



# THE GAME CHANGERS

The groundbreaking MaRS EXCITE program has announced its first three recipients of pre-market assessment of new health technologies **By Jane Langille**



All too often, innovators develop breakthrough technologies and then hit a major roadblock when they go to market because their brilliant new medical tools don't fit well into the healthcare system.

Ontario's MaRS EXCITE (Excellence in Clinical Innovation and Technology Evaluation) program hopes to change that by providing comprehensive pre-market assessments to enable new technologies to get to market faster, improving patient access (see *Health Research & Innovation*, Spring 2012).

"It's a disruptive approach to the use of evidence, a tool that has all too often been used to police rather than enable technology. If you can use evidence in the

pre-market space, you provide innovators with a quick sense of whether they're on the right track or not before they use a lot of investment capital," says EXCITE's chief scientific officer, Dr. Les Levin.

Based at the MaRS Discovery District in downtown Toronto, EXCITE is a collaboration involving industry, academia, the health system and government. Its "core evidentiary bundle" consists of large provincial clinical trials with embedded health economics and systematic review components, providing information required to support Health Canada licensing applications and inform review by the Ontario Health Technology Advisory Committee and the Ontario Ministry of Health and Long-Term Care.



**ApneaDx** portable home sleep apnea device, which avoids the need to be tested in a sleep clinic, is one of the first three technologies accepted in the EXCITE program.



## Pilot program innovators

EXCITE was unveiled in December 2011 and the first three recipients were announced on May 30, 2013. Each innovation offers "disruptive potential" — substantially better clinical outcomes and/or substantially lower costs than existing approaches for patient treatment. Clinical studies are currently in progress for all three innovations.

# 10 of 20 innovators applying to date have been accepted in the program

ApneaDx Inc. makes a home monitor for diagnosing sleep apnea, a disorder characterized by abnormal interruptions in breathing and associated with a high risk of heart attack and stroke. Currently, sleep apnea affects about 10% of adults, and 85% of cases are undiagnosed.

The device consists of a microphone embedded in a small frame worn on the face to record breathing sounds during sleep, reducing the cost and inconvenience of treatment in sleep clinics. Cost is estimated at under \$100, a significant savings compared to the \$505 cost of a sleep lab in Ontario.

Medtronic of Canada's Symplicity Renal Denervation System is a surgical device to treat high blood pressure in patients who don't respond to three or more medications.

By threading a catheter via a leg artery up to a patient's kidney, doctors can deliver low-level radiofrequency energy to targeted renal artery nerves. Disabling those nerves has been shown to significantly lower drug-resistant hypertension in two large-scale clinical trials.

This surgical treatment could reduce long-term complications of pharmacotherapy as well as the number of medical visits. Hypertension currently affects over 5 million Canadians, and 4.5% have uncontrolled hypertension despite standard drug therapy.

Rna Diagnostics Inc. developed the RNA Disruption Assay, a diagnostic tool that identifies breast cancer patients who are not responding to chemotherapy early in treatment, so they can be quickly switched to an alternative, avoiding the harmful side-effects of ineffective chemotherapy and improving outcomes.

Currently, half of all breast cancer patients receive chemotherapy, but fewer than one-quarter gain a long-term survival benefit. This diagnostic tool dovetails well

with neoadjuvant therapy, where breast tumours are treated with chemotherapy prior to surgical removal, an approach not currently used in Ontario, but offered in other jurisdictions such as Europe and the United States, where it was recently recommended for treatment consideration by the American College of Surgeons.

## Primary incentives

Whether an innovation is the brainchild of a large multinational corporation or a small startup firm, all three first-round recipients are most excited about the potential to achieve market acceptance on a faster timeline. Obtaining regulatory approval is a secondary consideration.

While finalizing agreements with EXCITE, Medtronic's Symplicity Renal Denervation System received Health Canada approval on an expedited review basis, "but it was a conscious decision to continue with EXCITE, because we're most interested in the market acceptance part," says Hamid Sadri, director of health economics and health technology assessment for Medtronic of Canada.

