	NCT02150642	All	SUI	Recruiting
	Deep Brain Stimulation	NCT03053791	T10 & above Incomplete >6 mo post	SUI	Recruiting
	iCTuS-L (Interactive Computer based Therapy System for legs	NCT02149186	chronic > 1 year; acute < 3 months ASI C&D	SUI	Recruiting
	MRI to assess neuronal degeneration	NCT02149511	Acute	SUI	Recruiting
	INSTrUCT-SCI: INdependent Observational STUdy of Cell Transplantation	NCT03069404	T2-T11 Patients in Ph I&II HuCNS-SC trial	SUI	Active, not recruiting
	Transcutaneous cord stim	NCT03137108	≥12 mo post or ≥3 mo post	SUI	Recruiting
Uro-Research	Tissue Bonding Cystostomy	NCT01771159	>2 years post	US	Not yet recruiting
Vanderbilt University	Indego Exsoskelton	NCT03082898	C5 or lower 6 mos prefer > 1 yr post	US	Recruiting
	Intrathecal Baclofen for Spasticity	NCT02903823	SCI w/spasticity	US	Recruiting
	IntraSpinal Micro-Stimulation	NCT02899858	AIS A T2-T8 >1yr post	US	Recruiting
Vertex Pharma Inc.	VX-210 Drug	PH II&III NCT02669849	Acute C4 - C6 ASI A&B	US	Recruiting Add'tl. info

ONGOING CLINICAL TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
VA - Bronx	Cefazolin Into Chronic Pelvic-Region Pressure Ulcer	NCT02584426	>6 mos post ASI AorB Stage III or IV PU	US	Recruiting
	Albuterol to Improve Respiratory Strength	NCT02508311	C3-T6 1 yr post	US	Recruiting
	Brain and Nerve Stimulation for hand muscles	NCT02469675	C2 - C8 >12 mos post	US	Recruiting
VA Bronx and Mt. Sinai Hosp	Post-SCI Hypotension	NCT02919917	< 1 year post Non vent dependent	US	Recruiting
	Non-invasive Cervical Estim	NCT03414424	Chronic <12 mo post Incomplete C2-C8	US	Recruiting
VA Bronx and Kessler (NJ)	Denosumab-Prolia for bone loss	NCT03029442	AIS C&D < 6 mos post	US 2 locations	Recruiting
	Rx to regulate BP	NCT02893553	> 1 yr post	US 2 locations	Recruiting
VA Cleveland	Stimulation for bowel dysfunction	NCT02641483	6 mos post	US	Not yet recruiting
	IST-16 - Implanted stimulator-telemeter	NCT01923662	> 6 mos post C6 - T12	US	Recruiting
	Neuroport cortical reporting array	NCT03482310	Participant in BrainGate 2 trial	US	Recruiting
	Hand Function for Tetraplegia FIRSTHAND System	NCT00890916	Cervical injury	US	Active, not recruiting
	Estim for bladder hyperreflexia	NCT03472599	>6 mo post	US	Not yet recruiting
VA - Gainesville	Testosterone Plus Finasteride	NCT02248701	C4 - T7 >12 mos post ASI C&D Male	US	Recruiting
VA - Miami	Paired pulse induced spike-timing dependent plasticity	Ph IV NCT02701777	Detailed inclusion criteria	US	Recruiting
	rTMS Magnetic stimulation	NCT01915095	> 6 mos post L5 and above	US	Recruiting
	Non-invasive brain stim for grasping	NCT03447509	2 mo post L5 and above ASI A - D	US	Not yet recruiting
VA - Palo Alto	Electrical Stim for Continence Vocare Bladder System	NCT02978638	AIS A Below C4 >2 yr post	US	Recruiting
VA - Pittsburgh	Transcranial magnetic stim	NCT01915095	Chronic C8 or above Right-handed	US 3 locations	Active, not recruiting
VA - MD, NJ and NY	Exoskeletal-assisted walking (ReWalk, Ekso)	NCT02314221	>6 mo post Able to hold crutches	3 locations	Recruiting
VA - CA, FL, MA, MN, MO, NY, TX, VA, WI	Exoskeleton	NCT02658656	C6-T3 >6 mos post	US 11 locations	Recruiting
VA Richmond	Testosterone and Long Pulse Stim	NCT03345576	T10 & below ASI A&B	US	Not yet recruiting
Washington University	Nerve Transfers	NCT01714349	>6 mos post injury	US	Recruiting W2W Video
	Upper Extremity Surgery	NCT01899664	Cervical injury	US	Recruiting

