A world without paralysis after spinal cord injury

Business Plan for 2013 – 2018

Final Draft: October 2012
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Imagine a not too distant future where....

In 2018, a newly injured individual with a traumatic spinal cord injury (SCI) in Canada will have greater chances of some neurological recovery than today and certainly far greater than when Rick Hansen suffered his SCI in 1973.

They will be triaged at a Rick Hansen Institute (RHI) SCI network site which adheres to national SCI standards of care and they will have access to leading edge SCI research. Their treatment will consist of best practices agreed upon by International experts to ensure they have access to early surgery, guidelines are in place to minimize pain and programs are available to maximize physical function such as reaching, grasping and walking. They will also be encouraged to enrol in International clinical trials that can promote neurological recovery within their lifetime. And throughout the continuum of care they will be an active participant in their treatments and will receive the information in a personal and timely manner to ensure they can actively manage their injury and achieve full participation when they return to the community.

Data on the clinical practice will be collected in the Rick Hansen SCI Registry (RHSCIR) using internationally agreed upon data standards and this data will be aggregated with other Canadian and International sites. This state of the art information technology platform will also collect imaging and biomarkers, paving the way for an era of personalized medicine.

Decision-makers in government and health authorities, meanwhile, will be able to evaluate improvements in patient care, outcomes and cost savings, which can be viewed as a model for other health conditions.

It is within our reach...

Every year, care and treatment for Canadians with traumatic SCI costs our health care system approximately $2.7 billion. As the population ages, the number of injured, and the related care costs, will grow.

Thanks to the support of our federal government, RHI remains focused on galvanizing the world’s best researchers, scientists, surgeons, and rehabilitation practitioners to collaborate on accelerating the translation of the most promising research into practical solutions for individuals with SCI.

With continued government support, the glimpse of the near term future offered above can be achieved and is only a few years away.

This Business Plan for the period 2013-2018 outlines the steps – the broad strategies and specific tactics and projects – required to reach the next milestone in achieving a world without paralysis after SCI.
Over the next few pages, this document will outline how we will:

- Bridge short term activities with its long-term Vision
- Outline specific areas of focus, projects and core activities
- Show how and where we will use Government of Canada resources
- Deliver on specific outcomes, and
- Submit a budget for 2013-2018

**Background**

SCI is one of the greatest survivable catastrophes experienced by a human being. Regardless of cause or age at injury, SCI has a devastating impact on an injured person’s health and well-being, and far reaching consequences for individuals, their families and the health care system.

Required care is highly specialized and complex - including costs for acute, rehabilitative, emergency, primary, mental health, home and long term care and adaptive equipment – resulting in substantial financial costs for governments. In Canada, the cost of care for people with traumatic SCI is now estimated at approximately $2.7 billion a year.

The provision of SCI care across the country is not standardized. As a result, not all newly injured Canadians benefit from any emerging treatment advances as they become available. Therefore, there is a critical need to ensure that standards and best practices are implemented nationally. Availability of standardized care across Canada will not only ensure equitable care for individuals with SCI but also result in efficiencies and cost savings. Furthermore, recovery of the newly injured is complex and often fraught with secondary complications such as pressure ulcers, pain and bladder infections. The prevention and care of these secondary complications through the standardization of care for the newly injured is equally important and necessary when considering a path towards the cure.

Although there is still much that remains to be done for both the newly and chronically injured, we recognize that ultimate success will be limited if care and mechanisms across the country are not standardized to disseminate and apply life-saving and cost-saving new knowledge.

**Before 2007 – A Disconnected Patchwork**

Despite the commitment of well-trained and educated scientists, researchers, surgeons and clinicians, SCI research and care had changed relatively little since World War II.

Hampered by isolation, different standards of clinical care, a lack of clear best practices and an uncoordinated health care system, it was impossible until very recently to track injuries, interventions and outcomes across provincial jurisdictions, to recruit enough subjects for clinical trials and to conduct multi-centre SCI clinical trials.

Prior to 2007, the limited funds available for SCI research in Canada were directed primarily to basic science rather than to the translational research needed to address priority needs for people with SCI. Scientists and researchers worked in pockets, with no integrated national strategy or mechanism to collect and share data, to set priorities and manage funds efficiently; nor to standardized care across the country.
When Health Canada committed to a five-year funding agreement with the Rick Hansen Foundation, in 2007, it demonstrated a progressive and insightful approach to tackle the staggering costs of SCI to our health care system, and to the quality of life of affected Canadian individuals and communities. The funding enabled the Foundation to launch the RHI, its most significant program, to begin to address the needs of Canadians with spinal cord injuries. This commitment also established Canada as a thought-leader in SCI research.

NOTE: Before 2007, GoC (through WD) provided $15M over seven years to begin the first work to bring disconnected SCI stakeholders and consumers together for the first time. The work led to a submission to Health Canada promoting the concept of a national network, which has ultimately become the RHI today.

**Progress to Date**

Despite having faced challenges typically encountered by any new organization, RHI has matured into one that works effectively and efficiently with a strong focus on collaboration, outcomes and accountability.

While the name of the organization has changed over the years, collaboration remains the key to its success, as does its vision: *a world without paralysis after SCI*.

In five short years, progress has been made to improve treatment and ultimately outcomes for people with SCI. RHI’s focus has tightened on maximizing impact in areas of strategic importance to individuals with SCI, continuing the advancement of our Rick Hansen SCI Registry (RHSCIR) and Global Research Platform (GRP), and accelerating progress with new partnerships and greater International collaboration.

In 2007, RHI, after extensive consultation with SCI stakeholders, developed a national strategy for cooperation in research and standardization of care for people with SCI. Since then, it has undertaken 67 projects in translational research and best practice implementation in the treatment and care of people with SCI. It has developed a pan-Canadian registry of SCI patients, and provided support to improving the lives and community participation of individuals across Canada.

To date, and in a modest timeframe, it has achieved progress in its program areas and created infrastructure that is leading to unprecedented collaboration in the field of SCI research and care.

**Barriers to Further Progress**

**The Missing Link: A Global Strategy to Cure SCI**

Although an impressive amount of work has been done and continues to be done to generate scientific and clinical evidence towards the cures for SCI (including the use of stem cells in neuro-regeneration of damaged tissue after SCI), *there is no Global Strategy or roadmap in place guiding these efforts*. To date there is no consensus on what clinical studies should be done or what preclinical (animal) studies need to be undertaken to inform these studies.
Instead institutions are working in silos without a single overall vision. There are frequent published reports of animal and human studies that provide promise to individuals with SCI about restoring function but almost all of these studies are too preliminary for assessment due to the limited size of the studies or the lack of demonstrated repeatability. These potentially risky trials may further jeopardize the health and safety of Canadians living with SCI participating in these trials. Part of the Global Strategy to Cure SCI must include a scientifically rigorous appraisal of all novel therapies developed internationally.

Any strategy towards the cure will require an assessment of existing knowledge, identifying gaps, a definition of the path forward with defined milestones and targets and the resources required to execute the strategy. The development of the Global Strategy to Cure must include consultation with experts in the respective fields and must include involvement from International representatives from various stakeholders such as people with SCI, regulatory agencies, ethicists, industry and policy makers. Finally, the success of the execution of the strategy will require collaboration from all stakeholders. The collaborations will encompass participation in International studies, sharing of research data, knowledge translation (KT) and ensuring that the trial patients all receive standardized care before and after initial treatment to reduce variability in study outcomes.

RHI recognizes that the development of a global cure strategy is an important first step towards meeting its vision. In the past five years, RHI has developed partnerships with international stakeholders, and with the RHI International Clinical Trials Network, is well positioned to facilitate strategy development and execution.

**The Need for Standardized Treatment of SCI in Canada**

At this time, although there are no known regenerative cures for the restoration of neurological function in people with chronic SCI (those currently living with paralysis from previously sustained injury), the newly injured have a greater chance of recovery due to advances in surgical interventions, the timing of these interventions after injury and advances in rehabilitation efforts. However, not all newly injured Canadians benefit from these advances as they are not universally available across the country. This disparity in care is due to a lack of institutional standards for SCI care across the country and limited clinical practice guidelines that are either available or have been implemented for the care of people with SCI across the health care continuum. In addition, there is limited consensus on the outcome measures that are necessary to evaluate the impact of treatment for people with SCI in the clinical setting.

