WORKING 2 WALK

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

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VOICE OF THE CURE

SCIENCE & ADVOCACY SYMPOSIUM

OCTOBER 13th & 14th, 2017

Hilton Miami Airport

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October 13, 2017

Welcome to our 12th annual Working 2 Walk Science & Advocacy Symposium. We're so happy that you chose to join this incredible gathering of advocates, scientists, clinicians, and entrepreneurs, all of whom are fighting for recovery from paralysis after spinal cord injury. Our goal is that each of you leave here inspired to take this fight to your own communities and networks around the world.

Everyone here is hungry for knowledge and the desire to find compatriots who will join the cure advocacy effort. As we know, the push for a cure can either drift slowly along, or it can drive forward, full steam ahead. In a very real sense, that choice is ours to make.

A few words of friendly advice:

- **Make some friends.** This community is full of incredible people, all of whom were strangers to one another at one time. We're eager to get to know you. Really.

- **Pace yourself.** Someone said that being at Working 2 Walk is like drinking from a fire hose. There's a great deal to absorb, but you really don't have to rely on your own notes or pictures or video to capture it. That means you're free to choose the presentations or speakers that interest you most; read up ahead of time and focus on them. You can easily catch up on anything you miss later, because there will be video online as well as the real time live blog and twitter feeds.

- **Ask questions.** Some of us are good at that in a crowd setting, and some of us would rather do it one on one. There will be chances for you to do both, and we can't say strongly enough how important it is that every speaker hears from you and learns what you care about. The flow of information at Working 2 Walk goes both ways; that's what makes it unique.

- **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 that they're here for us.

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.

We hope that each of you will leave Working 2 Walk with a realistic action plan, whatever that means in the context of your life and skills. If you are unsure of what to do or what you can do, seek one of us out or email matthewrodreick@unite2fightparalysis.org

With best wishes from

Your friends at Unite 2 Fight Paralysis

Working 2 Walk 2017 Program Contents

Schedule of Events

Thursday, October 12, 2017 — Arrival Day

5:00 – 7:00 pm:	**Early Registration & Check-In** Continental Room Foyer

Friday, October 13, 2017

7:30 – 9:00 am:	**Registration & Continental Breakfast — Exhibitor Visits** Continental Room Foyer
9:00 am – 5:00 pm:	**General Session** — International Ballroom: Salon 3/4
9:00 – 9:15 am:	**Opening Remarks** Matthew Rodreick, Executive Director, Unite 2 Fight Paralysis
9:15 – 9:40 am:	"**Current Progress on Neuroprotection and Repair following Spinal Cord Injury: The Miami Project Experience"** W. Dalton Dietrich, PhD, The Miami Project to Cure Paralysis
9:40 – 9:50 am:	**Question & Answer Session**
9:50 – 10:10 am:	**"Enhancement of Functionally-Relevant Host-Graft Connectivity Following Neural Progenitor Cell Transplantation into Cervical Spinal Cord Injuries"** Paul Reier, PhD, University of Florida
10:10 – 10:20 am:	**Question & Answer Session**
10:20 – 10:50 am:	**Break —** Exhibitor Visits
10:50 – 11:20 am:	"**The Cure Map"** Matthew Rodreick – Moderator Kelsey Peterson, The Cure Map Madeline Brown, MFA, The Cure Map
11:20 – 11:30 am:	**Question & Answer Session**
11:30 – 11:50 am:	**"Improving Hand and Arm Function after Spinal Cord Injury"** Chet Moritz, PhD, University of Washington
11:50 – 12:00 pm:	**Question & Answer Session**

12:00 – 12:30 pm:	**Cure Advocacy Network Panel Discussion: Update on Washington State's Recent Appropriation for SCI Research** Chet Moritz, PhD, University of Washington Kate Willette, *Don't Call It A Miracle* Kelsey Peterson, The Cure Map Matthew Rodreick — Moderator
12:30 – 1:30 pm:	**Lunch –** Exhibitor Visits
1:30 – 1:50 pm:	**"Long-term Human Neural Stem Cell Transplant for Repair of Spinal Cord Injury: Neurogenesis, Gliogenesis, and Axon Persistence"** Paul Lu, PhD, University of California – San Diego
1:50 – 2:10 pm:	**"Combined Gene Therapy and Stem Cell Transplantation for Spinal Cord Injury"** Murray Blackmore, PhD, Marquette University
2:10 – 2:30 pm:	**Question & Answer Session with Drs. Blackmore & Lu**
2:30 – 2:50 pm:	**"Cellular Transplantation Strategies after Spinal Cord and Peripheral Nerve Injury"** Allan Levi, MD, PhD, FACS, University of Miami
2:50 – 3:00 pm:	**Question & Answer Session**
3:00 – 3:30 pm:	**Break —** Exhibitor Visits
3:30 – 4:10pm:	**Stem Cell Panel Discussion with Drs. Lu, Reier, Levi & Blackmore** Edward D. Wirth, III, MD, PhD, Asterias Biotherapeutics — Moderator
4:10 – 4:45 pm:	**Table Discussion — How do Science and Advocacy Intersect?**
4:45 – 4:55 pm:	**Introducing *Spinal Cord Injury Research Evidence (SCIRE) Community*, a new evidence-informed web resource for people living with SCI** Christina Cassady, MScPT, University of British Columbia
5:00 pm	**Day 1 Wrap-Up**
5:00–7:00 pm:	**Networking Reception** — Pool Deck

Dinner on your own

Saturday, October 14, 2017

8:00 – 9:00 am:	**Registration & Continental Breakfast – Exhibitor Visits** Continental Room Foyer
9:00 am – 4:00 pm:	**General Session** — International Ballroom Salon 3/4
9:00 – 9:10 am:	**Welcome** Matthew Rodreick, Executive Director, Unite 2 Fight Paralysis
9:10 – 9:40 am:	**"Improving Upper Extremity Function in Cervical Spinal Cord Injury— Focus on Nerve Transfer Surgery"** Ida Fox, MD, Washington University
9:40 – 10:00 am:	**"Restoring Function with Neuroprosthetics: Three Decades of Patient Outcomes"** Megan Moynahan, MS, Institute for Functional Recovery
10:00 – 10:30 am:	**Question & Answer session with Dr. Fox and Ms. Moynahan**
10:30 – 11:00 am:	**Break —** Exhibitor Visits
11:00 – 11:30 am:	**Discussion of an Activity Based Therapy Strategy** Michele Towle, DP Clinical Eric Harness, NueroEX Cristina Sadowsky, MD, Kennedy Krieger Institute Dave Font, MPA, HRD, Push to Walk Matthew Rodreick — Moderator
11:30 – 11:50 am:	**"Big-data Analytics: Bringing 'Dark Data' to Light for Enhancing Discovery and Translation in Spinal Cord Injury"** Adam Ferguson, PhD, University of California – San Francisco
11:50 – 12:05 pm:	**Question & Answer session with Dr. Ferguson**
12:05 – 12:25 pm	**From Injury to Advocacy** Sabrina Cohen, Sabrina Cohen Foundation
12:25 – 1:30 pm	**Lunch —** Exhibitor Visits
1:30 – 1:50 pm:	**"Overcoming Proteoglycan Barriers to Axon Regeneration and Sprouting in the Chronically Paralyzed Respiratory System"** Jerry Silver, PhD, Case Western Reserve
1:50 – 2:20 pm:	**A Translatable Peptide to Overcome Glia Scarring After Spinal Cord Injury** Yu-Shang Lee, PhD, Cleveland Clinic
	Subcutaneous Application of Small Peptide Removes Glial Scar and Facilitates Outgrowth on Dorsal Root Ganglia Ching-Yi Lin, PhD, Cleveland Clinic

2:20 - 2:40 pm: **Question and Answer session with Drs. Silver, Lin & Lee**

2:40 - 3:10 pm: **Table Discussion — Where are you in the Cure Map?**

3:10 - 3:30 pm: **Breakout Overview**
Kim Anderson-Erisman, PhD, The Miami Project to Cure Paralysis

3:30 - 4:00 pm: **Break —** Exhibitor Visits

4:00 pm - End: **Miami Project Breakout Sessions**

Salon 1 **"Healthy Aging After Spinal Cord Injury"**
Gregory Bigford, PhD, Miami Project to Cure Paralysis
Eva Widerstron-Noga, DDS, PhD, The Miami Project to Cure Paralysis
Christine K. Thomas, PhD, The Miami Project to Cure Paralysis
Rachel Cowan, PhD, The Miami Project to Cure Paralysis

Salon 2 **"The Therapeutic Potential of Brain Stimulation"**
Brian R. Noga, PhD, The Miami Project to Cure Paralysis
Monica Perez, PT, PhD, The Miami Project to Cure Paralysis

Continental Room **"Clinical Research Participation"**
Kim Anderson-Erisman, PhD, The Miami Project to Cure Paralysis
Katie Gant, PhD — The Miami Project to Cure Paralysis

5:00 pm: **Day 2 Wrap-up**

End of Conference

2016 Working 2 Walk Speaker Bios

Kim Anderson-Erisman, PhD, is a Research Professor and the Director of Education for The Miami Project to Cure Paralysis at the University of Miami Miller School of Medicine. Her research has focused on translational investigations and bridging the gap between basic science, clinical science, and the public community living with spinal cord injury (SCI). Several of her studies have focused on obtaining the perspective of people living with SCI on various aspects of research, including functional priorities, acceptable benefits and risks, preferences for neuroprosthetics, and exercise participation. Her current projects focus on 1) the risk-benefit value of improvements in arm/hand and trunk function by an implanted electrical stimulation device targeting chronic cervical SCI, 2) determining the minimum amount of exercise and locomotor training required for clinical trials targeting chronic SCI, and 3) identifying the facilitators and barriers to clinical trial participation from the SCI consumer perspective. In addition to pursuing her own research regarding chronic injury, she is part of the leadership team running the Schwann cell transplantation clinical trials at the University of Miami.

Gregory Bigford, PhD, is a Postdoctoral Research Fellow at the University of Miami Miller School of Medicine & The Miami Project to Cure Paralysis. His professional work focuses on both clinical investigation and exploratory experimental research in the area of spinal cord injury. As a part of Dr. Nash's research program, his clinical work is aimed at evaluating outcome measures related to cardiometabolic risk factors and extant cardiovascular disease and diabetes. These data have been critical in identifying questions that have helped direct and develop experimental research studies. Specifically, the exploratory research program investigates underlying biological mechanisms that are incited following spinal cord injury related to chronic inflammation and metabolic dysregulation, primarily the neuro-endocrine and cardiovascular system. To this end, his goal is the seamless transition from investigation in animal experiments to human clinical trials, and then translation of findings for guideline assessment and clinical adoption.

Murray Blackmore, PhD, is an Associate Professor in the Biomedical Sciences Department at Marquette University. Dr. Blackmore received his undergraduate degree from Stanford University, and his graduate degree in neuroscience from the University of Minnesota. During his postdoctoral training at the Miami Project to Cure Paralysis, Dr. Blackmore studied axon regeneration and adopted High Content Screening methods to identify new gene targets to promote neural repair. Dr. Blackmore uses a gene therapy approach in rodent models of spinal cord injury to test new gene targets for the ability to promote axon regeneration in the injured spinal cord.

Madeline (Maddy) Brown received her MFA in photography from the San Francisco Art Institute and has based most of her creative endeavors around travel and cultural exchange. As a filmmaker she hopes to illustrate important realities and weave together stories that impact the world.

Sabrina Cohen is the Founder/President of the Sabrina Cohen Foundation. Born and raised in Miami Beach, Florida, Sabrina endured a severe C3-5 spinal cord injury in 1992 at the age of 14 from a car accident. For Sabrina, her life changed in an instant, when she hopped into the backseat of a car with some friends. She thought she was getting a ride to a party, but the teenage driver started drag racing and the car slammed into a tree. The car was demolished and Sabrina's spine was severely damaged. She has been confined to a wheelchair ever since.

Sabrina has advocated extensively for research and quality of life health initiatives since then. She appeared in the first ever US political commercial for stem cell research supporting a Floridian Congressman and has been linked to many political figures, including fellow stem cell advocate Michael J. Fox. She is presently on the Advisory Board of the Genetics Policy Institute and has traveled nationwide with the organization to attend educational and scientific conferences, including the World Stem Cell Summit at the University of Wisconsin, Harvard University, Stanford University, Baylor College of Medicine at the University of Texas, University of Michigan and at the United Nations.

In 2006, she established the Sabrina Cohen Foundation (SCF) to raise funds for research and quality of life initiatives focussed on adaptive fitness and recreation programs to its mission.

Sabrina's media coverage as the Foundation's spokesperson includes interviews with CNN, NBC, FOX, CBS, ABC, CNN Headline News, Good Morning America, Deco Drive, NPR, Jim Defede Show, WebMD Magazine (nominated a 2009 American Health Hero), The Miami Herald, Ocean Drive Magazine, Self Magazine, Sun-Sentinel and the Wall Street Journal.

Rachel Cowan, PhD, is an Assistant Professor at the Miami Project to Cure Paralysis. Dr. Cowan holds a Master's Degree (Wake Forest) in Exercise Science and a Doctoral Degree in Rehabilitation Science from the Human Engineering Research Laboratory of the University of Pittsburgh. She is an expert on the biomechanics of wheelchair propulsion, and assists in customizing the commercially available platform for the interpretation of Quantitative Ultrasound data.