COMPLETED AND TERMINATED TRIALS

SPONSOR	THERAPY	PHASE & NUMBER	INJURY INFO	WHERE	STATUS
Armed Forces Institute of Regenerative Medicine	Autologous Mesenchymal SCs	Ph I NCT02482194	Sub-acute, chronic thoracic ASI A	Pakistan	Results
Brigham & Women's Hosp	Drug V158866	Ph II NCT01748695	T5 or below Neuropathic pain	US	Results
Case Western Reserve	Stimulation to restore cough	NCT00116337	T5 or above	US	Completed
Charite University	Dolormin® extra (Ibuprofen)	NCT02096913	Acute, 4-21 days post AIS AorB C4-T4	Germany	Completed
Danish Pain Research Ctr	Diet Supplement - Normast	NCT0181499	>6 mos post injury	Denmark	Completed
Emory University	Intermittent Hypoxia	Ph I NCT01272336	C5 - T1 Incomplete >12 mos post injury	US	Completed
Gen Hosp of Chinese Forces	UMBCs	NCT01393977	UMBCs Thoracolumbar	China	Results
Hospital Sao Rafael	Autologous Mesenchymal SCs	NCT02152657	>6 mos post paraplegia	Brazil	Completed
Indian Spinal Injuries Ctr.	Autologous Bone Marrow SCs	Ph I/II NCT02260713	T1-T12 Acute ASI A 10 - 14 days post	India	Completed
Instituto de Rehabilitación Infantil Teletón Chile	Intermittent Hypoxia and Treadmill Training	NCT02441179	C5-T12 AIS C&D >6 mos post	Chile	Results
Kennedy Kreiger Institute	4-AP & Locomotor Training	Ph II NCT01621113	>12 mos post injury C4 - T10 ASI C or D	US	Completed
Miami Project to Cure Paralysis	Deep Brain Stimulation	Ph I NCT02006433	T6 and above	US	Completed
Montecatone Rehab Inst	Locomotor Training With Exoskeleton EKSO-GT	NCT02600013	Acute AIS C or D	Italy	Completed
Northwesstern University	Alendronate if previously treated w/Teriparatide	NCT02195895	Prior enrollment in trial # NCT01225055	US	Completed
Nordic Life Science Pipeline Collaborator-DOD	SPINALON CPG Tritherapy	Ph I & II NCT01484184	Incomplete C4 - C8 ASI B & C	Canada	Completed
Oregon University	AMES Treatment	Ph I & II NCT01498991	>12 mos post C4 - C6 ASI A	US	Completed Report
Puerto de Hierro Univ Hosp	Autologous BMSCs	Ph II NCT02570932	Chronic, stable All ASI levels	Spain	Completed
Renji Hospital	Electrical stimulation for neurogenic bladder	NCT02554201	Incomplete Neurogenic bladder	China	Completed
Oslo University Hospital	Intermittent Negative Pressure on Wound Healing	NCT02866708	non-healing leg/foot ulcer/pressure wound for > 6 wks	Norway	Completed
Shanghai Institute of Acupuncture/RenJi Hospital	TMS for Upper Limb Dysfunction	NCT02914418	AIS C or D >3 mos post injury	UK	Completed
Sheffield Teaching Hosp Northern Gen Hospital	(tDCS)	Ph I NCT01599767	History of pain	US	Completed
Spaulding Rehab Hospital	HuCNS-SC	Ph I & II NCT01321333	Chronic thoracic >6 wks post injury	Switzerland & Canada	Completed W2W Video Interim Results Nov '15
Stem Cells, Inc.	Long term follow up of HuCNS-SC Translantation	NCT01725880	T2 - T11 w/conus function	SUI	Terminated