Although there is still much that remains to be done for the newly and chronically injured to reduce paralysis after SCI, RHI recognizes that the success of future interventions and translation research findings around the cures will be limited if care across the country is not standardized with validated outcomes and mechanisms are not present for the dissemination of new knowledge. Therefore, our ability to better understand, measure and standardize the clinical environment will enable us to provide the cure to patients sustaining a SCI and measure the effects in clinical trials (i.e. improving the care for persons with SCI will prepare us for the cure). Treatments to minimize paralysis will need to be provided hours following injury and evaluated in multi-centre clinical trials. This will require a detailed understanding of the current health care system and the changes needed to provide treatments ‘out in the field’ hours following the injury.
Moving Research into Practice

As we strive towards developing a cure for SCI, it is important that the knowledge generated along the way is translated into practice. It was previously assumed that all research findings are incorporated and utilized by the intended users. However, in reality, it takes on average 17 years for new knowledge to be incorporated into practice and even when knowledge is translated, the utilization of the knowledge is inconsistent.¹

As described by the Graham et al ‘knowledge to action model,’ KT is a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the health care system.² KT takes place within a complex system of interactions between researchers and knowledge users that includes knowledge synthesis, dissemination, exchange and application. Knowledge users include other researchers, practitioners, administrators, policy makers and people with SCI. Implicit is the notion that evaluation and monitoring of KT initiatives, processes and activities are key components of the KT process. This overarching framework is critical to moving research into practice and will set the stage for the dissemination of the cure(s) for SCI when they are ready to be implemented. Furthermore, it will enable the impact of research initiatives to be evaluated and the successes and barriers to implementation into practice to be identified.

RHI recognizes that KT and the implementation of this knowledge into practice is as important as the research activities it undertakes to affect change towards the cure of SCI. Hence, RHI constantly strives to incorporate KT into all research activities with the ultimate goal of implementing best practices into the care of people with SCI. With this approach, RHI will shorten the 17 year time frame to achieve translation of knowledge into practice to ensure that all newly injured Canadians with SCI will have access to these cures as soon as they become available.

Economic and Sustainability Considerations for Best Practice Implementation

In Canada, we currently live in a time of limited government resources available for providing essential services to Canadians. Financial constraints in the health care system continue to be a major area of concern for health care providers and patients, particularly for SCI stakeholders where the annual economic burden of traumatic SCI is about $2.7 billion.³ Therefore, although improvements in care for people with SCI may become available through research, uptake of these improvements by the affected stakeholders may be limited if they do not offer cost savings to the health care system. It is therefore critical that economic sustainability be addressed for all research and best practices implementation endeavours at the onset to ensure uptake by stakeholders while providing benefit to people with SCI.

RHI recognizes the importance of economic sustainability of its BPI efforts and that these considerations are necessary during the design phase of all research studies that could lead to best practices. Therefore, RHI has identified economic sustainability as a major criterion for assessment of projects for investment.

**GOING FORWARD**

The objective moving forward is to refine RHI’s strategic research agenda towards a cure for paralysis, and focus on connecting the relevant national and International stakeholders to make this happen. Everything RHI does going forward must be focused on facilitating the efforts toward a cure and the translation of research results to ensure individuals with SCI receive the interventions they require.

RHF and RHI have recently received a commitment from the Canadian government for $35 million towards the continuation of its programs. RHI is submitting a new five-year business plan, details of which are included in this document, to guide activities towards meeting its objectives using these funds. RHI continues to recognize the importance of focusing on generating knowledge about SCI and the importance of translating the knowledge and affecting change in practice to result in better outcomes for people with SCI.

This five-year business plan reflects the commitment of RHI build on its success and move closer to fulfilling RHI’s vision:

*A world without paralysis after SCI.*

*RHI’s mission is to lead collaboration across the global SCI community by providing resources, infrastructure and knowledge; and to identify, develop, validate and accelerate the translation of evidence into best practices.*

RHI recognizes that research must lead to action. For this reason, KT is integrated throughout the lifecycle of RHI research projects. This ensures that each project, from the design phase to best practice implementation, involves engagement of the appropriate stakeholders, and especially the ultimate consumers – people with SCI. This integrated approach towards knowledge development and application maximizes the general relevance of any project, while making sure that it incorporates translation strategies relevant to specific stakeholders.

This model – a national network with common goals, supported by infrastructure, resources and knowledge dissemination – is already making a difference, and will continue to result in better outcomes for individuals with SCI. This innovative model is unique in Canada and internationally for the SCI community. This model could also potentially be used for other health conditions such as traumatic brain injury or stroke.
Roadmap Towards the Cure: A 25-year Plan

In consultation with our stakeholders, RHI has developed 5, 10 and 25 year milestones to achieve its vision.

25 Year Milestones (2038)

By 2038, RHI envisions that all newly injured Canadians with SCI (traumatic and non-traumatic) will have access to novel therapies that will reduce paralysis and restore physical function in specific types of spinal cord injuries. There will be ongoing international collaboration working on a pipeline of other potential therapies being investigated through the RHI International Clinical Trials Network. In addition, all newly injured Canadians with SCI will receive comprehensive personalized treatments for their injury to minimize paralysis.

10 Year Milestones (2023)

By 2023, RHI envisions that there will be international collaboration on five promising neuro-restorative novel therapies [(i.e., neuro-regeneration, neuro-protection or neuro-plasticity) (e.g., stem cells)] in clinical trials utilizing the RHI International Clinical Trials Network that have been approved by the International SCI community. In Canada, 75% of all newly injured persons sustaining a traumatic SCI will be receiving standardized care in SCI Centres that are part of the RHI Network.

5 Year Milestones (2018)

By 2018, RHI envisions that there will be global collaboration among the International SCI Community based on a Global Strategy to Cure SCI. As part of this effort, RHI will be participating in two or more existing or new international clinical studies in neuro-restorative therapies. In Canada, 50% of all newly injured persons sustaining a traumatic SCI will be receiving standardized care in SCI Centres that are part of the RHI Network. RHI anticipates that a reduction of at least 11% in permanent paralysis could be achieved by providing available neuro-protective treatments such as early surgery and Minocycline for specific types of SCI.4

The pathway to achieve RHI’s vision through the aforementioned goals is depicted below.

**GOALS AND DELIVERABLES FOR THE NEXT FIVE YEARS**

**The Opportunity**

RHI is a catalysing, science-based institution with plans to lead collaboration on a global scale to help accelerate research in a wide range of clinical foci – from acute care to re-integration into the community – and encourage the application of new knowledge to improve health for people with SCI.

The SCI cure and care communities in Canada are invigorated, focused on priority areas of research, and engaged in national and International collaborations that are improving health outcomes for individuals with SCI, while reducing health care costs.

After only a few years of pursuing its mission, RHI has arrived at the intersection of unprecedented scientific progress in knowledge and transformative global communications technology. With its multi-faceted, integrated and collaborative strategies, RHI is galvanizing an army of people across this country and around the world to harness and share their collective knowledge and ability to deliver results at an astonishing rate.

RHI believes that rigorous implementation of this strategy to its fullest potential will have a far-reaching impact — not only for Canadians and our health care system, but for people around the world, and will further solidify Canada’s reputation as an inventive, global leader in SCI research and care.

At this time of unprecedented scientific progress and transformative global communications technology, a world without paralysis after SCI is possible.
RHI has identified the following four goals to be achieved by 2018:

1. Improved and standardized delivery of care across Canada and internationally
2. SCI research accelerated through greater access to data, increased researcher capacity, informatics support and leveraged funds
3. Lower re-hospitalization rates
4. Greater number of innovations brought to market

These goals will contribute towards achievement of the longer-term objectives in our mission: reduced incidence and severity of paralysis, improved health care outcomes, reduced long-term costs, and improved quality of life for those living with SCI. Ultimately, our work aims towards achievement of our Vision.

