

# MaRS EXCITE Case Example: Insertable Cardiac Monitor (ICM)

## Clinical Condition: Atrial Fibrillation (AF) Post-Cryptogenic Stroke

- Stroke is a leading cause of morbidity and mortality in Canada & is associated with significant patient, societal & economic costs
- Most strokes result from a blockage of blood flow to the brain (ischemic stroke); 20 - 40% of those are classified as 'cryptogenic', meaning that the mechanism of stroke remains unclear despite extensive diagnostic testing
- Atrial Fibrillation (AF) is a type of abnormal heart rhythm that is a risk factor for stroke and leaves patients with a 5-fold increase in ischemic stroke risk; standard of care to detect AF involves external electrocardiogram (ECG) monitoring
- In Ontario, external ECG monitoring is limited to a 14 or 30-day duration; however, research has shown that a certain proportion of patients with previous stroke remain at risk of AF after 30 days. Therefore, if monitoring stops at 30 days, approximately 82% of patients with previous stroke who remain at risk of AF would not be monitored
- Detection and subsequent diagnosis of AF allows for medication management ultimately mitigating the risk of secondary stroke

## Technology Solution: Insertable Cardiac Monitor (ICM)

The Medtronic Reveal LINQ™ insertable cardiac monitor (ICM) is an ECG monitor that is placed just under the skin of a patient's chest and records heart arrhythmias for up to three years, ultimately identifying episodes of AF that would be missed by 14 or 30-day external ECG monitoring. Despite the evidence supporting the use of long-term monitoring strategies such as ICM for the diagnosis of AF, public funding for ICM technologies (for cryptogenic stroke patients) in the province of Ontario does not exist.



Medtronic Reveal LINQ™

## Process: Robust Evaluation

### Objective

Given the demonstrated clinical benefits of ICM and uptake of these devices in global markets, [EXCITE](#), in collaboration with [the HUB](#), generated contextual evidence to support decision making for adopting this technology in Ontario and thereby allowing patient access to this innovative technology.

### Methods

- 1) **A qualitative study:** conducted (with 4 stakeholder groups) to gain a deeper understanding of the role of cardiac monitoring in patients who suffered an episode of cryptogenic stroke, including barriers and facilitators to the uptake of ICM.
- 2) **A budget impact analysis:** conducted and contextualized to the Ontario health system to examine the cost of a new diagnostic pathway of AF detection for patients who had previous cryptogenic stroke compared to usual care over 5 years.
- 3) **Implementation Planning:** a multi-stakeholder collaborative exercise identifying potential market access pathways for ICM in Ontario.

## Key Results

- Clinical experts described an “ideal” monitoring pathway for cryptogenic stroke patients, supporting a progressive ramp-up to longer-term monitoring strategies, including the use of ICM
- Patients characterized prolonged external monitoring (7+ days) as burdensome and intrusive; a preference for ICM was demonstrated
- Based on targeted ICM use within a sub-group of cryptogenic stroke patients, incremental costs to the Ontario Ministry of Health and Long-Term Care (MOHLTC) were estimated to be \$1.7M in Year 1 and \$3.9M in Year 5

## Outcomes

After reviewing the evaluation results, the EXCITE Management Board recommended to the Ontario MOHLTC that ICM technologies, as a class, be considered for adoption into the Ontario health system. A final report outlined adoption and implementation strategies for the MOHLTC to consider, with the ultimate goal of expediting uptake of ICM technologies for cryptogenic stroke patients in Ontario.

*\*References available upon request*