COMPLETED AND TERMINATED TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
	HuCNS-SC Transplantation	Ph II NCT02163876	C5 - C7 ASI B or C >12 wks post	US	Terminated
	Extracorporeal Shock Wave Therapy (ESWT) for Spasticity	NCT02203994	>2 yrs post injury C3 - T10	SUI	Completed
Swiss Paraplegic Centre Nottwil	Local Heat Application	NCT03001531	T2-T12 >12 wks post	SUI	Completed
Swiss Paraplegic Centre	Pressure Ulcer Healing With Microcyn	NCT02001558	Stage III/IV Pressure Ulcer	US	Completed
U of AL - Birmingham	Transcranial E-Stim	Ph II NCT01874782	Acute Cervical	Canada	Completed
University of British Columbia	Vaporized Cannabis	Ph II & III NCT01555983	Neuropathic pain	US	Results
Univ. of California - Davis	Deep Brain Stimulation for pain and AD	NCT02006433	T12 and above w/o history of pain	US	Completed
University of Miami	Robot aided arm therapy	NCT02434237	Upper body disability	Switzerland	Completed
University of Texas	Transcutaneous Tibial Nerve Stimulation	NCT02573402	T9 and above <6 wks of injury	US	Completed
University of Zurich	Locomotor Training	NCT01147185	ASI B & C	Spain/SUI	Completed
US Bionics	Phoenix Exoskeleton for SCI	NCT03175055	All SCI under #220	US	Completed
VA Bronx	Animated Bowel Biofeedback	NCT02406859	> 1 yr post injury	US	Completed
VA Cleveland	Implanted neuroprosthesis	Ph I & II NCT00890916	Cervical	US	Results
VA Palo Alto	Neural Adaptation After Tendon Transfer	NCT02768103	C4-C7 1 yr post	US	Completed

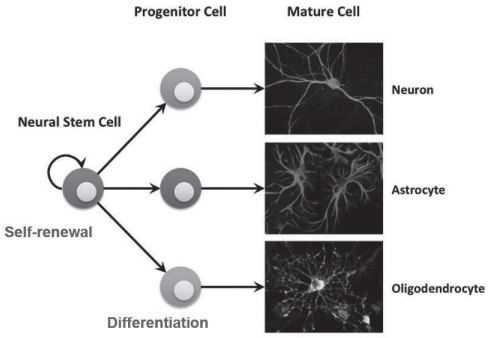
WHAT ARE STEM CELLS?

Stem cells are the foundation cells for every organ and tissue in our bodies. The highly specialized cells that make up these tissues originally came from an initial pool of stem cells formed shortly after fertilization. Throughout our lives, we continue to rely on stem cells to replace injured tissues and cells that are lost every day, such as those in our skin, hair, blood and the lining of our gut. Stem cells have two key properties: 1) the ability to **self-renew,** dividing in a way that makes copies of themselves, and 2) the ability to **differentiate**, giving rise to the mature types of cells that make up our organs and tissues.

TISSUE-SPECIFIC STEM CELLS

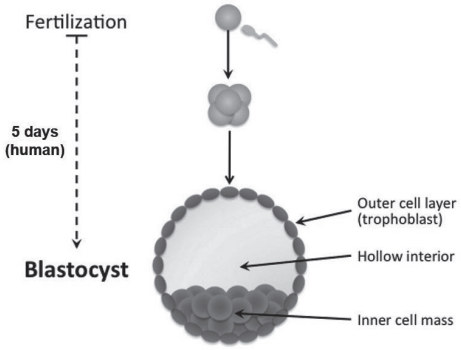
Tissue-specific stem cells, which are sometimes referred to as **"adult"** or **"somatic"** stem cells, are already somewhat specialized and can produce some or all of the mature cell types found within the particular tissue or organ in which they reside. Because of their ability to generate multiple, organ-specific, cell types, they are described as **"multipotent."** For example, stem cells found within the adult brain are capable of making neurons and two types of glial cells, astrocytes and oligodendrocytes.