In order to meet these goals, RHI has identified the following five broad strategies to deliver on the WD funds for the years 2013-2018:

1. Support and undertake Translational Research Studies,
2. Support and undertake Best Practice Implementation Projects,
3. Engage in further Network Development in Canada and abroad,
4. Develop and accelerate the use of Informatics related to TR and BPI—based on the Global Research Platform (GRP) and
5. Support the next generations of SCI specialists, aka the Best and Brightest.
Resource Requirements 2013 to 2018

The funds received from the Government of Canada are expected to be $35 million and will cover the fiscal years 2013-2018. Based on recent stakeholder engagement exercises as well as the results from the recently concluded Summative Evaluation, RHI has identified the aforementioned objectives for completion by 2018 using these funds. The estimated cost of each strategy over the funding period are presented below.

### RHI

**Summary of Projected Revenue and Expenses**

**2013/14 to 2017/18**

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<td>725,000</td>
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<td>3,625,000</td>
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In addition to continuing the support of key existing national TR and BPI projects, RHI intends to fund new TR and BPI initiatives that address its objectives and priorities during the 2013-2018 period. Many of these projects require start up activities with relative low costs and whose durations are unpredictable. These activities include seeking and obtaining approval from institutional ethics boards and regulatory agencies (e.g. FDA and Health Canada), patient recruitment and sourcing of pharmaceutical products for clinical studies. The low cost of project set up and potential delays in such activities at the beginning of projects requires flexibility in the disbursement of funds. RHI therefore requests that it receive the funds according to the scheduled proposed and that it be permitted to retain unused funds from year to year to cover the increased cost expected to be incurred once the new projects are underway.
As RHI moves towards achieving its goals, it has identified the following five functional strategies it will pursue in order to support these activities:

1. Support and undertake **Translational Research Studies**
2. Support and undertake **Best Practice Implementation Projects**
3. Develop and accelerate the use of **Informatics related to TR and BPI**—based on the RHI Global Research Platform (GRP)
4. Engage in further **Network Development** in Canada and abroad
5. Support the **Best and the Brightest** individuals in SCI related research.

This section describes the five strategies and the necessary infrastructure that will be developed to support the strategies.

**Strategy 1: Support and Undertake Translational Research (TR) Studies**

RHI supports and undertakes translational research (TR) studies to generate knowledge about SCI and to seek ways to improve outcomes for people with the injury. These research projects are therefore critical to the Core Business and ultimate outcomes of RHI. **Translational research** is a branch of medical research that attempts to more directly connect research with patient care by turning basic discoveries (developed, for instance, through multi-centre research studies) into new treatments and approaches that tackle the most pressing needs of individuals with SCI.

The following activities either directly align with or support RHI’s vision: A world without paralysis after SCI.

RHI will undertake the following Translational Research activities:

1. Develop a Global Strategy to Cure Paralysis after SCI.
2. Participate in two or more new or existing neuro-restorative therapies (i.e., neuro-regeneration, neuro-protection or neuro-plasticity) (e.g., stem cells).
3. Continue existing clinical studies.
4. Support at least two pre-clinical studies towards identification of readiness for clinical trials.
5. Establish an International Biobank for SCI.
6. Develop and/or validate outcome measures for clinical studies and treatment.
7. Continue observational studies utilizing the Rick Hansen SCI Registry (RHSCIR) data and continue supporting the RHSCIR sites across Canada.
8. Support emerging innovative technologies and interventions for SCI.
9. Implement health economic evaluation for all translational research projects.

The details for each of these activities and the relevance to the vision are described herein.
1. Develop a Global Strategy to Cure Paralysis after SCI

Relevance to RHI’s Vision: The Global Strategy to Cure Paralysis after SCI will guide all future International translational research activities related to curing SCI.

Deliverable: A Global Strategy to Cure Paralysis after SCI

A cure for paralysis after SCI will involve an assessment of numerous therapies and technologies. Stem cells offer the most promising option for neuro-restoration and will be the centre piece of any cure strategy. Stem cells are undifferentiated cells that have the ability to differentiate into specialized cells and form tissue depending on the site of implantation. Treatment involves the administration of transplanted stem cells at diseased or injury sites where tissue damage may have occurred. In SCI, it is envisioned that stem cells may help injured spinal cord tissue regenerate after treatment and restore neurological function (see Appendix 5 for more information on the use of stem cells in the treatment of SCI).

There are frequent published reports of animal and human studies that provide promise to people with SCI about restoring function (e.g. stem cells) but almost all of these studies are too preliminary for assessment due to the limited size of the studies or the lack of demonstrated repeatability. These potentially risky trials may further jeopardize the health and safety of Canadians living with SCI participating in these trials. Part of the Global Strategy to Cure Paralysis after SCI must include a scientifically rigorous appraisal of all novel therapies developed internationally.

Any strategy towards the cure will require an assessment of existing knowledge, identifying gaps, a definition of the path forward with defined milestones and targets and the resources required to execute the strategy. The Global Strategy will consist of methods to assess the readiness of emerging therapies for use in human clinical trials. An assessment of ongoing clinical trials and ways to address regulatory and funding hurdles will be included. The development of the strategy must include consultation with experts in the respective fields and must include involvement from International representatives from various stakeholders such as people with SCI, regulatory agencies, ethicists, industry and policy makers. Finally, the success of the execution of the strategy will require collaboration from all stakeholders. The collaborations will encompass participation in International studies, sharing of research data, KT and ensuring that the trial patients all receive standardized care before and after initial treatment to reduce variability in study outcomes.

2. Participate in two or more new or existing neuro-restorative therapies

Relevance to RHI’s Vision: These studies will investigate the safety and efficacy of cure related therapies.

Deliverable: Participation in two or more International neuro-restorative clinical trials.

Based on the aforementioned Global Strategy to Cure Paralysis after SCI, RHI intends to participate in two or more multinational multi-centre human clinical studies in neuro-restorative therapies.
These therapies will include neuro-regeneration (interventions to replace lost neural tissue or induce growth of neural elements), neuro-protection (early interventions that will maximize neurological impairment by minimizing secondary injury) and neuroplasticity (activity-based interventions that maximize functional recovery).

Research in this area will include neuro-regeneration, neuro-plasticity and additional neuro-protection studies. RHI’s role in these studies may include co-funding, sponsoring (where RHI is the responsible partner) or by providing support through project management, data capture (using the RHI-GRP) and data management services. RHI may also consider participating in existing International safety, proof of concept or pivotal trials.

RHI recognizes that there are significant ethical and legal issues surrounding the use of stem cell therapy. Therefore, RHI will only participate in stem cell studies within the context of ethical and legal confines.

Wherever possible, RHI will seek funding partners for these studies and may leverage additional funding to support these trials. Because of the regulatory and recruitment challenges associated with these types of SCI clinical trials, RHI does not expect to complete any of the new clinical trials by 2018.

3. Complete two existing clinical studies

*Relevance to RHI’s Vision:* Results from these studies will inform the Global Strategy to Cure Paralysis after SCI.

*Deliverable:* Completion of two existing neuro-protection clinical studies.

RHI is currently supporting two neuro-protection studies, The Canadian Multi-Centre CSF Pressure Monitoring and Biomarker Study (CAMPER) and Minocycline (See Appendix 6 for details). The CAMPER study will provide important insight in the management of blood and intrathecal pressures in acute human SCI, and validate the use of cerebrospinal fluid (CSF) biomarkers to predict long term outcomes of SCI.

The Minocycline study will determine whether Minocycline (a generic antibiotic) is efficacious in the neuro-protection of the spinal cord after injury. These multi-centre studies are currently underway in Canada but RHI intends to expand them internationally and expects to complete them by 2018.

4. Support at least two pre-clinical studies towards identification of readiness for clinical trials

*Relevance to RHI’s Vision:* These studies will inform the Global Strategy to Cure Paralysis after SCI.