W. Dalton Dietrich, PhD, is Scientific Director at The Miami Project to Cure Paralysis and Kinetic Concepts Distinguished Chair in Neurosurgery at the University of Miami Miller School of Medicine. He received his PhD in Anatomy from the Medical College of Virginia in 1979 and completed a postdoctoral fellowship in the Department of Pharmacology at Washington University, St. Louis, MO, 1981. Dr. Dietrich has published 4 books, 70 book chapters, over 300 refereed journal articles, 260 abstracts, and 20 editorial comments. He serves on study sections for NIH, Department of Defense, Veteran's Administration, and several Editorial Boards. Research in Dr. Dietrich's laboratory is focused on clarifying the pathophysiology of brain and spinal cord injury with the ultimate goal of developing new therapies to protect and enhance recovery of function.

Dr. Adam R. Ferguson is an Associate Professor of Neurosurgery at the University of California San Francisco (UCSF) and principal investigator in the Brain and Spinal Injury Center (BASIC) at the Zuckerberg San Francisco General Hospital, and the San Francisco VA Medical Center. He holds a MS/PhD in behavioral neuroscience and statistical psychology, and completed 6 years of postdoctoral training in cellular and molecular neuroscience. He received a postdoctoral National Research Service Award and a National Institutes of Health Early Stage Investigator Award, and the Michael Goldberger Prize from the National Neurotrauma Society. He has published over 95 peer-reviewed scientific papers and 100 conference proceedings focusing on neuroscience and the role of big-data analytics for accelerating scientific discovery and healthcare decision-support for spinal cord injuries and related conditions.

Dave Font is the Executive Director for Push to Walk, a nonprofit gym for people living with paralysis due to spinal cord injury, traumatic brain injury, stroke, multiple sclerosis, cerebral palsy, and other neurological conditions. Before joining Push to Walk, he worked in various positions with the Boys & Girls Clubs of Northwest New Jersey for over seventeen years. While with the Boys & Girls Clubs, Dave served as a contract National Training Associate for Boys & Girls Clubs of America and he is currently a Part-Time Lecturer in the School of Public Affairs & Administration at Rutgers University – Newark. He holds a Masters of Public Administration from Rutgers University – Newark and a Masters of Human Resource Development from Clemson University.

Ida Fox, MD is Associate Professor of Surgery in the Division of Plastic and Reconstructive Surgery at Washington University School of Medicine. Her clinical interest is to assess the safety and efficacy of nerve transfers, a well-established surgical technique in peripheral nerve transfer injury, to improve upper extremity function and health related quality of life (QoL) in patients with cervical spinal cord injury (SCI). As a reconstructive plastic surgeon, her clinical practice is focused on complex patient populations, including those with upper extremity and peripheral nerve trauma and SCI. Her clinical expertise and skills are well suited to treat patients with the unique challenges associated with SCI and she has extensively coordinated a multi-disciplinary team with the SCI physical and rehabilitation medicine, neurology, physical and occupational therapy and anesthesiology specialists as well as hospital nursing and other support services. She performs these surgeries at both Barnes Jewish Hospital and at the VA Health Care System Hospital in Saint Louis, Missouri. Current grant funding from the Craig H. Neilsen foundation supports a comprehensive retrospective and prospective study on nerve transfers to restore upper extremity function in SCI. Her new project is entitled: Supporting Patient Decisions About Upper-Extremity Surgery in Cervical Spinal Cord Injury. This multi-site multidisciplinary study, plans to define key information about improvement of upper extremity function after SCI and communicate this information to patients and clinicians to support their treatment decisions particularly with respect to less well-known nerve transfer surgery. This work is funded by the Department of Defense Congressionally Directed Medical Research Program, Spinal Cord Injury Research Program, Investigator-Initiated Research Award. She has

presented and written extensively on this subject, hosted a multinational and multidisciplinary workshop on SCI nerve transfers in December of 2014, and assisted on the first two such nerve transfer in SCI surgeries done in Canada in 2015. Recently, she brought this procedure to the St. Louis VA hospital system population and performed the first surgery of this kind there in December of 2015.

Dr. Fox is delighted to participate in the 2017 Working 2 Walk Science and Advocacy Symposium in Miami and looks forward to a collaborative and inspiring experience!

Katie Gant, PhD is an Assistant Scientist at The Miami Project to Cure Paralysis and Department of Neurological Surgery at The University of Miami. She is a part of The Miami Project's clinical trials program, where she is responsible for the recruitment and screening of research participants, as well as the collection and analysis of research data. She also contributes to The Miami Project's educational program and outreach efforts.

Eric Harness. With a strong background in athletic training and sports performance combined with 18+ years extensive experience training those with neurological and physical disabilities, Eric Harness brings a unique perspective to the adaptive performance and neuro recovery fields. After graduating from San Diego State University with a BSc in Kinesiology, he became an NSCA Certified Strength and Conditioning Specialist and started San Diego Sports Training where he excelled at improving the strength and performance of high school, college, and Olympic athletes. In 1999, Eric co-founded the first spinal cord injury (SCI) recovery center in Southern California and served as their Director of Research and Development for 13 years. In that time period he spent over 20,000 hours working hands on with physically challenged clients to increase their functional capacity. His clientele included not only SCIs, but stroke, TBI, multiple sclerosis, amputee, and ALS. He has worked with major hospitals and universities on several grant funded research projects examining the effects of exercise on individuals with SCI. These projects have led to multiple authored and co-authored publications in peer-reviewed journals. As a leader in this field, he has been invited to speak and present at many major medical conferences, hospitals, and industry events. Eric continues to partner with the leaders in the rehabilitation field on research projects and equipment design as he advances his work in neuro recovery and takes adaptive performance to the next level.

Yu-Shang Lee, PhD, is Asst. Staff Scientist at the Cleveland Clinic and an Associate Professor at Case Western Reserve University. Dr. Lee's main research goal is to investigate underlying mechanisms after trauma to the central nervous system, including spinal cord injury (SCI), and to develop novel repair strategies to promote anatomical plasticity and functional regeneration such as bladder control in experimental models of SCI. He began this work when he joined the graduate program at the University of California-Irvine and continued to have post-doctoral training there. His research programs have been funded by both federal funding agency and private foundation. Overall, his long-term goal is to translate effective treatments from experimental animal research to humans with SCI. A major line of research in Dr.

Lee's lab is to study an auto-peripheral nerve graft (PNG) repair strategy combined with other favorable factors to facilitate nerve regeneration and functional recovery in rats and mice with complete SCI. The PNG has re-emerged as an extremely useful biological conduit to guide axon re-growth. In terms of functional assessment, his lab is focusing on using nerve regeneration strategies to promote bladder function recovery after SCI. Neurogenic bladder dysfunction is a primary source of urinary tract infection and other complications in animals or patients with SCI above the lumbosacral level. But even with the magnitude of the problem, there are relatively few studies focused on bladder recovery after SCI compared to the number focused on locomotor recovery. In ongoing collaboration with Drs. Jerry Silver and Ching-Yi Lin, Dr. Lee continues to work on developing promising repair strategies to treat SCI.

Allan D. Levi, MD, PhD, FAANS, was born in Montreal, Quebec, Canada in 1961. His parents immigrated from Italy to Canada during WW II. He attended undergraduate and medical school at the University of Ottawa and completed his neurosurgical training at the University of Toronto. During his residency, he earned a PhD at the University of Miami under the supervision of Dr. Richard Bunge in the field of human Schwann cell biology. He completed his neurosurgical training by doing a complex spine fellowship with Dr. Volker Sonntag at the Barrow Neurological Institute in 1996. Dr. Levi joined the neurosurgical faculty at the University of Miami in 1997 and became a full Professor in 2007. He currently serves as Professor and Chairman of the Department of Neurosurgery since 2015.

Ching-Li Lin, PhD, is Project Staff Scientist at the Cleveland Clinic and an Assistant Staff Scientist at Case Western Reserve University. Her graduate training in Taiwan focused on veterinary medicine, biochemistry,and molecular and cellular biology, with an emphasis on signaling pathways from clinical perspectives. Dr. Lin's postgraduate training at the University of California-Irvine focused on the roles of integrins (adhesion receptors for the extracellular matrix) and brain derived neurotrophic factor (BDNF) in adult and aging brains, with an emphasis on plasticity. Since 2001, her research has also explored how pathophysiology develops after spinal cord injury (SCI) with dedicated efforts to develop novel therapeutic approaches for SCI patients. In collaboration with Drs. Yu-Shang Lee and Jerry Silver at Cleveland Clinic, Dr. Lin has investigated how peripheral nerve transplantation, when combined with both growth factors and Chondroitinase ABC, can enhance functional recovery of both locomotion and micturition. However, after SCI the pathologically up-regulated glial scars cannot be efficiently removed by Chondroitinase ABC and remain as significant barriers to nerve regeneration and functional recovery. Her lab's dedication to optimizing functional recovery inspired Dr. Lin to design a translatable small peptide, chondroitin sulfate proteoglycan (CSPG) reduction peptide (CRP), to efficiently remove CSPG, which is the major component of the glial scar. There is exciting preliminary data showing that (1) CRP can quickly, specifically, and effectively decrease CSPG upregulation both in-vitro and after SCI in-vivo, and (2) CRP can significantly improve both motor and bladder functions in rat SCI models following subcutaneous Injection.

Paul Lu, PhD, is a Research Health Science Specialist at VA San Diego Healthcare System and an Associate Adjunct Professor, University of California at San Diego. Dr. Lu"s primary research focuses on gene therapy and neural stem cells for spinal cord injury. Recently, Dr. Lu's team develops a new protocol to improve neural stem cell tracking, survival, and differentiation/maturation in the severely injured adult spinal cord by embedding neural stem cells into fibrin matrices containing growth factor cocktails. This protocol results in retention of neural stem cells and greatly supports their survival within the lesion site as they completely filled the large lesion cavity with a cellular matrix containing great numbers of differentiated neurons. Most remarkably, the grafted neurons extended their axons in remarkable densities and over extraordinary distances in the host spinal cord. This remarkable axonal extension from grafted neurons is consistent in rodent developing central nervous system (CNS) derived neural stem cells, human developing CNS, embryonic stem cells (ESCs), and induced pluripotent stem cells (iPSCs) derived neural stem cell graft. These results indicate that, despite the initial non-growth-supporting environment of the lesioned adult CNS, their protocol transforms the lesion site into one that is highly permissive for growth of neural stem cells. Furthermore, these grafted axons are remyelinated and exhibit extensive synapse formation with host neurons. Host supraspinal axons, including corticospinal tract axons, regenerated into and made synaptic connections with grafted neurons. Thus, grafted neurons could serve as neuronal relays to restore functional connectivity between the injured spinal cord segments. Some of these works are recently published in the Cell, Neuron (Lu et al., 2012, 2014), Nat Med (Kadoya et al., 2017), J Clin Invest (Lu et al., 2017).

Chet Moritz, PhD, received his doctoral degree from the University of California, Berkeley, followed by a post-doc at the University of Colorado. A second post-doc at the University of Washington began his interest in brain-computer interfaces and neuroprosthetic technology to treat paralysis. He is now an Associate Professor in the departments of Rehabilitation Medicine and Physiology & Biophysics. He was named an Allen Distinguished Investigator, appointed to the Christopher & Dana Reeve International Consortium on Spinal Cord Repair, and serves as the Co-director for the Center for Sensorimotor Neural Engineering, and NSF Engineering Research Center (ERC). He is the founding director of the Restorative Technologies Laboratory (RTL), focusing on developing technologies to treat paralysis and other impairments due to brain and spinal cord injury.

Megan Moynahan, MS, is the Executive Director of the Institute for Functional Restoration, a non-profit organization based at Case Western Reserve University whose mission is to restore function to people with spinal cord injury by building a sustainable commercial enterprise for neuromodulation systems. The IFR's unique commercialization approach assures the steady translation of proven technologies out of research and into stable commercial availability. The IFR is currently shepherding a multi-function neuroprosthetic system through the regulatory and commercialization stages, with support from both philanthropy and traditional grants. Prior to this, Megan enjoyed a 17-year career at the US

Food and Drug Administration's Center for Devices and Radiological Health, where she served as its Associate Director for Technology and Innovation, leading a variety of projects including directing the White House sponsored Entrepreneurs-in-Residence program at FDA, and the Innovation Pathway program designed to streamline the regulatory process for innovative medical devices. She holds a BS in Biomedical Engineering from Johns Hopkins University and a MS in Biomedical Engineering from Case Western Reserve University.

Brian Noga, PhD, obtained his Ph.D. at the Department of Physiology, University of Manitoba in the laboratory of Dr. Larry Jordan. His Ph.D. research focused on the role of various brainstem centers and descending reticulospinal pathways involved in the initiation and control of walking. Later, as a postdoctoral fellow in the laboratory of Dr. Elzbieta Jankowska at the University of Gothenberg, Sweden, he studied the brain's control of identified spinal neurons involved in reflex pathways related to locomotion. In particular, he became interested in the influence of monoamines on the activity of spinal reflex circuits and spinal locomotor networks. At The Miami Project to Cure Paralysis, he has continued this line of research examining the monoaminergic innervation and receptor profiles of spinal locomotor neurons and the properties of spinal monoamine release during electrical activation of the descending monoaminergic pathways. He presently pursues research on the effects of electrical deep brain stimulation of descending locomotor pathways on recovery of walking following incomplete spinal cord injury. Currently, he is the Host Editor for a Frontiers in Neural Circuits Research Topic entitled "Recent Advances in Neuromodulatory Control of Spinal Function in Health and Disease", with 20 articles published to date

Monica A. Perez, PT, PhD, is an Associate Professor at the Department of Neurological Surgery and The Miami Project to Cure Paralysis at the University of Miami. She received her Ph.D. in physical therapy from the University of Miami School of Medicine in 2003. She completed postdoctoral fellowships at the University of Copenhagen (2003-2005) and at the National Institute of Neurological Disorders and Stroke (2005-2008). Dr. Perez' research interests focus on understanding how the brain and spinal cord control voluntary movements in healthy humans and in individuals with spinal cord injury. This theme is mainly investigated from a neurophysiological point of view, using a combination of transcranial magnetic stimulation (TMS) and peripheral nerve stimulation techniques. Single and paired-pulse TMS and spinal cord reflex protocols are used to examine and maximize transmission in residual motor pathways in humans with spinal cord injury.

