



[RICK HANSEN INSTITUTE COMMERCIALIZATION PROGRAM]

SUPPORTING THE COMMERCIALIZATION OF INNOVATIONS FOR SPINAL CORD INJURY

This document is a roadmap that describes the Rick Hansen Institute's (RHI) Commercialization Program, its objectives and activities. It was developed based on recommendations provided by the RHI Commercialization Program Advisory Committee which included a face to face meeting on May 10, 2014.

➔ BACKGROUND

Translating Research into Healthcare Products

It is very challenging to translate innovative research into products that are adopted by patients and physicians and deliver improved clinical outcomes to patients with SCI over the long-term. The various transitions from bench-to-bedside are so fraught with obstacles that they are often referred to as "valleys of death". RHI's seeks to bridge the translational "valleys of death" in SCI research through its Praxis Model¹. Praxis (from the Greek "doing") is a solutions-focused model developed in order to overcome specific obstacles in the research continuum of SCI discoveries to achieve the ultimate goal of improved healthcare outcomes for people with SCI and decreased financial impact on the healthcare system. This model aims to accelerate the rate in which research knowledge is translated into practice.

¹Barrable, B., Thorogood, N., Noonan, V., Tomkinson, J., Joshi, P., Stephenson, K., et al. (2014). **Model for bridging the translational "valleys of death" in spinal cord injury research.** Journal of Healthcare Leadership, 15-27.

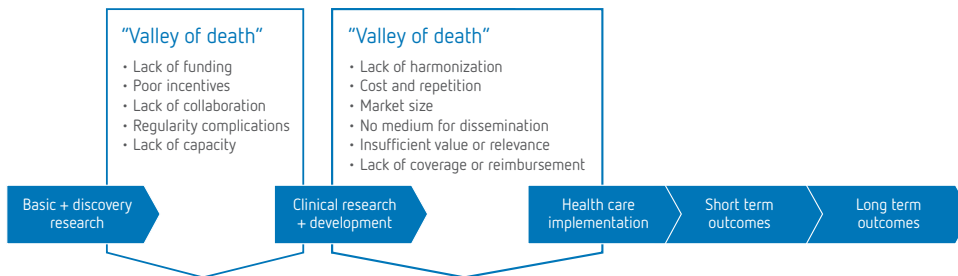
RHI'S VISION

A world without paralysis
after spinal cord injury.

RHI'S MISSION

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 and best practices to reduce the incidence and severity of paralysis after SCI, improve health care outcomes, reduce long-term costs, and improve the quality of life for those living with SCI.

The Praxis Model bridges the “valleys of death” and thus accelerates the development of innovations for SCI towards commercialization. The figure below provides a summary of the “valleys of death” in the research to outcome continuum.



How Does RHI Define Commercialization?

RHI defines commercialization as the process of introducing a new product or production method into the market, including the sustainable implementation into the delivery of healthcare, in order to achieve a return for stakeholders. Commercialization is the goal while development is the series of activities leading towards commercialization.

RHI defines Return on Investment (ROI) as improved outcomes divided by the cost of obtaining those improved outcomes.

Commercialization in SCI

Commercializing innovations that will directly benefit people with SCI through traditional models is extremely challenging. The reasons for this primarily relate to the complexity of SCI and the relatively lower incidence and prevalence as compared to other chronic health conditions. For potential investors the view of high scientific risk combined with a small addressable market can lead to the perception that SCI is an unattractive area to invest in.

However, there are numerous benefits for investors to commercializing innovations for SCI:

- People with SCI have clear unmet medical needs.
- There are numerous incentives to commercialize products for SCI by regulatory authorities in jurisdictions that have specific guidance for rare diseases and conditions, such as the Orphan Drug Designation and the Humanitarian Use Device programs in the United States.
- Innovations that address the secondary complications following SCI (e.g. pressure ulcers, neuropathic pain, urinary tract infections) may be applied to other health conditions and thus provide access to larger markets.
- People with chronic SCI are stable and thus represent a baseline in which to assess the effect of a therapy against. Stable baseline data enables investigators to more accurately measure the efficacy of a given intervention.