*Deliverable:* Support at least two pre-clinical studies towards identification of readiness for clinical trials.
The translation of studies from animal to humans needs to happen in both directions. Although pre-clinical animal studies are often forward translated to inform human clinical study designs, back translation from human to animal studies is often required to address questions raised in human studies. RHI will therefore provide support for at least 2 pre-clinical animal studies related to promising neuro-restorative therapies or in understanding the molecular basis of SCI. The latter will determine the feasibility of using intracellular genetics (genomic) or protein (proteomic) markers in predicting long-term outcomes of SCI and identifying targets for intervention in the treatment of SCI. (See description of genomics and proteomics in Appendix 5 below)

5. Establish an International Biobank for SCI

**Relevance to RHI’s Vision:** The Biobank will support the clinical studies towards personalization of the cure.

**Deliverable:** Establishment of an International Biobank for SCI.

Biobanks are centralized collections of human biological samples that often contain linked information about health, lifestyle, environmental factors, and family disease histories. Types of biological samples warehoused in a Biobank include blood, urine, biopsy samples, bone marrow, semen and cerebrospinal fluid (CSF). These samples may be used for in-vitro studies, transplantation, clinical care, health research, and a number of other uses, some of which have yet to be conceived.  

RHI intends to develop a Biobank of CSF from subjects in acute care studies such as the CAMPER and minocycline studies. The CSF samples from the SCI patients may potentially be used for proteomic and/or genomic studies, or for future in-vitro assessment of promising pharmaceuticals for the treatment of SCI. An increasingly common practice in SCI research is to include biomarker analysis in order to obtain a better understanding of the biochemistry of injury and treatment. The development of a Biobank will enable SCI researchers worldwide to be innovative in their approach to this area.

The establishment of a Biobank will require the creation of governance, infrastructure and privacy requirements and will be done through partnerships with well-established Canadian organizations in this area, such as the BC BioLibrary, the Canadian Tumour Repository Network (CTRNet), and those embarking on similar endeavours, such as the Canadian Partnership Against Cancer (CPAC).

6. Develop and/or validate five outcome measures for clinical studies and treatment

**Relevance to RHI’s Vision:** The development and/or validation of outcome measures are required to measure the efficacy of cure related studies and will be incorporated into the accreditation of SCI Centres in Canada.

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6 See http://www.bcbiolibrary.icapture.ubc.ca/.
7 See http://www.partnershipagainstcancer.ca/priorities/research/strategic-initiatives/canadian-partnership-for-tomorrow-project/.
Deliverable: Development and/or validation of five outcome measures for clinical studies and treatment.

Outcome measures are a means to establish the baseline impact of a disease on an individual and the changes experienced over time. In particular, they allow the effectiveness of an intervention to be tested. There are currently more than 150 outcome measures that have been developed for use in individuals with SCI. These include assessment of the severity of neurological impairment following injury, physical body structure, physiological function, mobility, self-care, societal participation and quality-of-life. Despite the plethora of outcome measures, there is a general agreement within the SCI community that there is a need to validate as many of these measures for use in SCI clinical trials. (see Appendix 5 for additional details).

RHI will plan to support studies examining the psychometric properties of five outcome measures.

7. Continue observational studies utilizing the Rick Hansen SCI Registry (RHSCIR) data and continue supporting the RHSCIR sites across Canada.

Relevance to RHI’s Vision: The ongoing analysis of RHSCIR data will inform the Global Strategy to Cure Paralysis after SCI. The support for the RHSCIR sites will support the implementation of clinical trials and the implementation of accreditation standards.

Deliverable: Completion of 10 national studies utilizing RHSCIR data to include SCI epidemiology, modeling of health services, and health economics

The RHSCIR is the only Canadian prospective, observational, longitudinal study which follows people with traumatic SCI from the time of injury over their lifetime. It involves identifying eligible participants, obtaining consent, study enrolment, and data collection about the patient’s injury to follow-up data collection at one, two, five and then every five years thereafter from the date of their injury until the participant dies or withdraws from the RHSCIR study. In order to obtain a comprehensive picture of SCI in Canada, a minimal data set of all eligible patients is also collected as part of the study. There are currently 3,000 patients enrolled in RHSCIR increasing with an approximate rate of 45 patients per month. The overall objectives for creating the national RHSCIR study were to create a data repository to inform the Global Strategy to Cure Paralysis after SCI and support the effort to accredit SCI Centres.

It is our belief that the cure will come about in a non-linear fashion. All spinal cord injuries are not the same and we believe that a personalized approach to identifying those subgroups of injury patterns that are most amenable to dramatic outcome improvements will lead to a “cure”. RHI will encourage research that enhances our understanding of the injury and repair process in specific subgroups of injuries collected in the RHSCIR, particularly incomplete, central cord, high cervical, conus/cauda equina injuries. RHI will promote collaboration across disciplines and make patient data available so researchers can access (and link) clinical data to other innovative approaches that may lead to the cure. RHSCIR data will also continue to support studies such as the Access to Care and Timing (ACT, see Appendix 6) to model the pre-hospital phase of care, since this will inform the provision of cure related therapies that will need to be applied within hours following injury.
Given the importance of RHSCIR data and having a SCI network in Canada, RHI will continue to support the RHSCIR sites.

8. Support emerging innovative technologies and interventions for SCI

Relevance to RHI’s Vision: New emerging innovations may support the translational research pipeline and will be consistent with the Global Strategy to Cure Paralysis after SCI.

Deliverable: Not applicable as support of emerging innovations may occur in various forms depending on status of development and is therefore difficult to predict (e.g. product at proof-of-concept stage may require financial support only and products in clinical research may require extensive project or data management support).

In health care, there is a constant stream of novel technologies and interventions that are being developed which may have applicability to the treatment and care of people with SCI. RHI will support the development of select emerging innovations which are consistent with RHI’s 5 year goals. This support will also apply to innovations that have been proven effective in other indications and have sufficient rationale for testing in SCI.

9. Implement health economic evaluation for all translational research projects

Relevance to RHI’s Vision: Economic evaluations of SCI and cure related therapies provide critical information for funders, policy makers and decision makers for the justification of RHI’s activities.

Deliverable: Not applicable as this activity provides ongoing support.

Information on the lifetime economic burden following SCI is limited, especially in Canada. Much of the existing data on the economic burden of SCI is from the US, which limits comparison given the dramatic differences between the Canadian and US healthcare systems. RHI has recently completed the first study that attempts to model the current lifetime economic burden associated with traumatic SCI in Canada. All SCI studies should include a health economics evaluation to facilitate cost-effectiveness studies, which can inform future health care decision making. This research will inform healthcare decision-making with an aim to improving care at lowered costs.

Strategy 2: Support and Undertake Best Practice Implementation Projects

The success of cure strategies will be dependent on changes in practice within the existing the health care delivery system. The time to implement best practices is currently 17 years and this needs to be dramatically shortened to ensure Canadians with SCI will benefit in their lifetime.

RHI intends to become the world leader in promoting and implementing best practices for the care of people with SCI. With RHI’s network, we are uniquely positioned to influence behaviour change, and ultimately lead SCI research into action. The overall aim of RHI’s Best Practice Implementation projects is to lead the process of improving access to and adoption of knowledge, in order to help support evidence-based decision-making in SCI care in Canada and internationally.
The following activities either directly align with or support RHI’s vision: A world without paralysis after SCI.

RHI will undertake the following Best Practice Implementation activities.

1. Continue existing BPI efforts to identify needs of people with SCI, services available and validation of research evidence.
2. Expand the Knowledge Mobilization Network (KMN).
3. Develop three new clinical practice guidelines.
4. Seek accreditation of SCI centres that are a part of the RHI Network.
5. Develop a national program for SCI patient self-management.
6. Facilitate investment into commercialization of innovative therapeutics, medical devices and diagnostics with applications to SCI.

The details for each of these activities and the relevance to the vision are described herein.

1. **Continue existing BPI efforts to validate research evidence**

   **Relevance to RHI’s Vision:** These previously funded RHI projects will provide the necessary evidence to further develop and support the accreditation of SCI Centres across Canada.