Kelsey Peterson received her BA in dance in 2008 from the University of Montana, and has since pursued choreography, as well as teaching dance and yoga. After her spinal cord injury in 2012, she has been pursuing other creative endeavors. After working on the board of Get Up Stand Up to Cure Paralysis out of Minneapolis, she has since embarked on her journey with The Cure Map, and looks forward to her continued efforts for the SCI community and other creative projects.

Paul Reier, PhD, received his doctoral degrees from Case Western Reserve University. He began working in spinal cord repair in the 1980s studying the possibility of repairing spinal cords with transplanted stem cells. His early studies demonstrated that embryonic cells could survive in, and integrate with a damaged spinal cord. Moreover, they showed that even a relatively small number of cells could grow, multiply and differentiate to replace damaged gray matter. By the mid-1990s, his research progressed to demonstrating the safety and feasibility of transplanting embryonic nerve tissue in a small number of people with SCIs. This was the first clinical translation of its kind in the United States and only second worldwide to a single patient study conducted in Russia. This technique has now been reproduced by several others in both academic and biotechnological settings using a variety of proprietary cell lines. The experimental and clinical replication of this treatment demonstrates the promising nature of the approach. Recently, other labs have also reported independent evidence of the potential to establish novel, functional relays by transplantation of neural precursor cells. However, significant technical and biological challenges still remain. Dr. Reier and his former postdoctoral fellow, Dr. Michael Lane of Drexel University, are currently exploring a promising experimental cell therapy approach with emphasis on defining the targets for intervention and optimization of promising strategies such as the use of neural progenitors (i.e., neural stem or stem-like cells). His team's therapeutic approaches and injury models are designed to address future bench-to-bedside translational issues with attention to experimental rigor, transparency, and independent replication. Dr. Reier and his colleagues' studies focus on gaining insights related to: (a) the contribution of gray matter pathology to post-SCI functional outcomes, (b) the development of a neuroengineering approach to reactivate a spinal circuit silenced by SCI, and (c) development of research proposals to use such neuroengineering approaches to promote more directed host-graft interactions following intraspinal transplantation of neural precursors.

Cristina Sadowsky, MD is the Clinical Director at the International Center for Spinal Cord Injury at the Kennedy Krieger Institute. Dr. Sadowsky was born in Romania and attended the Institute of Medicine and Pharmacy in Bucharest from 1983 to 1989. She completed an internship and residency in internal medicine at Meridia Huron Hospital/Case Western Reserve University in Cleveland, OH in 1994. She served as chief resident from July 1994 to June 1995. From there, she began a residency in physical medicine and rehabilitation at Barnes-Jewish Hospital/Washington University School of Medicine in St. Louis, MO. She was named chief resident of that program in April 1997. Immediately following the completion of her second residency, she began a fellowship in spinal cord injury (SCI) medicine at Barnes-Jewish Hospital/Washington University School of Medicine. At the same time, she became a clinical instructor in the school's Department of Neurology and later assumed an assistant professorship in neurology in the Division of Rehabilitation, SCI Unit. In October 2004, she moved to Baltimore, joining the Kennedy Krieger Institute as director of the Paralysis Restoration Clinic and Clinical Director of the International Center for SCI. She frequently serves as an invited clinical scientific peer reviewer for the American Journal of Physical Medicine and Rehabilitation, Archives of Physical Medicine and Rehabilitation, Journal of Rehabilitation Research and Development, the Journal of Spinal Cord Medicine, Translational Research. She also serves as a section editor for Physical Medicine and Rehabilitation Reports.

Professional honors include receiving the Outstanding Resident Award in Medicine from Meridia Huron Hospital in 1995, being named Best Resident of the Year in Physical Medicine and Rehabilitation at Washington University School of Medicine in 1998 and Best Teaching Attending of the Year in 1999, receiving the 2000 Outstanding Performance Award from the SCI Board and being named one of Top Doctors in Baltimore in 2007, Best Doctors in America 2007-present and consistently one of America's Top Physicians since 2008.

Dr. Sadowskys' research interests center on the prevention of complications in patients with paralysis and the efficacy of activity-based restoration therapies in helping individuals with long-term SCI and paralysis recover sensation, movement and independence.

Jerry Silver, PhD, is Professor of Neurosciences at Case Western Reserve University. Dr. Silver received his Ph.D. from Case Western Reserve in 1974 and was the recipient of the Herbert S. Steuer Memorial Award for Meritorious Original Research in Anatomy. He did post-doctoral work at Harvard University in the Department of Neurosciences at The Children's Hospital and in the Neuropathology Department at Harvard Medical School. Dr. Silver is currently Professor in the Department of Neurosciences at the Case Western Reserve University and adjunct Professor in the Department of Neurosurgery at the Cleveland Clinic Foundation. He is a recipient of several prestigious awards including the Ameritec Prize the Reeve-Irvine Medal, the Jacob Javits Neuroscience Investigator Award, the 2008 Erica Nader Award. In 2011 he was honored to become a fellow of the American Association for the Advancement of Science (AAAS). Dr. Silver has served on a number of editorial boards including the journals Glia, The Journal of Neurocytology, Developmental Neurobiology, The Journal of Neuroscience, Scientific Reports and Experimental Neurology. He regularly reviews articles for over 35 high impact journals and he reviews grants for 18 national and international organizations. He has served on a variety of NIH study sections since 1982 including the Neurobiology Review Group, Neurology B2, The Visual Sciences C Study Section, and the Clinical Neurology, Neurotransmitters and Transplantation Study Section. He has served as lead or senior author on more than 160 publications.

Christine K. Thomas, PhD, is a Professor in the Department of Neurological Surgery at The Miami Project to Cure Paralysis. Her research examines the consequences of spinal cord injury (SCI) on skeletal muscle. These studies examine the neurophysiology of human SCI, involve development of animal models that mimic the muscle consequences of human SCI, and test intervention strategies in humans or animal models that influence long-term functional capability following SCI. Much of this work requires use of various electrophysiological techniques, software and hardware development, as well as surgery, neuron transplantation, immunohistochemistry, and viral vectors. The data we gather are essential to improve muscle rehabilitation and health after injury, a situation in which uncontrollable spasticity, atrophy, weakness, denervation, and fatigue are major unresolved problems.

Michele Towle is the Assistant Director of the Spinal Cord Injury (SCI) Program at DP Clinical, Inc. headquartered in Rockville, MD. Michele has 18 years of experience in SCI clinical research and has monitored and managed SCI clinical trials for DP Clinical since 2003. DP Clinical is a Contract Research Organization (CRO) specializing in SCI Phase I-IV clinical programs for pharmaceutical,

biotech, and medical device companies. Since 1994, DP Clinical has worked on many of the acute and chronic SCI studies conducted, including the Sygen benchmark study as well as studies using autologous macrophages, stem cells, and devices. Our knowledgeable and experienced staff have applied important lessons learned to improve SCI trial design, conduct, performance, and reporting. DP Clinical provides a full complement of clinical development services including trial management, monitoring, data management, biostatistics, regulatory, safety, and medical writing for commercial, academic, and government sponsors. We have a strong reputation for maintaining high quality standards and data integrity, running cost-effective studies, and developing collaborative and successful client partnerships.

Eva Widerström-Noga, PhD, is a Professor of Neurological Surgery and Rehabilitation Medicine and the Principal investigator of the Clinical Pain Research Laboratory of The Miami Project to Cure Paralysis. Her expertise is in cross-disciplinary pain research (pain physiology and pain psychology) in neurotrauma populations (spinal cord injury and traumatic brain injuries). She has performed human pain research for more than 24 years and in the field of SCI for over 20 years. Dr. Widerström-Noga has adapted outcome measures used to classify and assess pain in other chronic pain populations to people with SCI. She has published over 60 peer reviewed journal articles and written eight book chapters on pain and pain assessment. Her present research program is interdisciplinary and involves both qualitative and quantitative pain methodologies including quantitative sensory testing and MR spectroscopic brain imaging.

Edward D. Wirth, III, M.D., Ph.D., is the Chief Medical Officer at Asterias Biotherapeutics. Prior to this, Dr. Wirth served as Chief Science Officer at InVivo Therapeutics Corporation from 2011 to 2012. From 2004 to 2011, Dr. Wirth served as Medical Director for Regenerative Medicine at Geron Corporation, where he led the world's first clinical trial of a hES cell-derived product, GRNOPC1 in patients with subacute spinal cord injuries. Dr. Wirth held academic appointments at Rush-Presbyterian St. Luke's Medical Center and at the University of Chicago from 2002 to 2004, and was a member of the faculty of the University of Florida from 1996 to 2002. Dr. Wirth received his Ph.D. and M.D. from the University of Florida in 1992 and 1994, respectively.

Overviews

Current Progress on Neuroprotection and Repair following Spinal Cord Injury: The Miami Project Experience

W. Dalton Dietrich, PhD, Scientific Director, The Miami Project to Cure Paralysis, Senior Assoc. Dean for Discovery Science, Prof. of Neurological Surgery, Neurology and Cell Biology, University of Miami, Leonard M. Miller School of Medicine

Over the last several years, The Miami Project to Cure Paralysis has initiated several clinical studies and trials targeting acute and chronic spinal cord injury. This lecture will summarize recent findings utilizing therapeutic hypothermia, human Schwann cell transplantation and extensive rehabilitation strategies to improve long term function in subjects with severe spinal cord injury. Clinical studies as well as FDA approved trials are demonstrating the safety and efficacy of these experimental treatments.

Enhancement of Functionally-Relevant Host-Graft Connectivity Following Neural Progenitor Cell Transplantation into Cervical Spinal Cord Injuries.

Paul Reier, PhD, Anne and Oscar Lackner Professor & Eminent Scholar, Department of Neuroscience, University of Florida

Electrical stimulation to activate silenced neural circuits following spinal cord injury (SCI) has become a rapidly expanding area of interest. We are now proposing to take this approach to another level by exploring whether a spinal stimulation approach can be used to enhance spinal cord repair via neural progenitor cell (NPC) transplantation. Transplantation of NPCs has been shown to be a viable option for promoting spinal cord repair with safety and feasibility having already been demonstrated in human SCI subjects. One of the major challenges however, is to reduce the variable functional outcomes inherent to this therapeutic strategy. Approaches are especially needed to encourage more consistent and functionally relevant connections between host and graft circuits. Several lines of evidence suggest that electrical stimulation or fields can direct nerve fiber outgrowth. This presentation will provide a rationale and technical considerations related to studies that are being initiated to investigate whether physiologically-patterned electrical stimulation of host and graft tissue will induce axonal growth and connectivity relevant to a desired functional network. The focus of the proposed exploratory research is on upper cervical SCI and spinal circuitry associated with diaphragm function. Intraspinal microstimulation (ISMS) is one of at least two other neuroengineering/spinal stimulation approaches that may ultimately serve as an integral adjunct to a cell-based repair intervention for SCI. Our central objective is to determine whether ISMS triggered by spared respiratory signals will enhance the formation of novel host-graft axonal projections that can lead to permanent respiratory improvement not requiring continuous stimulation.

The Cure Map

Kelsey Peterson
Madeline Brown, MFA

Madeline Brown and Kelsey Peterson are: The Cure Map. After traveling around the country conducting interviews and gathering information, the mission of The Cure Map is to create both a documentary film and a Movement that elevates, unites and empowers the Spinal Cord Injury community, in order to help expedite a cure. If we want change, we ALL have to believe.

Improving hand and arm function after spinal cord injury

Chet Moritz, PhD, Associate Professor, Division of Physical Therapy Dept. of Rehabilitation Medicine, Dept. of Physiology & Biophysics, University of Washington

Neural devices have tremendous potential to improve quality of life after spinal cord injury. Neuroprostheses that record and stimulate neural activity have progressed from animal studies to human trials, including the approach of using brain activity to control Functional Electrical Stimulation (FES) of paralyzed hand muscles. Another promising method for restoring movement and enhancing rehabilitation is direct stimulation of the spinal cord. Skin surface, epidural and intraspinal stimulation can activate neural circuits below an injury, leading to either direct muscle contraction or facilitating therapy and enabling volitional movements. Our goal is to combine innovative neural devices and physical therapy to improve function and quality of life following spinal cord injuries.