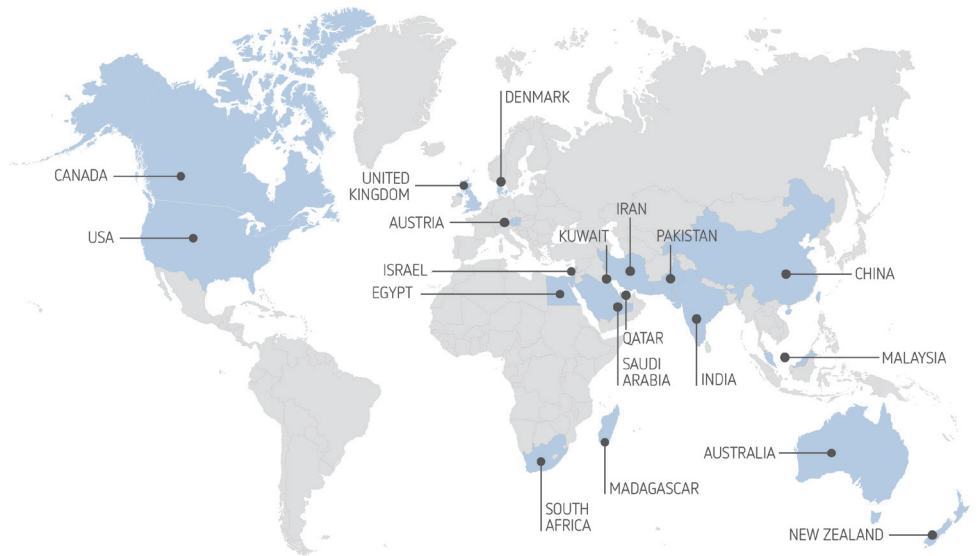
✓ THE COMMERCIALIZATION PROGRAM AT RHI

RHI's most valuable resource is its network. The network has largely been developed through the Rick Hansen Spinal Cord Injury Registry (RHSCIR) and related collaborative research initiatives. The potential value of this global network of collaborations in SCI research and care (see figure below) to those developing and commercializing innovations to benefit people with SCI is substantial. The value of RHI's network is driven by access to the following:

- Subjects for quick enrollment into Proof-of-Concept Clinical Trials
- Investigators with expertise in SCI research and care
- SCI Consumers who can provide feedback on the applicability of an innovation for people with SCI and input into the product design process

RHI's Global Network of Collaboration in SCI Research and Care

The Commercialization Program at RHI is focused on leveraging the strengths and resources of RHI's network in SCI research and care ("domain expertise") to gain development and commercialization expertise ("process expertise"). The strategic direction of the Commercialization Program is provided by the Program Advisory Committee. This Committee's mandate is to advise RHI on how it can best leverage its strengths, while ensuring alignment with RHI's Cure, Care and Consumer Programs. The Committee is comprised of professionals with a wide range of business development and commercialization expertise in the life sciences.



LOOKING AHEAD RHI'S PROJECTED TIMELINE OVER THE NEXT 25 YEARS

2013

Renewed funding from the Government of Canada and the Rick Hansen Foundation

2014

RHI international SCI cure strategy

2018

International collaboration on two promising neurorestorative novel therapies
Facilitated by: 50% of newly-injured Canadians receive standardized care

2023

International collaboration on five promising neurorestorative novel therapies
Facilitated by: 75% of newly-injured Canadians receive standardized care

2038

All Canadians have access to SCI-specific novel therapies
Facilitated by: All newly-injured Canadians receive standardized care

Goal of the RHI Commercialization Program is:

**Greater number of innovations brought to market
that will directly benefit people with SCI**

Objectives of the RHI Commercialization Program are:

- Accelerating the commercialization process for innovative therapeutics and medical devices for paralysis and secondary complications following SCI.
- Increasing the pipeline of potential innovative therapeutics and medical devices for SCI and secondary complications.
- The implementation of innovative therapeutics and medical devices into the delivery of healthcare for people with SCI.
- Increasing investor and industry engagement and participation in SCI research and development.

**AREAS OF FOCUS**

RHI will act as an *Accelerator* for innovative technologies (therapeutics, medical devices, diagnostics and Health-IT technologies) that will benefit people with SCI. It will do this through the following three areas:

- **RHI network:** RHI will determine how to operationalize resources within its network in support of development and commercialization initiatives. RHI will expand and continue to strengthen its global network of collaborations in SCI research and care. Expansion will include connection into existing networks of investors, industry, payers and service providers internationally. In order to ensure alignment to RHI's Consumer Program, this process will also include more engagement of local and international consumer groups.
- **Early stage evaluation of technologies:** RHI will introduce mechanisms/criteria that will proactively evaluate technologies for their applicability and benefit to people with SCI from a commercialization perspective. The types of technologies that will be evaluated through these mechanisms/criteria will be limited to those that align to the Cure and Care programs.
- **Policy and advocacy:** RHI will develop mechanisms related to health economic evaluation, impact analysis, regulatory considerations and advocacy in order to provide the evidence for reimbursement of innovations by payers. These mechanisms will leverage resources of RHI's Care Program.

In order to contribute to the sustainability of RHI's Commercialization Program, these three areas will ultimately inform a funding strategy for the program.