   **Deliverable:** Complete periodic updates of the research evidence resources as required.

   Since 2007, RHI has supported a number of BPI projects that have centred around the rehabilitation services currently available to people with SCI [SCI Rehabilitation (E-Scan) Atlas Project] and synthesized research evidence for clinicians [SCI Rehabilitation Evidence (SCIRE) Project] (see Appendix 6 for the RHI Project Overview) for details of these projects). These projects will continue to receive support during the 2013-2018 period as they inform current and future BPI efforts.

2. **Expansion of the Knowledge Mobilization Network (KMN)**

   **Relevance to RHI’s Vision:** The KMN will provide the necessary infrastructure required to implement best practices and support accreditation in Canada.

   **Deliverable:** Expansion of the Knowledge Mobilization Network to include acute centres.

   RHI recognizes the importance of developing an infrastructure of leaders in knowledge translation for the effective dissemination and promotion of the uptake of knowledge and best practice guidelines. RHI has therefore initiated a pilot KMN comprised of six sites in Alberta, Ontario and Quebec. The network consists of leaders working collectively to implement guidelines in real-world practice. The scope of the KMN is to:
   
   - Identify specific topics in the areas of acute, rehabilitation and secondary complications
   - Identify the corresponding clinical practice change desired
- Identify which performance indicators to collect and assess (e.g. implementation process measures, clinical outcome measures at patient level, systems level changes such as improved access to care, reduced length of stay, decreased economic burden of care and so on)
- Contribute to the body of knowledge on implementation science

Therefore, this project addresses multiple objectives from knowledge synthesis and infrastructure building to BPI.

During the period 2013-2018, RHI will undertake the following activities related to the KMN:
- Expand the KMN nationally to include British Columbia and the Atlantic provinces and implement the pressure ulcer guidelines previously developed for the pilot KMN project in Ontario, Quebec and Alberta.
- Implement at least five best practices relevant to implementation of the cure related therapies.

3. Develop three new clinical practice guidelines

  Relevance to RHI’s Vision: These clinical practice guidelines will provide the necessary evidence to further develop and support the accreditation of SCI Centres across Canada.

  Deliverable: Completion of three new clinical practice guidelines

During the 2013-2018 period, RHI will develop 3 clinical practice guidelines (CPG) for implementation through the KMN. These guidelines will be developed from existing guidelines developed internationally (e.g. by the Paralysed Veterans of America) and/or developed using Delphi surveys of subject matter experts or using existing RHI-funded resources such as SCIRE. These new CPG will address areas such as pain, bladder management or autonomic dysreflexia.

4. Accreditation of SCI Centres

  Relevance to RHI Vision: Accreditation of SCI Centres in Canada will ensure Canadians receive standardized care which will maximize neurological function and facilitate the implementation of clinical trials.

  Deliverable: Accreditation of 50% of SCI centres that are a part of the RHI Network.

Accreditation of health care facilities by a recognized body is a common approach to validate the implementation of best practices. This is due to the fact that accreditation is associated with validated and recognized best practices and accreditation provides credibility to institutions. In addition, in many countries, accreditation is required to obtain governmental funding and for licensing purposes.

Accreditation Canada (AC), a recognized and highly respected accreditation organization, in partnership with RHI, has developed Canada’s first accreditation standards for SCI institutions.
Through this partnership RHI will accomplish the following:

- Wide and broad distribution of evidence based care standards for SCI through AC standards.
- An accountability requirement for SCI institutions to demonstrate the compliance to AC standards to impact care.
- Process to update and revise standards as new discoveries and knowledge become available.
- Opportunities to expand AC standards for SCI care to International SCI sites.

The development of the standards and a pilot implementation study involving 5 sites in Canada have recently been completed. By 2018, RHI intends to ensure that at least 50% of all SCI centres in Canada that are a part of the RHI Network have achieved accreditation. This corresponds to over 50% of all Canadians who sustain a traumatic SCI receiving standardized care. RHI will achieve this target through a strategic publicity and KT campaign and by providing resources and incentives to sites to achieve and to continue to maintain compliance to the accreditation standards.

5. **Develop a national program for SCI patient self-management.**

*Relevance to RHI Vision: This program will complement cure related therapies, maximize quality of life for those living with SCI and concomitantly reduce health care costs.*

*Deliverable: A national pilot program for SCI patient self-management.*

It is reasonable to expect that cures will encompass a spectrum from partial to complete full physical function. Those who regain partial function will still require lifelong care, albeit to a lesser degree than someone who experiences no recovery. These individuals who are partially cured will benefit from a self-management program to limit secondary complications (including urinary tract infections, pressure ulcers, and autonomic dysreflexia). These secondary complications result in repeated emergency visits and re-hospitalization for people with SCI and the associated cost and demands on the patients and the healthcare system in general.

It is believed that these secondary complications can be prevented, monitored or even managed in some cases by the patients themselves, through a self-management program. The key elements of such a program are education, delivery of the program and adequate resources for implementation and follow-up.

During the period 2013-2018, RHI intends to develop a strategy and implement a pilot SCI patient self-management program. This program will be developed and implemented in partnership with all stakeholders including clinicians, people with SCI and consumer organizations. The successful implementation of this program will result in not only lower re-hospitalization rates, but an increase in the quality of life of people with SCI as they will be empowered to self-manage other issues such as physical activity, diet and sexual health.
6. Facilitate investment into commercialization of innovative therapeutics, medical devices and diagnostics with applications to cure-related therapies SCI.

**Relevance to RHI Vision:** This program will support the development of cure-related therapies for testing in clinical trials.

**Deliverable:** Sponsor annual Investor Forums.

Best Practices Implementation (BPI) includes the commercialization of new and innovative therapeutics, medical devices and diagnostics into the delivery of healthcare. Due to the regulatory requirements of being able to market a new therapeutic, medical device or diagnostic, the product development pathway is lengthy and expensive. Many of these innovations are under development by small and medium enterprises (SMEs). SMEs typically must obtain funding from investors such as Angel Investors or Venture Capital, in order to be able to progress their innovation through the product development pathway. These investors will typically only invest in SMEs in which there is potential for a strong return on their investment. Obtaining this sort of funding, especially in a difficult economic climate, is extremely challenging and investors in the life sciences, biotechnology and healthcare industries have become increasingly conservative due to poor investment returns in recent years. This challenge is even more difficult for SMEs developing an innovation that has application to SCI as it lacks many of the hallmarks of an attractive investment opportunity, such as a large market size, and is often viewed as being too ‘niche’ a market to receive much attention from investors.

Therefore, SMEs developing SCI-related innovations need to demonstrate that their product or service does, in fact, represent a viable investment opportunity. The SME must be able to demonstrate that the innovation provides a solution to a real problem faced by those with SCI and that the innovation can be effectively implemented into the delivery of healthcare of those with SCI.

RHI and its network of researchers and clinicians with expertise in SCI possess resources that can be leveraged to help these SMEs become a more attractive investment opportunity, thus facilitating the needed investment required to further advance the development of the innovation. In the 2013-2018 period, RHI will continue to develop and implement mechanisms that will facilitate greater investment into these companies in order to result in an increased number of new therapeutics, medical devices and diagnostics that will benefit those with SCI. These mechanisms include hosting SCI-focused investor forums in which selected SMEs will present their company and innovation(s) to potential investors and utilizing resources within RHI and its network to help validate the innovation’s utility with respect to SCI treatment and care. RHI will also consider providing funding to SMEs for well-defined projects that have promise for commercialization.
Strategy 3: Develop and Accelerate Informatics Activities

Access to a robust source of data on individuals with SCI is required to maximize the benefits of both research studies and best practice projects. This sort of patient-specific information creates the foundation for high-powered clinical trials, and the potential for validating best practices as they are implemented with different subtypes of injuries to the spinal cord. Such a data set becomes increasingly useful as more individual patients are included, and their progress monitored over time as they pass through the health care continuum from acute to community-based care. Towards this end, RHI has developed a powerful web-based Informatics resource (the RHI Global Research Platform) that currently enables the electronic capture and warehousing of patient study data using an easy-to-use web platform.