Long-term Human Neural Stem Cell Transplant for Repair of Spinal Cord Injury: Neurogenesis, Gliogenesis, and Axon Persistence

Paul Lu, PhD, Research Health Science Specialist, VA San Diego Healthcare System, Associate Adjunct Professor, University of California at San Diego

Neural stem cells (NSCs) differentiate into both neurons and glia, especially neurons that could re-connect disrupted neural circuits to restore function following spinal cord injury (SCI). However, the time period of maturation for human NSCs in adult injured CNS is not well defined, posing fundamental questions about the design and implementation of NSC-based therapies. We assessed human H9 NSCs that were implanted into sites of SCI in immunodeficient rats over a period of 1.5 years. Notably, grafts showed evidence of continued maturation over the entire assessment period. Markers of neuronal maturity were first expressed 3 months after grafting. However, neurogenesis, neuronal pruning, and neuronal enlargement continued over the next year, while total graft size remained stable over time. Axons emerged early from grafts in very high numbers, and half of these projections persisted by 1.5 years. Mature astrocyte markers first appeared after 6 months, while more mature oligodendrocyte markers were not present until 1 year after grafting. Astrocytes slowly migrated from grafts. Notably, functional recovery began more than 1 year after grafting. Thus, human NSCs retain an intrinsic human rate of maturation, despite implantation into the injured rodent spinal cord, yet they support delayed functional recovery, a finding of great importance in planning human clinical trials.

Combined Gene Therapy and Stem Cell Transplantation for Spinal Cord Injury

Murray Blackmore, PhD, Associate Professor, Marquette University

Spinal cord injury interrupts axons that carry information between the brain and lower spinal cord, and fostering regeneration of these cut axons remains a central goal of spinal injury research. Two main obstacles prevent axon growth: the damaged spinal tissue contains factors that block axon advance, and many adult neurons fail to re-initiate the intrinsic cellular programs that are needed for axon growth. Using rodent models of spinal cord injury, we have taken a gene therapy approach to improve the innate growth ability of adult neurons. We force the activation of genes that are normally only present in embryonic periods, when axon growth ability is high. This approach shows promise, yet we have found that the damaged spinal tissue remains a formidable barrier even to the genetically stimulated axons. We have therefore adopted a transplantation approach, in which stem cells are placed into the site of spinal tissue. Excitingly, the genetically stimulated axons extend robustly into the stem cell grafts and continue beyond into spinal tissue below the injury. Furthermore, we have shown these regenerated axons make effective connections with spinal neurons below the injury site. Finally, we have recently harnessed a gene delivery system called Retro-AAV that vastly improves gene expression in the research setting, and which opens the door for practical clinical translation of gene therapy. In summary, combined gene therapy and stem cell transplantation shows promise for improving axon regeneration and outcomes after spinal injury.

Cellular Transplantation Strategies after Spinal Cord and Peripheral Nerve Injury

Allan D. Levi MD, PhD, FAANS, Professor and Chairman of Neurosurgery, University of Miami MILLER School of Medicine, Chief of Neurosurgery, Jackson Memorial Hospital, Robert M. Buck Distinguished Chair in Neurological Surgery

Dr. Levi's basic science research interests focus on developing cellular transplantation strategies to repair injuries within both the human central and peripheral nervous system. Schwann cells are the principal support cells with the peripheral nervous system and have the capacity to promote regeneration of central nervous system neurons as well as remyelinate central axons which have lost their insulation. Dr. Levi has a strong academic portfolio with a focus on bench to bedside translational research. In the last 12 years, he has had the opportunity in bringing basic science findings in cellular transplantation and neuroprotection discovered in the laboratory to patients with spinal cord and peripheral nerve injuries. He has served as PI on four clinical trial initiatives – three of which have received FDA approval. The first is a phase I clinical trial evaluating "The safety of autologous human Schwann cells (ahSC) in subjects with sub-acute SCI". This represents a first 'in man" dose escalation study of autologous human SCs, for patients with sub-acute thoracic spinal cord injuries (T3 to T11). He also has received FDA approval for conducting a similar trial for patients (n=12) with chronic SCI in which the goals is to fill cystic lesion cavities in both the cervical and thoracic spinal cord with ahSCs. He recently transplanted two young patients with a devastating sciatic nerve injury resulting in a long segmental defect with sural nerve grafts supplemented with ahSC. The results of the technique including safety of injecting neural derived fetal stem cells in a multi-center clinical trial after chronic cervical SCI was recently published in Neurosurgery and Dr Levi was the lead author. Hypothermia continues to show promise in a variety of acute central nervous system (CNS) injuries. Mild (modest) levels of hypothermia (T 32-34C) have been shown to provide significant protection against traumatic and ischemic neuronal cell death. He is currently the PI of the institutional protocol studying systemic hypothermia induced via an intravascular catheter and continued for 48 hours after acute cervical SCI. Over 50 patients have been recruited over the last 10 years and numerous articles have been published on safety and clinical outcomes with this approach. The Joint Spine section has recently published guidelines for the use of hypothermia after SCI that have incorporated these results. Dr. Levi is currently the PI of a multi-institutional (n=4) prospective, randomized trial examining the safety and efficacy of cooling in SCI.

Introducing *Spinal Cord Injury Research Evidence (SCIRE) Community,* a new evidence-informed web resource for people living with SCI

Christina Cassady, MScPT, SCIRE Community Coordinator, University of British Columbia

SCIRE Community is a new web resource that provides plain language information based on research evidence for people living with spinal cord injury and their families. This presentation introduces the resource, how it was created, and explains how it can be used by the spinal cord injury community.

Improving Upper Extremity Function in Cervical Spinal Cord Injury—Focus on Nerve Transfer Surgery

Ida Fox, MD, Associate Professor, Surgery Division of Plastic and Reconstructive Surgery Washington University School of Medicine

Traditional options for the restoration of upper extremity function in cervical spinal cord injury (SCI) include tendon transfers, observation, and physical therapy. Nerve transfers have shifted the paradigm for the treatment of peripheral nerve injury. Early results for nerve transfers in SCI suggest that something similarly important will occur in this field. But with this innovation will come concern: What approach is best? Who is an appropriate candidate for this procedure?

What is the information needed to decide between different treatments.

Over the last five years, Dr. Fox has been doing these surgeries with a focus on developing criteria for clinical treatment. This includes a comprehensive preoperative assessment, careful tracking of outcomes, complications and the development of individualized treatment plans based on personal preferences and goals of function. She will share what she has learned regarding clinical assessment, intraoperative technical details, postoperative recovery, therapy and longer term outcomes. Future directions for her research interests will also be discussed.

Restoring Function with Neuroprosthetics: Three Decades of Patient Outcomes

Megan Moynahan, MS , Executive Director, Institute for Functional Restoration
Case Western Reserve University

Through the coordinated activation of neural pathways, neuroprosthetics have successfully demonstrated the ability to restore hand function, trunk stability, respiration, bladder function, standing, and stepping for people with spinal cord injury. These promising outcomes have been demonstrated in research programs over several decades, with studies regularly reported in the literature. What kinds of outcomes can users of these systems expect? What is the safety profile of a neuroprosthetic system? This presentation will summarize the results of three decades of research on neuroprosthetics across the spectrum of their use. It will also highlight the commercialization efforts underway by the Institute for Functional Restoration.

Big-data Analytics: Bringing 'Dark Data' to Light for Enhancing Discovery and Translation in Spinal Cord Injury

Adam Ferguson, PhD, Associate Professor of Neurosurgery at the University of California, San Francisco, Principal Investigator, at Zuckerberg San Francisco General Hospital and the San Francisco VA Medical Center.

Spinal cord injury (SCI) data can be broadly stratified into preclinical discovery data that comprises the scientific basis for medical decision-making, and clinical data that reflects the data used by healthcare providers to deliver effective treatments in real-time. In many cases, both preclinical discovery data and clinical data reside in digitally-inaccessible formats including paper charts, laboratory notebooks, and handwritten notes. These so-called 'dark data' are thought to comprise that vast majority of data collected across the $240-billion dollar biomedical research enterprise annually worldwide. The National Institutes of Health (NIH) and other funding bodies have convened around the goals of increasing data access, data sharing, data publication, and data citation to improve scholarly communication, reproducibility and bench-to- bedside translation. Major journals are responding by demanding that data underlying publications be made available in public repositories for data reuse to fuel ongoing discoveries from pooled scientific data. To accelerate these efforts in the SCI research community our team has begun assembling multicenter, multispecies raw data records and building an Open Data Commons for SCI (ODC-SCI). The website address is scicrunch.org/odc-sci and it will go live January 2018. I will discuss our ongoing efforts to render dark data from preclinical (laboratory) and clinical studies into an actionable format, and will present recently-published work demonstrating the value of advanced data analysis and machine learning tools for discovery of new therapeutic horizons for SCI.

Overcoming Proteoglycan Barriers to Axon Regeneration and Sprouting in the Chronically Paralyzed Respiratory System

Jerry Silver, PhD, Professor of Neurosciences, Case Western Reserve University

The glial scar that develops after CNS trauma as well as the perineuronal net that forms around synapses throughout the CNS are major obstacles to axon regeneration, sprouting and functional recovery. The entrapment of axons by the scar and net is due to the production of inhibitory extracellular matrix molecules knowns as the chondroitin sulfate proteoglycans (CSPGs). Their effects can be almost totally removed by enzymatic digestion using local injections of chondroitinase ABC (ChABC). Many labs have demonstrated a modest recovery of function can be achieved following acute SCI through application of ChABC. However, the ability to recover function following chronic SCI has been a daunting prospect. We wondered whether combining ChABC and a form of respiratory therapy called Intermittent Hypoxia (IH) might achieve some meaningful amount of restoration of diaphragm function at greatly protracted, chronic stages after cervical hemisection. We have examined the potential for restoration of this motor system up to 1.5 years following severe cervical (C2) hemisection where there is no evidence of spontaneous recovery. In spite of complete hemidiaphragm paralysis for up to 18 months, a single injection of ChABC into the ipsilateral phrenic motor pool could robustly restore near normal diaphragm function mediated in large part by sprouting of the serotonergic system. IH rehabilitation combined with this treatment minimally strengthened and refined the recovered activity to increase the functional effects. The remarkable degree and speed of patterned respiratory motor recovery due solely to the enzyme were completely unforeseen, being both greatly superior to that which occurs acutely and even gaining strength over time. Indeed, our data uniquely establish that increasing plasticity can recover essentially normal respiratory function after a near lifetime of diaphragm paralysis. The treatment after chronic injury is likely permanent, since robust diaphragm activity remains intact for a full 6 months. However, when driven to excess the effects of this combination strategy can cause debilitating tonic activity. Through the controlled regulation of serotonergic sprouting, our strategy triggered a mechanism that ensured robust, patterned respiratory recovery regardless of time post injury. These data give hope that we may functionally improve respiratory related motor system circuitry in chronic injuries.

A Translatable Peptide to Overcome Glia Scarring After Spinal Cord Injury

Yu-Shang Lee, PhD, Asst. Staff Scientist, Cleveland Clinic, Associate Prof., Case Western Reserve University

The glial scar that forms following spinal cord injury (SCI) is a particularly challenging clinical complication that limits nerve regeneration and functional recovery. Chondroitinase ABC, which is the currently available enzyme to remove molecular glial scar barriers, (1) is thermally unstable and thus has short longevity in vivo, and (2) must be applied locally, both of which limit its efficiency and clinical application. Alternative attempts have been made to apply Lentivirus or Adenovirus systems to deliver Chondroitinase ABC in order to achieve longer-lasting effects. However, those virus engineered systems need to be injected locally weeks before SCI and have biosafety concerns, which limit their clinical application. Such potently inhibitory glial scarring surrounding the lesion becomes a major barrier to successful functional recovery after SCI. Thus, it is imperative to identify effective new therapeutic strategies that can remove glial scars in SCI patients. We have designed a translational small peptide, chondroitin sulfate proteoglycan (CSPG) reduction peptide (CRP), which can be applied subcutaneously and efficiently to remove CSPG, which is the major component of the glial scar. The CRP includes an N-terminal cell membrane-penetrating domain, a central CSPG binding domain, and a C-terminal lysosome-targeting domain for directing the CRP-CSPG complex to lysosomes for degradation. Our preliminary data show that CRP treatment for

one hour efficiently reduces Neu7 cell-produced CSPG to comparable or even reduced levels compared to that of Chondroitinase ABC. Unlike Chondroitinase ABC, CRP treatment has no effects on heparan sulfate proteoglycan (HSPG) levels, which are known to have beneficial effects on nerve growth/regeneration. Indeed, when dorsal root ganglia (DRG) are co-cultured on the non-permeasive Neu7 cells monolayer, CRP treatment significantly facilitates neurite outgrowth of DRG as compared to that of Chondroitinase ABC and especially to vehicle treatment. These data support the further pursuit of CRP as a clinically feasible and effective treatment to facilitate functional recovery after SCI and related disorders.