Tissue-specific stem cells have been found in several organs that need to continuously replenish themselves, such as the blood, skin and gut and have even been found in other, less regenerative, organs such as the brain. These types of stem cells represent a very small population and are often buried deep within a given tissue, making them difficult to identify, isolate and grow in a laboratory setting.



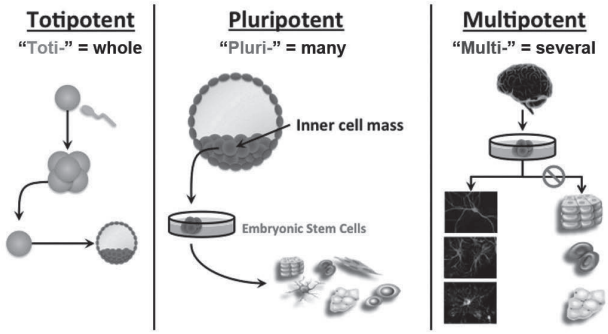
Neuron – Dr. Gerry Shaw, EnCor Biotechnology Inc.
Astrocyte – Abcam Inc.
Oligodendrocyte – Dhaunchak and Nave (2007).
Proc Natl Acad Sci USA 104:17813-8

EMBRYONIC STEM CELLS



Embryonic stem cells have been derived from a variety of species, including humans, and are described as **"pluripotent,"** meaning that they can generate all the different types of cells in the body. Embryonic stem cells can be obtained from the **blastocyst,** a very early stage of development that consists of a mostly hollow ball of approximately 150-200 cells and is barely visible to the naked eye. At this stage, there are no organs, not even blood, just an "inner cell mass" from which embryonic stem cells can be obtained. Human embryonic stem cells are derived primarily from blastocysts that were created by ***in vitro* fertilization** (IVF) for assisted reproduction but were no longer needed.

The fertilized egg and the cells that immediately arise in the first few divisions are **"totipotent."** This means that, under the right conditions, they can generate a viable embryo (including support tissues such as the placenta). Within a matter of days, however, these cells transition to become pluripotent. None of the currently studied embryonic stem **cell lines** are alone capable of generating a viable embryo (i.e., they are pluripotent, not totipotent).



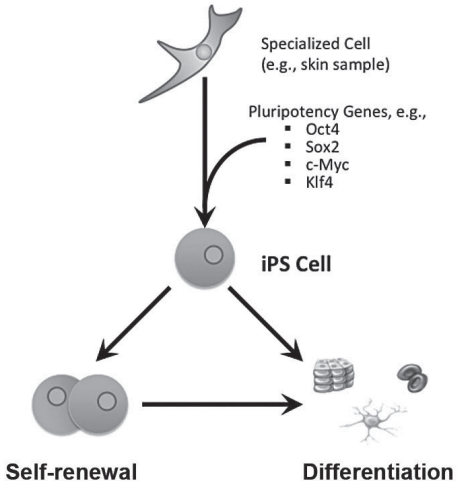
WHY ARE EMBRYONIC STEM CELLS SO VALUABLE?

Unlike tissue-specific (adult) stem cells, embryonic stem cells have the potential to generate every cell type found in the body. Just as importantly, these cells can, under the right conditions, be grown and expanded indefinitely in this unspecialized or "undifferentiated" state. These cells help researchers learn about early human developmental processes that are otherwise inaccessible, study diseases and establish strategies that could ultimately lead to therapies designed to replace or restore damaged tissues.

INDUCED PLURIPOTENT STEM CELLS

One of the hottest topics in stem cell research today is the study of induced pluripotent stem cells (iPS cells). These are adult cells (e.g., skin cells) that are engineered, or "reprogrammed," to become pluripotent, i.e., behave like an embryonic stem cell. While these iPS cells share many of the same characteristics of embryonic stem cells, including the ability to give rise to all the cell types in the body, it is important to understand that they are not identical.