The web platform permits extensive connectivity between multiple sites and therefore enables multi-site, multi-national clinical studies.

In addition to the collection and managing of SCI data, the informatics resource at RHI also develops information technological solutions for researchers and clinicians that facilitate research and BPI activities. These solutions include collaboration enabling and decision making tools based on ease of use and validated evidence.

Key support for Translational Research and BPI operations involves the ability to collect and synthesize pertinent data, particularly patient information. Informatics provides the tools and the services to RHI and RHI partners/customers to collect accurate patient health data, analyze that data, support the subject selection and analytic components of research projects, and ultimately maximize program adoption and patient outcomes.

The following activities either directly align with or support RHI’s vision: A world without paralysis after SCI.

RHI will undertake the following Informatics activities.

1. Expansion of the Global Research Platform (GRP) to support collection and analysis of proteomics, genomics and imaging data.

2. Develop clinical support tools to improve data quality for clinical trials and to facilitate the standardization of care.

3. Data warehousing, reporting, statistical support and data management.

The details for each of these activities and the relevance to the vision are described herein.

1. Expansion of the Global Research Platform (GRP) to support collection and analysis of proteomics, genomics and imaging data.

   Relevance to RHI Vision: The expansion of GRP to collect molecular and imaging data will enable the development of new classifications and outcome measures that will assist in the prediction and evaluation of cure related therapies.

   Deliverable: The Global Research Platform (GRP) is collecting proteomics, genomics and imaging data.
The Informatics group at RHI is responsible for developing and implementing all software and hardware solutions required to support RHI programs. The dominant expression of this effort currently is the RHI Global Research Platform (GRP), an SCI specific electronic data capture and warehousing system. The longstanding RHSCIR program and the collaborative networks of RHI now depend on the GRP as the technological infrastructure for managing data and SCI-related studies.

The RHI GRP currently enables the collection of standardized and high quality SCI data that includes demographic and clinical data. Although the data collected provide important information regarding the injury, it currently lacks critical non-clinical information to not only better understand the nature of the injury but also permit the evaluation of additional outcome measures for assessing recovery.

Examples of informative non-clinical data include molecular (proteins and DNA) data that predict outcomes after SCI and imaging data that provide a more detailed visualization of the injury (see Appendix B for details). Availability of such individualized information about a patient will enable a personalized approach to the treatment and care, thus increasing the probability of improved outcomes. Such an approach to “personalized medicine” is considered to be an innovative approach to ensuring patient specific and thus optimal care in treatment of many diseases and adoption and analysis of some of the aforementioned data will benefit people with SCI.

During the 2013-2018 period, RHI intends to adapt the GRP to interface and capture data from external systems containing patient imaging, proteomics/genomics, and electrophysiology data. Collection of this data will enhance the value of RHSCIR to researchers as they will have access to more comprehensive data related to the patients’ injuries.

2. Develop clinical support tools

Relevance to RHI Vision: The development of clinical support tools will improve data quality for clinical trials and will facilitate the standardization of care.

Deliverable: The release of the International Standards for the Neurological Classification of SCI (ISNCSCI) algorithm to the International SCI Community

A number of other software solutions are under consideration by RHI that are complementary to the RHI GRP. For example, RHI is currently collaborating with American Spinal Injury Association (ASIA), and the International Spinal Cord Society (ISCoS) to develop a calculator for the International Standards for the Neurological Classification of SCI. The calculator will be compatible with a tablet or other mobile device that a clinician can use to capture and calculate neurological impairment using the standards with fewer errors than seen in manual calculation. This tool will be coupled with the GRP to allow for neurological assessment data capture for participating facilities and patients. During the 2013-2018 period, RHI will explore other needs from researchers and develop appropriate applications that support other evidence-informed practices.

3. Data warehousing, reporting, statistical support and data management

Relevance to RHI Vision: Data warehousing, reporting, statistical support and data management will be critical to support the Global Strategy to Cure Paralysis after SCI and cure related therapies.

Deliverable: Not applicable as this activity provides ongoing support.
The RHSCIR study activities and the support of clinical trials require the collection, warehousing, analysis and reporting of large sets of data that are collected as part of the studies.

The RHI GRP provides a robust technical solution for these needs. The data collection capability of the GRP, which is optimized for flexibility, allows the addition of multiple studies with different datasets from multiple sites and multi-lingual features.

The data warehouse capability of GRP, currently under development, will provide a facility for linkage between different data sources, the ability to analyze and report on data, and easily produce data extractions for research use.

All data extractions will be de-identified at the secure hosting facility before any research use. The use of this data will provide capabilities to enhance the understanding of and planning for individuals with SCI.

During the 2013-2018 period, RHI will continue a number of mission-critical services that support network activities. These comprise of the following:

- **Data Management**, including data collection form development, data linkage, data quality assurance, data transformation, data importing, managing requests for data access, and the creation of study metadata (e.g., data dictionaries) that support the TR and BPI needs of RHI project teams and RHI partners/customers.

- **Data Analysis**, such as statistics and reporting to TR and BPI needs, provided to RHI project teams and to RHI partners/customers.

- **Program/Project Consulting**, to support partners/customers in implementing their own research programs or projects. Informatics services available to partners/customers include: project management; study/registry design; privacy protection solutions and information technology (IT) support.

- **Other Support Services**, such as ongoing IT support to internal and external customers using RHI technical solutions in their registries, research studies, etc.

RHI’s informatics support will enable Canadian SCI researchers and clinicians to access the RHSCIR and other study data (through RHI Data Use and Disclosure policy and procedures) for analysis and reporting. These capabilities will also enable the linking of RHSCIR data with other International datasets, thus providing a means of International collaborations on SCI related studies.

**Strategy 4: Engage in Further Network Development**

RHI recognizes that the engagement of key stakeholders across areas of practice and geography is important to achieve its mission. Therefore, RHI will continue the development of networks of SCI stakeholders to facilitate research collaborations and best practice implementation nationally and internationally. RHI recognizes that it needs to forge strategic partnerships with various entities, nationally and internationally, for the purposes of funding and otherwise facilitating TR and BPI activities as part of enhancing the network. These entities include governments, granting bodies, corporations, research and health care organizations, and accreditation agencies.
From its inception, RHI has recognized the importance of collaboration to advance the cause of SCI research, and the implementation of best practices in SCI care. RHI has since succeeded in creating a highly collaborative and productive national network of SCI stakeholders.

Although the network was originally built through the expansion of the RHSCIR study, it now enables researchers to work collaboratively on numerous research projects including multi-site clinical trials. The use of the web-based RHI GRP facilitates interactions within the network by centralizing the data collection and warehouse capabilities.

During the 2013-2018 period, RHI will continue to support the national network and expand it internationally to create a truly global network of SCI researchers for collaboration in research endeavours, including multi-site clinical trials.

**The Rick Hansen International Clinical Trials Network**

The Rick Hansen SCI Registry (RHSCIR) study was established in Vancouver in 2004 and since has expanded to 31 facilities across Canada, effectively creating a clinical research network. This collaboration – largely due to the need to increase the number of participants available for clinical trials, and to enable interactions between researchers world-wide is now expanding internationally. This network will foster collaboration in the following manner:

- Utilize the RHI Global Research Platform as the primary clinical data collection tool.
- Collect standardized International SCI Data Sets, which aim to standardize the collection, sharing and reporting of clinically-relevant information.
- Recruit participants into clinical trials that would result in a substantial increase in the number of multi-centre and single site clinical trials being conducted world-wide.
- Identify and select the most promising therapeutic interventions with the best chance of advancing to clinical trial, irrespective of country of origin.
- Advance the adoption of best clinical practices at the international sites through appropriate accreditation processes.

RHI is already in discussions with SCI research and clinical institutions around the world to collaborate on international research activities. The countries that RHI has engaged include Australia, China, the United States, countries in the European Union and Israel.