Subcutaneous Application of Small Peptide Removes Glial Scar and Facilitates Outgrowth on Dorsal Root Ganglia

Ching-Li Lin, PhD, Project Staff Scientist, Cleveland Clinic, Asst. Staff Scientist, Case Western Reserve University

We now know that regeneration failure is a complex phenomenon mediated by both intrinsic limitations to axon growth/sprouting within the neuron and extrinsic forces produced by various types of reactive glial cells that curtail re-growth/sprouting via inhibitory molecules. Chondroitin sulfate proteoglycans (CSPGs) are the major components of the glial scar and are significantly increased after injury/trauma to both the peripheral and central nervous systems. The newly designed CSPG reduction peptide (CRP) can efficiently reduce T8 acute contusive spinal cord injury (SCI)-induced overexpression of CSPGs. Importantly, subcutaneous injection of CRP beginning one day after SCI significantly improved locomotion and bladder function after SCI. Anatomically, we found that CRP increased serotonin(5-HT) sprouting/regeneration, which is a critical pathway regulating both locomotion and bladder functions, below the SCI lesion and even in the lumbar spinal cord. In addition, CRP treatment also effectively reduced perineruonal nets at lumbosacral levels correlating with 5-HT sprouting/regeneration. We also have more exciting preliminary studies demonstrating that simple systemic administration of CRP alone or especially when combined with intracellular sigma peptide (ISP) can improve both locomotion and bladder function after chronic (two months)contusive SCI. These animals were treated by daily subcutaneous injection of peptides for three months. They showed improvements in locomotion,gait patterns, voiding patterns, and urodynamic assessments. This combinatory peptide treatment provides a promising and potentially translatable therapeutic strategy to repair chronic SCI.

Miami Project Breakout Sessions

There are 3 breakouts and all of the participants are associated with the Miami Project to Cure Paralysis at The University of Miami

Healthy Aging After Spinal Cord Injury

Greg Bigford, PhD, Assistant Scientist
Eva Widerstom-Noga, PhD, Professor of Neurological Surgery and Rehabilitation Medicine, Principal investigator of the Clinical Pain Research Laboratory
Christine Thomas, PhD, Professor, Department of Neurological Surgery
Rachel Cowan, PhD, Asst. Professor, Department of Neurological Surgery

Everyone experiences changes in health with age. Spinal cord injury can exacerbate these changes, and functional independence. Aspects of healthy aging to be discussed with the audience in this breakout session include:

- How can nutritional guidance, moderate-intensity exercise conditioning, and structured behavioral retraining reverse cardiovascular disease risk after spinal cord injury?
- Does exercise have to be tailored to reduce muscle weakness and function with age?
- How can you reduce the impact of various pain conditions on quality of life?
- What approaches can be taken to preserve functional independence with age?

The Therapeutic Potential of Brain Stimulation

Monica Perez, PT, PhD, Associate Professor, Department of Neurological Surgery
Brian Noga, PhD, Associate Professor, Department of Neurological Surgery

During the last decades, invasive and non-invasive brain stimulation techniques have been used to assess transmission on residual neural pathways as well as a means to modulate motor output and enhance plasticity in individuals with disabilities. *The goal of our session is to discuss some of the most common brain stimulation methodologies used in human subjects focusing on transcranial magnetic stimulation and deep brain stimulation.* Transcranial magnetic stimulation is a noninvasive procedure that uses magnetic fields to stimulate nerve cells in the brain to enhance voluntary motor output after central nervous system injury. During deep brain stimulation an electrode implanted in the brain can send signals to block abnormal activity and also enhance neural activity. This technology can be combine with Brain Computer Interfaces. Advances and limitations in these areas of stimulation in relation to spinal cord injury will be highlighted.

Clinical Research Participation

Kim Anderson-Erisman, PhD, Research Professor, Director of Education
Katie Gant, PhD, Assistant Scientist

Clinical research involves more than just clinical trials; it could be a survey, an observational study, the development of an outcome measure, the collection of information about a disease population (epidemiology), behavioral observations, evaluation of health services, etc. Clinical trials are one aspect of clinical research, but participation in all clinical research is equally important. Aspects of clinical research participation to be discussed with the audience in this breakout session include:

- Why participate?
- What to expect?
- What are your responsibilities?
- What are the researchers' responsibilities?
- How can you make a difference for our community living with spinal cord injury?

Notes

Unite 2 Fight Paralysis Leadership Team

Board Of Directors:

President: Marilyn Smith 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 has served as Executive Director since 2009.

David Zacks is from Erie, Pennsylvania, where he joined his family's manufacturing business in 1993. Quickly learning about all facets of running a successful small business, his passion and energy soon translated into strong leadership skills that helped fuel the company's growth and eventual international expansion. Married and the father of 3 children, David's flourishing life was rudely interrupted in January 2005 when a snowmobile accident left him with a C5/6 complete spinal cord injury. Determined to take action rather than wait for curative therapies, David visited the Keck Center at Rutgers University to learn about the current state of research science. Convinced that the future could be much brighter than the picture painted in the SCI community, he asked himself, "What can I do?" With U2FP, that question is answered.

Secretary: Donna Sullivan of Dublin, Ohio, joined the paralysis community in 2005 when her son sustained a spinal cord injury. She believes whether you're advocating for specific research or legislation to support it, individuals must first understand that spinal cord injury is more than a chronic condition – its complications are life threatening. Her role as Special Projects 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. Previously, she worked as the Operations Manager for GTE/Sylvania Hospital Products Division and as Enrichment Coordinator at an elementary school. Working alongside gifted researchers and determined advocates fuels her commitment to advancing a cure for spinal cord injuries.

Barry Munro (B.A., L.L.B., CDO) 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. 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 the majority of his life to assisting people living with disabilities and improving their quality of living.

Mike Burris is from Colorado Springs, CO. He 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.

Staff:

Executive Director: Matthew Rodreick of Minneapolis, Minnesota, entered the 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.

Special Projects Director: Donna Sullivan (see above for bio)

Research Consultant: Chris Powell of Alliance, Nebraska owns and operates a residential real estate business and works on the family farm. She is married and has two children. Chris and her son 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.

Team U2FP Director: Kathryn Mahoney 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. 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.

Advocacy Advisor: Rob Wudlick is from Excelsior, Minnesota and studied Industrial & Management Engineering at Montana State University. While living there he skied, climbed, and rafted the mountains and rivers around Bozeman, Montana. During a rafting trip down the Grand Canyon in 2011, Rob suffered a diving accident that made him a quadriplegic. Since then, he has become an effective advocate for spinal cord research and care by playing an integral part of starting the Minnesota Spinal Cord & Traumatic Brain Injury Research Program by leading government advocacy for this initiative. Wudlick also is chairman and a cofounder of Get Up Stand Up to Cure Paralysis, a local Minnesota nonprofit organization that advocates and supports SCI research and fitness. Rob is excited to be part of U2FP to help advance research and help others get engaged to make a difference. He believes that meaningful outcomes in medical research for spinal cord injury will be possible through community collaboration.

W2W Live Blog Writer: Kate Willette 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.

Program Manager: Ryan Romine of Minneapolis, Minnesota, has worked in managerial and administrative roles for mission driven organizations for the last 15 years. He has a strong background in communications, customer service, and project management. Additionally, Ryan is a Poetry Editor for the literary journal TLR – The Literary Review. His various creative projects include a few published poems and reviews, as well as a writer and producer of short films and screenplays. 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.

Notes

About 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 have facilitated over $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 the 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.

Scientific Advisory Board

In partnership with SCI Sucks, Unite 2 Fight Paralysis formed a Scientific Advisory Board (SAB) in September of 2012 to provide input on a pilot program to provide cost-free SAB oversight to organizations funding spinal cord injury research. Our intent was to provide investors in the SCI community with peer-reviewed recommendations on where to direct critical funding and information on specific research interests. As of January 2017, our SAB has received $5.7M in grant requests. A total of $3.8M in funding was granted and $1.1M in funding is currently pending. To learn more about this program, email donnasullivan@u2fp.org.

Unite 2 Fight Paralysis Scientific Advisory Board

Phillip G. Popovich, PhD, Chair – Dr. Popovich is a 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.

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.

Jean de Vellis, PhD – Dr. de Vellis is 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 has 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 welcome his valuable input to our Scientific Advisory Board.

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.

The SAB is made possible, in part, due to contributions from The Allergan Foundation (www.allergan.com)

Notes

U2FP's Cure Warrior Advocate Award

Unite 2 Fight Paralysis introduced its "Cure Warrior" Advocate Award in 2010, in recognition of a community member who exemplifies a passion and commitment to the cure effort that truly makes a difference. Recipients:

2016: Kate Willette is a prolific 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.

2015: Corinne Jeanmaire — A car accident in Indonesia in 2001 left Corinne, founder of the EndParalysis Foundation, paralyzed from the waist down. After liaising with the experts in the field of spinal cord injury, her determination to contribute to a world without paralysis kept growing. Despite her disability, she has continued to travel the world and has witnessed the consequences of paralysis, especially in young people. She has participated in many scientific conferences and met with various researchers, clinicians and patients, sharing the opinion that chronic spinal cord injury can and must be cured. When the opportunity presented itself after a career in the for profit world, Corinne decided to focus on chronic spinal cord injury research because tomorrow's breakthroughs will change lives.

2014: Matthew Rodreick — Matthew has been a passionate advocate for all things SCI recovery and cure related from the day his son was injured while body surfing in Costa Rica. A resident of Minneapolis, he has worked for the last several years in the effort to pass an SCI research funding bill in the state of Minnesota. Along the way he has connected to many members of the research and SCI communities; in the words of the person who nominated him for this award, he has exceptional skills as a "bridge-builder". Matthew helped found Get Up Stand Up to Cure Paralysis (GUSU2CURE), an advocacy organization dedicated to the advancement of recovery and curative therapies. His belief, energy, and dedication to advancing a cure make him an exceptional advocate.

2013: Perry Cross — Australia's Perry Cross won the 2013 U2FP Cure Warrior Advocate Award. Perry truly embodies his own motto, "Everything is possible." He became a C2 vent-dependent quadriplegic at the age of 19 in a rugby accident,

and gave his first motivational speech while still on life support. Perry earned his Bachelor of Communications degree in 2000, and that same year began his advocacy work on behalf of spinal cord injury research. In 2010 he started his own foundation to raise money for research. Despite the risks involved in long-distance travel, Perry has come from Australia for the last 3 years to attend Working 2 Walk, and is a true Cure Warrior. To find out more about Perry, visit the Perry Cross Spinal Research Foundation' website at pcsrf.org.au.

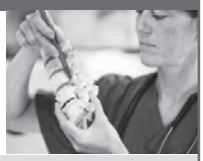
2012: Roman & Don Reed — The 2012 award was shared by two people who have been speaking out for years about the urgency to find cures for paralysis. They got involved, like most of us, when a spinal cord injury impacted their family. They chose to work in the legislative arena, and they NEVER seem to get discouraged by the amount of time it takes or the setbacks they encounter. Day after day, year after year, the Reeds do the grinding work behind the scenes. Writing letters, making phone calls, driving hundreds of miles, attending meetings. And in the end, they get results. As a direct result of their efforts, the RIRC received funding for several important research projects. They were leaders in the effort to pass the Roman Reed Spinal Cord Injury Act as well as the bill creating the California Institute for Regenerative Medicine.

2011: Geoffrey Kent — Geoff first attended Working 2 Walk in the spring of 2008, and he returned home determined to join the advocacy effort. He had taken up wheelchair racing after his spinal cord injury, and decided to put together a team for the Chicago Marathon with the goal of raising awareness. A small group of 7 athletes raised more than awareness, they raised $50,000 to support SCI research. At the same time Geoff founded a non-profit that he named "SCI Sucks ". It took courage to adopt such a name, but as their website banner says, "People tell us to change the name, but then we wouldn't be telling the truth." SCI Sucks continued to field teams in the Chicago Marathon for the next 7 years, and raised close to $1/2 million to support spinal cord injury research. In 2015, SCI Sucks joined forces with Unite 2 Fight Paralysis to create Team SCIS/U2FP. Thanks to Geoff's hard work laying the foundation for the team, it promises to expand and continue to provide desperately needed research funding.

2010: Karen Miner — Karen Miner, a founder of Research for Cure, suffered a C4 spinal cord injury in 1992. She suddenly saw her marriage end, leaving her a paralyzed mother of two little girls. Despite all of the other demands on her time, she took it upon herself to become an active advocate on behalf of cures for SCI. Research for Cure is a California non-profit that organizes several fundraisers each year to support the work of the Reeve-Irvine Research Center. Karen also worked on the successful campaigns for passage of the Roman Reed Spinal Cord injury Act, and Proposition 71 that created the California Institute for Regenerative Medicine. While raising her daughters to become successful adults, Karen has continued her advocacy work.

NSCISC
NATIONAL SPINAL CORD INJURY STATISTICAL CENTER

Spinal Cord Injury (SCI) Facts and Figures at a Glance



2016 SCI Data Sheet

This data sheet is a quick reference on demographics and the use of services by people with spinal cord injury (SCI).

Incidence

Given the current population size of 314 million people in the U.S., the recent estimate showed that the annual incidence of spinal cord injury (SCI) is approximately 54 cases per million population in the U.S. or approximately 17,000 new SCI cases each year.

- New SCI cases do not include those who die at the scene of the accident.
- Estimates are obtained from several studies and not derived from the National SCI Database.

Prevalence

The number of people in the U.S. who are alive in 2016 who have SCI has been estimated to be approximately 282,000 persons, with a range from 243,000 to 347,000 persons.

- Estimates are obtained from several studies and not derived from the National SCI Database.

The National SCI Database is a prospective longitudinal multicenter study that currently captures data from an estimated 6% of new SCI cases in the U.S. The database has demographic and condition status data through 2015 for 31,255 people with SCI.

Age at Injury

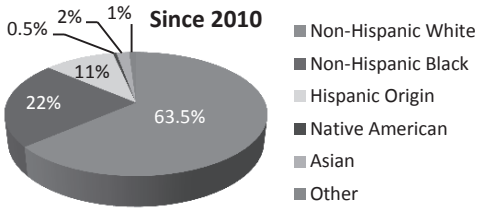
The average age at injury has increased from 29 years during the 1970s to 42 years currently.

