## Supporting high-quality clinical device research



Partnering with innovative clinical technology companies to deliver high-quality research

NHS Research Scotland Stroke
Network collaborate with
Microtransponder Inc to trial
the Vivistim® System for
treatment of post-stroke upper
limb mobility



Headquartered in Texas, USA, MicroTransponder Inc has developed therapies to treat several neurological conditions.

## **Vivistim® System**

The device used in this study is surgically implanted just below the collar bone and delivers electrical stimulation to the vagus nerve. The stimulation, which is given in conjunction with rehabilitation physiotherapy, is believed to cause the brain to be more receptive to the recovery training exercises.

"The results are pretty spectacular. Obviously this study is exploratory, but this raises a lot of hope" Dr Phillip Gorelick, MD, MPH, American Stroke Association Spokesperson



"The group receiving active stimulation with the device showed a **9-point** improvement in upper-limb Fugl-Meyer (UEFM) score. This magnitude of change would mean different things for different patients, depending on where they start on the scale. If they start at 20 — which is not much function at all — they might regain some grasp ability so they might be able to carry a plate, for example. If they were in the 30s to start with, they would probably already have the grasp function but they would be able to get back to do more specific tasks."

Prof Jesse Dawson (Lead Investigator)
University of Glasgow; Consultant Stroke
Physician, NHS Greater Glasgow & Clyde,
NRS Stroke Research Champion

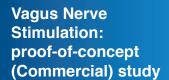
NHS Research Scotland (NRS) efficiently supports clinical research studies from all Life Sciences sector including pharmaceutical, biotechnology and medical technology companies.

We simplify access to Scotland's clinical research infrastructure, including world class facilities, expert investigators and well characterised groups of patients, enabling industry to benefit from:

- · A single point of contact for industry
- Single contract draft and commercial price for Scotland
- Co-ordinated access to clinical investigators and patients
- Strong collaboration between NHS, academia and industry
- Streamlined and timely clinical trial approvals
- Sustained permissions performance among the best in Europe
- · Efficient start up and managed delivery

"Despite this being a complex trial requiring surgical implantation of a medical device, the infrastructure, expertise and support available in Scotland enabled rapid start-up of this study and real-world testing of our device. Our Scottish site was our best recruiter and acted as a trusted partner in the development of our program. We look forward to working with the team on our phase 3 clinical trial."

Frank McEachern, CEO, MicroTransponder Inc.



- Approval: January 2013
- First patient: February 2013
- · Last patient: April 2014
- · Completed: August 2014

## Vagus Nerve Stimulation: randomised pilot (Academic) study

- · Approval: April 2015
- First patient: June 2015
- · Last patient: July 2016
- · Completed: November 2017

## Vagus Nerve Stimulation: UK-wide, multi-site

- Scotland as UK point of entry
- Led by NRS Stroke Network
- Established procedures for UK-wide working and set-up across 4 nations
- Ongoing study, recruiting 120 patients

"Our NRS Stroke Network brings together Scotland's leading clinicians, academics, carers and patients

alongside dedicated commercial support and UK wide engagement. This collaborative environment enables ambitious research projects to be conducted ultimately leading to improved treatment options and better outcomes for patients."

**Dr Jesse Dawson**, NRS Stroke Research Champion

"This collaboration showcases our national infrastructure in action, demonstrating how NRS can actively enable companies in the development of new technologies aimed at improving treatment options and outcomes for patients."

**Dr Steven Burke**, Industry Liaison Manager, NHS Research Scotland – Central Management Team (CMT)

To discuss industry partnerships in Scotland contact **Dr Steven Burke**, **Industry Liaison Manager** steven.burke@nrs.org.uk • +44 141 951 5508 • www.nrs.org.uk/industry

The results of this trial were presented at the International Stroke Conference (ISC) 2017 by Lead Investigator Dr Jesse Dawson, and the study was reported in a number of online and print media, including MedScape and WebMD.com. All studies were commercially sponsored.

NHS Research Scotland (NRS) is a partnership of Scottish NHS Boards and the Chief Scientist Office of The Scottish Government.

Registered Number: GB 236303. Registered address: The Golden Jubilee National Hospital, Fourth Floor East, Agamemnon St, Clydebank, G81 4DY.

Published by NHS Research Scotland. All rights reserved. Material contained in this publication may not be reproduced in whole or part without prior permission of NHS Research Scotland (or other copyright owners). Data in this case study was provided by NRS Stroke and MicroTransponder inc. Whilst every effort is made to ensure that the information given here is accurate, no legal responsibility is accepted for any errors, omissions or misleading statements.