**Benefits of the RHI Global International Clinical Trials Network to Canada**

Expanding the existing Canadian SCI research network globally will offer the following benefits to Canadian SCI stakeholders:

- The international network will provide access to a large population of people with SCI enabling the recruitment of more participants into an increased number of clinical trials
- The network of international scientists and clinicians will be able to collaborate with Canadian researchers to determine and validate the most promising discoveries in the world which should must then be assessed in clinical trials
• The international network of scientists and clinicians will be able to include participants from diverse populations, cultures, and socioeconomic groups

• The international network will enable the dissemination and adoption of standardized best practices in treatment and care of people with SCI, throughout all countries. Canadians with SCI will therefore benefit from best practices from other countries. Conversely, Canadian best practices may be adopted internationally, thus promoting the reputation of Canada as a global leader in SCI care

• The international network will enable financial support from multiple jurisdictions to be focused on the most pressing challenges and opportunities in the field of SCI

• Due to the increased interaction with international partners, Canadian researchers and people with SCI will be able to participate in high profile international SCI trials.

The following activities either directly align with or support RHI’s vision: A world without paralysis after SCI. RHI will undertake the following Network Development activities.

1. Participate in 1 or more International prospective SCI data studies involving 4 or more countries
2. Organize and sponsor network conferences and meetings.
3. Set up SCI knowledge management system.
4. Develop a central patient recruitment model for clinical studies.
5. Develop and nurture strategic relationships with national stakeholder organizations.
6. Seek co-funding and leverage funding opportunities for RHI projects nationally and internationally.

The details for each of these activities and the relevance to the vision are described herein.

1. Participate in 1 or more International prospective SCI data studies involving 4 or more countries

Relevance to RHI Vision: International SCI Dataset studies will enable sites to connect and share standardized data and cure related clinical trial data as part of the RHI International Clinical Trials Network.

Deliverable: Participation in 1 or more International prospective SCI data studies with data from a minimum of 4 countries.

RHI recognizes the value in collecting standardized and prospective health data about people with SCI. Towards this end, RHI is currently collaborating with the US National Institute of Health, International Spinal Cord Society and other International SCI institutions in identifying a standardized dataset that could be used to collect International data sets using the RHI-GRP. This collaborative effort will facilitate the collection and analysis of standardized, comprehensive health care datasets about people with SCI across the globe. In addition, the collection of standardized datasets on a single platform (GRP) will facilitate collaboration on International clinical trials. During the 2013-2018 period, RHI will participate in 1 or more International prospective data studies.
2. Organize and sponsor network conferences and meetings

Relevance to RHI Vision: Bringing international experts together will help to develop a Global Strategy to Cure Paralysis after SCI and regular meetings will facilitate the sharing of data, ideas and develop collaborations.

Deliverable: Host annual RHSCIR site coordinator meetings and one International SCI meeting.

RHI recognizes the importance of face-to-face meetings and conferences to enable KT and collaborations. Since 2010, RHI has been hosting annual RHSCIR site coordinator meetings and in May 2012, RHI and RHF co-hosted a successful International meeting in Vancouver, interdependence 2012 (i2012) that brought together over 500 members of the Canadian RHI clinical research network, International partners, representatives from regulatory agencies, companies focussed on SCI products, investors, and people with SCI.

Progress in research, KT and best practice implementation projects, (many of which were funded by RHI) was shared. Feedback from the participants meeting expressed that value of such meetings in fostering collaborations and uniting the global SCI research and care agenda. Participants have expressed interest that RHI should continue to host them on a periodic basis.

During the 2013-2018 period, RHI will continue to host the annual RHSCIR site coordinators in conjunction with an annual meeting of the RHI Canadian Clinical Research Network across the country; host a i2012-like event; and sponsor other smaller but focused meetings internationally that bring together key SCI key stakeholders for discussions relevant to RHI’s vision. A meeting to bring together world experts working a cure for paralysis after SCI is an example of such a meeting.

3. Set up SCI knowledge management system

Relevance to RHI Vision: Bringing International experts together will facilitate the development of a Global Strategy to Cure Paralysis after SCI as well as the sharing of data and ideas.

Deliverable: Launch of a SCI knowledge management system

A key component of a successful network is the ability to share and disseminate knowledge effectively between researchers, clinicians and other stakeholders, including people with SCI. Knowledge can include published papers, study protocols, clinical study documentation, standard operating procedures, training materials, conferences/meeting related information, updates on RHI and network member’s initiatives and clinical practice guidelines.

RHI currently utilizes Sharepoint to share knowledge across the SCI network. During the 2013-2018 period, RHI will maintain and update this platform to include other modules to meet knowledge dissemination needs as the RHI network expands to International jurisdictions. The additional modules may include social media (to create a real-time Community of Practice), virtual meeting tools and e-learning modules (to limit travel-related costs).
4. Develop a central patient recruitment model for clinical studies

Relevance to RHI Vision: The development of a central patient recruitment model for clinical studies will facilitate the implementation of international clinical trials on cure related therapies.

Deliverable: Complete the pilot of a central patient recruitment model for clinical studies

One of the major challenges faced by SCI researchers worldwide is the inability to recruit sufficient patients for clinical research studies. This can be attributed to a number of reasons which include an overall low number of people with SCI compared to other indications (e.g., cancer and cardiovascular disease) and limited ability of people with SCI to get to clinical research sites due to transportation, accommodation and Canadian distance issues. However, one of the main reasons for limited participation in clinical studies is the lack of awareness of the existing clinical research studies by people with SCI willing to participate in such studies.

During the 2013-2018 period, RHI intends to develop a patient recruitment model that will focus on creating an inventory of all SCI related clinical research studies and informing potential participants about eligibility in participating in these studies and trials.

In Canada, people with SCI who have participated in RHI-sponsored projects are asked to consent to future contact for new clinical research studies. RHI will explore the development of an International inventory, similar to the Canadian method, of patients who have consented to being contacted by clinical study researchers with the intention of bringing patients and the sponsors of clinical research and trials together. RHI will ensure that all features of this recruitment model will meet appropriate privacy and security standards.

5. Develop and nurture strategic relationships with national stakeholder organizations

Relevance to RHI Vision: The development and nurturing of relationships with national stakeholder organizations will be critical to the development of a Global Strategy to Cure SCI and accredit SCI Centres.

Deliverable: Formal partnerships with at least 5 new national stakeholder organizations to include funding agencies, non-SCI disease related organizations, consumer organization and research organization.

The success of RHI in its efforts to achieve its mission is dependent on the productive relationships it enjoys with all its strategic partners. The partners include consumer organizations (e.g. provincial Canadian Paraplegic Associations, SCI Canada), professional organizations (e.g. Canadian Medical Association, Canadian Spine Society), funding agencies (e.g. Michael Smith Foundation for Health Research), accreditation organizations (e.g. Accreditation Canada) and other disease related organizations and networks (e.g. Ontario Brain Institute, Canadian Stroke Network). A Strategic Partnership is a formally-documented relationship with an individual or organization with the intent of accelerating RHI’s vision and goals through collaboration or funding support. Strategic partnerships will be established with individuals, governments, non-governmental organizations, trade associations, research and healthcare institutions, or corporations, and are developed locally, nationally and internationally.
To achieve its mission, RHI endeavours to lead such collaborations that will accelerate finding a cure and improving health care outcomes for people with SCI. RHI has identified the following three areas in which it has forged and continues to forge strategic partnerships:

1. Research Activities
2. Best Practice Implementation and
3. Policy Change

The following list outlines potential strategic partnership development opportunities (Please note that some of the proposed partnerships are already in exploratory stages of discussions).

Research Activities

- **The Canadian Institute of Military and Veterans Health Research (CIMVHR)**
  Tasked by the federal government and Veterans Affairs, this new institute is dedicated to improving care and treatment for military personnel veterans and their dependents (over 700,000 Canadians). CIMVHR works closely with Veterans Affairs since Veterans Affairs responsibilities are met through various compensation programs and commemoration. Research varies from primary care and clinical research to mental health and societal issues. Knowledge acquired from research may be used to guide efforts in support of the health and well-being of Veterans Affairs clients.