Gender

Males account for approximately 80% of new SCI cases.

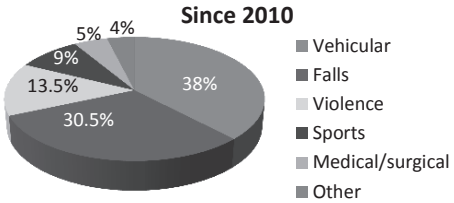
Race/Ethnicity

About 22% of injuries have occurred among non-Hispanic blacks since 2010, which is higher than the proportion of non-Hispanic blacks in the general population (12%).



Etiology

Vehicle crashes are currently the leading cause of injury, followed by falls, acts of violence (primarily gunshot wounds), and sports/recreation activities.

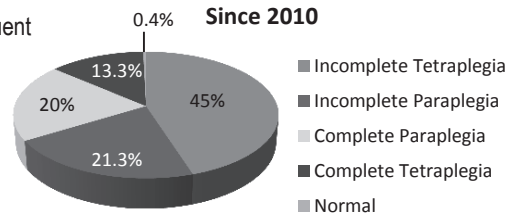


Lengths of stay

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 35 days currently.

Neurological level and extent of lesion

Incomplete tetraplegia is currently the most frequent neurological category followed by incomplete paraplegia, complete paraplegia, and complete tetraplegia. Less than 1% of persons experienced complete neurological recovery by hospital discharge.



National SCI Statistical Center
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Marital status

More than half of persons with SCI are single/never married at 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	51.4	50.2	41.4	35.3	29.5	21.3
Married	32.8	32.3	33.8	35.8	39.1	43.4
Divorced	9.5	11.2	19.1	23.5	24.6	21.3

Occupational status

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

Status (%)	At injury	Year 1	Year 10	Year 20	Year 30	Year 40
Employed	58.1	12.4	27.7	34.3	32.7	25.9
Student	15.1	15.8	6.9	2.6	0.7	0.0

Education

Over half of persons with SCI are high school graduates at 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	54.1	51.1	46.5	43.9	33.3
College or higher	10.9	12.2	21.8	29.1	35.7	43.7

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 $72,047 per year in 2015 dollars).

	Average Yearly Expenses (in 2015 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	$1,065,980	$185,111	$4,729,788	$2,599,411
Low Tetraplegia (C5–C8) AIS ABC	$770,264	$113,557	$3,455,879	$2,125,674
Paraplegia AIS ABC	$519,520	$68,821	$2,312,846	$1,517,851
Motor Functional at Any Level AIS D	$347,896	$42,256	$1,580,148	$1,115,312

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	59.5	52.6	45.1	40.0	35.7	19.3	52.9	45.5	40.7	36.9	25.3
40	40.6	34.2	27.7	23.5	20.1	8.9	34.5	28.1	24.1	21.0	12.6
60	23.1	17.9	13.1	10.3	8.1	2.2	18.2	13.4	10.6	8.7	4.0

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 only slight decrease in mortality due to respiratory diseases.

 The contents of this publication were developed under a grant from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant number 90DP0011). 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 28 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, 2016.

Clinical Trial Participation — The Basics

www.nih.gov/health-information/nih-clinical-research-trials-you/basics#1

What are clinical trials and why do people participate?

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. Treatments might be new drugs or new combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments. The goal of clinical trials is to determine if a new test or treatment works and is safe. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses.

People participate in clinical trials for a variety of reasons. Healthy volunteers say they participate to help others and to contribute to moving science forward. Participants with an illness or disease also participate to help others, but also to possibly receive the newest treatment and to have the additional care and attention from the clinical trial staff. Clinical trials offer hope for many people and an opportunity to help researchers find better treatments for others in the future.

What is clinical research?

Clinical research is medical research that involves people like you. People volunteer to participate in carefully conducted investigations that ultimately uncover better ways to treat, prevent, diagnose, and understand human disease. Clinical research includes trials that test new treatments and therapies as well as long-term natural history studies, which provide valuable information about how disease and health progress.

The idea

The idea for a clinical research study — also known as a clinical trial — often originates in the laboratory. After researchers test new therapies or procedures in the laboratory and in animal studies, the most promising experimental treatments are moved into clinical trials, which are conducted in phases. During a trial, more information is gained about an experimental treatment, its risks, and its effectiveness.

The protocol

Clinical research is conducted according to a plan known as a protocol. The protocol is carefully designed to safeguard the participants' health and answer specific research questions. A protocol describes the following:

- Who is eligible to participate in the trial
- Details about tests, procedures, medications, and dosages
- The length of the study and what information will be gathered

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

IRB review

Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) in order to ensure that the risks are minimal and are worth any 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. Potential research participants should ask the sponsor or research coordinator whether the research they are considering participating in was reviewed by an IRB.

Sponsors
Clinical trials are sponsored or funded by various organizations or individuals, including physicians, foundations, medical institutions, voluntary groups, and pharmaceutical companies, as well as federal agencies such as the National Institutes of Health and the Department of Veterans Affairs.

Informed consent
Informed consent is the process of providing potential participants with the key facts about a clinical trial before they decide whether to participate. The process of informed consent (providing additional information) continues throughout the study. To help someone decide whether or not to participate, members of the research team explain the details of the study. Translation or interpretive assistance can be provided for participants with limited English proficiency. The research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and who to contact for further information. The informed consent document also explains risks and potential benefits. The participant then decides whether to sign the document. Informed consent is not a contract. Volunteers are free to withdraw from the study completely or to refuse particular treatments or tests at any time. Sometimes, however, this will make them ineligible to continue the study.

Types of clinical trials
There are different types of clinical trials.

- **Natural history studies** provide valuable information about how disease and health progress.

- **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. Better approaches may include medicines, vaccines, or lifestyle changes, among other things.

- **Screening trials** test the best way to detect certain diseases or health conditions.

- **Diagnostic trials** determine better 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.

- **Quality of life trials** (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness.

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

- **Phase I trials**: Researchers test an experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects.

- **Phase II trials**: The experimental drug or treatment is administered to a larger group of people (100–300) to determine its effectiveness and to further evaluate its safety.

- **Phase III trials**: The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments, and collect information that will allow the experimental 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, seeking more information about a drug or treatment's risks, benefits, and optimal use.

Some concepts to understand
Typically, clinical trials compare a new product or therapy with another that already exists to determine if the new one is as successful as, or better than, the existing one. In some studies, participants 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 demonstrate the new product's therapeutic effectiveness. However, placebos are not used if a patient would be put at risk — particularly in the study of treatments for serious illnesses — by not having effective therapy. Most of these studies compare new products with an approved therapy. Potential participants are told if placebos will be used in the study before they enter a trial.

Randomization is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice. This is done to avoid any bias with investigators assigning volunteers to one group or another. The results of each treatment are compared at specific points during a trial, which may last for years. When one treatment is found superior, the trial is stopped so that the fewest volunteers receive the less beneficial treatment.

In ***single-*** or ***double-blind studies***, also called single- or double-masked studies, the participants do not know which medicine is being used, so they can describe what happens without bias. "Blind" (or "masked") studies are designed to prevent members of the research team or study participants from influencing the results. This allows scientifically accurate conclusions. In single-blind ("single-masked") studies, only the patient is not told what is being administered. In a double-blind study, only the pharmacist knows; members of the research team are not told which patients are getting which medication, so that their observations will not be biased. If medically necessary, however, it is always possible to find out what the patient is taking.

Who participates in clinical trials?

Many different types of people participate in clinical trials. Some are healthy, while others may have illnesses. A **healthy volunteer** is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention. Research procedures with healthy volunteers are designed to develop new knowledge, not to provide direct benefit to study participants. 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 (formerly called "normal volunteers") help define the limits of "normal." These volunteers serve as controls for patient groups and are often matched to patients on characteristics such as age, gender, or family relationship. They receive the same test, procedure, or drug the patient group receives. Investigators 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 in time and effort on behalf of the volunteer, and may involve some discomfort. The research procedure may also carry some risk. The consent process for healthy volunteers includes a detailed discussion of the study's procedures and tests.

A **patient volunteer** has a known health problem and participates in research to better understand, diagnose, treat, or cure that disease or condition. Research procedures with a patient volunteer help develop new knowledge. These procedures may or may not benefit the study participants.

Patient volunteers may be involved in studies similar to those in which healthy volunteers participate. These studies involve drugs, devices, or interventions designed to prevent, treat, or cure 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. Consequently, some patients serve as controls

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. A study's benefits may be indirect for the volunteers but may help others.

All clinical trials have guidelines about who can participate, called **Inclusion/Exclusion Criteria.** Factors that allow someone to participate in a clinical trial are "inclusion criteria." Those that exclude or not allow participation are "exclusion criteria." These criteria are based on factors such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers.

Some studies need both types. Inclusion and exclusion criteria are not used to reject people personally; rather, 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 participating?

Risks and benefits
Clinical trials involve risks, just as routine medical care and the activities of daily living. When weighing the risks of research, you can consider two important factors:

1. the degree of harm that could result from participating in the study, and

2. the chance of any harm occurring.

Most clinical studies 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 therapies. The specific risks associated with a research protocol are described in detail in the informed consent document, which participants are asked to sign before participating in research. Also, a member of the research team explains the major risks of participating in a study and will answer any questions you have about the study. Before deciding to participate, carefully consider possible risks and benefits.

Potential benefits
Well-designed and well-executed clinical trials provide the best approach for participants to:

- Play an active role in their health care.

- 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.

- Help others by contributing to medical research.

Potential risks
Risks to participating in clinical trials include the following:

- There may be unpleasant, serious, or even life-threatening side effects to experimental treatment.

- The study may require more time and attention than standard treatment would, including visits to the study site, more blood tests, more treatments, hospital stays, or complex dosage requirements.

What questions should I ask if offered a clinical trial?

If you are offered a clinical trial, 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 checked?
- How long will the study last?
- What will my responsibilities be if I participate?

Possible risks and benefits

- What are my possible short-term benefits?
- What are my possible long-term benefits?
- What are my short-term risks, such as side effects?
- What are my possible long-term risks?
- What other options do people with my disease have?
- How do the possible risks and 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 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 ahead what to ask — but don't hesitate to ask any new questions you think of while you're there.
- Write down your questions in advance, to make sure you remember to ask them all.
- Write down the answers, so that you can review them whenever you want.
- 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 Am I Protected?

Ethical guidelines
The goal of clinical research is to develop knowledge that improves human health or increases understanding of human biology. People who participate 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 patient volunteers. By placing some people at risk of harm for the good of others, clinical research has the potential to exploit patient volunteers. The purpose of ethical guidelines is both to protect patient volunteers and to preserve the integrity of the science. Ethical guidelines in place today were primarily a response to past research abuses.

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 someone decide whether to participate, members of the research team explain details of 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 the participant decides to enroll in the trial, the informed consent document will be signed. Informed consent is not a contract. Volunteers 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) in order to ensure that the risks are minimal and are worth any 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. Potential research participants should ask the sponsor or research coordinator whether the research they are considering participating in was reviewed by an IRB.

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 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 agent or intervention because it was unsafe or ineffective. When a phase III trial is completed, the researchers examine the data 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 news media and discussed at scientific meetings and by patient advocacy groups before they are published. Once a new approach has been proven safe and effective in a clinical trial, it may become the 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 the outcome of clinical research make a difference?

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

Notes

Update on STIMO: Epidural Electrical Simulation (EES) With Robot-assisted Rehabilitation in Patients With Spinal Cord Injury (STIMO)

Over the past decade, Prof. Courtine's team has systematically developed activity-based interventions combined with neuroprosthetic technologies to improve motor recovery after spinal cord injury in animal models, with the ultimate goal to translate these findings into innovative clinical neurorehabilitative approaches. A novel gravity-assist robot together with chemical neuromodulation and epidural electrical stimulation (EES) of the spinal cord enabled highly participative overground gait rehabilitation in rats with severe SCI and restored supraspinal control over hindlimb movements. A technological breakthrough was the development of spatio-temporal EES, which selectively delivers stimulation to the appropriate spinal circuits with the correct timing to facilitate flexor and extensor synergies for locomotion. In a rodent model of SCI, closed-loop spatio-temporal EES generated robust stepping and allowed for real-time control over limb motions. Recently, spatio-temporal EES with human-ready technology was successfully tested in non-human primates with SCI. Together, these studies constituted the technological and conceptual framework to translate these pre-clinical findings into the First-in- Man clinical study STIMO that started in July 2016.

STIMO is a feasibility clinical study that combines a cutting-edge body-weight support system with closed-loop control of spatiotemporal EES to enable will-powered overground locomotion in individuals with severe incomplete SCI in a safe rehabilitation environment. The objective is to evaluate the safety of this combined treatment and its efficacy in improving voluntary movement and secondary autonomic functions.

The participants are surgically implanted with a spinal cord stimulator enabling real-time control of stimulation protocols through wireless links. After a period of personalization of the spatial location, temporal structure and stimulation parameters of the EES therapy, the participants follow a 5-month period of intensive locomotor training. Monthly evaluations using a range of advanced neurobiomechanical recordings, well-established electrophysiological measurements, and standard clinical tests assess the evolution of the trained individuals. Several participants are currently enrolled in the study. Preliminary results suggest that real-time control of spatiotemporal EES results in considerable immediate facilitation of leg kinematics and muscle activity. This facilitation allows the performance of locomotion under challenging conditions that would otherwise not be possible for these patients, e.g., overground walking under partial body weight support, but without any further assistance. The participants are now following the Intensive training program. These preliminary results provide encouraging insights into thepotential of this novel intervention to augment neural plasticity and functional recovery after incomplete SCI.