About RHI's Programs

The Rick Hansen Institute's Commercialization Program is one of four key programs under RHI's strategic direction for 2013-2018. The key program areas are Cure, Care, Consumer and Commercialization and are supported by six strategies (translational research, best practices implementation, informatics, network development, consumer engagement and supporting the next generation of "Best & Brightest" researchers). Together, these programs and strategies will help support RHI's vision of a world without paralysis after spinal cord injury.

Learn more about RHI's strategic direction for 2013-2018 at www.rickhanseninstitute.org/about-us/who-we-are/strategic-direction.

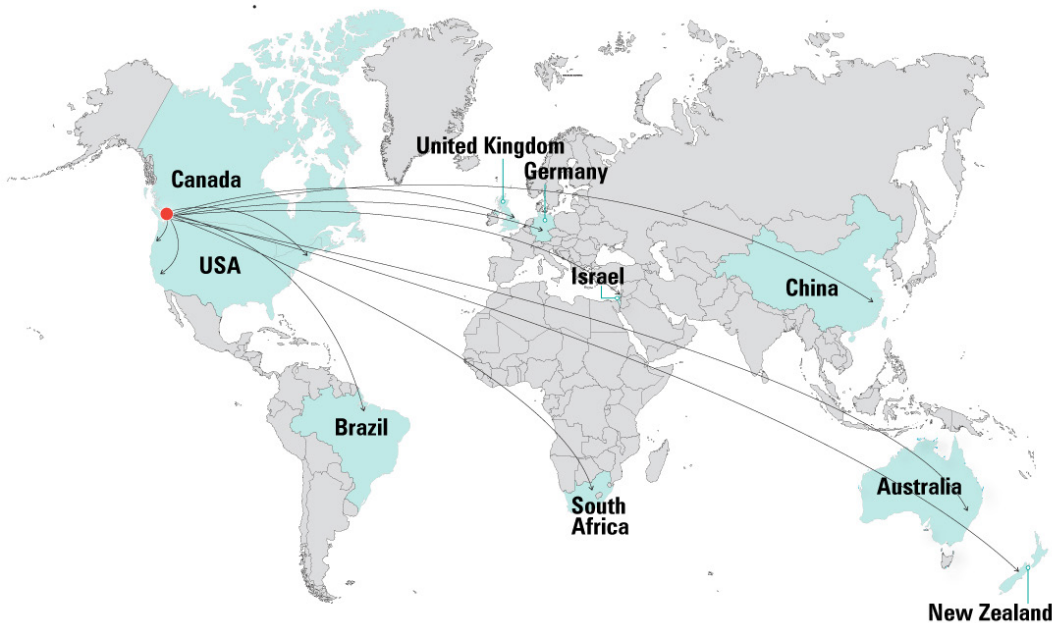
MOVING FORWARD

RHI will introduce mechanisms to support initiatives related to the objectives and areas of focus of the Commercialization Program. Some new projects, such as those related to the evaluation of early stage technologies, will be identified through open and/or targeted Requests for Proposals (RFP). RFPs will be evaluated through external peer-review as per RHI's review policies. The mechanisms for other new initiatives, such as those around policy and advocacy, are to be determined.

RHI will operationalize resources within its network and expand its network for commercialization purposes. The expansion will initially target regions in which there exists a critical mass of investors and industry (see figure below). The network expansion will seek to build relationships in the primary biotechnology and life sciences clusters in the United States, such as San Francisco, Boston and San Diego. Also, RHI will look to build relationships in biotech and life sciences clusters in Europe, such as the "golden triangle" (London, Cambridge and Oxford) in the United Kingdom and the various regional clusters in Germany. There will be also be an effort to build relationships with industry and investors in the regions in which RHI already has collaborative research partnerships: Israel, China, Australia and New Zealand. A particular emphasis may be placed on Israel given the country's thriving 'start-up' ecosystem. In the long term RHI may look to expand its network into South America and Africa, with Brazil and South Africa potentially representing the most logical place to initiate those efforts, respectively, due to their developing biotechnology clusters.

The engagement of local and international SCI consumer groups will be driven through RHI's Consumer Program.

RHI's Targeted Global Network Expansion in Support of the Commercialization Program



The Rick Hansen Institute would like to thank the following for their support: Government of Canada through Western Economic Diversification Canada, Health Canada, Rick Hansen Foundation, and the governments of BC, Alberta, Ontario, Manitoba, Saskatchewan, New Brunswick and Yukon Territory.

The Rick Hansen Institute is a Canadian-based not-for-profit organization with the goal of creating a world without paralysis after spinal cord injury. It works towards this goal by accelerating research and translating clinical findings into practical solutions to develop new treatments, improve health care outcomes, reduce long-term costs and improve the quality of life for those living with spinal cord injury. www.rickhanseninstitute.org.