- **International Collaboration on Repair Discoveries (ICORD).** ICORD is an inter-disciplinary research organization focused on SCI, and is affiliated with Vancouver Coastal Health and the University of British Columbia. ICORD is co-located with RHI at the Blusson Spinal Cord Centre (BSCC) in Vancouver. ICORD and RHI are increasingly working together towards developing expertise at the BSCC in pre-clinical validation of novel basic science discoveries to identify promising areas of research that have the highest likelihood and impact of success to advance through clinical studies, trials and evaluations.

- **Canadian Spine Society (CSS).** The CSS is an organization composed of spine surgeons and health care workers focussed on advancing care for spine patients, and supports research in spine care. A strategic partnership will enable CSS-funded researchers to utilize the RHI GRP for research purposes.

Best Practice Implementation

- **Accreditation Canada.** A not-for-profit, independent organization that provides health organizations with an external peer review to assess the quality of their services based on standards of excellence. Participating in accreditation demonstrates an organization’s commitment to quality health care. Thousands of health organizations voluntarily participate in Accreditation Canada’s programs each year.

- **Canadian Medical Association (CMA).** A national, voluntary association of physicians that advocates for access to high quality health care, and provides leadership and guidance to physicians. The CMA aims to improve health status by educating and equipping the public, and advocating for effective disease prevention and health promotion, in addition to the treatment of disease, injuries and disabilities. There are 12 provincial and territorial medical associations that are divisions of the CMA but are autonomous, with specific responsibilities in their jurisdictions.
Policy Change

- **Provincial and national SCI associations** (SCI Canada and provincial associations). With divisions in all 10 provinces and 47 regional offices, SCI Canada, their affiliated provincial chapters and other SCI consumer advocate organizations provides a wide variety of services to their membership. SCI Canada and their provincial chapters have a membership of more than 30,000 Canadians who have a SCI or other mobility impairment. Efforts from these organizations have helped in creating policies, legislation, and public awareness to remove barriers that exclude people with SCI from fully participating in society. These organizations are currently working closely with RHI to use the results of the RHI-sponsored SCI Community Survey to not only shape their strategic plans, but to actively create policy briefings to improve the conditions for people with SCI within their jurisdiction.

- **Health Authorities** (e.g., Vancouver Coastal Health, Alberta Health Services). Health authorities in Canada are tasked with providing health services to the public in various jurisdictions, RHI will work with health authorities to implement operational and health care practice policies for the care of people with SCI.

Significant effort is required to develop and nurture these relationships through co-sponsorship and co-hosting of events, advertising, and face-to-face meetings, co-funding activities of mutual benefit and collaborating on efforts for policy changes. During the 2013-2018 period, RHI will actively continue its relationship with existing partners and develop new ones with those that align with its objectives.

6. Seek co-funding and leverage funding opportunities for RHI projects nationally and internationally.

Relevance to RHI Vision: *Co-funding and leveraging funding opportunities to support RHI projects nationally and internationally is important to ensuring the sustainability of the Institute and Network.*

Deliverable: *Funding leveraged from at least 5 provinces, one of the national tri-council agencies and one International source.*

RHI recognizes the importance of leveraging Government of Canada funding to seek funding from other sources to ensure its sustainability and the sustainability of its network. In partnership with the Rick Hansen Foundation, RHI will seek funding from provincial governments, persons of high net worth and corporations. RHI will also actively seek opportunities of co-funding projects with provincial funding organizations (e.g. Michael Smith Foundation for Health Research) and other SCI organizations and governments around the world. RHI has significant experience in this area and was successful in leveraging the original Government of Canada funding for the period 2007-2012 ($30 Million) for an additional total of $38.7 million from provincial governments. RHI was also successful in co-funding several projects with other organizations (e.g. Ontario Neurotrauma Foundation and Alberta Paraplegic Foundation and British Columbia Institute of Technology).
During the 2013-2018 period, RHI, with the leadership of the Rick Hansen Foundation, will seek to obtain funding from aforementioned entities. The efforts required to obtain funding involve travel and meetings with key individuals, attending conferences and network events, hosting events showcasing RHI and network accomplishments and the use of consultants.

**Strategy 5: Support the Best and Brightest**

*Relevance to RHI Vision: Building research capacity in Canada related to stem cell research towards the cure and its implementation into clinical practice supports RHI’s Vision.*

*Deliverable: Support two post-doctoral scholars.*

Although Canada has several world class researchers in SCI, there is an on-going need to increase the amount of SCI research capacity in Canada and to encourage promising young researchers to pursue research in SCI. Towards this goal, RHI intends to co-fund academic Post-doctoral Scholars in research areas of SCI. The intention is to encourage young Canadian researchers by leveraging funding from RHI’s national partnerships with academic, granting, industry, professional and accreditation institutions. These proposed RHI Scholars will offer significant benefit to the SCI research field in Canada that include:

- Developing leadership and expertise in targeted areas of science that are critical to RHI being able to make progress on its Mission and Vision.
- Creating opportunities to generate additional resources from research funding organizations.
- Developing the capacity in SCI research in Canada.

RHI will therefore provide matching funds (in collaboration with the aforementioned partners) for one Post-Doctoral scholar in each of the following fields:

- Late stage preclinical stem cell research in the treatment of SCI, and
- Implementation and KT sciences

During the 2013-2018 period, RHI will fund the aforementioned scholars for a minimum of two years, depending on co-funding availability.

Although RHI has committed direct funding for 2 scholars only, it is important to note that many of the project grants described in this document will include support for graduate students and post-doctoral fellows. Therefore, RHI’s efforts will result in the indirect and direct support of several young researchers in SCI over the 2013-2018 period.
Corporate Infrastructure

Administration costs are distinguished between those that are directly related to running a program and those that are support functions.

Direct Program Administration costs include the program employees, specialist consultants from programs, review committees, memberships of associated organizations, attendance and presentations at program specific conferences, and meetings with current and potential partners nationally and internationally. These costs are included in the program costs.

Leadership, coordination and program support incorporates the corporate infrastructure and support services and costs. These include the staff costs and expenses relating to the internal leadership and support staff, governance (boards and committees), and external consultants and contractors (including legal and audit). The support services include accountability, finance, human resources, operations, compliance, resource development, communications, marketing and IT needs. The costs include legal, audits, insurance, bank and management fees, occupancy (rent, utilities, leasehold improvements, etc.) telecommunications, computer and office equipment and supplies, licenses, and other office overheads.

Over the next five year period the Rick Hansen Foundation (RHF) and RHI will continue to collaborate in support of the goal to accelerate progress to find cures for SCI. RHI will lead on the scientific program while RHF will lead in the provision of shared services, including support for International outreach, Finance and Accountability, Marketing and Communications and Resource Development.

Under the shared services agreement, which is designed to bring efficiencies with the Rick Hansen organizations and alignment with Rick Hansen’s vision of cures after SCI, the support for accountability, finance, resource development, communications and marketing will be provided by RHF under a shared service agreement. All other support and overhead expenses will be incurred directly by RHI.
Resource Requirements 2013 to 2018

The funds received from the Western Economic Diversification Canada (WD) are expected to be $35 million and will cover the fiscal years 2013-2018. Based on recent stakeholder engagement exercises as well as the results from the recently concluded Summative Evaluation, RHI has identified the aforementioned objectives for completion by 2018 using these funds. The estimated cost of each strategy over the funding period are presented below.

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In addition to continuing the support of key existing national TR and BPI projects, RHI intends to fund new TR and BPI initiatives that address its objectives and priorities during the 2013-2018 period. Many of these projects require start up activities with relative low costs and whose durations are unpredictable. These activities include seeking and obtaining approval from institutional ethics boards and regulatory agencies (e.g. FDA and Health Canada), patient recruitment and sourcing of pharmaceutical products for clinical studies. The low cost of project set up and potential delays in such activities at the beginning of projects requires flexibility in the disbursement of funds. RHI therefore requests that it receive the funds according to a proposed schedule and that it be permitted to retain unused funds from year-to-year to cover the increased cost expected to be incurred once the new projects are underway.