SPINAL CORD INJURY
CLINICAL TRIALS CHART

unite2fight paralysis

This information was compiled for the benefit of the spinal cord injury community and is updated via our live chart at u2fp.org/educate/clinical-trials/. The live chart includes links to related news, results, videos and a direct link clinicaltrials.gov for specific details for each trial. Unite 2 Fight Paralysis does not imply or infer an endorsement or recommendation of the below mentioned research.

Questions and comments are welcome at trials@u2fp.org

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**
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**
SCI	**Spinal Cord Injury**
SMA	**Spinal Muscular Atrophy**
TMS	**Transcranial Magnetic Stimulation**
UC-MSC	**Human Umbilical Cord-derived Mesenchymal Stem Cells**

ONGOING CLINICAL TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
AOSpine Europe	Surgical Decompression Study	NCT01674764	Acute <14 days post injury	Sites in Europe	Recruiting
AOSpine North American	Riluzole Oral Therapy	Ph II&III NCT01597518	Acute <24 hrs post injury Video presentation	US/Canada	Recruiting News
Aristotle University Of Thessaloniki	Brainwave Control of a Wearable Robotic Arm	NCT02443558	Cervical SCI	Greece	Recruiting by invitation
Asterias Biotherapeutics	AST-OPC1	Ph I & II NCT02302157	ASI A&B C5 -C7 Complete < 25 days post injury	US	Recruiting - W2W Video 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
Burke Medical Research Institute	Non-Invasive Paired Stimulation and Anklebot Robot to Improve Lower Extremity Motor Recovery in Chronic SCI	Ph 1	Chronic < 1 year Incomplete Asia B,C,D	US: NY	Recruiting
California Institute of Tech	Brain Machine Interface	NCT01964261	High cervical injury	US 3 locations	Recruiting
Case Western Reserve	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 injury C4-T12 ASI A-C	US	Recruiting
	Stimulation to restore cough	NCT00116337	T5 or above	US	Ongoing Not recruiting
	Stimulation to restore cough	NCT01659541	C8 or above 12 mo post incomplete 6 mo post complete	US	Recruiting
Centre Hospitalier Universitaire Vaudois	Epidural Elec Simulation 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
Charite University	Dolormin® extra (Ibuprofen)	NCT02096913	Acute, 4-21 days post AIS AorB C4-T4	Germany	Ongoing but not 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 injury 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 ASIA A	China	Recruiting
Cleveland Clinic	Non-invasive brain stimulation	NCT01539109	Incomplete Chronic >6 mos post injury	US	Recruiting
Craig Hospital	Simvastatin to treat bone loss	NCT02946424	<3 mo post injury Acute AIS A-C	US	Recruiting
Da Nang Hospital	Bone Marrow-derived Mononuclear Cells	NCT02923817	3 wks-1 yr post injury ASI AorB	Vietnam	Recruiting
École polytechnique fédérale de Lausanne	STIMO: Epidural Electrical Simulation (EES) With Robot-assisted Rehabilitation	NCT02936453	Detailed criteria Incomplete C&D T10 and above 12 mo post	Switzerland	Recruiting

ONGOING CLINICAL TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
Ekso Bionics	Lower extremity exoskeleton	NCT02566850	Be able to balance with arms	US	Recruiting by invitation
	Walking Improvement for SCI With Exoskeleton (WISE)	NCT02943915	C1-T10 AIS C&D	US	Recruiting
Emory University	Acute Intermittent Hypoxia	Ph I & II NCT02274116	>1 yr post injury	US	Recruiting
	Intermittent Hypoxia	NCT02323945	C2 - T12 >1 yr post	US	Recruiting
	Caffeine and Low Oxygen Therapy on Leg Function	PhI&II NCT02323698	>1 yr post C2 - T11 motor incomplete	US	Recruiting
	Intermittent hypoxia	NCT02632422	C4 - T12 ASI B-D 2-4 mo post injury	US	Recruiting
Fed. Research Clinical Ctr Novagenesis Fdn/Fortuna Fix	Neural Stem Cells	Ph I & II NCT02326662	ASI A or B Acute & Chronic	Russia	Ongoing not 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
Helsinki University Central Hospital	Transcranial Magnetic & Peripheral Nerve Stim	NCT03045744	Incomplete SCI	Finland	Recruiting by invite only
Hospices Civils de Lyon	Ulcer Related Osteomyelitis: Surgery w/Antimicrobial	NCT03010293	pressure ulcer-related osteomyelitis	France	Recruiting
Hospital Nacionalde Parapléjicos de Toledo	Autoantibodies	NCT02493543	Less than 45 days post injury	Spain	Recruiting by invitation
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 injury	Spain	Information Link
Indian Spinal Injuries Ctr.	Autologous Bone Marrow SCs	Ph I/II NCT02260713	T1-T12 Acute ASI A 10 - 14 days post	India	Ongoing not recruiting
Instituto Nacional de Rehabilitacion	Robotic Gait Training	NCT02749357	>6 mos post ASI C or D	Mexico	Recruiting
Institut Guttmann	Baclofen for Neuro Pain	NCT02705950	> 1 yr post injury	Spain	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® Treatment of Urinary Incontinence	PH III NCT02660138	6 mos post injury T1 or below	US & Canada	Recruiting
	Dysport® Treatment of Urinary Incontinence Study 2	NCT02660359	6 mos post injury T1 or below	US & Canada	Recruiting
Kennedy Krieger Institute	FES Arm & Shoulder	Ph I & II NCT01005615	Chronic C1-C6	US	Ongoing not recruiting
	Aquatic vs. Land Locomotor Training	NCT02774603	C1-C7 ASI C or D >12 mos post injury	US	Recruiting
	Transcutaneous Stimulation Single Session	NCT03046875	Above T10 >1 yr post injury	US	Recruiting
	Testosterone w/elec stim for bone mass	NCT02317640	C6-T10 >6 mos <10 yrs post injury AIS A, B&C	US	Recruiting
Kessler Foundation	4-AP & Locomotor Training	Ph II NCT01621113	>12 mos post injury C4 - T10 ASI C or D	US	Recruiting
	Testosterone, Standing and Electrical Stimulation	NCT02317640	Male, C6 - T10 ASI A, B or C	US	Recruiting
	Robotic Exoskeleton	NCT02324322	>1 yr post injury C6-T10	US	Recruiting

ONGOING CLINICAL TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
Kessler Foundation (cont'd)	MRI to study plasticity	NCT03069222	< 3 wks post injury	US	Recruiting
	Mirabegron and Oxybutynin Safety and Efficacy (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 injury T1 - T12 ASI A	Hong Kong	Recruiting
Lawson Health Research Inst.	Mirabegron for Neurogenic Bladder	NCT02044510	Stable bladder >3 mos	Canada	Recruiting by invitation
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 recruiting
Massachusetts Gen'l Hosp Case Western - Stanford - Providence	BrainGate2	NCT00912041	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
McMaster University	Repetitive Transcranial Magnetic Stimulation	NCT02351921	>1 yr post Incomplete C4 to T1	Canada	Unknown status
Metro Health Med. Center	Implant Myoelectric Control	NCT00583804	Chronic pediatric	US	Ongoing not recruiting
	Neuroprosthetic System	NCT02329652	C4 - C8	US	Recruiting
Miami Project to Cure Paralysis	Deep Brain Stimulation	Ph I NCT02006433	T6 and above	US	Recruiting
	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
Montecatone Rehab Inst	Locomotor Training With Exoskeleton EKSO-GT	NCT02600013	Acute AIS C or D	Italy	Recruiting
Mt. Sinai Hospital	Botox to treat pain	NCT02736890	Pain at level of SCI	US	Recruiting
Neuralstem	neural stem cell (HSSC)	NCT01772810	More than 1 year, but less than 2. T2-T12 & C5-C7	UCSD Medical Center USA	Recruiting
Neurogen Brain & Spine Institute	Autologous BMSCs	Ph II NCT02009124	All AIS and Injury levels	India	Recruiting
New York University	Indego Exoskeleton After SCI	NCT02793635	>1 year post LE function	US	Recruiting
Nantes University Hospital	Zoledronic Acid -Bone Loss	NCT01802658	<12 wks post C5 - L2 AIS A to D	9 Locations France	Recruiting
	Delay in Surgery Cervical Central Cord Injury in Canal Stenosis	NCT02673320	AIS A-D C2 - T1	4 Locations France	Not yet recruiting
NHS Greater Glasgow and Clyde	Neuro feedback for Neuropathic pain	NCT02678494	C5 - T12	UK	Recruiting
Northwell Health	Biomarkers of Spontaneous Recovery	NCT02731027	0 -14 days post injury	US 3 Locations	Recruiting
Northwestern University	Zoledronic Acid for bone loss	NCT02325414	<120 days post injury	US	Recruiting

ONGOING CLINICAL TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
Northwestern University (cont'd)	Teriparatide for bone loss	Ph II NCT02025179	Acute & Chronic Observational Study	US	Ongoing not recruiting
	Effect of Alendronate on patients previously treated withTeriparatide	NCT02195895	Prior enrollment in trial # NCT01225055	US	Recruiting Invite only
Ohio State University	Neural Bridge Implant System	NCT01997125	Tetraplegic C4- C6 ASIA A: 12 mo post injury	US	Recruiting
Oslo University Hospital	Botox for bladder dysfunction	Ph 4 NCT01698138	C6 - T11 <4 wks post injury	Norway	Recruiting
	Intermittent Negative Pressure on Wound Healing	NCT02866708	non-healing leg/foot ulcer/pressure wound for > 6 wks	Norway	Ongoing not recruiting
Ottawa Hospital Research Institute/Washington Univ	Nerve Transfers to Restore Hand Function	NCT02861612	C5 to C7	US	Recruiting
Puerto de Hierro Univ Hosp	Autologous BMSCs	Ph II NCT02570932	Chronic, stable All ASI levels	Spain	Ongoing not recruiting
Rehab Institute of Chicago	Drug Lexapro	Ph I NCT01753882	C1 - T10 ASI C or D 1 - 9 mos post injury	US	Not recruiting
	ReWalk Exsoskeleton	Ph II NCT02104622	Sub-acute incomplete C1 - T10	US	Not recruiting
	Ekso Exoskeleton	NCT01701388	C6 - L5	US	Not recruiting
	Motor learning in a customized Body-Machine interface	NCT01608438	C3-C6 ASI A,B or C	US	Recruiting
St. George's U of London	Spinal Cord Pressure Eval (ISCoPE)	NCT02721615	AIS A-C Within 72 hrs of injury	UK	Recruiting
	Human Olfactory Ensheathing Stem Cells (hOESC)	NCT02870426	Brain dead donors to donate olfactory bulbs	UK	Not yet recruiting
Seoul National Univ Hospital	Transcutaneous Stimulation	NCT02863315	Cervical/High thoracic >6 mos post injury	So Korea	Not yet recruiting
Shepherd Center	Stimulation	NCT02611375	C1-C8 Limited hand function	US	Recruiting
	Enhancing Corticospinal Excitability to Improve Functional Recovery	NCT03237091	Cervical C1-C8 at least 6 mo post ASI: A-D	US	Not yet recruiting
	Spinal Cord Stimulation to Augment Activity Based Therapy	NCT03240601	All SCI	US	Recruiting
Spaulding Rehab Hospital	Non-invasive ventilation	NCT02865343	Chronic AIS A,B or C T3 or above	US	Recruiting
Stem Cells Arabia	Autologous BMSCs or Leukapheresis-Derived SCs	Ph I&II NCT02687672	6 - 60 mos. post injury	Jordan	Ongoing not recruiting
Stony Brook University	Health Outcomes After Locomotor Training	NCT02201173	Detailed criteria	US 3 Locations	Recruiting
Swiss Paraplegic Centre	Rivaroxaban to treat thromboemlism	NCT02970773	AIS A >3 mos post	SUI	Not yet open
	Electrostimulation on Denervated Muscles	NCT02265042	>2 yrs post injury T10-L5 ASI A	SUI	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
The 3rd Affiliated Hospital of Sun Yat-sen University	UC Mesenchymal SCs	NCT02481440	2 wks - 1 yr post All injury and ASI levels	China	Recruiting
Thomas Jefferson University	Zoledronic Acid for Bone Loss	NCT01642901	C4-T10 ASI A	US	Recruiting
Toronto Rehab Institute	Electrical Stimulation	Ph III NCT01292811	Chronic T10-L5 ASI A	Canada	Ongoing not recruiting
University of Alabama Birmingham	Pressure Ulcer Healing With Microcyn	NCT02001558	Stage III/IV Pressure Ulcer	US	Recruiting