The original iPS cells were produced by using viruses to insert extra copies of three to four genes known to be important in embryonic stem cells into the specialized cell. It is not yet completely understood how these three to four "reprogramming" genes are able to induce pluripotency; this question is the focus of ongoing research. In addition, recent studies have focused on alternative ways of reprogramming cells using methods that are safer for use in clinical settings.



DISEASE-OR PATIENT-SPECIFIC PLURIPOTENT STEM CELLS

One of the major advantages of iPS cells, and one of the reasons that researchers are very interested in studying them, is that they are a very good way to make pluripotent stem cell lines that are specific to a disease or even to an individual patient. Disease-specific stem cells are powerful tools for studying the cause of a particular disease and then for testing drugs or discovering other approaches to treat or cure that disease. The development of patient-specific stem cells is also very attractive for cell therapy, as these cell lines are from the patient themselves and may minimize some of the serious complications of rejection and immunosuppression that can occur following

MOVING STEM CELLS INTO THE CLINIC

Clinical translation is the process used to turn scientific knowledge into real world medical treatments. Researchers take what they have learned about how a tissue usually works and what goes wrong in a particular disease or injury and use this information to develop new ways to diagnose, stop or fix what goes wrong. Before being marketed or adopted as standard of care, most treatments are tested through clinical trials. Sometimes, in attempting new surgical techniques or where the disease or condition is rare and does not have a large enough group of people to form a clinical trial, certain treatments might be tried on one or two people, a form of testing sometimes referred to as **innovative medicine.**

For more information on how science becomes medicine, please visit **www.closerlookatstemcells.org.**

CURRENT THERAPIES

Blood stem cells are currently the most frequently used stem cells for therapy. For more than 50 years, doctors have been using bone marrow transplants to transfer blood stem cells to patients, and more advanced techniques for collecting blood stem cells are now being used to treat leukemia, lymphoma and several inherited blood disorders. Umbilical cord blood, like bone marrow, is often collected as a source of blood stem cells and in certain cases is being used as an alternative to bone marrow transplantation.

Additionally, some bone, skin and corneal diseases or injuries can be treated by grafting tissues that are derived from or maintained by stem cells. These therapies have also been shown to be safe and effective.

POTENTIAL THERAPIES

Other stem cell treatments, while promising, are still at very early experimental stages. For example, the **mesenchymal stem cell**, found throughout the body including in the bone marrow, can be directed to become bone, cartilage, fat and possibly even muscle. In certain experimental models, these cells also have some ability to modify immune functions. These abilities have created considerable interest in developing ways of using mesenchymal stem cells to treat a range of musculoskeletal abnormalities, cardiac disease and some immune abnormalities such as graft-versus-host disease following bone marrow transplant.

REMAINING CHALLENGES

Despite the successes we have seen so far, there are several major challenges that must be addressed before stem cells can be used as cell therapies to treat a wider range of diseases.

First, we need to identify an abundant source of stem cells. Identifying, isolating and growing the right kind of stem cell, particularly in the case of rare adult stem cells, are painstaking and difficult processes. Pluripotent stem cells, such as embryonic stem cells, can be grown indefinitely in the lab and have the advantage of having the potential to become any cell in the body, but these processes are again very complex and must be tightly controlled. iPS cells, while promising, are also limited by these concerns. In both cases, considerable work remains to be done to ensure that these cells can be isolated and used safely and routinely.

Second, as with organ transplants, it is very important to have a close match between the donor tissue and the recipient; the more closely the tissue matches the recipient, the lower the risk of rejection. Being able to avoid the life-long use of immunosuppressants would also be preferable. The discovery of iPS cells has opened the door to developing patient-specific pluripotent stem **cell lines** that can later be developed into a needed cell type without the problems of rejection and immunosuppression that occur from transplants from unrelated donors.

Third, a system for delivering the cells to the right part of the body must be developed. Once in the right location, the new cells must then be encouraged to integrate and function together with the body's other cells.