"Technology needs help not only from a funding perspective, it also needs system readiness. The hospitals need to be ready, the surgeons need to be comfortable, and we need to mobilize referral pathways to move patients from community cardiology offices or family physician offices to tertiary treatment centres."

For ApneaDx, regulatory approval is pending, but obtaining reimbursement status quickly is a key motivator for participation.

"We've now published six papers on this device and could get Health Canada approval without EXCITE. The program is about moving more quickly into the healthcare system in Ontario so a doctor could prescribe the test and then OHIP would pay for it," says Dr. Geoff Fernie,



**Dr. Les Levin of EXCITE:** "If you can use evidence in the pre-market space, you provide innovators with a quick sense of whether they're on the right track or not before they use a lot of investment capital."

## EXCITE by the numbers

# \$10,000

Acceptance fee, which is transferred to the methodological centre to cover the cost of protocol development

# \$1-3 million

Typical cost of evaluations



**Hamid Sadri of Medtronic of Canada**

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# 5 & 24

## Number of participating specialized methodological centres and research hospitals

director of research at the Toronto Rehabilitation Institute and professor at the Institute of Biomaterials and Biomedical Engineering at the University of Toronto. The ApneaDx device was invented by Dr. Fernie along with Dr. T. Douglas Bradley and Dr. Hisham Alshaer at Toronto Rehab.

Regulatory approval works differently for Rna Diagnostics, says says Dr. Kenneth Pritzker, the company's chief executive officer. "We've had discussions with Health Canada and we're proposing to do this as a laboratory test, falling under a self-regulatory process of laboratory accreditation rather than Health Canada regulation. We would identify a provider lab and ensure that all protocols are in place, meeting all external criteria. Health Canada accepts this and so do the U.S. and Europe."

Participants say that rigorous, arm's-length evaluation will set their innovations apart in the market. "All of the protocol design is developed independently of the company by MaRS EXCITE. This was done deliberately to ensure the absence of bias, an important criterion for consideration for standard-of-care reimbursement," says Dr. Pritzker.

"There's no home sleep apnea monitoring device on the market today that has undergone the kind of testing that MaRS EXCITE will do — arm's-length testing with very strict processes, data collection and interpretation," says Dr. T. Douglas Bradley, co-inventor of ApneaDx and director of the Sleep Research Laboratory and Cliff Nordal Chair in sleep apnea and rehabilitation research at Toronto Rehab.

"This may change the ball game. If EXCITE works out, then more devices may be subjected to this kind of stringent testing in the future."

### Two-way street for refinement

Moving evidence-based assessment into the pre-market space is allowing innovators to make refinements to their technologies or to modify how they're used in clinical practice.

"I can say without any doubt that the protocol design has often changed the way academia, industry and government have viewed the technology and what's required to move it into the health system," says Dr. Levin.

"In one clinical study, some of the questions being asked would have been unfair for industry to answer, so we've managed to iron that out in protocol development. In other cases, we've managed to bring the point of view of the health system to industry, to say it's a wonderful concept but unless you make adjustments, it wouldn't be feasible."

Early testing has benefits for the future too. "The methodology centres have asked questions about testing the technology in ways the technology was never developed to answer, setting the ground for future applications that might come out of subsequent studies," says Dr. Levin.

The world is watching to see if this bold new evidence-based evaluation model can speed innovations to market and improve patient access. Assessments for the first three program recipients will be completed by mid-2015 and, if they're positive, market uptake should happen soon thereafter. Time is of the essence, because innovations usually enjoy only about 18 months of market exclusivity before competitors enter.



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**Dr. Kenneth Pritzker**  
of Rna Diagnostics

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**Dr. Geoff Fernie (right)**  
and **Dr. Douglas Bradley (above)** of Toronto Rehab and ApneaDx.

The EXCITE program 'is about moving more quickly into the health-care system,' says Dr. Fernie. 'This may change the ball game,' adds Dr. Bradley.



### EXCITE by the numbers

# 12-30 months

Estimated time to complete evaluations