ONGOING CLINICAL TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
University Health Network Toronto	Reactive Stepping Training	NCT02960178	AIS C or D >1 yr post injury	Canada	Recruiting
University of Alberta	Exoskeleton - Rewalk	NCT02322125	>1 yr post injury	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 injury	Canada	Recruiting
	Changes to Gut Bacteria	NCT02903472	SCI	Canada	Not yet open
	CSF Monitoring and Biomarker Study (CAMPER)	NCT01279811	Acute within 48 hrs Cervical & Thoracic	US & Canada	Recruiting
University of CA - LA	Neuromodulation Arm	NCT02313194	C1 - C5 >12 mos post	US	Recruiting U2FP Report
	Neuromodulation Bladder	NCT02331979	C2 - C8 >12 mos post	US	Recruiting
UCLA/Casa Colina/Caltech	Brain Implant for Neural Control of a Computer	NCT01958086	High cervical injury	US	Recruiting @ Casa Colina
University of Florida	Intermittent Hypoxia to Enhance Motor Function	NCT03071393	>6 mos post C4-T12	US	Recruiting
	Intermittent Hypoxia to Enhance Motor Function	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 Louisville	Epi Stim	NCT02339233	Above T10	US	Recruiting
	Recovery of Bladder & Sexual Function through ABTs	NCT03036527	Medically stable	US	Recruiting
	Epidural Stimulation for Cardiovascular Function	NCT02037620	AIS A,B or C Cervical injury	US	Recruiting
University of Miami	Corticospinal Function	NCT02451683	≥ 6 months post injury C8 and above	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
	Deep Brain Stimulation for pain and AD	NCT02006433	T12 and above w/a history of pain	US 2 locations	Recruiting
	Therapeutic Hypothermia (ARTIC)	Ph I NCT01739010	Acute	US	Recruiting
	Male Fertility Program	NCT01467869	Male	US	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

ONGOING CLINICAL TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
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	Effects of Transcranial Magnetic Stimulation	NCT02899637	Incomplete, nonprogressive	Brazil	Not yet recruiting
University of So. California California Institute of Tech.	NeuroPort Array Brain-Machine Interface (BMI)	NCT01849822	High cervical injury	US	Ongoing not recruiting
	Neural Prosthetic System 2	NCT01964261	High cervical injury	US 3 locations	Recruiting
University of Texas	Capsaicin 8% Patch Low Dose Capsaicin 0.04% gel	NCT02441660	Neuropathic pain	US	Recruiting
	Algorithmic-Based Approach for Robotic Gait Training	NCT03057652	> 6 mo post	US	Recruiting
	Transcutaneous Tibial Nerve Stimulation	NCT02573402	T9 and above Within 6 wks of injury	US	Recruiting
University of Washington	Transcutaneous Elec Spinal Stim (ADDRESS)	NCT03184792	C7 and above >1yr post injury	US	Recruiting
University of Zurich	Deep Brain Stimulation	NCT03053791	Incomplete T10 and up > 6 mos post	SUI	Recruiting
	Kinematic & EMG Changes	NCT02150629	All	SUI	Recruiting
	Exoskeleton Robot ARM	NCT02720341	Detailed criteria	SUI	Recruiting
	White and Grey Matter Changes	NCT02148887	All SCIs	SUI	Ongoing not recruiting
	Probing Neural Circuitry for the Control of Movement	NCT02150642	All	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	Not yet recruiting
	Transcutaneous Spinal Cord Stimulation on Residual Voluntary Motor Control	NCT03137108	Chronic ≥ 12 mos post or subacute ≥ 3 mos post	SUI	Recruiting
Uro-Research	Tissue Bonding Cystostomy	NCT01771159	>2 years post injury	US	Not yet recruiting
US Bionics	Phoenix Exoskeleton for SCI	NCT03175055	All SCI under #220	US	Recruiting
Vanderbilt University	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
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 injury	US	Recruiting

ONGOING CLINICAL TRIALS					
SPONSOR	**THERAPY**	**PHASE & NUMBER**	**INJURY INFO**	**WHERE**	**STATUS**
VA Bronx (cont'd)	ReWalk Exoskeleton	NCT02118194	Prior participation in 20 ReWalk Sessions	US	Unknown status
	ReWalk Exsoskeleton	NCT01454570	Paraplegia > 6 mos	US	Unknown status
	Animated Bowel Biofeedback	NCT02406859	> 1 yr post injury	US	Ongoing not recruiting
	Brain and Nerve Stimulation for hand muscles	NCT02469675	C2 - C8 >12 mos post injury	US	Recruiting
	Neurostimulation and Physical Exercise	NCT03076632	>12 mos post injury Between C2-C8	US	Not yet open
VA Bronx and Mt. Sinai Hosp	Post-SCI Hypotension	NCT02919917	< 1 year post injury Non vent dependent	US	Not yet recruiting
VA Cleveland	Stimulation for bowel dysfunction	NCT02641483	6 mos post injury	US	Not yet recruiting
	IST-16 - Implanted stimulator-telemeter	NCT01923662	> 6 mos post injury C6 - T12	US	Recruiting
Veterans Affairs Gainesville	Testosterone Plus Finasteride	NCT02248701	C4 - T7 >12 mos post ASI C&D Male	US	Recruiting
Veterans Affairs Miami	Paired pulse induced spike-timing dependent plasticity	Ph IV NCT02701777	Detailed inclusion criteria	US	Not yet recruiting
	rTMS Magnetic stimulation	NCT01915095	> 6 mos post injury at or above L5	US	Recruiting
Veterans Affairs Palo Alto	Electrical Stim for Continence Vocare Bladder System	NCT02978638	AIS A Below C4 >2 yr post	US	Recruiting
	Neural Adaptation After Tendon Transfer	NCT02768103	C4-C7 1 yr post injury	US	Recruiting
Veterans Affairs Pittsburgh	Transcranial magnetic stim	NCT01915095	Chronic C8 or above Right-handed	US 3 locations	Recruiting
Veterans Affairs Centers Maryland,NJ and NY	Exoskeletal-assisted walking (ReWalk, Ekso)	NCT02314221	>6 mo post injury Able to hold crutches	3 locations	Recruiting
VA Bronx and Kessler (NJ)	Denosumab(Prolia) for bone loss	NCT03029442	AIS C&D < 6 mos post injury	US 2 locations	Not yet recruiting
	Rx to regulate BP	NCT02893553	> 1 yr post injury	US 2 locations	Recruiting
Veterans Affairs CA, FL, MA, NY, TX, VA	Exoskeleton	NCT02658656	C6-T3 > 6 mos post	US 8 locations	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	Published Results
Brigham & Women's Hosp	Drug V158866	Ph II NCT01748695	T5 or below Neuropathic pain	US	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
Instituto de Rehabilitación Infantil Teletón Chile	Intermittent Hypoxia and Treadmill Training	NCT02441179	C5-T12 AIS C&D >6 mos post	Chile	Results
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
Shanghai Institute of Acupuncture/RenJi Hospital	Electrical stimulation for neurogenic bladder	NCT02554201	Incomplete Neurogenic bladder	China	Completed
Sheffield Teaching Hosp Northern Gen Hospital	TMS for Upper Limb Dysfunction	NCT02914418	AIS C or D >3 mos post injury	UK	Completed
Spaulding Rehab Hospital	(tDCS)	Ph I NCT01599767	History of pain	US	Completed
Stem Cells, Inc.	HuCNS-SC	Ph I & II NCT01321333	Chronic thoracic >6 wks post injury	Switzerland & Canada	Completed W2W Video Interim Results Nov '15
	Long term follow up of HuCNS-SC Translantation	NCT01725880	T2 - T11 w/conus function	SUI	Terminated
	HuCNS-SC Transplantation	Ph II NCT02163876	C5 - C7 ASI B or C >12 wks post	US	Terminated
Swiss Paraplegic Centre Nottwil	Extracorporeal Shock Wave Therapy (ESWT) for Spasticity	NCT02203994	>2 yrs post injury C3 - T10	SUI	Completed
Swiss Paraplegic Centre	Local Heat Application	NCT03001531	T2-T12 >12 wks post	SUI	Completed
University of British Columbia	Transcranial E-Stim	Ph II NCT01874782	Acute Cervical	Canada	Completed
Univ. of California - Davis	Vaporized Cannabis	Ph II & III NCT01555983	Neuropathic pain	US	Results
University of Zurich	Robot aided arm therapy	NCT02434237	Upper body disability	Switzerland	Completed
	Locomotor Training	NCT01147185	ASI B & C	Spain/SUI	Completed
VA Cleveland	Implanted neuroprosthesis	Ph I & II NCT00890916	Cervical	US	Results

Notes

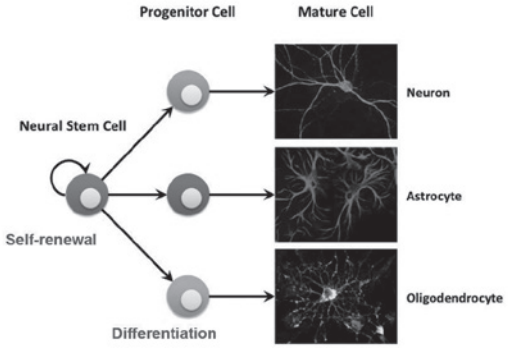
WHAT ARE STEM CELLS?

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

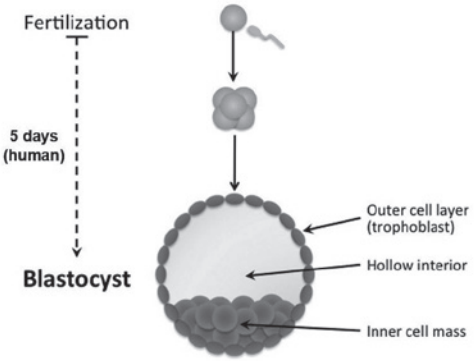
Tissue-specific stem cells, which are sometimes referred to as **"adult"** or **"somatic"** stem cells, are already somewhat specialized and can produce some or all of the mature cell types found within the particular tissue or organ in which they reside. Because of their ability to generate multiple, 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.

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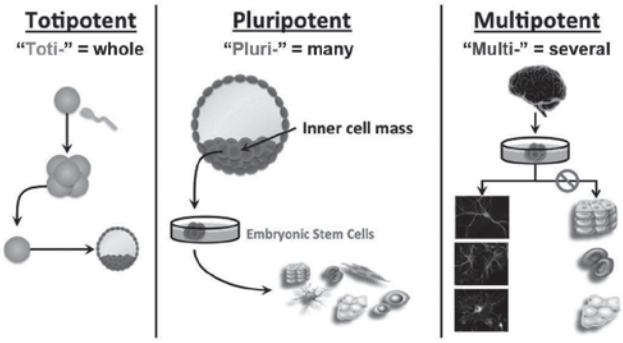
The fertilized egg and the cells that immediately arise in the first few divisions are **"totipotent."** This means that, under the right conditions, they can generate a viable embryo (including support tissues such as the placenta). Within a matter of days, however, these cells transition to become 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).



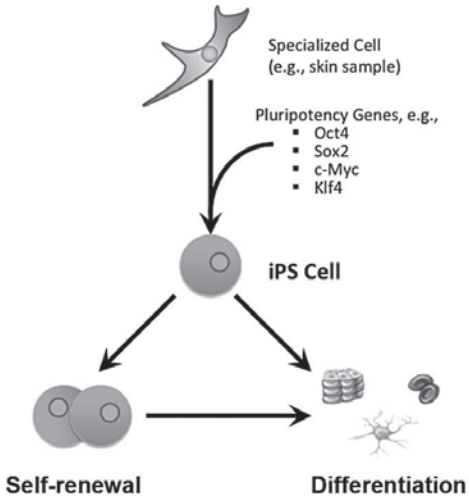
WHY ARE EMBRYONIC STEM CELLS SO VALUABLE?

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.



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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.

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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.

THE MIAMI PROJECT TO CURE PARALYSIS®

The Miami Project to Cure Paralysis is a research Center of Excellence at the University of Miami School of Medicine

We have many clinical research studies for people living with spinal cord injury to participate in, including studies about pain, spasticity, exercise, aging, hand function, diet, sleep disruptions, and male fertility. We also have clinical trials involving cell therapies and devices. Find more details at www.themiamiproject.org or call 305-243-7108.

To be considered for current and future research studies, you will need to complete a short Intake Form. This can be done online at https://is.gd/miamiprojectintakeform or you can call 305-243-7108 and request an Intake Form be mailed to you.

You can also complete an Intake Form to receive periodic research updates.

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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

International Working 2 Walk Symposium

Our annual 2-day event convenes the leading scientists and researchers alongside members of the spinal cord injured community. The conference connects advocacy organizations, foundations, clinicians, biotech's and industry representatives to confer on the state of research and the community's role in expediting it.

Cure Advocacy Network (CAN)

A national network of advocates lobbying for smarter spinal cord injury research funding. Currently there are CAN partners working in Minnesota, Pennsylvania & Washington; with advocates forming new groups in Ohio, Wisconsin & Georgia. Since it's inception 3 years ago our partner advocates have helped achieve $8 million in state legislative funding for research targeted at curative therapies.

Scientific Advisory Board (SAB)

A board of active and respected scientists that assists and advises small to medium sized foundations on the value and merit of a variety of research proposals. U2FP covers the cost for the participating organizations. Since the pilot program started 5 years ago, the U2FP SAB has reviewed grants totaling just over $6M.

Team U2FP

Team U2FP helps connect runners and wheelers who wish to raise money for our work. Our principal race is connected to the Chicago Marathon but we assist runners/wheelers with races across the US.

SCI CureCast

Our podcast attempts to distill the complexities around the research economy. Our Executive Director, Matthew Rodreick and Kate Willette (author of "Don't Call It A Miracle: The Movement To Cure Spinal Cord Injury") conduct interviews with scientists, advocates and others in order to unpack some of the science.

www.u2fp.org

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