GLOSSARY

Blastocyst
A very early embryo that has the shape of a ball and consists of approximately 150-200 cells. It contains the inner cell mass, from which embryonic stem cells are derived, and an outer layer of cells called the trophoblast that forms the placenta.

Cell line
Cells that can be maintained and grown in a dish outside of the body.

Clinical translation
The process of using scientific knowledge to design, develop and apply new ways to diagnose, stop or fix what goes wrong in a particular disease or injury.

Differentiation
The process of development with an increase in the level of organization or complexity of a cell or tissue, accompanied by a more specialized function.

Embryo
The early developing organism; this term denotes the period of development between the fertilized egg and the fetal stage.

Embryonic stem cell
Cells derived from very early in development, usually the inner cell mass of a developing blastocyst. These cells are self-renewing (can replicate themselves) and pluripotent (can form all cell types found in the body).

Induced pluripotent stem (iPS) cell
Induced pluripotent cells (iPS cells) are stem cells that were engineered ("induced") from non-pluripotent cells to become pluripotent. In other words, a cell with a specialized function (for example, a skin cell) that has been "reprogrammed" to an unspecialized state similar to that of an embryonic stem cell.

Innovative medicine
Treatments that are performed on a small number of people and are designed to test a novel technique or treat a rare disease. These are done outside of a typical clinical trial framework.

***In vitro* fertilization**
A procedure in which an egg cell and sperm cells are brought together in a dish to fertilize the egg. The fertilized egg will start dividing and, after several divisions, forms the embryo that can be implanted into the womb of a woman and give rise to pregnancy.

Mesenchymal stem cells
Mesenchymal stem cells were originally discovered in the bone marrow, but have since been found throughout the body and can give rise to a large number of connective tissue types such as bone, cartilage and fat.

Multipotent stem cells
Stem cells that can give rise to several different types of specialized cells, but in contrast to a pluripotent stem cell, are restricted to a certain organ or tissue types. For example, blood stem cells are multipotent cells that can produce all the different cell types that make up the blood but not the cells of other organs such as the liver or brain.

Pluripotent stem cells
Stem cells that can become all the cell types that are found in an implanted embryo, fetus or developed organism. Embryonic stem cells are pluripotent stem cells.

Self-renewal
The process by which a cell divides to generate another cell that has the same potential.

Stem cells
Cells that have both the capacity to self-renew (make more stem cells by cell division) and to differentiate into mature, specialized cells.

Tissue-specific stem cells
(also known as adult or somatic stem cells)
Stem cells found in different tissues of the body that can give rise to some or all of the mature cell types found within the particular tissue or organ from which they came, i.e., blood stem cells can give rise to all the cells that make up the blood, but not the cells of organs such as the liver or brain.

Totipotent stem cells
Stem cells that, under the right conditions, are wholly capable of generating a viable embryo (including the placenta) and, for humans, exist until about four days after fertilization, prior to the blastocyst stage from which embryonic stem cells are derived.

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Leveraging a global network of engaged individuals and organizations, the **Rick Hansen Institute** is committed to driving innovation in spinal cord injury research and care. We strive to improve the lives of people living with SCI in Canada and around the world.

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The Craig H. Neilsen Foundation is pleased to support

Unite 2 Fight Paralysis and the Working 2 Walk Science & Advocacy Symposium

• • •

The Neilsen Foundation's funding is dedicated to supporting both programs and scientific research to improve the quality of life for those affected by and living with spinal cord injury.

www.chnfoundation.org

CONTEXTSTRATEGYVOICE

1. CONTEXT

The SCI Community must understand the broader context within which the scientific and clinical enterprise is operating. Relatedly, the Research Enterprise must understand the broader context of the lived experience with SCI so that the targets being sought match our Community's priorities

2. STRATEGY

Once we have a more realistic understanding of the context, we can then make intelligent and factually based decisions on strategic initiatives

3. VOICE

Then we can build an effective chorus of voices from amongst the community and our various stakeholders to demand the cures we seek

Working 2 Walk
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John Chernesky & Phalgun Joshi - Rick Hansen Institute
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Kate Willette - Live Blog
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